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<i>Case</i>	<i>No</i>
<i>COMP/M.3083</i>	—
<i>GE/Instrumentarium</i>	

Only the English text is available and authentic.

REGULATION (EEC) No 4064/89
MERGER PROCEDURE

Article 8 (2)
Date: 02/09/2003



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 02.09.2003
C(2003) 3156 final

COMMISSION DECISION

of 02.09.2003

**declaring a concentration to be compatible with the common market
and the functioning of the EEA Agreement**

(Case No COMP/M.3083 – GE/Instrumentarium)

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to the Agreement on the European Economic Area, and in particular Article 57 thereof,

Having regard to Council Regulation (EEC) No 4064/89 of 21 December 1989 on the control of concentrations between undertakings¹, as last amended by Regulation (EC) No 1310/97², and in particular Article 8(2) thereof,

Having regard to the Commission's decision of 3 April 2003 to initiate proceedings in this case,

Having regard to the opinion of the Advisory Committee on Concentrations³,

Having regard to the final report of the Hearing Officer in this case⁴,

1 OJ L 395, 30.12.1989, p. 1; corrected version OJ L 257, 21.9.1990, p. 13.

2 OJ L 180, 9.7.1997, p. 1.

3 OJ C

4 OJ C

WHEREAS:

- (1) On 28 February 2003, the Commission received notification of a proposed concentration pursuant to Article 4 of Regulation (EEC) No 4064/89 (“the Merger Regulation”), whereby the US company General Electric Company (hereinafter referred to as “GE”) proposes to acquire sole control of the whole of the Finnish company Instrumentarium OYJ (hereinafter: “Instrumentarium”), by way of a public tender offer announced on 18 December 2002.
- (2) On 3 April 2003, having examined the notification, the Commission concluded that the notified operation fell within the scope of the Merger Regulation and that it raised serious doubts as to its compatibility with the common market and the EEA Agreement. The Commission therefore initiated proceedings in accordance with Article 6(1)(c) of the Merger Regulation.
- (3) On 28 April 2003, the Commission adopted a decision pursuant to Article 11(5) of the Merger Regulation, due to the fact that GE had not provided full responses to a request for information dated 7 April 2003 relating in particular to bidding and other data which was necessary to determine the competitive position of GE in the markets for patient monitors, mammography devices and C-arms. GE had been requested to supply the information by 14 April 2003. GE supplied the requested information on 15 May 2003. Accordingly, pursuant to Article 9 of Commission Regulation (EC) No 447/98 of 1 March 1998 on the notifications, time limits and hearings provided for in Council Regulation (EEC) No 4064/89⁵ on the control of concentrations between undertakings, the time periods referred to in Article 10(1) and (3) of the Merger Regulation were suspended for a total of 18 days.
- (4) Following an in-depth investigation of the case, the Commission takes the view that, although the notified proposal is liable in itself to lead to dominant positions as a result of which effective competition would be significantly impeded in a substantial part of the common market, the commitments given by the notifying party serve to remove the concerns as to the compatibility of the concentration.
- (5) The Advisory Committee discussed the draft of this Decision on 12 August 2003.

I. THE PARTIES

- (6) GE is a diversified company, active in various manufacturing, technology and service businesses, including medical systems. GE Medical Systems specialises in medical diagnostic imaging technology, including patient monitors, and related services and health care products.
- (7) Instrumentarium is active in the development, manufacture and sale of medical equipment and technology related to the areas of anaesthesia and critical care, including patient monitors and anaesthesia delivery machines, in particular, under the names Datex-Ohmeda, Spacelabs Medical and Ziehm.

⁵ OJ L 61, 2.3.1998, p. 1.

II. THE OPERATION AND THE CONCENTRATION

- (8) The proposed operation concerns the acquisition of sole control of Instrumentarium by GE. The acquisition, according to a Combination Agreement signed on 18 December 2002 by the two parties, is performed by way of a voluntary public tender offer, made through a newly formed Finnish entity that is a wholly owned subsidiary of GE.
- (9) On the basis of the foregoing, the proposed acquisition, whereby GE acquires sole control over Instrumentarium, constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

III. COMMUNITY DIMENSION

- (10) The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 billion (GE EUR 141,023 million and Instrumentarium EUR 1,163.8 million in 2001)⁶. Each of GE and Instrumentarium have a Community-wide turnover in excess of EUR 250 million (GE EUR [...] * million and Instrumentarium EUR [...] * million in 2001), but they do not achieve more than two-thirds of their aggregate Community-wide turnover within one and the same Member State. The notified operation therefore has a Community dimension within the meaning of Article 1(2) of the Merger Regulation.

IV. COMPETITIVE ASSESSMENT OF THE NOTIFIED CONCENTRATION

THE RELEVANT MARKETS

A. THE RELEVANT PRODUCT MARKETS

- (11) The proposed concentration relates to the field of medical equipment, the main market segments affected by the notified transaction being patient monitors, mobile C-arms and mammography devices.

1. PATIENT MONITORS

General description of the products

- (12) Patient monitors are machines that take measurements of physiological parameters as a representation of a patient's well-being. These functions are performed whilst a patient is either undergoing treatment or recovering. Sensors attached to the patient detect different parameters (electrical, mechanical and chemical events) which are converted to electrical signals displayed on a screen (or printouts). The parameters are vital signs, which vary from the very basic (namely temperature) to the very advanced (such as an electroencephalograph). Patient monitors can measure a number of them simultaneously and are used together with other medical equipment, in particular

⁶ Turnover calculated in accordance with Article 5(1) of the Merger Regulation and the Commission Notice on the calculation of turnover (OJ C66, 2.3.1998, p25). To the extent that figures include turnover for the period before 1.1.1999, they are calculated on the basis of average ECU exchange rates and translated into EUR on a one-for-one basis.

* Parts of this text have been edited to ensure that confidential information is not disclosed; those parts are enclosed in square brackets and marked with an asterisk.

ventilators, anaesthesia machines and, in some cases, with clinical information systems.

- (13) Patient monitors can be sold either configured or in modules. In configured monitors the parameters to be measured are built-in during the manufacturing process and are fixed for the monitor's life. Modular monitors have a display and a central unit which contains a processor and a number of slots where modules to measure different parameters can be inserted.

Distinction between different types of monitors

- (14) The notifying party has submitted that patient monitors are used in various care areas within a hospital and that, in each of the care areas, the parameters to be measured determine the characteristics needed for the monitors. In each area, the shares of the merging parties and the purchasing processes are different, there are price variations, and the building up of a reputation as a credible supplier is difficult.
- (15) In this context, the notifying party suggests a segmentation whereby three markets can be distinguished: (i) Perioperative Monitors ("PO"), (ii) Critical Care Monitors ("CC") and (iii) General Ward Monitors ("GW").
- (16) PO monitors are used in the perioperative area, that is, mainly in the operating rooms ("OR") as well as in the induction rooms and the recovery room (post-anaesthesia care units - "PACU"). This type of monitor can be connected to anaesthesia machines in operations performed under general anaesthesia, where the inhaled and exhaled gases need continuous monitoring in order to ensure a sufficient level of anaesthesia and successful recovery. PO monitors usually include specific modules to measure parameters not used in CC, such as respiratory gases (O₂, CO₂, N₂O), anaesthetic gases (in connection with anaesthesia machines), the BIS (a parameter which measures the effects of anaesthesia on the patient) or neuromuscular transmission (to measure the patient's response to nerve stimulation and regional block). Other monitoring needs vary depending on the complexity of the operation. PO monitors, as opposed to CC monitors, are not yet frequently networked with other care areas of the hospital.
- (17) CC monitors are used in areas of a hospital where a high level of patient care is required such as intensive care units ("ICU"), neo-natal intensive care units ("NICU"), coronary care units ("CCU"), and emergency rooms ("ER"). This type of monitor generally measures a large number of parameters also measured by PO monitor, such as ECG (electrocardiogram), SpO₂ (haemoglobin oxygen saturation), NH₃P (non-invasive blood pressure), IBP (invasive blood pressure), temperature, CO₂ or cardiac output, but not the effects of anaesthesia on patients. CC monitors are often networked and linked to a central station where the data can be processed or stored and where the patient's vital signs can be observed at a remote location.
- (18) GW monitors are less complex than PO and CC monitors, and only measure basic parameters such as NIBP, SpO₂, temperature and ECG. This type of monitor is used for sub-acute activities such as general medical and surgical wards or obstetrics. GW monitors are configured rather than modular and can be linked to a central station or used as stand-alone units. Not all patients in the general ward area need to be monitored and consequently monitors are moved from bedside to bedside according to patient's

monitoring requirements; for this they need to be physically easy to shift around the area.

- (19) The market investigation has confirmed the product market segmentation submitted by the notifying party regarding patient monitors. The arguments that support this product market definition come from both the demand side and the supply side. Since the GW market is not an affected market (Instrumentarium is not active in this market), the analysis focuses only on the PO and CC markets.

(i) Demand side considerations

- (20) First, their technical requirements are so different that, even if PO monitors can sometimes be used in the CC area, the substitution of PO for CC monitors is not possible in the vast majority of cases. These technical requirements refer not only to the specific types of parameters to be measured in each care area, but also to the network capabilities and physical characteristics needed⁷.
- (21) With regard to the substitutability of PO monitors for CC monitors or vice-versa, the investigation has shown that each type of monitor is exclusively used in its intended care area, because of the initial specifications and parameters that are required at the time of purchase⁸.
- (22) Furthermore, as was emphasised by the notifying party, these differences in technical requirements are confirmed by the differences in prices that can be observed between the three segments⁹.
- (23) The purchasing decision also differs from one segment to another. The market investigation has shown that, for PO monitors, the decision about the monitor's technical specifications is mainly taken by the anaesthesiologist, whereas for CC monitors the clinicians of the relevant departments (namely ICU, NICU or CCU) have a great influence in the final decision¹⁰. Moreover, for the acquisition of equipment by either hospitals or the public authorities in charge of the hospitals' procurement, separate tenders are usually organised for each care area, with particular specifications for each case¹¹.
- (24) Moreover, it is a common practice in the industry (in studies carried out by independent consultants and the manufacturers themselves), to segment the general patient monitor market according to the care area involved.

⁷ Form CO pages 40, 41 and 42.

⁸ Customers in each country were asked whether they would sometimes use perioperative monitors in the critical care area and vice versa. A vast majority of respondents indicated that this would not be the case (France, 81%; Spain: 86%; the United Kingdom: 62%; Sweden: 69%; Italy: 58%).

⁹ Form CO, p. 43.

¹⁰ For the five bigger markets at national level, the market investigation shows that: for PO monitors, the proposal to purchase a given type of monitor is made in most of the cases by the anaesthesiologist (France 95%, Germany 97%, Italy 94%, Spain 100% and the United Kingdom 72%) and only in a few cases by other medical departments; for CC monitors the influence is exerted by the relevant medical departments.

¹¹ The market investigation results regarding the last tender organised by the respondents show that the percentage of tenders organised exclusively for PO or CC monitors is France 65%, Germany 69%, Italy 73%, Spain 70% and the United Kingdom 67%.

- (25) There are also important differences with regard to the type of software used. The software defines the settings of the monitors (alarms, algorithm performance or report configurations), that are directly linked to the intended use of the monitor, that is, to the care area. Since patients usually spend only a few hours in the OR area while they can spend days or even weeks in the CC area, this leads to different software configurations and to different needs in the time scale for printed reports.

(ii) Supply side considerations

- (26) The notifying party submits that from the manufacturing point of view, switching production from one type of monitor to another is easy and can be achieved at a low cost. Different care area monitors can be manufactured on the same production platforms. Moreover, the monitor's manufacturers are mainly assemblers and source a large proportion of their inputs from third parties, which are component manufacturers. Co-operation with third parties can therefore enhance this flexibility in production¹².
- (27) However, each supplier manufactures models that can be specifically designed for the PO or the CC area. Some players, including the main suppliers, are more active only in some care areas than in others (for example, before the acquisition of Spacelabs, Instrumentarium was only marginally present in CC monitors and is not active, like Siemens, in GW monitors, whereas GE and Philips are present in the three segments)¹³. This is particularly true as regards small suppliers, which tend to focus more on CC areas, where technological barriers to enter the market remain generally lower than in the perioperative area.
- (28) The market investigation has also shown that the R&D efforts of monitor suppliers are focused on the specific applications of their products and differ substantially depending on whether their products are designed for the perioperative or the critical care areas. In that respect, the various suppliers have indicated that the latest innovative developments have indeed been different for perioperative and critical care monitors. Amongst the most important technological developments specific to the perioperative area, suppliers mention *inter alia* the introduction of software specifically adapted to the operating room, networked monitoring for the operating room, integrated anaesthesia record keeper and specific ergonomics. As regards parameters, the various suppliers also mention important developments, varying according to the market concerned. For instance, the latest innovations for PO monitors concern elaborate electroencephalogram and neuro-muscular measurements, in order to measure the effects of anaesthesia. For CC monitors, technological developments have focused, *inter alia*, on the introduction of non-invasive parameters aimed at measuring cardiac output and blood pressure. All these elements indicate that, given the costs of R&D and the time required to develop new products adapted to the care area for which they are used, there are important technological barriers to recustomizing CC monitors as PO monitors, and vice versa.
- (29) The market shares of the parties and their competitors in each care area are also quite different, suggesting the same market segmentation. Were PO and CC to be considered as belonging to the same relevant product market, similar market shares for each segment would be expected, which is not the case.

¹² Form CO page, 47.

¹³ Form CO, page 44.

- (30) These facts constitute a clear indication of the difficulties in switching from one segment to the others. In this respect, the notifying party acknowledges¹⁴ that *“The costs of switching between the different care areas is foremost determined by the costs and time of developing a suitable product and, even more importantly, of building up a reputation as a reliable supplier within a certain care area.”* The market investigation has indeed shown that, among the various reasons both to change or not to change of supplier, reputation is a key factor in the decision¹⁵. Consequently, a given company not present in one of the markets is unlikely to obtain a reliable reputation for the provision of these services, at least in the short term. These switching difficulties suggest that the three defined care areas are distinct product markets.
- (31) In the light of the above, PO, CC and General Ward monitors constitute separate relevant product markets.

2. ANAESTHESIA EQUIPMENT

- (32) Anaesthesia equipment is used to deliver anaesthetic gases to patients during operations, to supply them with oxygen during the operation, to provide artificial respiration if necessary and to monitor the patient during the entire period of narcosis.
- (33) In case No COMP/M.2861–Siemens/Drägerwerk/JV¹⁶ the Commission concluded that anaesthesia equipment as a whole constitutes a relevant product market, the key arguments being the high differentiation of the product and the particular specifications that the equipment must meet. The Commission’s market investigation did not reveal any new evidence indicating that this conclusion is not valid any more.

3. CLINICAL INFORMATION SYSTEMS (CIS)

- (34) According to the notifying party, IT solutions for medical equipment are commonly divided between Hospital Information Systems (HIS), Clinical Information Systems (CIS) and Picture Archiving Communication Systems (PACS). CIS is used for automating patient records, patient medical readings and other clinical information. The parties’ activities overlap in CIS. GE is active in the critical care and perioperative areas with its “Centricity Critical Care” and “Centricity Perioperative” products. Instrumentarium is present in the same care areas through its “Deio” and “Clinisoft” products. In addition to CIS, GE is also active in HIS and PACS. From a demand-side perspective, hospitals which require a CIS product to satisfy their needs for automated recording, for electronic exchange of data between different devices and automated patient records cannot turn to substitute products. Likewise, from a supply-side perspective, CIS

¹⁴ Form CO, page 43.

¹⁵ The results from the market investigation (questionnaire sent to patient monitors customers on 7 May 2003, questions 19 and 21) indicate that, for example, for PO monitors the more important reasons not to change of supplier are: in France and Spain the proven track record and better technology of the current supplier, in the United Kingdom the proven track record and the avoidance of switching cost, and in Germany that PO and CC are of the same brand. The more important reasons to change are: in France and Spain the proven track record and better technology of the new supplier, in the United Kingdom the better technology, the connection capabilities and the proven track record and in Germany the better technology and the electronic interoperability.

¹⁶ OJ L 311, 14.12.2002, p. 12.

has distinct characteristics which differentiate it from other types of software, notably its ability to exchange medical electronic data in real time at the point of care. Accordingly, for the purpose of this Decision and taking into account the fact that it is still an emerging market, the Commission considers that there are strong indications pointing towards a distinct CIS product market.

4. MOBILE C-ARMS

General description of the product

- (35) C-arms are mobile fluoroscopic X-ray machines used in hospitals and clinics to provide continuous viewing in real-time during diagnostic, surgical and interventional procedures. In comparison to general radiography where a static X-ray or an X-ray picture is provided, fluoroscopy offers a dynamic X-ray, or X-ray movie, used for the imaging of the flow of contrast media in a variety of body parts and organs.
- (36) A C-arm consists of a piece of metal forged in the shape of letter “C” with an X-ray tube at one end of the “C” and an image intensifier attached to the other. The image intensifier enhances the picture generated by the X-ray which would otherwise not be clearly visible for the human eye.¹⁷
- (37) C-arms can be either large C-arm systems which are mounted on the ceiling (“fixed C-arm systems”) and form a fixed part of a radiology & fluoroscopic room of a hospital, or mobile C-arms, which are attached to a wheeled device that allows the machine to be brought to the patient during operations and medical procedures.¹⁸ Mobile C-arms are used in the operating room as well as outside the perioperative units in the coronary care unit or the intensive care unit. According to the notifying party¹⁹, fixed fluoroscopic systems account for more than 80% and mobile C-arms less than 20% of the fluoroscopic X-ray market. It is understood that the price of a fixed system can be significantly higher than that of a mobile C-arm. The notifying party takes the view that even if fixed systems are technically capable of offering an alternative to some, especially high-end, C-arms and provide to an extent a competitive constraint to mobile systems, it is not necessary to determine whether C-arms are part of a larger market for fluoroscopic X-ray devices, as no competition concern arise in a narrower defined mobile C-arms market. Both GE and Instrumentarium manufacture mobile C-arms but Instrumentarium does not manufacture fixed C-arm systems.
- (38) It is also stated by the notifying party that most mobile C-arms on the market are full-size C-arms but that there are also mini C-arms. Mini C-arms also provide real-time X-ray imaging but their use is limited to basic orthopaedic procedures on extremities, namely arms and legs. The size of the mini C-arms market is significantly smaller than that of full-size C-arms. According to a report by the industry consultancy Frost & Sullivan, “US Fluoroscopy and Mobile C-arms Markets”²⁰, in 2001 the European market for full-size C-arms comprised 941 unit shipments and produced revenues of USD 63.0 million, whereas the market for mini C-arms comprised of 49 unit

¹⁷ Frost & Sullivan US Fluoroscopy and Mobile C-arms Markets 2002, 2-1, 2-2.

¹⁸ Form CO, page 62, footnote 77.

¹⁹ Form CO, page 62, footnote 78.

²⁰ Frost & Sullivan US Fluoroscopy and Mobile C-arms Markets 2002, Chapter 6 World Mobile C-arm Market, 6-1.

shipments and USD 3.0 million in revenues²¹. In comparison, the European mini C-arms market is about 10% of the size of the US market²². Whereas both GE and Instrumentarium manufacture full-size C-arms, Instrumentarium does not manufacture mini C-arms.

Possible distinction between different types of mobile C-arms

- (39) The notifying party submits that even if all full-size C-arms perform the same basic function in providing real-time images of the part of the body under examination, a possible distinction may be drawn between mobile C-arms by distinguishing the medical application for which the equipment is utilised, given the various degree of complexity of the treatment, the necessary technical properties and the price of the C-arm.
- (40) Consequently, the notifying party suggests a possible segmentation of the mobile C-arms market into: (i) low-end C-arms, (ii) vascular C-arms and (iii) cardiac C-arms. The notifying party takes, however, the view that regardless of the market definition adopted, namely the overall full-size mobile C-arms or the segmentation by application, the transaction would not raise competition concerns. Both parties are active in vascular and low-end C-arms but only GE is active in cardiac C-arms.
- (41) Medical applications, for which all full-size C-arms, including low-end C-arms, can be utilised, include all orthopaedic examinations (extremities, hip and spine), general fluoroscopy (catheter placements, gastro-intestinal procedures, urology, lithotripsy), pain management procedures, laparoscopy (abdominal imaging), endoscopy, ear nose and throat procedures, pacemaker insertion and speech pathology. The applications of a lower tier of C-arms (“low-end C-arms”) therefore cover in essence orthopaedic applications and simpler surgical procedures.
- (42) The middle tier of C-arms (“vascular C-arms”) perform additionally basic minimally invasive and diagnostic vascular procedures (procedures involving blood vessels) including phlebography, arteriography and lymphography.
- (43) The high tier of C-arms (“cardiac C-arms”) consists of equipment which, in addition to the functions also carried out by low-end and vascular C-arms, can in most cases²³ also be used for advanced vascular procedures and vascular surgery, including coronary angiography, the placement of abdominal aortic aneurysm stents as well as neurosurgery and neurovascular examinations.
- (44) The Commission’s market investigation has largely confirmed the above product market segmentation²⁴. A number of market participants²⁵ consider, however, that a market definition based on a distinction of C-arms by their application is not appropriate. They suggest, for example, a distinction between high and low-end mobile C-arms or alternatively an overall market for mobile C-arms. The Commission

²¹ Frost & Sullivan US Fluoroscopy and Mobile C-arms Markets 2002, Chapter 6 World Mobile C-arm Market, 6-2.

²² Frost & Sullivan US Fluoroscopy and Mobile C-arms Markets 2002, Chapter 6 World Mobile C-arm Market, 6-1.

²³ The use of C-arms for cardiac applications is not permitted in national legislation in France and Germany.

²⁴ Replies to the Commission’s Art. 11 letter to hospitals (mobile C-arms customers) of 11 March 2003.

²⁵ Replies to the Commission’s Art. 11 letter to competitors of 11 March 2003.

concludes, however, that the assessment would not change significantly even if another segmentation or a wider market for mobile C-arms be applied. The arguments put forward by the notifying party for a further segmentation of the mobile C-arms market, which were largely confirmed by the market investigation, are, however, assessed in more detail below.

(i) Demand side considerations

- (45) According to the notifying party, as regards the technical differences, low-end C-arms, which represents some 500 units annually sold in the EEA, typically provide for a low generator power (1.4-5 kW²⁶), a stationary anode X-ray tube, basic imaging features, minimal image processing and image storage capacities and limited image display capacity. It is stated that low-end C-arms are limited in their use for vascular procedures by their inadequate power to provide imaging for the time required for the procedure. The price for a low-end C-arm is typically below EUR 65.000²⁷. In this range, GE manufactures the OEC 7700 models and Instrumentarium the Ziehm Compact and the Ziehm 8000 (previously Exposcop 8000 Compact and Exposcop 8000)²⁸.
- (46) Middle-tier vascular C-arms, which, according to the notifying party, also represent some 500 units annually sold in the EEA, also have lower generator power (1.3-5 kW²⁹) than cardiac C-arms and typically use a stationary anode X-ray tube. This is said to limit the use of vascular C-arms to more basic vascular procedures (such as orthopaedic and gastro-intestine examinations) and provides only for a lower penetration capability. The price for a vascular C-arm varies between EUR 60.000 and EUR 100.000³⁰. GE manufactures the OEC Flexiview 8800 and Instrumentarium the Ziehm Vision, Ziehm Vista Vascular and Ziehm Vista Endo (previously Exposcop 8000 Endo)³¹.
- (47) The notifying party submits that high tier cardiac C-arms, which represent approximate sales of 300 units annually in the EEA, feature a rotating anode X-ray tube enhancing the capacity of the machine, high generator power (5-20 kW³²), high resolution image processing and digital image storage capacity. Rotating anode allows for a continuous viewing during a cardiac procedure. The price for a cardiac C-arm is said to range between EUR 80.000 and EUR 200.000³³. GE manufactures the OEC 9800 models which can be upgraded for cardiac functions. [...] ³⁴.
- (48) With regard to the substitutability between the different types of C-arms, the market investigation³⁵ largely showed that, from a hospital's point of view, there are differences between the various types of C-arms, although from technical and medical

²⁶ Annex 6.8 to the Form CO.

²⁷ Annex 6.8 to the Form CO.

²⁸ Form CO, p. 64.

²⁹ Annex 6.8 to the Form CO.

³⁰ Annex 6.8 to the Form CO.

³¹ Form CO, p. 64.

³² Annex 6.8 to the Form CO.

³³ Annex 6.8 to the Form CO.

³⁴ Form CO, p. 63.

³⁵ Replies to the Commission's Art. 11 letter to hospitals (mobile C-arms customers) of 11 March 2003.

point of view the cut-off point is not always clear since the product lines to a certain extent provide for a continuum. The Commission also observes that the price of the equipment and the required service level from the supplier vary according to the complexity of the C-arm³⁶.

- (49) It must also be noted that despite technical differences between the proposed segments, first, there is a possibility for one-way substitution in the utilisation of technically more advanced C-arms (cardiac and vascular C-arms) to perform procedures typically appropriate for the application of the low-end C-arms. This is, however, not perceived by the surveyed hospitals as a factor influencing the preferred choice of a mobile C-arm, owing to other related factors such as the difference in price³⁷. Secondly, according to a number of market participants it is possible to upgrade a low-end C-arm to a vascular C-arm or a vascular C-arm to a cardiac C-arm. Such an upgrade would include, *inter alia*, installing necessary software options. The additional cost for upgrading a low-end C-arm to a vascular C-arm was, in general, estimated as EUR 10.000-20.000 and the cost was estimated significantly higher for an upgrade of a vascular C-arm to a cardiac C-arm. The latter would also require improvements to other specifications of the C-arm.³⁸
- (50) Frost & Sullivan does not further segment the market in its Reports on fluoroscopy and C-arms markets but makes a distinction between mobile full-size and mini C-arms and generally acknowledges, in respect of smaller suppliers of C-arms on the European market, that these mainly provide more general C-arms instead of C-arms used for a particular applications, like vascular surgery³⁹. The Commission's market investigation indicates that, in general, the smaller suppliers tend to concentrate either on the low-end C-arms or cardiac/vascular C-arms due to more limited resources available for R&D, manufacturing and marketing of a full range of mobile C-arms⁴⁰.

(ii) Supply side considerations

- (51) The notifying party submits that from the suppliers point of view, there are credible rivals in the market like Philips and Siemens that have extensive product offerings and in-depth geographic coverage, in addition to other competitors that successfully compete with the large competitors in their chosen product and geographic areas. It is also stated that there are no significant barriers to expanding production, distribution or after-sales service and that any supplier of C-arms could easily respond to an increase in demand. An increase in production would entail procurement of more materials and acquiring more personnel. The notifying party takes the view that although patents are common in the C-arms business, none of the competitors possess unique technology and that they source a large proportion of their inputs from third parties which are component manufacturers.
- (52) The market investigation has confirmed that, of the major players on the market (GE, Instrumentarium, Siemens and Philips), all, apart from Instrumentarium, have a

³⁶ Annex 6.16 to the Form CO.

³⁷ Replies to the Commission's Art. 11 letter to hospitals (mobile C-arms customers) of 11 March 2003.

³⁸ Replies to the Commission's Art. 11 letter to hospitals (mobile C-arms customers) of 11 March 2003.

³⁹ Frost & Sullivan, US Fluoroscopy and Mobile C-arms Markets, Chapter 6 World Mobile C-arm Market (2002), 6-1.

⁴⁰ Replies to the Commission's Art. 11 letter to competitors of 11 March 2003.

strong presence in all three proposed segments of mobile C-arms.⁴¹ At the EEA level, GE is the clear market leader in cardiac C-arms, Siemens the market leader in vascular C-arms and GE again in low-end C-arms. The market shares of the parties and their competitors in each segment vary from segment to segment which is considered as an indication of the segmentation of the market. Were the C-arms for low-end, vascular and cardiac applications to belong to an overall product market, such divergence in market shares in different segments would not be expected. The divergence in market shares in different segments is indicated in the table below (year 2002).

Market shares (in value) in the EEA in 2002

2002	Cardiac	Vascular	Low-end	Total
GE	[50-60]*%	[20-30]*%	[20-30]*%	[30-40]*%
Instrumentari	[0-10]*%	[20-30]*%	[20-30]*%	[10-20]*%
Combined	[50-60]*%	[40-50]*%	[40-50]*%	[40-50]*%
Philips	[20-30]*%	[20-30]*%	[20-30]*%	[20-30]*%
Siemens	[20-30]*%	[20-30]*%	[20-30]*%	[20-30]*%
Others	[0-10]*%	[0-10]*%	[0-10]*%	[0-10]*%

Table 1 (Source: the notifying party)

- (53) Furthermore, the Commission considers that technical differences related to the level of complexity of the medical procedures and the necessary after-service obligations, render the entry into the cardiac C-arms segment considerably difficult. [...]*
- (54) Therefore, on the basis of an overall assessment of the information gathered from the market investigation it seems that the conditions of competition appear sufficiently different to indicate that these three segments of mobile C-arms constitute separate relevant product markets. However, the question of the precise product market definition can be left open, since, even if another segmentation of the C-arms market or a wider product market comprising all mobile C-arms were appropriate, as suggested by the notifying party, the notified concentration would not lead to the creation or strengthening of a dominant position as a result of which effective competition would be significantly impeded in the common market or in a substantial part of it.

5. MAMMOGRAPHY DEVICES

General description of the product

- (55) Mammography is a specific type of X-ray imaging device exclusively used for medical examination of the female breast: X-rays produce an image of internal breast tissue with the purpose of detecting malignant growths. The device can be used both for screening, namely early detection of any malignant growth, and for diagnostic or interventional purposes. Breast screening campaigns aim at detecting any malignant growth in a large fraction of the female population at an early stage.
- (56) The image of the breast made by X-ray can be recorded on a film, using an X-ray cassette, or digitally recorded and displayed through a digital receptor (plate) and the

⁴¹ Replies to the Commission's Art. 11 letter to competitors of 8 May 2003.

utilisation of a computer. This factor distinguishes the two types of mammography equipment: analogue mammography and digital mammography.

- (57) According to a Frost & Sullivan report on World X-Ray Mammography Market⁴², in 2001, the European market for analogue mammography comprised of 1277 unit shipments and produced revenues of USD 106.8 millions, whereas the market for digital mammography amounted to 27 unit shipments and USD 10.4 million in revenues.

Distinction between analogue and digital mammography

- (58) Analogue technology has been available for some decades and constitutes the most established technology in the market. Digital technology has recently been introduced into the market and its growth is expected to be rapid in the years to come along with new developments in digital detectors with higher spatial resolution (smaller pixel size), contrast resolution, low-dose X-rays and 3D imaging.
- (59) Both parties are active in analogue mammography devices but only GE currently manufactures digital mammography devices. Instrumentarium does not currently manufacture full-field digital mammography devices [...]*
- (60) The notifying party submits that there are factors such as the significant price difference between analogue and digital devices that suggest distinct product markets for the two categories of mammography devices. Nevertheless, they propose that the relevant product market definition be left open as the market is in transition.
- (61) The market investigation has confirmed that there are substantial price differences between analogue and digital mammography devices: the average price for an analogue mammography device is around EUR 50.000 whereas it is around EUR 300.000 for a digital device. Currently digital devices form a small percentage of the overall sales of mammography device units in the EEA. In line with these figures, the overwhelming majority of customers responding to the Commission's market investigation⁴³ indicated that they would not switch from an analogue to a digital mammography device if the price of the former were to rise permanently by 5-10%.
- (62) Moreover, there are significant differences in technical performance (image quality and storage) between the two types of mammography devices. Digital mammography devices are expected to offer better contrast resolution and other image characteristics that will improve the capability to detect cancer at an early stage and to reduce errors in detection (so called false-positive). Improvements offered by the digital technology relate also to lower radiation doses and general functionality of digital technology, such as digital transmission and storage of imaging. Furthermore, it is expected that digital technology will enhance new applications, such as 3 Dimension (tomosynthesis) or a combination with ultrasound⁴⁴.
- (63) The notifying party states that digital mammography is more efficient than analogue in that it captures up to 20% more of the original X-ray signal and increases productivity, namely the number of examinations per day, by approximately

⁴² Frost & Sullivan, World X-Ray Mammography Market, 2001, Chapter 3.

⁴³ Replies to questionnaire to customers of 11 March 2003.

⁴⁴ Competitors' reply to the Commission's questionnaires on R&D in Mammography dated 28.5.2003.

40-50%⁴⁵. The Commission observes, however, that there has been some uncertainty as to the sharpness of the image resolution of digital mammography devices and the size of the X-rayed area in comparison to those offered by analogue equipment. Digital mammography devices have so far not been accepted in the national breast screening programs in some EEA countries, because screening requires both a precise and efficient device in terms of patient throughput. However, it is merely a question of time before these technical limitations are overcome.

- (64) Although analogue and digital mammography devices share some common characteristics and can be manufactured on the same product line, there is not a sufficient degree of supply-side substitutability between the two segments. There are substantial differences among the two kinds of devices. The development of digital mammography devices requires, on the part of the manufacturer, significant investments⁴⁶ in research and development to address specific issues related to digital devices, namely the conversion of X-ray signal into digital signal with respect to image resolution and speed. This requires innovation in the technology for full-field radiation detector as well as digital processing of the image for the visualisation of small structures inside dense breast tissues. As a result of such developments in digital mammography, GE holds more than [...] patents⁴⁷ in this field. As a half-way solution between analogue and fully digital devices, some companies⁴⁸ have developed solutions to upgrade analogue devices to produce digital images.
- (65) All these factors indicate a product market distinction between analogue mammography and digital mammography.

B. THE RELEVANT GEOGRAPHIC MARKETS

- (66) The notifying party takes the view that factors such as a common legal framework for a wide range of medical devices⁴⁹, significant level of supply substitution, centrally organised production, minimal transport costs and the non-existence of insurmountable barriers to entry in terms of setting up a distribution network, suggest that the geographic markets for patient monitors, C-arms and mammography devices are increasingly becoming EEA-wide.
- (67) The Commission's market investigation has shown, however, that the markets for patient monitors, C-arms and mammography devices are national in scope.

1. PATIENT MONITORS

- (68) Since the GW market is not affected (only GE is active in this market) the relevant geographic analysis is focused only on the PO and CC markets.

⁴⁵ Form CO, p. 93.

⁴⁶ According to Frost & Sullivan, GE has spent over \$100 million over ten years, while Siemens USD 50 million, and Fischer Imaging almost USD 30 million.

⁴⁷ Philips' reply to the Commission's questionnaire dated 28.05.2003 and dealing with R&D in Mammography, page 3.

⁴⁸ For instance: Instrumentarium, Siemens and Philips.

⁴⁹ Medical Devices Directive 93/42/EC of 14 June 1993.

Presence in the individual Member States

- (69) The market penetration of the major monitoring manufacturers differs among the Member States, in particular as regards perioperative monitors.
- (70) For example, GE has no reported sales of such products in countries such as [...]*, [...]*, and [...]*, while being present in neighbouring countries (Spain: [10-20]*%; Denmark: [10-20]*% and Germany [0-10]*%) Similarly, Instrumentarium, although present on all markets, has higher market shares in Spain ([60-70]*%) than in France ([40-50]*%) or Portugal ([30-40]*%) The same applies for other manufacturers: Siemens only has a [5-10%]* market share in the United Kingdom, while having [20-25%]* in Ireland, and [5-10%]* in Spain compared to [50-55%]* in Portugal. Similarly, Philips has a [20-25%]* market share in France, but only [5-10%]* in Spain and the United Kingdom.
- (71) These different market structures, even between neighbouring countries, suggest that the conditions of competition vary significantly amongst Member States. In particular, there is no evidence that a grouping of Member States can be considered as a distinct geographic market. These discrepancies in market shares across the Member States are also present in the market for CC monitors to a similar extent.

Price differences in the Member States

- (72) The notifying party submits that the differences in their list prices are due to the different discounting schemes in each country: where list prices are relatively higher in one Member State, this is offset by higher levels of discount.
- (73) However, the Commission found that there are differences in transaction prices. In particular, when analysing the information provided by the notifying party⁵⁰ even the distinct discounts applied in each country do not offset these price differences. The table below, where GE’s list prices and average discounts are summarised for some Member States, shows that there are countries with similar list prices but with different average discounts, which indicates that final selling prices are different. For example, list prices for DASH 2000 in [...]*are higher than in [...]*, while the average discount is lower, which leads to a higher final price. The same pattern can be found for other products and countries, supporting the conclusion that final selling prices do vary across the Member States.

Country	Average List Prices					Average discount	
	Models					Dash models	Solar models
	Dash 2000	Dash 3000	Dash 4000	Solar 8000	Solar 9500		
Austria	[3 – 8]*	[6 – 11]*	[8 – 13]*	[5 – 10]*	[13 – 18]*	[...]*	[...]*
Belgium	[3 – 8]*	[6 – 11]*	[8 – 13]*	[5 – 10]*	[14 – 19]*	[...]*	[...]*

* Parts of this text have been edited to ensure that confidential information is not disclosed; those parts are enclosed in square brackets and marked with an asterisk.

⁵⁰ Annex 6.16 to the Form CO.

France	-	[7 – 12]*	[9 – 14]*	-	-	[...]*	[...]*
Germany	[3 – 8]*	[6 – 11]*	[8 – 13]*	[5 – 10]*	[13 – 18]*	[...]*	[...]*
Italy	[3 – 8]*	[5 – 10]*	[7 – 12]*	[5 – 10]*	[13 – 18]*	[...]*	[...]*
Ireland	[4 – 9]*	[7 – 12]*	[10 – 15]*	[6 – 11]*	[15 – 20]*	[...]*	[...]*
Netherlands	[3 – 8]*	[6 – 11]*	[8 – 13]*	[5 – 10]*	[14 – 19]*	[...]*	[...]*
Portugal	[2 – 7]*	[5 – 10]*	-	[4 – 9]*	[10 – 15]*	[...]*	[...]*
Spain	[2 – 7]*	[5 – 10]*	-	[4 – 9]*	[10 – 15]*	[...]*	[...]*
Sweden	[3 – 8]*	[6 – 11]*	[9 – 14]*	[5 – 10]*	[15 – 20]*	[...]*	[...]*
UK	[4 – 9]*	[7 – 12]*	[10 – 15]*	[6 – 11]*	[15 – 20]*	[...]*	[...]*

Table 2 (Source: the notifying party) (*) Solar 8000

- (74) These final customer price differences are also confirmed by independent studies⁵¹, where average prices are calculated for multi-parameter patient monitoring systems and for all brands in Europe. The results show substantial price differences ranging from 16% to 32% between countries such as for example France or Spain and the United Kingdom.

Distribution and after-sales service

- (75) As stated above in the product market section, aspects such as after-sales service, maintenance and training are key factors in taking the final purchasing decision. The notifying party has also pointed out the importance of this issue stating that local distribution operations, including the provision of after-sales services, appears necessary to be an effective competitor in the country concerned. This need of services has been confirmed by the Commission market investigation, where, together with specification and quality, factors such as after-sales service, continuous maintenance, training and the capacity of providing maintenance and service over the whole life-cycle of the product are the more appreciated by the customers when taking the final purchasing decision⁵².
- (76) Furthermore, most small competitors in critical care monitoring are not present in all the Member States, which is a clear indication of the difficulties in obtaining a reliable after-sales service network even through third parties. By contrast, the main suppliers are present in, at least, all the large markets⁵³. Their distribution structure may however vary depending on the countries. For instance Instrumentarium sells direct to final customers in countries such as [...]*, while selling on a national basis through distributors in neighbouring countries. In that respect, the Commission has found no evidence that any group or cluster of Member States could form a distinct geographic market.

⁵¹ Frost & Sullivan report on the European Anaesthesia and Respiratory Equipment, 2001 (3981-56), pages 5-18, 6-17, 7-17, 8-17, 9-17, 10-15, 11-17.

⁵² In the market investigation the customers in the various countries were asked to assess the importance of 20 different factors when choosing a patient monitor's supplier. In Germany and Spain, the ability of the supplier to provide maintenance and service over the life cycle of the product was the second most important factor for respondents. In France and the United Kingdom, this was mentioned as the third most important factor, and in Sweden the fourth.

⁵³ See also T for G, 2000, 3.3. at page 131.

- (77) In light of these factors, the Commission has reached the conclusion that each Member State constitutes a separate relevant geographic market.

2. ANAESTHESIA EQUIPMENT

- (78) In Case COMP/M.2861–Siemens/Drägerwerk/JV the Commission concluded that the geographic market anaesthesia equipment was national. Key arguments supporting this view were the fact that the parties had very different market shares in the individual EEA countries and that they had different competitors in them, that most competitors operated in only one or two Member States, that a local distribution and servicing structure was of crucial importance to market success and that anaesthesia equipment was distributed predominantly through invitations to tender, with customer preferences playing an important role in the final purchasing decision.

3. CLINICAL INFORMATION SYSTEMS (CIS)

- (79) As explained above, CIS are mainly IT solutions used as accessories to medical equipment to enhance its capabilities. Indeed, CIS is a complicated IT system which requires installation by experts. Installation can take up to 18 months and is tailor-made to the hospital's needs. Training is also offered to the hospital staff by the installer of the CIS system. As such, a dedicated distribution, installation, maintenance and service network operating on a national basis is of great importance. In this context, the same arguments supporting the national market definition for PO and CC monitors suggest that the relevant geographic market for CIS is also national. In particular, it should also be noted that the sales of CIS go through the same distribution channels as the ones for patient monitors, on a national basis, and that the penetration rates differ across the various EEA member states.

4. MOBILE C-ARMS

Presence in the individual Member States

- (80) According to the information submitted by the notifying party, the parties' market position and that of competitors varies significantly in different Member States⁵⁴.
- (81) For example, in low-end C-arms, on the basis of 2002 figures, Instrumentarium has a strong market position in Finland ([50-60]*%), Denmark ([30-40]*%), Germany ([30-40]*%) and Belgium ([30-40]*%), while in some other Member States the markets shares are much lower. For example, in Italy ([10-20]*%), Norway ([10-20]*%) and France ([0-10]*%) its position is much weaker and in some Member States it did not have sales at all ([...]*) in 2002. These discrepancies in market shares are present for the main competitors in both low-end and vascular C-arms. Moreover, a number of smaller competitors are present in some Member States, in particular,

⁵⁴ Annex 6.9 to the Form CO. The total size figures are based on the parties' best estimates initially derived from publicly available data compiled by COCIR. Companies not providing information to COCIR include GMM, SIMAD, Sia, Eurocolumbus, Technix, Metaltronica, Gilardoni, and Villa, mainly active in Italy, Greece, Spain, Portugal. COCIR provides information on C-arms sales in Belgium, France, Italy, Germany, the Netherlands, the United Kingdom, Spain and Sweden. The parties do not have COCIR information for Finland, Norway, Ireland, Greece, Portugal, Denmark and Austria.

Italy, Portugal, Spain and Greece.⁵⁵ The following table shows some of these differences for the parties and their main competitors.

Low-end C-arms: market shares 2002

Company	High market shares		Low market shares	
Instrumentarium	Finland	[50-60]*%	France	[0-10]**%
	Denmark	[30-40]*%	Netherlands	[0-10]**%
GE	Spain	[40-50]*%	UK	[0-10]**%
	France	[40-50]*%	Austria	[0-10]**%
Philips	Netherlands	[50-60]*%	Italy	[10-20]**%
	Sweden	[50-60]*%	Finland	[0-10]**%
Siemens	Austria	[40-50]*%	Italy	[0-10]**%
	Belgium	[30-40]*%	Spain	[0-10]**%

Table 3 (Source: the notifying party)

Vascular C-arms: market shares 2002

Company	High market shares		Low market shares	
Instrumentarium	Austria	[70-80]*%	France	[0-10]**%
	Finland	[40-50]*%	Spain	[0-10]**%
GE	Norway	[60-70]*%	Germany	[0-10]**%
	France	[50-60]*%	Finland	[0-10]**%
Philips	Finland	[50-60]*%	Denmark	[10-20]**%
	Belgium	[50-60]*%	France	[0-10]**%
Siemens	Denmark	[50-60]*%	Austria	[0-10]**%
	France	[30-40]*%	Belgium	[0-10]**%

Table 4 (Source: the notifying party)

Price differences in the Member States

- (82) The investigation has shown that there are significant price differences between the Member States, suggesting national markets. The prices referred to in point (83) have been obtained from GE and are average net prices by country of direct sales for GE's mobile C-arms for a basic model for year 2002.
- (83) For instance, as regards GE's product [...]*, the price ranges from EUR [...]* in Germany to EUR [...]* in Norway (price difference of [15-20]**%). When considering the basic configuration of the [...]***⁵⁶, for example in Germany, the product is priced at EUR [...]* and in comparison in Italy at EUR [...]* and in Norway at EUR [...]* (price difference up to [25-30]**%). Similarly, significant differences in the price of [...]* can be established from EUR [...]* in Germany to EUR [...]* in Italy and EUR [...]* in Norway (price difference up to [40-45]**%)⁵⁷.

⁵⁵ Frost & Sullivan, US Fluoroscopy and Mobile C-arms Markets, Chapter 6 World Mobile C-arm Market (2002), 6-1 considers these as "smaller local companies and the value end of the market that are considered to be assemblers of full-size C-arms and not manufacturers. They procure parts such as X-ray tubes and image intensifiers from other manufacturers and assemble a general mobile C-arm as opposed to a user focused C-arms used for specific purposes such as vascular surgery".

⁵⁶ [...]***.

⁵⁷ Annex 6.16 to Form CO. GE's average net price 2002 with most basic configurations.

Distribution and after-sales service

- (84) The market investigation has confirmed that as regards vascular and low-end C-arms after-sales service, maintenance and training are important factors when taking a final purchasing decision. Third parties emphasise that local distribution operations, including the provision of after-sales services, is necessary for a supplier to be a credible supplier in the country concerned⁵⁸.
- (85) In addition to product specifications and quality, after-sales service, continuous maintenance, training and the capacity of providing maintenance and service over the whole life-cycle of the product are considered as important when taking the final purchasing decision. As regards training of personnel, the market investigation has indicated that training is considered as an important element and the level required varies. The notifying party acknowledges that, for example, in Sweden a high level of training is required for in-house technicians⁵⁹.
- (86) The results of the market investigation indicate that service is estimated to amount annually up to 10% of the final price of the product but with appreciable variations between Member States⁶⁰. Therefore, it also constitutes a not insignificant part of the supplier's revenues. In Italy, where the cost to the customer of the servicing of GE C-arms appears the highest (up to [10-20]*% per annum of the original equipment price), GE itself services [40-60]*% of its C-arms. Instrumentarium's internal documents also indicate servicing constituting approximately [10-20]*% of its diagnostic imaging sales in Europe and identify [...] as focus markets for its new strategy on service contract business⁶¹. GE distributes direct in all EEA Member States, whereas Instrumentarium uses distributors in [...]*
- (87) For the purposes of this Decision, therefore, each Member State constitutes a separate relevant geographic market.

5. MAMMOGRAPHY DEVICES

Presence in the individual Member States

- (88) The Commission's market investigation has shown that the markets for mammography devices are national in scope, as several factors generally accepted as indicators of a national dimension of a geographic market definition are present.
- (89) According to the figures submitted by the notifying party⁶² and the market-shares calculation performed by the Commission, the relative market positions of GE and Instrumentarium vary significantly between different Member States. The market penetration of the other principal multinational competitors, such as Siemens, Philips, or Planmed and Hologic/Lorad, also varies according to the Member State.

⁵⁸ Most hospitals' responses to Question 6 of the Commission's Article 11 letter of 23-27 May 2003 gave most weight to factors such as continuous maintenance, local customer support, and after-sales service in addition to specifications, quality and price.

⁵⁹ Annex 6.16 to Form CO, p. 9.

⁶⁰ Replies to the Commission's Art. 11 letter to hospitals (mobile C-arms customers) of 11 March 2003. See also Annex 6.13 to Form CO.

⁶¹ Instrumentarium Diagnostic Imaging - Strategic plan 2002.

⁶² Annex 6.11 to Form CO.

- (90) For example, in 2002, GE had a market share above [40-50]*% in Belgium, Germany, Greece and Portugal but only [10-20]*% in the Netherlands. Equally, Instrumentarium had a market share above [40-50]*% in Finland and Norway, [10-20]*% in Italy but only [0-10]*% in Germany. Furthermore, GE did not have any sales in Denmark, Finland, Sweden and Norway, while Instrumentarium was either not present or had market shares below [0-10]*% in Austria, Germany, Ireland, and Portugal.
- (91) Similarly, the presence of the parties' competitors varies significantly from one Member State to another. Even though Siemens is generally represented throughout the EEA area, albeit with different levels of market presence in individual Member States, all the other competitors, such as Planmed, Hologic, Philips, Giotto and Metaltronica, operate in only a few Member States.

Price differences in individual Member States

- (92) The Commission's market investigation has shown that purchases by private and public customers are made at local level and that manufacturers are able to apply different prices at national level.
- (93) GE has national price lists for its products presenting substantial price differences in different Member States⁶³: GE's list prices are significantly higher, for instance, in [...] than in [...]*, [...]* and [...]*. They are even lower in Spain. Instrumentarium has used EEA-wide price lists for the last years but applies differentiated discounts to its distributors depending on the country. These discounts vary from [...] to almost [...] %⁶⁴.

Regional or national distribution networks

- (94) The distribution strategy followed by each of the parties also varies from one country to another. GE and Instrumentarium sell direct to the final customers in certain countries while they rely on distributors in others. For instance, Instrumentarium sells [90-100]*% of its mammography devices through distributors⁶⁵ in [...] but [...] (only [20-30]*% of sales effected through distributors), [...] and [...] ([80-90]*% through distributors), [...] and [...]*. These distributors are independent companies that operate in one given Member State or in a region within a Member State. This enhances the local characteristics of the markets for mammography devices.
- (95) GE used to sell through distributors only in [...]*. It ceased to sell through its [...] distributors in 2001 and acquired its Irish distributor early in 2003. Consequently, GE currently sells its mammography devices to final customers through its own distribution network.

Distribution and after-sales service

- (96) The Commission's market investigation has showed that customer/supplier relationships are formed principally on a national basis. Successful sales and the

⁶³ See GE's answer to question 9 of the Art. 11 letter dated 08/05/2003.

⁶⁴ See Instrumentarium's answer to question 4 in the Commission's questionnaire dated 16/05/2003.

⁶⁵ See Instrumentarium's answer to question 1 of the Art.11 letter dated 08/05/2003.

degree of each mammography producer's penetration in a given national market depend quite decisively on the distribution activity and after-sales servicing staff being available and ready to provide assistance to hospitals and to private practitioners on an immediate basis. Training and maintenance services are generally provided by the manufacturers and are usually agreed as part of the purchase of the equipment⁶⁶.

- (97) When it comes to purchasing decisions in hospitals or in private organisations and decisions on tender specifications, the familiarity and reputation of each manufacturer are of primary importance to decision-makers. The purchase decision is taken in most Member States by the hospital administration's commercial department or by private organisations in co-ordination with the appropriate medical staff familiar with the equipment, the radiologists. Specifications defined by doctors and their needs in terms of product specificity and application priorities are decisive factors in purchase decisions. This is the reason why manufacturers present their equipment at trade fairs and medical congresses and pursue customer contacts with practitioners.
- (98) The results of the investigation confirm that customers require assistance and expert knowledge on the part of the supplier's distribution and servicing staff. In fact, customers consider it very important that manufacturers should be able to provide after-sales service and continuous maintenance over the life span of the equipment. Local distribution services are particularly necessary for customers of mammography devices, given the number of private practitioners and private clinics that operate at local level being among the customers of these devices.
- (99) Furthermore, GE and Instrumentarium, as well other competitors, are not present in all Member States. This indicates that there are some difficulties in obtaining a reliable after-sales service network even through third parties. For example, GE is not active in [...]*, [...]*, [...]* and [...]*, while Instrumentarium is not present in [...]* and [...]*.

Conclusion

- (100) In the light of the above elements supported by the Commission's market investigation, the geographic markets for mammography devices are considered to be national in scope.

⁶⁶ In the market investigation public and private customers were asked to assess the importance of 20 different factors when choosing a mammography devices supplier (Art. 11 questionnaires). The more valued factors in each national market were: specifications, quality continuous maintenance, maintenance and service over the whole life-cycle of the product, after-sales service, price and training.

C. COMPATIBILITY OF THE CONCENTRATION WITH THE COMMON MARKET

A. HORIZONTAL EFFECTS

1. PATIENT MONITORS

1.1 Perioperative patient monitors

General market features

- (101) External studies⁶⁷ provided by the notifying party underline that the perioperative monitoring market has been experiencing several changes in the various European countries in the last few years. The market has become a stable and mature market⁶⁸ in which pricing strategy, technological innovation and consolidation have become crucial factors.
- (102) Perioperative patient monitors are differentiated products. The products offered by the various suppliers present different strengths and weaknesses depending on customers' preferences. This is also the case where hospitals meet their needs for these products through calls for tenders. Their product preferences find expression via detailed technical specifications and thus restrict the range of products that come into consideration. The Commission's enquiries have established in particular that, in most countries, the anaesthesiologist, who is the primary user of this equipment, plays an important role in making the choice of a perioperative patient monitor.
- (103) Although they generally want to obtain lower prices, technical specifications required from hospitals therefore play a major role in their purchasing decisions. That is why hospitals award procurement contracts on the basis of the "most economically advantageous" procedure that allows them to select products primarily on the basis of their quality and performance, rather than exclusively on the basis of a "lowest price" offer. Furthermore, the technical specifications requested by customers have become more and more complex and demanding for manufacturers. Not only multiparameter monitors have now become standard practice within the perioperative area, but manufacturers have also added new features and capabilities to their monitors as a result of a demand for sophisticated measurements from hospitals and, in particular, anaesthesiologists⁶⁹. The latest innovative developments include new parameters to measure the depth of anaesthesia and the effects of anaesthetics on the brain, which are becoming more important for the users⁷⁰. Computer technology has also become an important feature of these products with the upgrading or development of new software specifically adapted to the operating room in order to enhance the quality of the anaesthesia record.
- (104) Finally, the market has been going through a strong period of consolidation. According to Frost & Sullivan ("F&S"), *"a few market players are indeed in control of most of the market and the other players tend to divest and focus their resources on*

⁶⁷ Frost & Sullivan (F&S), European Anaesthesia and Respiratory Equipment Markets Report, 2001, 3981-56; T for G market report: Monitors and Ventilators (December 2000).

⁶⁸ T for G, page 10; F&S, 2001, p. 4-47.

⁶⁹ F&S, page 4-41; T for G, page 31.

⁷⁰ See also T for G, page 16.

a country basis or they even tend to concentrate on other markets”⁷¹. More generally, F&S observes that the European anaesthesia and respiratory equipment market (including the perioperative monitoring market) is a mature market, in which even a small gain in market share can be of important value⁷².

Market shares

- (105) According to the information provided by the notifying party in their Form CO, in the case of *perioperative* monitors, the concentration would result in the following market shares:

Perioperative patient monitors

2002 %	EEA	A	BE	DK	DE	FI	FR	GR	UK	IRL	IT	NL	PT	ES	SW	NO
GE	[0-10]*	[0-10]*	[0-10]*	[0-10]*	[0-10]*	[0-1]	[0-1]	[0-1]	[0-1]	[10-20]	[0-1]	[0-1]	[0-10]	[10-20]	[0-1]	[0-1]
Instrumentarium	[40-50]	[50-60]	[30-40]	[20-30]	[30-40]	[80-90]	[30-40]	[20-30]	[60-70]	[30-40]	[40-50]	[30-40]	[20-30]	[50-60]	[40-50]	[0-1]
Combined	[40-50]	[50-60]	[30-40]	[20-30]	[30-40]*	[80-90]	[30-40]	[20-30]	[70-80]	[40-50]	[40-50]	[40-50]	[20-30]	[60-70]	[50-60]	[0-1]
Philips	[10-20]	[0-10]	[10-20]	[20-30]	[10-20]	[0-1]	[10-20]	[20-30]	[10-20]	[20-30]	[10-20]	[20-30]	[10-20]	[10-20]	[10-20]	[20-30]
Siemens	[10-20]	[30-40]	[20-30]	[10-20]	[10-20]	[0-1]	[10-20]	[10-20]	[0-1]	[10-20]	[10-20]	[10-20]	[40-50]	[10-20]	[20-30]	[20-30]
Datascope	[0-10]*	[0-1]	[0-1]	[0-1]	[0-10]*	[0-1]	[0-1]	[0-1]	[0-1]	[10-20]	[0-1]	[0-1]	[0-10]	[0-1]	[0-1]	[0-1]
Others	[10-20]	[0-1]	[20-30]	[30-40]	[30-40]	[0-10]	[30-40]	[30-40]	[0-1]	[10-20]	[10-20]	[20-30]	[10-20]	[10-20]	[0-1]	[50-60]

Table 5 (Source: the notifying party)

- (106) The notifying party thus estimates the merging parties’ combined EEA market share in 2002 at [40-50]*%, having been [40-50]*% in 2000 and [40-50]*% in 2001, with fringe competitors representing a substantial part of the market ([10-20]*%, but [30-40]*% and above in some national markets).
- (107) The notifying party indicates⁷³ that, because of a lack of reliable publicly available sources, they have based these market share calculations on their own estimates, after having used two sources: their respective patient monitoring sales and the sales data provided by the European Co-ordination Committee of the Radiological Electromedical Industry (“COCIR”), a grouping of five medical equipment companies (Instrumentarium, Dräger, GE, Philips, and Siemens). The notifying party, however, considers that COCIR understates the sales of small rivals by approximately [30-40]*% in the perioperative market. They explain that they have thus adjusted the data accordingly and that, in some countries, this ratio was adapted to reflect national differences.
- (108) However, despite the indication by the notifying party that fringe manufacturers account for around [20-30]*% of the EEA market (and for [30-40]*% in some large

⁷¹ F&S, p. 4-50.

⁷² F&S, page 3-4.”*The European anaesthesia and respiratory equipment market is going through a period of significant consolidation. Smaller players are leaving the market and focusing their resources on other sectors of healthcare. F&S also noticed a trend toward divesting, that is, some companies are focusing on a specific country. Finally, there has been a high degree of collaborations and alliances between companies. The major issue is to understand which are the companies that will take advantage of this situations. In a mature market, even a small gain in market share can be of important value, thus market consolidation represents a major challenge for all the market players*”.

⁷³ Annex 6.5 of the Form C/O.

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national markets), external market studies⁷⁴ indicate substantially lower market shares for small competitors and consequently, higher market shares for the parties.

(109) In view of the discrepancies between the estimates of the parties and external market studies, the Commission has done its own market share calculations based on the sales figures of perioperative monitors given by them during the investigation and by companies quoted by the notifying party as competitors on the relevant market⁷⁵. The Commission also requested from the parties and their competitors to provide a breakdown of their sales between direct sales to final consumers and sales to distributors, as well as an estimate of the profit margins of these distributors. These figures were used to calculate the sales of perioperative monitors of each player to end-users⁷⁶.

(110) The concentration leads to significant market shares additions in some national markets. The following picture emerges for the years 2000, 2001 and 2002:

Perioperative monitors: Commission's findings*

2002 %	EEA	A	BE	DK	DE	FI	FR	GR	UK	IRL	IT	NL	PT	ES	SW
GE	[0-5]*	[0-5]*	[0-5]*	[10-15]*	[5-10]*	[0-5]*	[5-10]*	[0-5]*	[5-10]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[15-20]*	[5-10]*
Instrumentarium	[55-60]*	[75-80]*	[55-60]*	[35-40]*	[40-45]*	[95-100]*	[45-50]*	[45-50]*	[70-75]*	[50-55]*	[50-55]*	[65-70]*	[35-40]*	[65-70]*	[70-75]*
Combined	[65-70]*	[75-80]*	[60-65]*	[50-55]*	[45-50]*	[95-100]*	[55-100]*	[45-50]*	[80-85]*	[55-60]*	[50-55]*	[65-70]*	[35-40]*	[80-85]*	[75-70]*
Philips ¹	[10-15]*	[5-10]*	[10-15]*	[30-35]*	[15-20]*	[0-5]*	[20-25]*	[35-40]*	[5-10]*	[20-25]*	[15-20]*	[15-20]*	[5-10]*	[5-10]*	[5-10]*
Siemens	[15-20]*	[10-15]*	[20-25]*	[15-20]*	[30-35]*	[0-5]*	[10-15]*	[10-15]*	[5-10]*	[20-25]*	[20-25]*	[15-20]*	[50-55]*	[5-10]*	[10-15]*
Datascope	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[5-10]*	[0-5]*	[0-5]*	[0-5]*	[5-10]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*
Others	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*
Market size (mEUR)	125.4	4.6	3.9	2.3	23	4.3	15.6	1.6	32.9	1.4	14	5.3	2	7.8	4.2

Table 6 (Source: the Commission's investigation)

2001 %	EEA	A	BE	DK	DE	FI	FR	GR	UK	IRL	IT	NL	PT	ES	SW
GE	[5-10]*	[5-10]*	[5-10]*	[0-5]*	[10-15]*	[0-5]*	[5-10]*	[0-5]*	[5-10]*	[0-5]*	[5-10]*	[15-20]*	[0-5]*	[25-30]*	[10-15]*
Instrumentarium	[55-60]*	[55-60]*	[45-50]*	[70-75]*	[40-45]*	[95-100]*	[45-50]*	[80-85]*	[70-75]*	[60-65]*	[50-55]*	[50-55]*	[55-60]*	[50-55]*	[65-70]*
Combined	[65-70]*	[60-65]*	[55-60]*	[70-75]*	[50-55]*	[95-100]*	[55-60]*	[80-85]*	[80-85]*	[60-65]*	[60-65]*	[70-75]*	[55-60]*	[80-85]*	[75-80]*
Philips	[10-15]*	[5-10]*	[10-15]*	[5-10]*	[10-15]*	[5-10]*	[20-25]*	[0-5]*	[10-15]*	[20-25]*	[10-15]*	[10-15]*	[10-15]*	[5-10]*	[5-10]*
Siemens	[15-20]*	[30-35]*	[25-30]*	[20-25]*	[30-35]*	[0-5]*	[10-15]*	[10-15]*	[0-5]*	[10-15]*	[15-20]*	[10-15]*	[30-35]*	[5-10]*	[15-20]*
Datascope	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	5.9	[0-5]*	[5-10]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*
Others	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*
Market size (mEUR)	118.4	3	3.7	2.2	23.5	2.8	15.4	1.1	29.5	1.4	13.5	6.1	2.0	8.0	3.4

Table 7 (Source: the Commission's investigation)

⁷⁴ See for instance, Frost & Sullivan 2001, "European Anaesthesia and Respiratory Equipment Markets Report", ("F&S 2001"); T for G market report: Monitors and Ventilators (December 2000).

⁷⁵ The small players mentioned in the form CO (page 44) as being active in the market for perioperative monitors were Criticare Medical Systems, Datascope, Fukuda-Denshi, Huntleigh, Invivo, Nihon Kohden, and Welch Allyn Protocol. In the course of the investigation, the parties were asked, in respect of the unattributed market shares, to give a full list of their competitors.

⁷⁶ When firms did not provide the requested breakdown between direct and indirect sales, the average margin indicated by the parties (as being common in the industry) was added to the companies' turnover. This methodology was used in order not to over-estimate the market shares of the parties to the concentration.

2000 %	EEA	A	BE	DK	DE	FI	FR	GR	UK	IRL	IT	NL	PT	ES	SW
GE	[10-15]*	[0-5]*	[5-10]*	[0-5]*	[5-10]*	[0-5]*	[10-15]*	[0-5]*	[10-15]*	[15-20]*	[5-10]*	[25-30]*	[0-5]*	[25-30]*	[5-10]*
Instrumentarium	[50-55]*	[65-70]*	[55-60]*	[65-70]*	[45-50]*	[85-90]*	[45-50]*	[50-55]*	[60-65]*	[35-40]*	[50-55]*	[35-40]*	[30-35]*	[50-55]*	[60-65]*
Combined	[65-70]*	[70-75]*	[60-65]*	[65-70]*	[55-60]*	[85-90]*	[55-60]*	[50-55]*	[75-80]*	[55-60]*	[60-65]*	[65-70]*	[30-35]*	[75-80]*	[65-70]*
Philips	[10-15]*	[0-5]*	[5-10]*	[10-15]*	[10-15]*	[10-15]*	[15-20]*	[0-5]*	[10-15]*	[25-30]*	[10-15]*	[5-10]*	[5-10]*	[5-10]*	[5-10]*
Siemens	[15-20]*	[20-25]*	[25-30]*	[15-20]*	[30-35]*	[0-5]*	[20-25]*	[35-40]*	[0-5]*	[10-15]*	[15-20]*	[25-30]*	[55-60]*	[5-10]*	[25-30]*
Datascope	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[5-10]*	[0-5]*	[5-10]*	[0-5]*	[0-5]*	[5-10]*	[0-5]*
Others	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*
Market size (mEUR)	111.3	3.7	3.5	2.9	23.5	2.0	15.1	0.7	23.0	1.6	13.6	5.2	3.2	8.3	2.9

Table 8 (Source: the Commission's investigation)

- (111) The parties' market share estimates in the Form CO are thus significantly lower than the market shares estimated by the authors of external studies on the European market known to the Commission and by the Commission's market investigation itself.
- (112) The merger would therefore bring together two of the four largest suppliers of perioperative patient monitors in the EEA. At the EEA-wide level, the merging parties would become the leading supplier of perioperative patient monitors with only two remaining sizeable competitors, Philips and Siemens.
- (113) The notifying party argues⁷⁷ that, even on the basis of the Commission's figures, their market position does not give rise to dominance since the overlap is minimal, with GE having around [5-10]*% at the EEA level in 2002, behind Philips and Siemens. Furthermore, during the course of the market investigation, Instrumentarium has contested the provisional estimate made by the Commission of the overall market size of the perioperative patient monitoring market by arguing that they did not match the estimates of the publicly available external studies. However, the Commission's estimates are consistent with F&S's forecasts⁷⁸.
- (114) On the basis of the Commission's investigation, the parties' market position at a national level will indeed lead to a minimal overlap in a certain number of countries where GE had no activity or *de minimis* sales in 2002 ([...]*⁷⁹).
- (115) However, the parties' combined market shares would be close to or in excess of 50% with an overlap exceeding at least 5% in a certain number of countries. At national level, the merger would lead to significant combined shares⁸⁰ in particular, France ([...]*), Germany ([...]*), Spain ([...]*), Sweden ([...]*), and the United Kingdom ([...]*⁸¹).
- (116) At least in countries where they exceed 50% (France, Spain, Sweden and the United Kingdom), the combined market shares may in themselves be evidence of the

⁷⁷ Response to the 6.1.c decision, page 3.

⁷⁸ See the F&S's report (2001), at page 4-44.

⁷⁹ In [...]*, GE's 2002 market share corresponded to sales amounting to EUR [...]* and, in 2000 and 2001, [...]*. As a result, market shares for 2002 on their own are not sufficiently reliable.

⁸⁰ 2002 market shares

⁸¹ The Commission notes that, if the market shares were to be calculated on the weighted average over the last three years, the market shares of the new entity would be as follows - France: [55-60]**%; Germany: [50-60]**%, Spain : [80-85]**%, the United Kingdom: [80-85]**% and Sweden: [75-80]**%.

existence of a dominant position, in particular in view of the fact that the merged entity would be twice the size of its two main competitors, namely Philips and Siemens. In Germany, the combined market share of the merged entity is indicative of a dominant position insofar as it would be in excess of 40% and well above the market shares of its two main competitors, Siemens and Philips.

(117) The notifying party considers that, despite this combined share, the elimination of Instrumentarium as an independent entity would not lead to the creation of a dominant position on these markets because of the following factors⁸²:

- (a) the market is a bidding market, characterised by intense rivalry, where GE is not a major player in the perioperative area and is not a close competitor to Instrumentarium;
- (b) major rivals as well as smaller players would constrain any hypothetical attempt by the merged entity to increase prices;
- (c) the competitive pressure will remain enhanced by hospitals, which are to be considered powerful buyers.

Purchasing processes

(118) Most purchases of perioperative patient monitors in France, Germany, Spain, Sweden, and the United Kingdom are made through a tendering procedure. In these countries, a high proportion of hospitals are public sector facilities⁸³, which, as such, are subject to public tendering rules. As is shown by bidding data provided by the notifying party and their competitors, private clinics also tend to organise tenders. Accordingly, the notifying party estimates at about 60% to 100% the proportion of the sales made through a tendering procedure depending on the Member State concerned⁸⁴.

(119) When deciding to launch a tender for patient monitors the decision-making process is generally described as follows by customers. Purchasing decisions typically include the clinicians working in the relevant medical department where the monitors are to be used. They also involve, to a lesser or greater degree, the hospital's biomedical engineers responsible for maintaining the equipment, and the administrative staff who have responsibility for the financial operations of the hospital. The need for new equipment triggers the purchase of new material. As regards perioperative patient monitors, the customers' survey has confirmed that this is largely done by anaesthesiologists who primarily use this equipment, in particular in the Operating room. They are therefore mainly responsible for determining the technical specifications that the monitors must meet. Depending on the countries, the purchasing decision is then triggered by the general manager⁸⁵ or by an economic

⁸² Form CO p. 54.

⁸³ Form CO, annex 6.1: This goes from 40% in France, 45% in Spain, 50% in Germany, to 80% in the United Kingdom and Sweden.

⁸⁴ Form CO Annex 6.1. 60% in Spain and Germany, 70% in France, 80% in the United Kingdom and Sweden.

⁸⁵ This is the case in the United Kingdom, Germany and Spain (See customers' survey and also T for G, Section 3.2, page 4-7).

committee⁸⁶ or by a commission of medical specialists⁸⁷ but in all instances after negotiations with the doctors and the medical staff needing the equipment.

(120) Because hospitals primarily value the quality and the specifications of the products when they make a choice, winning bids are not generally allocated to the lowest-price bidder, but to the supplier that best meets the individual hospital's requirements on both technical and economic grounds. As was observed in point (103), procurement contracts are awarded on the basis of the "most economically advantageous offer", rather than by following the "lowest price" procedure.

(121) The qualitative requirements are expressed mostly by anaesthesiologists via detailed technical specifications, which thus restrict the range of the products in question according to their preferences. Suppliers respond to the official tender by submitting bids and hospitals then choose the supplier that best meets their requirements on the basis of various cumulative criteria. According to the market investigation, the following criteria are the most important when choosing a monitor with slight variations across countries⁸⁸: the quality and specifications of the product, the price, the technical service (training and after-sale maintenance over the whole life-cycle of the product), and the ability of the supplier to innovate and develop new products. Conversely, the ability of a manufacturer to offer anaesthesia machines as well plays a very limited role in the final decision⁸⁹.

Actual competition

(122) In this case, the fact that purchases mostly go through a tendering procedure in the various Member States does not fundamentally affect the value of market shares as a strong indication of the merged entity's market power. The market investigation has shown that, on average, in each of the Member States concerned, the value of each contract won on a tender is relatively low and the number of tenders for perioperative monitors annually is fairly high⁹⁰. In addition, customisation in this market is fairly restricted since the specifications of the tender already determine whether a given supplier will submit a bid or not. Finally, there are no significant variations in the size of the market for perioperative monitors in particular in France, Germany, Spain, the

⁸⁶ This is the case in France (See customers' survey and also T for G, Section 3.2, page 6).

⁸⁷ This is mostly the case in Sweden according to the customers' survey.

⁸⁸ According to the customers' survey, in France, quality, specifications, and after-sales service were the most important factors before price. In Germany, the long-term prospects of the supplier and its ability to innovate are also mentioned as important factors before price. In Spain, customers put emphasis on quality and specifications as well as on after-sales, training and compatibility with existing monitors. In the United Kingdom, the ability of the supplier to provide training came as the first mentioned factor, just before quality, after-sales service and specifications. In Sweden, after-sales service, quality and training came as the first mentioned factors.

⁸⁹ In all countries, this came as one of the least important factors together with the need to have a local production plant.

⁹⁰ Bidding data submitted by Instrumentarium thus revealed that, out of [...] bids in the EEA, [80-90]% of them were less than EUR 100.000 in value. In France, for example, the proportion reached [90-100]% between 1998 and 2002. In Spain, Instrumentarium mentions [...] bids to which it participated between 1998 and 2002. Out of [...] bids that they won, [...] were less than EUR 100 000. The same proportions can be observed in Germany ([...] won bids, out of which [...] were less than EUR 100.000) and the United Kingdom ([...] won bids out of which [...] were less than EUR 100.000).

United Kingdom and Sweden, and in the market shares⁹¹ of the main competitors, between 2000 and 2002.

- (123) Furthermore, the market for perioperative monitors is not significantly different from a standard differentiated product market. Although products are procured through a tendering process, customers' preferences are reflected in the technical specifications of the tender which, in turn, determine the number of eligible bidders. Customers have individual preferences for specific devices and would consider switching to another model only in response to a more or less significant price rise (relative to competitors). The relative closeness of substitution between the various products, even within one and the same relevant product market, thus forms an important parameter of competition in these markets and has an important influence on suppliers' market power. Market shares thus contain important information as they reflect real purchasing decisions by customers in a given year.
- (124) Consequently, the Commission does not share the view that market shares are meaningless in this particular market.
- (125) In order to assess whether the market shares of the merging parties overestimate or underestimate their market power, the Commission has proceeded to an in-depth analysis of the nature of competition in this bidding market. First, given that competition in these tenders is determined by the number and identity of competitors present, the frequency of encounters of the various market players has been scrutinised. Secondly, since in a differentiated product market competition is all the more intense as competitors are close substitutes, the closeness of substitution is further analysed both on qualitative and quantitative grounds. Last, the Commission sought to determine, on the basis of the available data, the possible price impact of the proposed operation.

GE's positioning on the perioperative market

- (126) The notifying party claims that GE is not a major player in the perioperative area and, as such, does not appreciably affect Instrumentarium's current position⁹². According to the notifying party, GE and Instrumentarium are not, therefore, close competitors in the perioperative monitoring market⁹³. Market shares thus overstate -- it is argued -- the competitive impact of the transaction.
- (127) The notifying party relies *inter alia* on the range of products offered by GE and its market positioning primarily focused on the critical care area. However, the notifying party acknowledges that GE offers several types of monitors for use in the perioperative area (the Solar 9500, the Solar 8000M and the DASH Series⁹⁴), and that each of them present some strengths in comparison to competitors' products. GE's offerings thus include a wide range of monitors, from the low to the high-end, with parameters and functionalities specifically adapted to this market. GE is even quoted by several market participants as a leader in terms of research and development in the

⁹¹ [...]*.

⁹² Form CO page 54.

⁹³ Form CO page 51.

⁹⁴ Form CO page 52.

field of perioperative monitors⁹⁵. Therefore, the fact that GE is a stronger player in the critical care area does not disqualify it as one of the four major suppliers of perioperative monitors.

- (128) The good reputation of GE's monitors in the perioperative area is further confirmed by external studies. T for G thus stresses, as regards the image perception of the parties' products, that "*GE- Marquette has a rather high image in anaesthetics*"⁹⁶. Frost & Sullivan also include GE in the second tier of competitors alongside Philips and Siemens, with Instrumentarium being in the first tier⁹⁷.
- (129) The hospitals surveyed by the Commission's market investigation generally consider that GE, Instrumentarium, Siemens and Philips all supply perioperative patient monitors of comparable quality. In each country, GE's monitors are considered by respondents as high quality monitors in the operating room, with the highest average mark in some Member States in terms of specifications⁹⁸. On average, all four major suppliers are ranked at the same high level in the various countries concerned.
- (130) These elements contradict the assumption made by the notifying party that, from a qualitative viewpoint, GE should be considered neither a major player nor a close competitor to Instrumentarium.

Statistical analysis conducted by the Commission

- (131) In order to assess the intensity of competition between the merging parties, the Commission conducted a series of statistical analyses based on the bidding data provided by Instrumentarium, GE, Draeger, Philips and Siemens. The data provided by Siemens were not useable for this type of analysis. The bidders present in each tender were identified in 3,355 cases throughout the EEA over the last five years. In the following analysis, the Commission considered the sample of bids won by either GE (either direct or via Draeger), Instrumentarium or Philips to be representative.
- (132) The Commission first analysed how often the merging parties encountered each other within those 3,355 tenders. Given that suppliers select the auctions in which they participate, so that a firm does not bid if it believes it has no chance of winning, the more frequently two firms face each other in a given country relative to other potential bidders the more likely it is that their products can be considered close substitutes – at least from the sellers' perspective. In addition, the presence of a supplier in a tender is constrained by the technical specifications required by the hospital which thus restricts the range of competitors that can potentially win the bid.
- (133) At the EEA level, it appears that the merging parties encountered each other in [50-60]*% of the cases. Moreover, they faced no competitor in [20-30]*% of the cases and only one single competitor in [20-30]*% of the cases. When looking at the identity of the parties' competitors, it turns out that in [30-40]*% of the cases, irrespective of

⁹⁵ See responses to the Commission's Article 11 letter to competitors on R&D of 28.5.2003.

⁹⁶ T for G, page 26.

⁹⁷ F & S 3981-56, page 4-49.

⁹⁸ This is the case for instance in France. In Sweden, GE and Instrumentarium come first before Philips and Siemens. In the United Kingdom, Instrumentarium comes first before Philips, GE and Siemens. In Spain, customers ranked Instrumentarium first before GE, Siemens and Philips. In Germany, Instrumentarium comes first, before GE, Philips and Siemens at the same level.

how many competitors were present, the merging parties faced neither Siemens nor Philips but only various fringe players. This would suggest that the merger may result in a reduction of the number of significant players from two to one in one tender out of three.

- (134) The competitive constraint exerted by the merging parties on each other also appears in the bidding data⁹⁹ provided by Philips: the latter won [70-80]*% of the tenders where neither GE nor Instrumentarium were present, [60-70]*% of those where only Instrumentarium was present, [50-60]*% of those where GE only was present and only [30-40]*% of those were both GE and Instrumentarium were present. Therefore, Instrumentarium appears to bid lower when GE is present. In addition, when both Instrumentarium and GE are present, Philips tends to bid lower. The merging parties together thus exert a stronger competitive constraint on Philips.
- (135) At the national level there are strong contrasts, depending on the country.
- (136) As regards the German market, the results suggest that GE provided by far the strongest competitive constraint on Instrumentarium. Both met in [70-80]*% of all 432 tenders under consideration. This figure may overestimate¹⁰⁰ the proportion of bids where both parties actually met in Germany, since it has not been possible to use in this analysis the bidding data provided by Siemens. Indeed, Germany is the national market where Siemens' turnover is the highest. Nevertheless, the above figure strongly contrasts with those relating to Philips or Siemens: Philips only participated in bids against Instrumentarium in [10-20]*% of cases and Siemens in [20-30]*% of the cases.
- (137) Furthermore, the statistical analysis of the bidding data revealed that the merging parties encounter no other competitor in [40-50]*% of the tenders where they meet¹⁰¹, and only one single competitor in a further [30-40]*% of these tenders. As a result, the merging parties face one or no competitor in [70-80]*% of the tenders where they encounter each other. Moreover, it turns out that, in [80-90]*% of the cases, this extra competitor is neither Siemens nor Philips, but a fringe player. These figures suggest that, given the impact of technical specifications on the presence of competitors in tenders, the merger is likely to lead to a reduction of the number of significant players from two to one in most of the tenders where the merging parties used to compete head-to-head.

⁹⁹ 551 data points out of Philips' bidding data were useable for this analysis.

¹⁰⁰ Under certain assumptions, it is possible to assess to what extent the analysis overestimates the frequency of encounters of both parties in Germany. As a matter of fact, it could reasonably be assumed that GE and Instrumentarium met in the bids won by Siemens roughly as often as in the bids won by Philips, i.e. [20-30]*% of the cases, according to a study submitted by Philips on 8 May 2003. Since Siemens' market share (i.e. won bids in value) in Germany is in the range of [30-40]*%, it can be inferred that GE and Instrumentarium meet in [70-80]*% of the cases in [70-80]*% of the bids (those won by either Instrumentarium, GE or Philips) and in [20-30]*% of the cases in [30-40]*% of the remaining bids (those won by Siemens). This lead to an extrapolated frequency of encounter of [50-60]*%. This figure shows that Instrumentarium encounters GE still significantly much more often than Siemens ([20-30]*%) or Philips ([10-20]*%).

¹⁰¹ Among the 432 tenders in Germany where the information about the present bidders was available, the parties were simultaneously present in [300-350]* tenders. Among those, the parties were the only bidders in [100-150]* tenders, faced one single other competitor in [100-150]* bids, among which [50-100]* corresponded to a fringe player (i.e. any player but Siemens, Philips or the parties).

- (138) In Spain, the figures also suggest that GE again provides the main source of actual competition to Instrumentarium. They face each other in [60-70]*% of tenders (out of a total of 542 tenders). Siemens, however, also remains a close competitor ([60-70]*%) but less than GE and all three firms compete in only [40-50]*% of the cases. Philips, in contrast, competes against Instrumentarium rather infrequently ([30-40]*%). Besides, the merging parties face no, or only one, extra competitor in [60-70]*% of the tenders where they encounter each other. Among these tenders, the merging parties face neither Siemens nor Philips in [20-30]*% of the cases.
- (139) As far as France is concerned, GE also appears to be by far the strongest competitive constraint on Instrumentarium: GE competed with Instrumentarium in [70-80]*% of all 1,122 tenders analysed. In contrast, Siemens faced Instrumentarium only in every other tender ([50-60]*%), Philips only in less than 1 tender out of [...] ([10-20]*%). All four competitors meet very rarely ([0-10]*%).
- (140) In the remaining countries, the figures suggest that GE and Instrumentarium met more occasionally. In the United Kingdom, for instance, GE faced Instrumentarium in [20-30]*% of a total of [...] tenders, while Philips competed with Instrumentarium in almost every other tender ([40-50]*%). Nevertheless, among the bids where GE and Instrumentarium met, they faced no other competitor in [60-70]*% of the cases and only one extra-competitor in further [20-30]*% of the tenders. This suggests that there is one or less competitor facing the merging parties in [80-90]*% of the tenders where they meet.
- (141) The picture is similar in Belgium (both parties competed against each other in [10-20]*% of [...] tenders) as well as in Finland (they met in [0-10]*% of [...] tenders). In other EEA countries, the number of useable tenders was too limited to draw any reliable conclusion. For instance, in Sweden, the results tend to show that GE competed against Instrumentarium slightly more often ([40-50]*%) than Philips ([30-40]*%) or Siemens ([30-40]*%). However, the Commission only had at its disposal all the necessary information to run this analysis for 19 tenders in Sweden over the last five years. Therefore, only limited statistically significant results can be derived from these data.

Win-loss analysis provided by the notifying party

- (142) Economics Ridyard, Bishop & Baker (“RBB”) has submitted, on behalf of the notifying party, an analysis of win-loss data to corroborate the contention that the market shares of GE and Instrumentarium do not accurately reflect, and, in fact, they overstate, the competitive impact of the notified transaction. The notifying party considers that, *“to the extent that GE provides a more competitive constraint on the behaviour of Instrumentarium than other suppliers in the relevant market, one would expect to see GE as the second-placed bidder for a large number of those bids won by Instrumentarium and vice-versa”*¹⁰².
- (143) The RBB win/loss study is based on [2000-2500]* tenders for perioperative monitors that Instrumentarium won across the EEA¹⁰³ between 1998 and 2003¹⁰⁴. The study

¹⁰² RBB Study, page 3.

¹⁰³ The data include only less than ten data points in Austria and Norway.

identifies the “runner-up”, meaning the second-placed bidder in each tender won by Instrumentarium for which the information was available to the merging parties. The runner-up is taken to be the closest competitor to Instrumentarium.

- (144) Although the notifying party primarily relies on this study to argue that GE was not Instrumentarium’s closest rival, these data show that between 1998 and 2003 GE was the most frequent runner-up to Instrumentarium in the perioperative monitoring in Europe. According to the data submitted by the parties, at the EEA level, bids containing GE’s perioperative monitors are reported as runners-up in [30-40]*% of all tenders won by Instrumentarium, either when they were sold through Draeger then acting as an exclusive distributor for GE ([700-800]*) or when GE directly participated in the tender ([100-200]*). Philips’ bids are recorded as runner-up in [30-40]*% of the tenders, and [10-20]*% for those of Siemens. Other competitors account for [10-20]*% of the runner-up bids, including Datascope with [0-10]*%.
- (145) GE is by far the most frequent runner-up to Instrumentarium in three countries: [...]*, [...]*and [...]*¹⁰⁵. GE’s monitors qualify as runner-up less frequently than Siemens or Philips in all other countries: Siemens is a runner-up in [...]*¹⁰⁶, [...]*, [...]*¹⁰⁷, whilst Philips is a runner-up in [...]*, [...]*, and in the [...]*.
- (146) Of the [300-400]* tenders that occurred in France for which the parties had relevant information, GE’s monitors were runners-up to Instrumentarium’s in [50-60]*% of the cases, either when they were sold through Draeger ([100-200]* tenders) or when GE directly participated in the tender ([0-100]*). Philips was a runner-up in [...]* tenders, or [10-20]*% of cases, while Siemens and Datascope came in second place in [...]* and [...]* tenders respectively. In the [300-400]* tenders for Germany, GE’s monitors were runners-up to Instrumentarium’s in [70-80]*% of cases, either when sold through Draeger ([...]*) or when GE directly participated in the tender ([...]*), before Siemens ([...]* – [10-20]*% of cases), and Philips ([...]* – [10-20]*%). In Spain ([400-500]* data points), GE is runner-up in [60-70]* % of cases either through Draeger ([200-300]*) or direct ([0-100]*), that is significantly more often than Philips ([20-30]*%) and Siemens ([10-20]*%).
- (147) This would therefore suggest that, at least in France, Germany, and Spain, GE is the closest competitor to Instrumentarium. These data would strengthen the presumption that, alongside a high market share on these markets, the merged entity would have the ability to appreciably increase prices for a significant proportion of its customers without being challenged by its competitors. In such a situation, the take-over of the closest rival would lead to a considerable loss of competition since, in any new bidding round, the merged entity will have the ability to increase its price in the knowledge that the dissatisfied customer would tend to buy its alternative product line.
- (148) The notifying party, however, considers that other factors indicate that GE was not, in fact, Instrumentarium’s closest competitor.

¹⁰⁴ The data set contains more than 10 observations for the following countries: Belgium ([200-300]*), Finland ([200-300]*), France ([300-400]*), Germany ([300-400]*), Greece ([0-100]*), Italy ([100-200]*), the Netherlands ([0-100]*), Spain ([400-500]*) and the United Kingdom ([300-400]*).

¹⁰⁵ GE/Draeger is also identified as the runner-up in Norway in [50-60]*% of cases but on the basis of 9 data.

¹⁰⁶ There are, however, only [0-10]* observations relating to Portugal.

¹⁰⁷ Siemens is actually identified by the sales forces as the runner-up in [...]* out of [100-200]* bids.

- (149) First¹⁰⁸, according to the notifying party, the absence of a systematic correlation in substitution patterns across the different countries show that there is nothing intrinsic in the features of the products supplied by the parties. The Commission notes however that, if brand preferences vary across countries, this only reflects the still different conditions of competition within each Member State. Furthermore, the fact that Draeger was not the runner-up in certain countries is also explained by the fact that it had a limited presence in the Member State concerned. Indeed, in the countries where, according to the parties' data, Draeger was not the runner-up (Belgium, Finland), it appears that Draeger had a very limited presence in the tenders.
- (150) Secondly¹⁰⁹, the notifying party argues that the competitive constraint provided by Draeger/GE is overstated insofar as, during this period, Draeger was also actively marketing other suppliers' monitors (such as Philips's) despite its alliance with GE. The Commission however notes that there is no evidence that Draeger was actively selling other manufacturers' monitors during the period in question where it had an exclusive distribution contract with GE. In response to a Commission's question in that respect, the notifying party was only able to quote two examples of bids where it believed that Draeger had actively marketed other suppliers' monitors¹¹⁰. Bidding data provided by Draeger show that its sales of competitors' monitors have in fact been extremely limited. Finally, even assuming that Draeger had been occasionally bidding third parties' products, these bids would not alter the significant trend evidenced by the parties' data, as Philips and Siemens were each considered as runners-up in only limited proportions.

The GE-Draeger alliance

- (151) The notifying party also considers¹¹¹ that the relative success enjoyed by GE/Draeger during the alliance was due to Draeger's established anaesthesia products, to its strong relationship with anaesthetists and to its distribution infrastructure, but not to the strength of GE's perioperative monitoring offering.
- (152) GE entered into an alliance with Draeger in March 1999, whereby Draeger distributed GE's monitors to the perioperative area on an exclusive basis in all EEA countries. The alliance then turned into a non-exclusive distribution agreement from February to May 2002, at which date Draeger announced its new joint venture agreement with Siemens.
- (153) In the course of the investigation, the notifying party provided the Commission with internal documents relating specifically to its commercial relationship with Draeger during the period 1999-2002. The general message that emerges from GE's internal documents is that the rationale for this agreement was to allow GE to have access to Draeger's distribution network and its good relationship with anaesthesiologists. This is because GE had entered the market in 1998 with the purchase of Marquette and needed to have access to the perioperative market through an established distribution network. GE's internal documents state, for example, that there were two reasons for

¹⁰⁸ RBB study, page 10.

¹⁰⁹ RBB Study, page 10.

¹¹⁰ Response to Article 11 request of 10 June 2003, page 2.

¹¹¹ RBB Study, page 10.

the alliance: “one was distribution; the other was to ensure a closer relationship with anaesthesiologists”¹¹².

- (154) The Commission acknowledges that Draeger’s presence in the upstream market for anaesthesia delivery machines may have had a positive effect on GE’s sales of perioperative monitors.
- (155) However, far from suggesting that GE had no strong product offerings in the perioperative market, internal documents also indicate that Draeger’s position could clearly benefit from this alliance thanks to GE’s products. An internal document of 1999¹¹³ thus states that, amongst other things, Draeger would have [...] * and that [...] *. This therefore suggests that Draeger would equally benefit from GE’s patient monitors offerings on the anaesthesia machine market when competing with Datex-Ohmeda.
- (156) In the course of the investigation, the Commission has tried to assess, in those countries where GE/Draeger appeared as a runner-up to Instrumentarium, the reasons why Draeger’s customers had bought perioperative monitors. The respondents only represented a very small sample and the results appear contradictory depending on the countries. In Germany, a large majority of respondents indicated that they had bought GE’s monitors because of their own characteristics rather than because they were sold by their anaesthesia supplier. Conversely, in Spain, respondents tend to put more emphasis on the fact that the monitors were provided by Draeger, whilst in France the results were split.
- (157) More generally, however, the customers’ survey seem to contradict the suggestion by GE that its selection in bids as the most frequent runner-up in the perioperative area should only be attributed to Draeger’s position in the anaesthesia equipment market. Indeed, a vast majority of customers choose a particular brand of monitors because they meet the technical specifications required. They also strongly rely on the ability of the supplier to rely on a good distribution network able to provide continuous maintenance and after-sales services. Customers further rank GE’s monitors amongst the highest quality products together with those of Instrumentarium, Philips and Siemens. Conversely, the ability of a supplier to also offer anaesthesia machines does not appear as an important factor. The Commission’s survey also shows that, when purchasing new perioperative monitors, customers rely mainly on the proven track record of the monitors’ supplier and the technology offered, whether or not switching from one supplier to another.
- (158) In light of the foregoing, there is reason to consider that GE’s position in the perioperative area compared to other competitors, when bidding against Instrumentarium, should also be attributed to the quality of its monitors and the effectiveness of its distribution network through Draeger, rather than only to the fact that Draeger also had a product offering in the anaesthesia and the ventilation markets. This seems also confirmed by GE’s initial submission in its notification¹¹⁴, as regards its relationship with Draeger, that the success of a competitor’s product in the market depends on the effectiveness of its sales force, as well as its size.

¹¹² See e-mail of 25 September 2001 (from P. van Ryzin to K. King).

¹¹³ Internal document of GE, [...] *

¹¹⁴ Form CO, page 47.

- (159) The notifying party claims that GE was only the runner-up in countries where Draeger had a strong position in the anaesthesia machine market and mostly in tenders where monitors were sold together with the anaesthesia machine. Nevertheless, they provide figures which, in some countries, show no correlation between Draeger's market shares in the anaesthesia market and the number of bids where GE was runner-up to Instrumentarium. Thus, in [...]*, the notifying party submits that GE was never a runner-up to Instrumentarium despite a [20-30]*% market share for Draeger in the anaesthesia machines market. Similarly, the notifying party acknowledges that GE was never a runner-up to Instrumentarium in [...]*, and only in [0-10]*% of the bids in [...]*, despite Draeger's market shares amounting to [20-30]*% and [30-40]*% respectively in those countries.
- (160) As to the argument that GE was mostly a runner-up to Instrumentarium when Draeger was not bidding for solo monitors, the study relies on [100-200]* bids won by Instrumentarium in France and [100-200]* in Spain¹¹⁵. In France, the notifying party claims that, of the [0-100]* projects where Draeger was selected as a runner-up, [70-80]*% were for packaged bids and [20-30]*% for solo monitors. The Commission notes that the study relies on data that only represent a minor part of all bids in France where Instrumentarium was identified as the winner ([300-400]*) and GE/Draeger as the runner-up ([200-300]*). Furthermore, the notifying party themselves acknowledges that, even when taking into account this limited sample of bids, GE/Draeger remained the runner-up to Instrumentarium before all other competitors (GE/Draeger [...]*; Siemens, [...]*; Philips [...]*)¹¹⁶. In Spain, the notifying party indicates that Draeger was only a runner-up in packaged bids, but relies on [100-200]* identified bids out of [400-500]* previously identified bids.
- (161) The parties were also asked to provide figures for solo and package bids in Germany. There, the parties provided [0-100]* examples of bids where Instrumentarium won¹¹⁷. Draeger was a runner-up to Instrumentarium not only in packaged bids ([...] out of [...]*, i.e. [80-90]*%) but also in [60-70]*% of the solo bids won by Instrumentarium ([...] out of [...]*)).
- (162) Finally, the notifying party argues that, following the termination of the Draeger alliance in February 2002, GE's market position has significantly deteriorated whilst Draeger's position in the perioperative segment has not weakened¹¹⁸. The notifying party relies on the fact that GE's perioperative monitoring sales have declined in 2002 and that GE was rarely selected as a runner-up to Instrumentarium between October 2002 and March 2003.
- (163) The Commission notes however that GE's relative decline in market shares in 2002 is inherent to a situation where a supplier's relationship with its distributor deteriorates, rather than to Draeger's activities as such. The notifying party acknowledges that any supplier on the perioperative monitoring market needs a dedicated distribution and sales staff¹¹⁹ and that GE's relationship with Draeger had deteriorated as from

¹¹⁵ RBB Study, page 14.

¹¹⁶ See pages 14-15 of the RBB study.

¹¹⁷ Response to Article 11 request dated 10 June 2003.

¹¹⁸ RBB Study, page 16.

¹¹⁹ Form CO page 47.

February 2002. An internal document suggests that GE itself viewed this decline in market shares as a mere “transition”¹²⁰.

- (164) Because of its size and its financial means, GE has indeed the ability to establish a distribution network and dedicated sales force on the perioperative market. Furthermore, given its position in the critical care monitoring market and its presence in other neighbouring markets for medical equipment such as Clinical Information Systems, GE would have a strong incentive in maintaining and growing its activities on the perioperative monitoring market in order to present customers with a full range of products. Finally, even during this transitory period where it has to re-establish a distribution network, GE was still able in 2002 to retain a sizeable market share, in particular in [...] where it remains the number [...]*, in [...]*, [...]*, [...]*, and [...]*, and to remain present in tenders, thereby constituting a significant competitive constraint to other major bidders such as Instrumentarium. In [...]*, GE was even able to gain market shares despite not being distributed there in previous years.
- (165) Therefore, the Commission considers that the temporary reduction of GE’s sales cannot be assumed to reflect the competitive constraint that GE has exerted on Instrumentarium prior to the merger and would have been likely to exert in the absence of the merger. It follows in particular that the 2002 market shares only reflect partially GE’s actual presence in the market. As a result, average market shares over the years 2000, 2001, 2002 better capture the likely market position of the merging parties in the five countries under consideration (France, Germany, the United Kingdom, Spain, Sweden).

Price impact due to the merger

- (166) In order to better assess the impact of the transaction the Commission has conducted a series of econometric analyses and has examined econometric studies provided by a third party and the parties.
- (167) The Commission has conducted its own analysis of the likely price effect of the merger, based on the set of bidding data collected from the parties and the main competitors. The objective was to identify the effect that the presence of Instrumentarium has on the price charged by GE/Draeger to its customers, and vice versa. The Commission also analysed data from Philips and Siemens to determine the price impact of the joint presence of GE and Instrumentarium on the market.
- (168) The data set for this analysis consists of electronic files submitted by each party to the merger as well as competitors (Philips and Siemens), and of a series of paper invoices and bidding documents from the parties. Based on the available data, the Commission attempted to measure the likely price effects of the merger between GE and Instrumentarium using various econometric models, mainly multi-variable linear regressions.
- (169) The price impact is measured via the impact on the discounts proposed by the various competitors, in order to account for the fact that individual projects vary greatly in terms of specifications, equipment packages, and accessories, so that the actual transaction prices are not immediately comparable between different tenders.

¹²⁰ [...]*

(170) A number of problems were encountered in matching the invoice data recorded in paper form with the bidding data submitted in electronic form. These problems prevented the Commission from computing the percentage discount applied to the list price for many observations. As a result, the Commission was not able to use the data for Instrumentarium.

The likely price effect in France

(171) The Commission gathered data from bids submitted by GE alone and by Draeger. Most of the useable observations were recorded in tenders organised in France.

(172) The analysis of the bidding data¹²¹ provided by Draeger suggests that the presence of Instrumentarium in tenders does indeed impact on the Draeger's prices: the average discount offered by the latter when Instrumentarium was present in the bid is [35-45]*% to be compared with [25-35]*% when Instrumentarium was not present. This difference is statistically significant at 99% level of confidence.

(173) When using linear regressions controlling for various parameters¹²², the econometric analysis carried out by the Commission led to the conclusion that Draeger's discount is [5-10]*% to [5-10]*% higher when Instrumentarium is present than when Instrumentarium does not participate in the tender. This leads to an average impact on Draeger's discount of [5-10]*% on average. These results are statistically significant at 99% level of confidence. They provide empirical evidence that Instrumentarium impacts on the pricing behaviour of Draeger in France¹²³.

(174) As regards the bidding data provided by GE, an analysis of the discounts offered by GE shows that they are on average in the range of [20-30]*%, when GE faces only Siemens, [30-40]*% when facing only Philips and [40-50]*% when facing only Instrumentarium. As for Draeger, the Commission also ran regressions in order to identify Instrumentarium's influence on GE's discounts, if any. Given the characteristics of GE's data set, the econometric model used by the Commission is slightly different from the one used with the Draeger discount data. The results from the estimation show that GE discounts are on average [10-20]*% higher when Instrumentarium is present alone than that when Instrumentarium is not present. This result is statistically significant at 99% level of confidence. The Commission notes,

¹²¹ [50-100]* tenders where Draeger won, from 2000 through 2002 in France.

¹²² Given the data limitation, several variables were included in the model to explain variations in Draeger's discount. For example, the value of the final tender is one of these variables. Large discounts may be associated with high tender value. Also, when some customers may receive larger discount either because they organise many tenders, or the overall value of their tenders is important. The presence of other major bidders may also affect the size of the discount offered by Draeger. In the [50-100]* bid recorded that Draeger won, Instrumentarium and Siemens but not Philips participated in the bids. Interestingly enough, when Siemens is present, Instrumentarium is always bidding as well. Conversely, when Instrumentarium participate in a tender, Siemens is not always a rival bidder. As a result, we let the impact of Instrumentarium varies with the presence of Siemens. [5-10]*% and [5-10]*% refer to the variation of Draeger's discount due to, respectively, Instrumentarium along with Siemens and Instrumentarium alone.

¹²³ The Draeger average discount when Instrumentarium is present is about [30-40]*%. Using this as a basis, a decrease of [5-10]*% (respectively [5-10]*%) in the discount of Draeger after the removal of Instrumentarium would lead to a price increase of [5-10]*% (respectively [15-20]*%) for the tenders in which Instrumentarium was present.

however, that these econometric results were obtained using a small number of observations¹²⁴.

- (175) The results of the data analysis for France shows that the Draeger's (selling GE's monitors) and GE's discounts are larger when Instrumentarium participates in a bid than when it does not. In addition, the Commission econometric analysis appears to bring additional evidence that Instrumentarium constrains the sales of GE's monitors. It thus further supports the presumption associated with the merging parties high combined market share.

The likely price effect at the EEA level

Philips's bidding data

- (176) Philips submitted an econometric analysis of its bidding data aimed at showing that the merging parties are close competitors and that the merger would lead to price increases.
- (177) NERA Economic Consulting ("NERA") on behalf of Philips submitted, on 10 June 2003, an econometric study in order to assess the possible impact of the merger on prices in the perioperative and critical care patient monitors markets. The study uses Philips' own data based on recorded information about the calls for tenders in which Philips participated in 1999, 2000 and 2001 in several EEA countries, namely, Belgium, Finland, France, Germany, Italy, Netherlands, Spain, the United Kingdom, Portugal and Sweden. The data set contains observations in most countries where the merging parties hold strong positions, except for Denmark, Ireland and Greece where no data were available. The database specifies for each tender, according to Philips, which suppliers were present, which one won, the value of the bid submitted by Philips and the relating discount offered by Philips on its list prices.
- (178) The study considers the level of discount offered by Philips as an indicator of the level of price. NERA considers that a direct comparison between prices would not be possible because the characteristics of each product sold in the bids are different.
- (179) Controlling for other relevant factors, the study attempts to show to what extent the discount offered by Philips is affected by the presence of certain competitors, and more specifically whether the combined presence of GE and Instrumentarium affects the final discount offered by Philips to win a bid. The explanatory variables include, *inter alia*, a set of country dummies to control for the possible difference in discount from one country to another, the total value of the auction (in logarithm) and a set of competitor dummies.
- (180) The results of the econometric estimation show that Philips discounts are [5-10]* percentage points lower when GE is present, but not Instrumentarium, and [5-10]* percent lower when Instrumentarium is present, but not GE compared to situations where both merging parties are participating in the bidding round¹²⁵. These reductions of discounts correspond to price increases of [15-20]*% and [5-10]*%,

¹²⁴ [50-100]* tenders where GE won, from 1998, 1999, 2001 and 2002 in France.

¹²⁵ The results are statistically significant.

respectively, given Philips' average discount¹²⁶. These results are based on tenders in which Philips participated irrespective of whether Philips won or lost the bid. These results, therefore, measure the likely impact of the merger on Philips' pricing behaviour.

- (181) In order to assess the impact on actual market prices, the Commission requested NERA to reproduce the same analysis on Philips' winning bids only¹²⁷. In this case, there is still a difference in the discount offered by Philips when GE is present but not Instrumentarium compared to a situation where both merging parties are participating to the bid. However, there is no longer any statistically significant difference in the discount when Instrumentarium is present but no GE compared to when both parties are present.
- (182) It thus emerges from the analysis provided by Philips that Instrumentarium provides a competitive constraint to Philips, as the latter is forced to significantly increase its discount. When focusing on the win and loss data, it appears that Philips offers higher discount when the two merging parties are present in a bid relative to when only one of them is present. This would suggest that, as the result of the merger, Philips would be likely to offer lower discounts and would therefore be less constrained when bidding in tenders.
- (183) The Commission's econometric analysis of Philips' bidding data led to similar results to those presented by Philips, thus confirming the latter. Although these results relate to the average price effect of the merger at the EEA level, it can be expected that this price effect would be stronger in countries where the parties hold a high combined market share, i.e. France, Spain, the United Kingdom, Germany and Sweden.

Siemens' bidding data

- (184) The Commission conducted a separate econometric analysis based on bidding data supplied by Siemens. As for the Instrumentarium data, no information on list prices or discounts was available. In addition, it was not possible to identify winning bids from losing bids. Using the price deviation from average as described above, the analysis aim at measuring the impact of the combined presence of GE and Instrumentarium on the price offered by Siemens in tenders where it either won or lost. The results indicate that on average the combined presence of the merging parties has a substantial effect on the pricing behaviour of Siemens. The Commission, however, is cautious about these results given the poor quality of the original data.

GE's econometric study

- (185) RBB on behalf of the notifying party submitted an econometric study¹²⁸ based on Instrumentarium's bidding data. For the same reason indicated above with regard to the NERA study, the econometric model presented by RBB uses the percentage discount off the list price as the relevant variable of interest, and not on the final

¹²⁶ Philips' average discount for perioperative monitors is around [30-40]*%, based on the study submitted by Philips on 8 May 2003.

¹²⁷ See exhibit 3 in Philips' study dated 10 June 2003, column (a).

¹²⁸ RBB study "A preliminary critique of NERA's econometric analysis of the perioperative monitoring market", dated 24 June 2003.

transaction price. The study concludes that the presence of GE/Draeger in those bids won by Instrumentarium does not affect the final discount offered by Instrumentarium. In addition, the econometric results suggest that Philips represent the main competitive constraint to Instrumentarium. Several questions, however, remain unanswered on the empirical method used by RBB, which cast significant doubts about the validity of the results presented by RBB.

- (186) The econometric study uses data from four countries, namely Italy, Germany, Spain and the United Kingdom. However, a previous win/loss analysis submitted by RBB contained a large amount of data points from France. It is not clear at this stage why these data points were discarded from the econometric study. Finally, the Instrumentarium discount data used by RBB appears to be based on the recollection of the company's country managers. As there is no objective way for the Commission to verify the validity of these discounts, the Commission cannot rely on the results of the econometric study submitted by RBB.

Fringe players and potential competition

- (187) The notifying party argues that smaller competitors on the perioperative market would be able to prevent the merging parties from unilaterally raising prices following the transaction.

Actual market presence

- (188) In its Form CO¹²⁹, GE mentions several companies as being active on the perioperative market: Criticare, Datascope, Fukuda-Denshi, Invivo, Nihon Kohden, and Welch Allyn Protocol. In the course of the investigation, the notifying party also mentioned Tyco-Nellcor, Kontron, Huntleigh, and Schiller. According to the notifying party's estimates, the companies together hold a market share of [10-20]*% of all sales in the EEA and more than [30-40]*% in France and Germany.
- (189) These figures largely exceed the various estimates provided by external surveys and by the Commission's own reconstruction exercise based on competitors' sales as from 2000. According to the Commission's investigation, the aggregate market shares of smaller manufacturers was, as a result, close to [0-10]*% in the EEA and represented less than [0-10]*% of total sales in all countries in 2002, except in Italy (²[0-10]*%).
- (190) According to the notifying party, Datascope is a credible rival. The notifying party considers that Datascope's market share is somehow comparable to the one of GE's¹³⁰. However, although Datascope constitutes the strongest firm amongst the smaller competitors, its position is not comparable to GE's. First, Datascope's positioning in the perioperative area still remains focused on the low-end¹³¹. Contrary to GE, and the other three main suppliers, Datascope does not therefore offer a range of monitors from the low to the high end. Secondly, bidding data provided by the notifying party suggest that this firm does not actually represent the competitive constraint alleged by the notifying party. In their win-loss analysis submitted to the

¹²⁹ Form CO page 44.

¹³⁰ Form CO, page 50.

¹³¹ See T for G, Positioning and tactics, 3.3.2 at page 130.

Commission, the notifying party identified Datascope as runner-up in only [0-10]*% of perioperative projects won by Instrumentarium in the EEA¹³².

- (191) On the basis of the bidding data provided during the investigation, the Commission, also examined the level of presence of Datascope reported by Instrumentarium. Of the [1500-2000]* bids for perioperative monitors reported by Instrumentarium in which it participated in France between 1998-2002, Datascope is mentioned only [50-100]* times as one of the suppliers present in the bid and only [0-50]* times as a runner-up. Of the [500-1000]* bids in Germany between 1998-2002, Datascope is mentioned only [0-50]* times as one of the suppliers present in the bid (and at the same time as a runner-up). Of the [1000-1500]* bids reported by Instrumentarium in which it participated in the United Kingdom between 1998-2002, Datascope is mentioned [100-150]* times as one of the suppliers present in the bid. Finally, of the [200-250]* bids reported by Instrumentarium in which it participated in Spain between 1998-2002, Datascope is not mentioned at all.
- (192) With respect the bids reported by GE, there is reliable data on other bidders only for France. Of the [1000-1500]* bids reported by GE for the French market between 1998-2002, Datascope is mentioned only [0-50]* times as one of the suppliers present in the bid and only [...]* as a runner-up. Other firms, quoted in the form CO as credible rivals, are not even mentioned or only once (Welch Allyn; Nihon Kohden).
- (193) The absence of small manufacturers in tenders for perioperative monitors is also confirmed by the customers' survey. Hospitals were asked, in particular, to specify the strengths and weaknesses of the various suppliers, including of small competitors mentioned by the notifying party. Hospitals were also asked to identify the various companies that had been bidding in the last tenders for perioperative or critical care patient monitors. Fringe players quoted by GE as being credible rivals were only present, short-listed, and ultimately selected in tenders for perioperative monitors in a very few number of bids reported by customers.
- (194) The absence of fringe players in most short-lists in tenders for perioperative monitors results from the fact that, alongside the price offered, customers rank specifications and quality, as well as the ability of the supplier to provide after-sales services and continuous maintenance over the life cycle of the product as the main factors for choosing perioperative patient monitors. As a consequence, customers favour high-end suppliers, since they meet their specifications/quality requirements, as well as suppliers with an established distribution network. In addition, when purchasing new monitors either from the incumbent supplier or from new suppliers, customers clearly put the priority on the proven track record of the supplier and its technology¹³³.

Barriers to entry and expansion

- (195) The notifying party also claims that there are no significant barriers to entry or expansion on the patient monitoring market, neither in terms of capacity constraints or

¹³² RBB study page 9.

¹³³ Preference for the brand is also mentioned as the next important factor but, logically, only by customers who have not switched.

R&D nor at the distribution level¹³⁴, preventing other companies, including smaller suppliers, to pose a real competitive constraint.

- (196) The market for perioperative monitors is a differentiated product market. In particular, the market investigation has shown that the offerings of the four main manufactures highly differentiate them from those of smaller competitors. Capacity plays a minor role in manufacturers' decisions on prices.
- (197) Conversely, as shown by the market investigation and external studies¹³⁵, innovation in the field of patient monitoring is an important parameter of competition. From a customer' point of view, the Commission's survey has also shown that the ability of a supplier to develop new products constitute an important factor when purchasing monitors. Market participants generally rank the development of new parameters (in particular for measuring the in-depth of anaesthesia), the development of software specifically adapted to the operating room, as well as the product range, as the latest important innovative developments. Further important innovations are expected in the next years in the fields of, *inter alia*, in-depth of anaesthesia monitoring and computer technology.
- (198) The notifying party however claims that many components of patient monitors are bought from OEMs on a non-exclusive basis and that none of them has exclusive access to third-party suppliers. Nevertheless, several market participants have expressed concerns in that respect, underlining that access to technologies developed by innovative OEM suppliers is almost impossible for small suppliers because of their alliances with major manufacturers.
- (199) Furthermore, the market investigation has shown that the development of a new perioperative monitor takes between two to five years and requires many internal and regulatory steps, as well as financial capabilities. In their ranking of the various market players in the perioperative area, GE and Instrumentarium appear as the main innovative suppliers, together with Siemens and Philips, while small competitors are not mentioned. In those conditions, entry or expansion of small competitors in the market for perioperative monitors does not appear to be likely, or sufficient in magnitude and scope to pose a significant competitive constraint to the merged entity.
- (200) As concerns more specifically Siemens and Philips, the time required to develop new products would also inevitably render difficult and costly a repositioning of their product lines in the medium term in order to respond to a price increase by the merged entity.
- (201) As regards the importance of service and support to customers, the market investigation has shown that, when purchasing perioperative patient monitors, customers put emphasis on the ability to provide maintenance and service over the whole-life cycle of the product, that is from seven to ten years. It follows that suppliers must not only have a good reputation and a proven track record, but also rely on a

¹³⁴ Form CO page 47.

¹³⁵ See for example F & S 2001, at pages 4-49 and 4-50, which lists, among the competitive factors "*the gaining of a competitive advantage through technological innovation*" and where it is stated that „*pricing strategy and the degree of technological innovation will always remain crucial issues that will play a key role in this market*”.

good distribution network. In that respect, the notifying party acknowledges that “*the main players for patient monitoring have well-established sales and distribution networks throughout Europe*”¹³⁶. Conversely, it has not been shown, nor submitted, that this is also the case for smaller competitors.

- (202) The absence of smaller companies and the strategic advantage held by large companies in this respect is actually confirmed by external studies such as T for G. T for G’s study states, in particular, that “*all big players in the markets of patient monitors, ventilators and anaesthesia machines are present in the large markets. The larger companies are directly present in all markets: Agilent, Draeger, GE-Marquette and Siemens. A company like Datex works through very strong distributors in certain countries. In terms of performance, these distributors can be looked on as directly present. Small companies are not present in all countries*”¹³⁷.
- (203) In light of the foregoing, the Commission considers that, contrary to the notifying party’s submissions, the merged entity would not be faced with a significant competitive constraint from other firms on the market for perioperative monitors in the various Member States where it will already hold a strong position.

Lack of countervailing buyer power

- (204) The notifying party considers that the merged entity will still face powerful buyers who seek to obtain the most competitive offers available. The notifying party bases its argument on the following factors: (i) whilst technical specifications are important, they can almost always be met by various suppliers; however, faced with increasingly tight hospital budgets, typically fixed well in advance, suppliers have to submit competitive prices; (ii) hospitals can defer purchases unless offered improved technology and/or cheaper prices because of the ready availability of upgrades; (iii) buyers can switch to products of competing suppliers without incurring disproportionate switching costs¹³⁸.
- (205) The Commission’s investigation has not corroborated the notifying party’s assertions.
- (206) First, as is acknowledged by the notifying party, technical specifications remain important in the purchasing decision taken by a hospital. In each country, a vast majority of respondents has confirmed that the proposal to purchase perioperative monitors, including the definition of the specifications that must be met by the patient monitors, is taken by anaesthesiologists, sometimes in co-ordination with biomedical engineers. The decisive influence of anaesthesiologists in deciding to purchase a specific type of patient monitors is further enhanced by the fact that, according to the customers’ survey, quality, performance (which means the ability of the product to meet the specifications required), and service are the most important factors in the final decision taken by a hospital. External studies such as T for G confirm this ranking of priorities in the purchasing decision process: „*Performance and Quality are*

¹³⁶ Form CO, page 47.

¹³⁷ T for G at page 131. T for G further also indicates that, with respect to large companies, “*there is a national training and response centre in all countries*”.

¹³⁸ Form CO page 45.

the most important criteria followed by Service and Product durability. Price is obviously less important”¹³⁹.

- (207) Internal documents submitted by the notifying party also show that suppliers are conscious that influencing anaesthesiologists in defining the specifications for the tender may be decisive for winning a bid. For example, in one of GE’s internal documents, it is stated that [...]”¹⁴⁰. These various elements strongly suggest that the ability of a supplier to meet the technical specifications still prevails as the most important factor for hospitals when deciding to purchase a specific brand of monitors, whilst prices offered by suppliers are only a secondary element in practice.
- (208) Secondly, as was previously explained, the Commission’s investigation has shown that, contrary to the notifying party’s argument, only major suppliers are generally able to meet the technical requirements of hospitals. This considerably restricts the number of suppliers actually short-listed by hospitals in the course of the purchasing process. In practice, buyers are therefore faced with a limited choice when purchasing perioperative monitors since, in the vast majority of cases, only (some of) the four major suppliers are short listed by hospitals in the course of the bidding process. Furthermore, once tenders are organised in order to meet the hospitals’ needs, the actual purchase cannot realistically be delayed for a substantial period of time and competition occurs as from the opening of the tendering procedure.
- (209) Thirdly, the customer base is highly fragmented. Each individual tender accounts for a very limited proportion of a supplier’s turnover. Bidding data submitted by Instrumentarium thus revealed that, out of [7000-8000]* bids in the EEA, [80-90]*% were worth less than EUR 100.000. In France, for example, the proportion reached [90-100]*% between 1998 and 2002. The same proportions can be observed in the other relevant countries¹⁴¹. The lack of importance of each individual hospital in the overall amount of sales of a supplier is further reinforced by the fact that, due to the life cycle of monitors, tenders only need to be organised occasionally. For instance, Instrumentarium’s bidding data reveal that [70-80]*% of French hospitals only organised a tender once between 1998 and 2002 in which it participated.
- (210) Therefore, the Commission considers that customers of the merged entity on the relevant market will not have the ability to exercise a significant countervailing buyer power.

Conclusion

- (211) In light of the foregoing, the Commission concludes that the proposed operation would create a dominant position significantly impeding effective competition in five countries: Spain, the United Kingdom, Sweden, France and Germany:

¹³⁹ T for G, at page 25.

¹⁴⁰ GE/Draeger alliance, minutes of a meeting of 12 May 2000.

¹⁴¹ In Spain, Instrumentarium mentions [1500-2000]* bids to which it participated between 1998 and 2002. Out of [500-1000]* bids that they won, [500-1000]* were less than EUR 100.000. The same proportions can be observed in Germany ([1000-1500]* won bids, out of which [500-1000]* were less than EUR 100.000) and the United Kingdom ([1500-2000]* won bids out of which [1000-1500]* were less than EUR 100.000).

- (212) In Spain, the merger would lead to the combination of the first player by far (Instrumentarium, [50-60]*%) with the second one (GE, [20-30]*%) and would provide the merged entity with [80-90]*% market shares in average over the past three years. The second largest remaining player, Siemens, holds [0-10]*% market shares. Besides, GE turns out to be the main competitive constraint on Instrumentarium: it competed against the latter in [60-70]*% of all tenders and has been recorded as the runner-up to Instrumentarium in [60-70]*% of the tenders won by the latter. Last, the merging parties faced no, or only one, extra competitor in [60-70]*% of the tenders where they meet.
- (213) As regards the United Kingdom, on average over the past three years the combined market share of the new entity would be [80-90]*% while Philips would hold [0-10]*% and Siemens less than [0-10]*% of the market. The merger would be all the more detrimental, as the merging parties face no competitor in [60-70]*% of the tenders where GE and Instrumentarium compete against each other, and no, or only one, extra competitor in [80-90]*% of them.
- (214) On the Swedish market, the average combined market shares of the merging parties were as high as [70-80]*% over the last three years. Given Instrumentarium's high market shares ([60-70]*%), the addition of GE's [0-10]*% market shares is likely to have a significant impact on the market. The bidding data did not contradict the strong indications given by the combined market shares as to the significant market power of the new entity.
- (215) In Germany, the merger would allow the merged entity to become the market leader by far, holding average combined market shares of [50-60]*% over the last three years. The second player, Siemens, holds significant market shares ([0-10]*%). However, the analysis of past tenders showed that GE, despite being a smaller player, exerts a much stronger competitive constraint on Instrumentarium than Siemens or, to an even larger extent, Philips. Indeed, in terms of presence, GE bid against Instrumentarium in [50-60]*% to [70-80]*% of all tenders while Siemens competed with Instrumentarium in only [20-30]*% of the cases and Philips [10-20]*%. Furthermore, in most tenders where GE and Instrumentarium competed, they faced no other competitor ([40-50]*%) or only one fringe player ([30-40]*%). In terms of runner-up, the study submitted by the notifying party comes to the conclusion that GE was reported as the runner-up to Instrumentarium in [30-40]*% of the bids won by Instrumentarium, to be compared with [30-40]*% for Philips and [10-20]*% for Siemens.
- (216) Finally, in the case of France, the merged entity held over the last three years high market shares ([50-60]*%) with a significant overlap ([0-10]*%). The next player, Philips, held twice as less market shares ([20-30]*%) as the parties and encountered them very occasionally ([10-20]*%) whereas GE competes with Instrumentarium in [70-80]*% of all tenders. GE and Instrumentarium thus seem to exert the strongest competitive constraint on each other. This has been further confirmed by the econometric analysis of GE's and Draeger's discounts. This analysis shows that the presence of Instrumentarium in a tender led GE or its distributor, Draeger, to offer prices lower by [5-10]*% to [15-20]*% on average.
- (217) Therefore, the Commission has come to the conclusion that, in the above mentioned Member States, the merger will not only lead to the creation of a new entity holding high market shares but also will remove the significant competitive constraint that,

prior to the operation, the two merging firms exerted on each other. As a result of the merger, the merged entity would thus have the ability in those five countries to act, to an appreciable extent, independently from its competitors and ultimately consumers, and therefore to significantly raise prices charged to customers.

(218) For all the above reasons, the Commission has come to the view that the notified concentration is incompatible with the common market and the functioning of the EEA agreement, since it would create a dominant position in the market for perioperative patient monitors in France, Germany, Spain, Sweden, and the United Kingdom, as a result of which effective competition would be significantly impeded within the meaning of Article 2(3) of the Merger Regulation.

1.2 Critical care monitors

(219) According to the information provided by the notifying party in the Form CO, in the case of critical care monitors, the concentration would result in the following market shares:

Critical care patient monitors

2002%	EEA	A	BE	DK	DE	FI	FR	GR	UK	Irl	IT	NL	P	ES	SW	NO
GE	[10-20]	[0-10]*	[20-30]*	[10-20]*	[10-20]*	[0-10]*	[10-20]*	[10-20]*	[10-20]*	[10-20]*	[10-20]*	[10-20]*	[0-10]*	[10-20]*	[20-30]*	[10-20]*
Instru- mentarium	[10-20]	[10-20]*	[10-20]*	[0-10]*	[0-10]*	[20-30]*	[0-10]*	[0-10]*	[10-20]*	[0-10]*	[10-20]*	[0-10]*	[0-10]*	[10-20]*	[10-20]*	[20-30]*
Combined	[20-30]	[20-30]*	[30-40]*	[20-30]*	[20-30]*	[30-40]*	[10-20]*	[20-30]*	[30-40]*	[10-20]*	[20-30]*	[20-30]*	[0-10]*	[20-30]*	[30-40]*	[30-40]*
Philips	[30-40]	[30-40]*	[40-50]*	[20-30]*	[30-40]*	[20-30]*	[30-40]*	[10-20]*	[30-40]*	[30-40]*	[20-30]*	[30-40]*	[40-50]*	[30-40]*	[40-50]*	[30-40]*
Siemens	[20-30]	[20-30]*	[10-20]*	[20-30]*	[20-30]*	[20-30]*	[20-30]*	[10-20]*	[10-20]*	[10-20]*	[20-30]*	[20-30]*	[20-30]*	[20-30]*	[0-10]*	[10-20]*
Datascope	[0-10]*	[0-10]*	[0-10]*	[0-10]*	[0-10]*	[0-10]*	[0-10]*	[0-10]*	[0-10]*	[0-10]*	[0-10]*	[0-10]*	[0-10]*	[0-10]*	[0-10]*	[0-10]*
Others	[20-30]	[0-10]*	[0-10]*	[20-30]*	[20-30]*	[20-30]*	[20-30]*	[30-40]*	[20-30]*	[20-30]*	[20-30]*	[10-20]*	[20-30]*	[20-30]*	[10-20]*	[10-20]*

Table 9 (Source: the notifying party)

(220) On the basis of the Commission's investigation¹⁴², the market shares would be as follows:

2002%	EEA	A	B	DK	DE	FI	FR	GR	UK	Irl	IT	NL	PT	ES	SW	NO
GE	[10-20]	[0-10]*	[0-10]*	[0-10]*	[10-20]	[0-10]*	[10-20]	[30-40]*	[10-20]	[20-30]*	[10-20]	[20-30]*	[0-10]*	[10-20]	[10-20]	[20-30]*
Instru- mentarium	[10-20]	[20-30]*	[10-20]	[0-10]*	[0-10]*	[40-50]*	[0-10]*	[10-20]	[10-20]	[0-10]*	[10-20]	[10-20]	[0-10]*	[10-20]	[10-20]	[20-30]*
Combined	[20-30]*	[30-40]*	[20-30]*	[0-10]*	[20-30]*	[40-50]*	[20-30]*	[40-50]*	[30-40]*	[30-40]*	[20-30]*	[30-40]*	[0-10]*	[30-40]*	[30-40]*	[40-50]*
Philips ¹⁴³	[30-35]	[20-25]*	[45-50]*	[30-35]*	[25-30]*	[35-40]*	[45-50]*	[25-30]*	[25-30]*	[30-35]*	[25-30]*	[35-40]*	[20-25]*	[35-40]*	[40-45]*	[40-45]*
Siemens	[20-25]	[25-30]*	[25-30]*	[40-45]*	[35-40]*	[0-5]*	[15-20]*	[10-15]*	[10-15]*	[20-25]*	[30-35]*	[20-25]*	[55-60]*	[10-15]*	[20-25]*	[0-5]*
Others	[15-20]	[15-20]*	[0-5]*	[15-20]*	[15-20]*	[5-10]*	[10-15]*	[20-25]*	[25-30]*	[20-25]*	[15-20]*	[5-10]*	[5-10]*	[0-5]*	[0-5]*	[5-10]*

Table 10 (Source: the Commission's market investigation)

(221) The EEA market share of the parties would reach [25-30]*% behind Philips ([30-35]*%) and would be similar to Siemens ([20-25]*%). GE/Instrumentarium will become one of the three big market players alongside Siemens and Philips. At national

¹⁴² The same method as described for perioperative monitors was followed in the case of critical care monitors.

¹⁴³ Philips has not provided its sales for GR, DK and NO. The market shares indicated on this table are based on the figures that the notifying party has submitted in the Form CO.

level, the merger would lead to substantial overlaps in some countries (Austria, Finland, Greece, the United Kingdom, Ireland, Italy, the Netherlands).

- (222) Contrary to the perioperative market, other manufacturers have more important market shares in the critical care monitoring market. As shown by the market investigation, this is because the need for highly technical parameters is less acute in many of the critical care areas than in the perioperative are. The overall market share of the small and medium size companies, including Datascope, is therefore more important. However, many of these fringe players are not known to many customers and are considered as the low end of the market. Most customers do not consider them as credible competitors to GE, Instrumentarium, Siemens or Philips.
- (223) Furthermore, since the purchasing process of critical care monitors mostly involves a bidding procedure, where the technical specifications are mostly done by the doctors of the relevant medical department, the Commission has further examined the actual competitive constraints exercised by each of the merging firms on the market, as well as the likely effect of the merger on prices.

Closeness of substitution

- (224) The analysis of the conditions of competition in this bidding market also confirmed that Instrumentarium and GE could be not considered as close substitutes.
- (225) The Commission conducted the same type of statistical analysis as described in the part relating to perioperative patient monitors. This analysis showed that, among the 2727 tenders identified in the EEA where all the necessary information were available, Instrumentarium met GE in [20-30]*% of the cases, whilst it faced Philips in [30-40]*% of the cases and Siemens in [20-30]*%. Therefore, Instrumentarium has to compete against Philips more often than with GE. Moreover, in the tenders where the merging parties were both present, they faced two or more extra-competitors in [70-80]*% of these instances and either Philips or Siemens or both competitors in [80-90]*% of the cases. Therefore, in most tenders where the parties met, they are faced with a significant number of competitors.
- (226) The notifying party carried out a statistical study¹⁴⁴ in order to assess how often GE and Instrumentarium were winner/runner-up. In bids won by GE over the last five years, Instrumentarium appears as the runner-up in only [10-20]*% of cases¹⁴⁵ (out of [200-300]* tenders) on an EEA basis, far behind Philips ([60-70]*%). On a country-by-country basis, the proportion is similar but in the Netherlands where Instrumentarium is considered GE's runner-up in [70-80]*% of cases. Nevertheless, the result is based on only four tenders and is therefore not statistically significant.

Price impact

- (227) However, even though Instrumentarium and GE appear not to be close substitutes, they may exert a price constraint on each other through their pricing policy. In order to assess this possible impact, the Commission ran the same type of price analysis as

¹⁴⁴ RBB study. From page 20 on.

¹⁴⁵ RBB study. Table 8 page 20.

described in the part relating to perioperative patient monitors based on the bidding data provided by the notifying party and their main competitors¹⁴⁶.

- (228) Contrary to the analysis carried out on perioperative patient monitors, no statistically significant price impact has been identified in analysing Philips' as well as Instrumentarium's and GE's bidding data.

Conclusion

- (229) The merger will strengthen the parties' market position in critical care. GE/Instrumentarium will become one of the three big market players alongside Siemens and Philips. However, given the above mentioned market shares and the statistical analysis of bidding data, the Commission concludes that the combination of the parties market positions would not lead to the creation of a dominant position as a result of which effective competition would be significantly impeded.

2. Mobile C-arms

Market shares

- (230) The parties' activities overlap horizontally in (i) vascular C-arms and (ii) low-end C-arms in a number of Member States. In cardiac C-arms, no overlap occurs as only GE, but not Instrumentarium, is active in this market.

- (231) According to the notifying party, the operation would lead to the following market shares in vascular and low-end C-arms by value¹⁴⁷. The bottom row indicates each country's total market size in million EUR.

Vascular C-arms - National market shares by value

2002 %	AT	BE	DK	D	FI	FR	GR	UK	IRL	IT	NL	PT	ES	SW	NO
GE	[10-20]*	[10-20]*	[0-10]*	[0-10]*	[0-10]*	[50-60]*	[0-10]*	[20-30]*	[30-40]*	[30-40]*	[20-30]*	[0-10]*	[20-30]*	[20-30]*	[60-70]*
Instrumentarium	[70-80]*	[30-40]*	[30-40]*	[30-40]*	[40-50]*	[0-10]*	[0-10]*	[10-20]*	[0-10]*	[10-20]*	[0-10]*	[0-10]*	[0-10]*	[0-10]*	[0-10]*
Combined	[80-90]*	[50-60]*	[30-40]	[40-50]*	[40-50]*	[50-60]*	[0-10]*	[30-40]*	[30-40]*	[40-50]*	[20-30]*	[0-10]*	[20-30]*	[20-30]*	[60-70]*
Philips	[0-10]*	[50-60]*	[10-20]*	[30-40]*	[50-60]*	[0-10]*	[0-10]*	[20-30]*	[30-40]*	[10-20]*	[40-50]*	[0-10]*	[30-40]*	[30-40]	[10-20]*
Siemens	[0-10]*	[0-10]*	[50-60]*	[20-30]*	[0-10]*	[30-40]*	[0-10]*	[30-40]*	[30-40]*	[20-30]*	[20-30]*	[0-10]*	[30-40]*	[40-50]*	[10-20]*
Others	[0-10]*	[0-10]*	[0-10]*	[0-10]*	[0-10]*	[0-10]*	[0-10]*	[0-10]*	[0-10]*	[10-20]*	[0-10]*	[0-10]*	[0-10]*	[0-10]*	[0-10]*
<i>Market size mEUR (EEA: 35,1)</i>	2,0	0,6	0,6	15	0,2	5,0	0	4,0	0,2	2,0	2,0	0	2,0	0,8	0,8

Table 11 (Source: the notifying party)

Low-end C-arms - National market shares by value

2002 %	AT	BE	DK	D	FI	FR	GR	UK	IRL	IT	NL	PT	ES	SW	NO
GE	[0-10]*	[20-30]*	[0-10]*	[20-30]*	[10-20]*	[40-50]*	[10-20]*	[0-10]*	[0-10]*	[20-30]*	[10-20]*	[20-30]*	[40-50]*	[0-10]*	[20-30]*
Instrumentarium	[20-30]*	[30-40]*	[30-40]*	[30-40]*	[50-60]*	[0-10]*	[0-10]*	[20-30]*	[0-10]*	[10-20]*	[0-10]*	[0-10]*	[0-10]*	[20-30]*	[10-20]*
Combined	[20-30]*	[50-60]*	[40-50]*	[60-70]*	[70-80]*	[40-50]*	[10-20]*	[20-30]*	[0-10]*	[40-50]*	[10-20]*	[20-30]*	[50-60]*	[20-30]*	[30-40]*
Philips	[20-30]*	[10-20]*	[20-30]*	[20-30]*	[0-10]*	[10-20]*	[0-10]*	[30-40]*	[0-10]*	[10-20]*	[50-60]*	[0-10]*	[20-30]*	[50-60]*	[20-30]*
Siemens	[40-50]*	[30-40]*	[20-30]*	[10-20]*	[30-40]*	[20-30]*	[0-10]*	[30-40]*	[0-10]*	[0-10]*	[20-30]*	[0-10]*	[0-10]*	[20-30]*	[40-50]*

¹⁴⁶ Siemens and Philips. Eventually, Siemens' data set could not be used for the analysis because of the poor quality of the data.

¹⁴⁷ The volume market shares do not differ significantly.

Others	[0-10]*	[0-10]*	[0-10]*	[0-10]*	[0-10]*	[0-10]*	[80-90]*	[0-10]*	[0-10]*	[30-40]*	[0-10]*	[70-80]*	[10-20]*	[0-10]*	[0-10]*
Market size mEUR (EEA: 26,5)	0,4	1,3	0,4	8	0,2	5	0,3	4,0	0	3,0	0,4	0,2	2,0	0,7	0,6

Table 12 (Source: the notifying party)

- (232) The Commission’s market investigation broadly confirms the market shares submitted by the notifying party, in particular with regard to the relative sales of the four largest players, GE, Instrumentarium, Siemens and Philips.
- (233) In vascular C-arms, high market shares occur, in particular, in Austria ([...]*%), Belgium ([...]*%), Germany ([...]*%), France ([...]*%) and in Italy ([...]*%).
- (234) In the market for low-end C-arms, the combined entity will obtain high market shares with overlapping activities, for example, in Belgium ([...]*%), Denmark ([...]*%), Germany ([...]*%), Finland ([...]*%), France ([...]*%) and Spain ([...]*%).
- (235) The parties’ average market share across the EEA, according to their own figures, is [40-50]*% for vascular C-arms and [40-50]*% for low-end C-arms, respectively.
- (236) Whereas market shares have been quite stable in the larger markets between 2000 and 2002, they fluctuate widely in the smaller Member States, where sometimes only a handful of devices is sold each year and single orders can cause large swings in market shares. For example, GE/ Instrumentarium had a combined market share of [80-90]*% in Austria in 2002, but only [30-40]*% in 2000. In Belgium, the parties had [50-60]*% in 2002 after [10-20]*% a year earlier. Similar fluctuations in market shares can be observed in low-end C-arms.
- (237) The majority of respondents to the market investigation stated that prices for C-arms had been stable or declining in the past five years.
- (238) Capacity constraints appear to play a relatively minor role in manufacturers’ decisions on price and quantity.
- (239) The market share tables show, furthermore, that four players, GE, Instrumentarium (Ziehm), Siemens and Philips each achieve significant market shares across a range of EEA countries. GE, Siemens and Philips, in addition, all manufacture an extensive range of medical equipment and have strong distribution capabilities throughout the EEA (and, indeed, worldwide). Instrumentarium equally has strong positions in several medical equipment markets, although its product portfolio is somewhat narrower.
- (240) Besides, the Commission’s market investigation has also found that customers consider C-arms as relatively less differentiated than other medical devices, such as in particular anaesthesia delivery systems and patient monitors. Although failure of a C-arm device can have serious consequences, it does not normally lead to immediately life threatening situations (as for example in anaesthesia delivery or intensive care ventilation). Moreover, the main quality and performance parameters of a C-arm device (such as image quality or handling) are observable by a potential customer in advance, whereas for other types of equipment they are “embedded” in the supplier’s track record and reputation. (Again, anaesthesia delivery systems are the most salient

example for the latter product category.) Switching between the main suppliers of C-arms is, thus, comparatively easier.

- (241) A number of niche players, including Sias, Eurocolumbus, Apelem, Metaltronica and other achieve modest market shares, mainly in Italy. They are not generally known to customers outside their home country and are attributed to the bottom end of the market. Most customers do not consider them credible competitors to GE, Instrumentarium, Siemens or Philips.
- (242) By contrast, the hospitals surveyed by the Commission's market investigation generally consider that GE, Instrumentarium, Siemens and Philips all supply vascular and low-end C-arms of comparable quality and would be a viable alternative in response to even a small relative price rise. There will, hence, remain after the merger three competitors with an extensive portfolio of medical equipment and strong distribution capabilities in each of the national markets where the parties' activities overlap in either vascular or low-end C-arms.

Closeness of substitution

- (243) The notifying party has submitted an analysis of win-loss data to corroborate their contention that GE/Instrumentarium's market shares do not accurately reflect and, in fact, overstate the competitive impact of the notified transaction. Because only a limited number of data points is included in the study, the notifying party's analysis relates to bids for all types of mobile C-arms during the period 1998-2003. It looks at the number of times that Instrumentarium, as opposed to other competitors, was selected as runner-up in tenders that GE¹⁴⁸ won. Only for Germany the same analysis is also performed on tenders that Instrumentarium¹⁴⁹ won.
- (244) On the basis of bids where GE won, at the EEA level Siemens is reported as runner-up in [40-50]*% of all cases, followed by Philips ([30-40]*%) and Instrumentarium ([0-10]*%). Other competitors, including SIAS, Eurocolumbus and Gilardoni, account for [0-10]*%. They show up significantly only in Italy, in addition to Finland ([...]*from 1998 to 2003) and Spain ([...]*). According to this data, Instrumentarium qualifies as runner-up substantially less frequently than both Siemens and Philips in all countries, except in [...]*, where it is [...]* with Philips.¹⁵⁰ It occurs as runner-up less frequently than one would expect if all suppliers were equally close substitutes¹⁵¹.
- (245) Based on bids where Instrumentarium won (in Germany only), Philips was runner-up in [50-60]*% of cases, followed by Siemens ([20-30]*%) and GE ([10-20]*%). No

¹⁴⁸ The GE win data presented by the parties contains [400-500]* data points from tenders across the EEA¹⁴⁸ from 1998 to 2003 that GE won. The cross-country distribution of the data seems to be based simply on availability. More than 15 data points each are included from the following countries: Belgium ([50-100]*), France ([50-100]*), Germany ([50-100]*), Italy ([50-100]*), Spain ([0-50]*) and the United Kingdom ([50-100]*).

¹⁴⁹ The Instrumentarium win data presented by the parties contains [0-100]* data points from 1998 to 2002, all from Germany. The parties claim that, because Instrumentarium sells predominantly through independent distributors, they were unable to gather accurate bidding data for more EU countries to be included in their analysis.

¹⁵⁰ There are, however, only [0-10]* observations relating to Portugal.

¹⁵¹ The parties' conclusion from this analysis appears to go further, implying that GE and Instrumentarium would need to be *closest substitute* for a merger to lead to any competitive harm: [...]* The Commission does not follow this analysis.

other companies occur as runner-up in this country. Again, GE is listed as runner-up less frequently than one would expect if all suppliers were equally close substitutes.

- (246) Hence, the bidding data presented by the notifying party tend to indicate that market shares in this case overstate the impact of GE's and Instrumentarium's combined market power further to the merger.

Price impact

- (247) As for patient monitors, the Commission has conducted its own analysis on a more extensive set of bidding data collected from the parties and the main competitors¹⁵². The objective was to identify the effect that the joint presence of GE and Instrumentarium had on prices in past bidding rounds and, further, the price effect, if any, that the removal of Instrumentarium as an independent competitor would have.
- (248) The results of this extended empirical assessment were that the presence of Instrumentarium as an independent bidder in the auction and the number of bidders does not appear to have had any systematic influence over the size of the discount offered by GE in its bids. In none of the models that the Commission estimated was the coefficient of the dummy variable capturing the presence of Instrumentarium in the auction statistically significant. Such findings hold irrespectively of how the discount is computed or its proxy and whether the key European markets are considered collectively or individually (where data permit) or whether the focus is on winning bids only or all bids (both winning and losing bids).

Conclusion

- (249) The notified transaction will lead to relatively high shares in the markets for vascular and low-end C-arms in several Member States. Nevertheless, there will after the operation remain three credible competitors in both markets, which all have an extensive portfolio of medical products with market leading positions in at least some medical product markets and strong distribution capabilities across all EEA countries. The power of market shares as an indicator of market power is limited in this case by the high volatility of market shares, particularly in the smaller Member States, the fact that the parties' products are relatively distant substitutes as indicated by the win-loss analysis and the low level of differentiation between the leading suppliers' product ranges. Finally, the Commission's econometric analysis of bidding data has not shown any price effects from the joint presence of GE and Instrumentarium in tenders for C-arm equipment.
- (250) The analysis leads to the same conclusion if a wider product market, comprising all mobile C-arm devices, is used as a basis.
- (251) In view of these elements, the Commission concludes that the combination of the parties market positions would not lead to the creation of a dominant position as a result of which effective competition would be significantly impeded as far as mobile C-arms are concerned.

¹⁵² I.e. Siemens and Philips. Eventually, Philips' data set could not be used for the analysis because of the poor quality of the data.

3. MAMMOGRAPHY DEVICES

A. Analogue mammography

(252) Both GE and Instrumentarium are active in analogue mammography and the proposed operation will therefore lead to horizontal overlaps. As a result of the transaction GE/Instrumentarium will become the market leader in analogue mammography devices in the EEA and in almost all the Member States.

General Market Features

(253) The market investigation has shown that the analogue mammography market has become a mature market.

(254) From the supply side, both the market investigation¹⁵³ and external studies provided by the notifying party¹⁵⁴ underline that analogue technology is a mature technology (“*technology has reached its limits*”) and innovations are limited mostly to features such as image quality.

(255) Producers of analogue mammography devices are mainly assemblers as they source a large proportion of their inputs (around [70-80]*%) from third party component manufacturers. Competition in this market is mainly driven by investment on reputation, quality and the services offered with these products, as well as on prices.

(256) From the demand side, the sales of analogue mammography devices are overall declining both in terms of units and value and the main part of the demand arises from the replacement of obsolete equipment.

(257) This declining trend in the demand for analogue mammography equipment is expected to increase in the future because of the transition to digital equipment. The market investigation has showed that a significant number of customers envisage to upgrade analogue mammography to digital or to procure a full field digital equipment in the next three years. All producers have confirmed this transition to the digital field¹⁵⁵: It is expected that in 2004 40% of the revenues for mammography will come from digital, going up to 60% in 2006¹⁵⁶.

Market shares

(258) As for monitors and C-arms, the notifying party in the notification indicates that, because of lack of reliable publicly available sources, market share calculations were based on their own best estimates using their respective sales and the sales data provided by the European Coordination Committee of the Radiological Electromedical Industry (“COCIR”), a grouping of five medical equipment companies (Instrumentarium, Dräger, GE, Philips, and Siemens)¹⁵⁷. The notifying party considers that this calculation overstates their position because of the difficulty in establishing the sales of the smaller competitors through independent distributors.

¹⁵³ Competitors’ reply to the Commission’s questionnaires on R&D in Mammography dated 28.5.2003.

¹⁵⁴ Frost & Sullivan, World X-Ray Mammography Market, 2001, Chapter 3.

¹⁵⁵ Competitors’ reply to the Commission’s questionnaires on R&D in Mammography dated 28.5.2003.

¹⁵⁶ Frost & Sullivan, World X-Ray Mammography Market, 2001, Chapter 4.

¹⁵⁷ Annex 6.11 of the Form C/O.

(259) Therefore, the Commission has made its own market share calculations on the basis of its requests for information on the sales figures of mammography devices addressed to the merging parties and to its competitors on the relevant market.

(260) Based on the replies to these requests for information, the Commission estimates that the concentration leads to an EEA combined market share of [35-40]*% for analogue mammography. The main competitor, Siemens accounts for [20-25]*% of the market. Among the other players, Planmed accounts for around [10-15]*%, while Hologic/Lorad, Giotto and Metaltronica, for less than [10-15]*%.

(261) According to the data collected, at national level the operation would lead to the following market shares in analogue mammography by value¹⁵⁸. The bottom row indicates each country's total market size in million EUR.

Analogue Mammography-National market shares 2002

2002 % by value	EEA	AT	BE	DK	DE	ES	FIN	FR	GR	IRL	IT	NL	PT	SW	UK	NO
GE	[25-30]	[25-30]	[40-45]	[0-5]	[40-45]	[30-35]	[0-5]	[30-35]	[40-45]	[35-40]	[25-30]	[10-15]	[65-70]	[0-5]	[30-35]	[0-5]
Instrumentarium	[5-10]	[0-10]	[5-10]	[5-10]	[0-5]	[5-10]	[60-65]	[5-10]	[5-10]	[0-5]	[15-20]	[15-20]	[0-5]	[5-10]	[5-10]	[45-50]
Combined	[35-40]	[25-30]	[45-50]	[5-10]	[4-45]	[40-45]	[60-65]	[40-45]	[50-55]	[35-40]	[45-50]	[25-30]	[70-75]	[5-10]	[35-40]	[45-50]
Siemens	[20-25]*	[45-50]*	[20-25]*	[5-10]*	[30-35]*	[30-35]*	[20-25]*	[15-20]*	[10-15]*	[60-65]*	[5-10]*	[20-25]*	[5-10]*	[90-95]*	[40-45]*	[55-60]*
Philips	[0-5]*	[15-20]*	[0-5]*	[0-5]*	[10-15]*	[5-10]*	[0-5]*	[0-5]*	[15-20]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*
Hologic	[5-10]*	[0-5]*	[15-20]*	[10-15]*	[0-5]*	[0-5]*	[0-5]*	[5-10]*	[5-10]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[10-15]*	[0-5]*
Planmed	[10-15]*	[0-5]*	[0-5]*	[70-75]*	[5-10]*	[0-5]*	[15-20]*	[15-20]*	[0-5]*	[0-5]*	[5-10]*	[45-50]*	[5-10]*	[0-5]*	[0-5]*	[0-5]*
Giotto	[5-10]*	[5-10]*	[5-10]*	[0-5]*	[5-10]*	[5-10]*	[0-5]*	[5-10]*	[10-15]*	[0-5]*	[15-20]*	[0-5]*	[5-10]*	[0-5]*	[0-5]*	[0-5]*
Metaltronica	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[5-10]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[15-20]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*
Market size	47.85	1.82	1.33	0.80	5.10	3.40	0.61	12.1	1.01	0.39	9.33	1.31	1.72	0.85	5.91	0.44

Table 13 (Source: The Commission's investigation)

Analogue Mammography-National market shares 2001

2001 % by value	EEA	AT	BE	DK	DE	ES	FIN	FR	GR	IRL	IT	NL	PT	SW	UK	NO
GE	[35-40]*	[10-15]*	[45-50]*	[0-5]*	[40-45]*	[65-70]*	[0-5]*	[40-45]*	[55-60]*	[40-45]*	[35-40]*	[25-30]*	[65-70]*	[0-10]*	[30-35]*	[0-5]*
Instrumentarium	[10-15]*	[0-5]*	[5-10]*	[30-35]*	[5-10]*	[0-5]*	[85-90]*	[5-10]*	[0-5]*	[0-5]*	[10-15]*	[55-60]*	[15-20]*	[35-40]*	[0-5]*	[60-65]*
Combined	[50-55]*	[10-15]*	[50-55]*	[30-35]*	[45-50]*	[70-75]*	[0-5]*	[50-55]*	[60-65]*	[40-45]*	[50-55]*	[85-90]*	[80-85]*	[35-40]*	[30-35]*	[60-65]*
Siemens	[25-30]*	[75-80]*	[25-30]*	[15-20]*	[30-35]*	[10-15]*	[0-5]*	[15-20]*	[20-25]*	[35-40]*	[10-15]*	[5-10]*	[0-5]*	[60-65]*	[55-60]*	[35-40]*
Philips	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[5-10]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*
Hologic	[5-10]*	[0-5]*	[10-15]*	[35-40]*	[0-5]*	[5-10]*	[0-5]*	[5-10]*	[10-15]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[5-10]*	[0-5]*
Planmed	[5-10]*	[0-5]*	[5-10]*	[10-15]*	[5-10]*	[0-5]*	[10-15]*	[15-20]*	[0-5]*	[15-20]*	[10-20]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*
Giotto	[0-5]*	[5-10]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[5-10]*	[0-5]*	[5-10]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*
Metaltronica	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[5-10]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[20-25]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*
Market size	48.00	0.75	2.20	0.41	4.33	3.33	0.91	14.2	0.75	0.61	8.03	1.46	1.73	0.59	8.2	0.55

Table 14 (Source: the Commission's investigation)

¹⁵⁸ The volume market shares do not differ significantly.

Analogue Mammography-National market shares 2000

2000 % by value	EEA	AT	BE	DK	DE	ES	FIN	FR	GR	IRL	IT	NL	PT	SW	UK	NO
GE	[40-45]*	[35-40]*	[45-50]*	[0-5]*	[25-30]*	[60-65]*	[0-5]*	[45-48]*	[35-40]*	[45-50]*	[40-45]*	[25-30]*	[60-62]*	[0-5]*	[25-30]*	[0-5]*
Instru- mentarium	[5-10]*	[0-5]*	[5-10]*	[0-10]*	[5-10]*	[10-15]*	[50-55]*	[0-5]*	[0-5]*	[0-5]*	[10-15]*	[15-20]*	[10-15]*	[0-5]*	[0-5]*	[0-5]*
Combined	[45-50]*	[40-45]*	[55-60]*	[0-5]*	[30-35]*	[70-75]*	[50-55]*	[50-55]*	[35-40]*	[45-50]*	[55-60]*	[45-50]*	[70-75]*	[0-5]*	[25-30]*	[0-5]*
Siemens	[25-30]*	[35-40]*	[20-25]*	[25-30]*	[35-40]*	[5-10]*	[30-35]*	[15-20]*	[35-40]*	[55-60]*	[10-15]*	[15-20]*	[10-15]*	[95-100]*	[50-55]*	[95-100]*
Philips	[0-5]*	[10-15]*	[5-10]*	[0-5]*	[15-20]*	[5-10]*	[0-5]*	[0-5]*	[5-10]*	[0-5]*	[0-5]*	[30-35]*	[5-10]*	[0-5]*	[0-5]*	[0-5]*
Hologic	[0-5]*	[0-5]*	[10-15]*	[45-50]*	[0-5]*	[0-5]*	[0-5]*	[5-10]*	[10-15]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[5-10]*	[0-5]*
Planmed	[5-10]*	[0-5]*	[0-5]*	[20-25]*	[10-15]*	[0-5]*	[10-15]*	[15-20]*	[0-5]*	[0-5]*	[5-10]*	[0-5]*	[0-5]*	[0-5]*	[5-10]*	[0-5]*
Giotto	[0-5]*	[5-10]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[5-10]*	[0-5]*	[5-10]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*
Metaltronica	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[5-10]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[15-20]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*
Market size	52.29	1.06	2.42	0.26	4.05	3.50	0.84	14.6	0.72	0.80	10.2	1.33	1.46	0.76	10.7	0.25

Table 15 (Source: the Commission's investigation)

- (262) The Commission considers that market shares provide a first proxy to determine the relative market position of the various competitors from a customer point of view. Market shares contain important information as they reflect real purchasing decisions by customers in a given year.
- (263) The merger would lead to significant overlaps in many national markets with combined market shares above 40% in 2002 in Belgium, France, Germany, Greece, Italy, Portugal, Spain. Only in Greece the parties will attain market shares above 50% and a substantial overlap (exceeding at least 5%) (combined: [...]%), while in Portugal the parties will reach a [70-75]%% market shares but with a minimal overlap (GE: [65-70]%%; Instrumentarium: [0-5]%%).
- (264) Looking at the evolution of the GE/Instrumentarium combined market shares, these are declining both at the EEA level ([35-40]%% in 2002 from [50-55]%% in 2001 and [45-50]%% in 2000) and in all the countries where the merger leads to a significant overlap. For example, in France, the combined Market shares decreased from [50-55]%% in 2000, to [50-55]%% in 2001 and to [40-45]%% in 2002, while in Italy the market share declined from [55-60]%% in 2000, to [50-55]%% in 2001 and to [45-50]%% in 2002.
- (265) In Greece and Portugal where the parties' market shares are above 50%, the combined market shares decreased in 2002. In Portugal the market share declined from [80-85]%% in 2001 to [70-75]%% in 2002 and in Greece from [60-65]%% in 2001 to [50-55]%% in 2002.
- (266) Furthermore, in all the countries with significant overlaps, a number of credible competitors remain present. In addition to Siemens which will be the number 2 player in almost all the markets, Planmed, Hologic/Lorad, Philips, Giotto and Metaltronica will remain credible competitors in many of these countries. For example Hologic/Lorad had a significant market share in Belgium and is present in France, Greece and Spain, while Planmed has a significant market share in France and is present in Italy and Portugal. Finally, Giotto and Metaltronica have a significant presence in Italy.

Private/public customers and purchasing process

- (267) The market investigation has shown that, contrary to patient monitors and C-arms, demand for mammography devices comes to a significant extent from private organisations. According to GE's sales data, almost [50-70]*%¹⁵⁹ of its customers over the last five years were private organisations. The same proportion is also true for the sales by Instrumentarium¹⁶⁰.
- (268) Furthermore, the percentage of public/private demand differs in each Member State depending also on the existence of national screening programs and by national provisions allowing the involvement of private practitioners. For example, while in France private purchases account for almost [80-90]*% of the market, in Italy [70-80]*% of mammography devices are acquired by public hospitals¹⁶¹.
- (269) Contrary to public organisations, where equipment is mostly acquired through invitations to tender, private purchases do not require any tendering process. Even though some private practitioners may use tendering processes, most purchases are based on quotes provided by the local agent or the local distributor of the suppliers.
- (270) Also for public organisations that are obliged to launch tenders to purchase expensive equipment such as mammography devices a local presence of the supplier or its distributor is necessary. It resulted from the market investigation that the choice for a given supplier is based on the principle of "most economically advantageous" offer rather than on the "lowest price" offer, price being one important factor in addition to specifications, quality, after-sale services and maintenance of the mammography device. Therefore, once the potential suppliers have responded to the invitation to tender, they may need to demonstrate the different features of the tendered equipment to the radiologist who is the relevant decision maker in the acquisition process¹⁶².
- (271) The notifying party also argues that the market for mammography devices is a bidding market, where market shares cannot be considered a proxy for market power. In addition, the notifying party has submitted an analysis of win-loss data to corroborate their contention that GE/Instrumentarium's market shares do not accurately reflect and, in fact, overstate the competitive impact of the notified transaction.
- (272) The market for mammography devices does not significantly differ from a standard differentiated product market. When products are procured through a tender process, customers' preferences are reflected in the technical specifications of the tender which, in turn, determine the number of eligible bidders. Customers have individual preferences for specific devices and would consider switching to another model only in response to a more or less significant price rise (relative to competitors). The relative closeness of substitution between the various products, even within one and the same relevant product market, thus forms an important parameter of competition

¹⁵⁹ Among GE's bids for which the distinction private/public is made, around [1500-2000]* were private and around [500-1000]* public (for a total number of bids available of [2500-3000]*).

¹⁶⁰ Among Instrumentarium's bids for which the distinction private/public is specified, [100-150]* were private and [0-50]* public (total bids available to the Commission: [300-400]*).

¹⁶¹ [...]*

¹⁶² In the questionnaires sent to customers was required to indicate who makes the proposal to purchase and it came out that in all the countries this Decision is mostly taken by radiologists (90% in France, 95% in Spain, 72% in Italy).

in these markets and has an important influence on suppliers' market power. Market shares thus contain important information as they reflect real purchasing decisions by customers in a given year.

Closeness of substitution

- (273) As for patient monitors and C-arms, the notifying party conducted a statistical analysis in order to assess the closeness of substitution of the merging parties using as a proxy how often Instrumentarium, in comparison with other competitors, has been recorded as the runner-up in bids where GE¹⁶³ won.
- (274) Siemens turns out to be the competitor that is reported as the runner-up to GE most often at the EEA level as well as in every country. At the EEA level, Siemens is the runner-up in [50-60]*% of the tenders whilst Philips in [0-10]*% and Instrumentarium, Planmed and Hologic/Lorad in [0-10]*% of the cases. These results should nevertheless be considered cautiously since the distribution of tenders across the various countries does not reflect the relative size of the national markets.
- (275) At the national level, Siemens is the most frequent runner-up with percentages ranging from [40-50]*% (France) to [80-90]*% (Belgium). In contrast, Instrumentarium has been recorded as the runner-up in proportions ranging from [0-10]*% (Italy) to [30-40]*% (Spain) of the cases. It is worth noting that, in some countries, Instrumentarium does not appear by far as the competitor that exert the strongest competitive constraint on GE. This is the case for example in France (Siemens: [40-50]*%; Planmed: [10-20]*%; Philips: [0-10]*%; Instrumentarium: [0-10]*%), in Germany (Siemens: [70-80]*%; Philips [10-20%]*; Instrumentarium: [0-10]*%) or in the United Kingdom (Siemens: [80-90]*%; Hologic/Lorad: [0-10]*% Instrumentarium: [0-10]*%).
- (276) Therefore, the analysis submitted by the notifying party tend to show that Siemens exerts a stronger competitive constraint on GE than Instrumentarium. This is also the case of other competitors at the national level.

Price impact

- (277) In addition, the Commission has conducted its own analysis of the likely price effect of the merger, based on an extensive set of bidding data collected from the parties and the main competitors¹⁶⁴. The objective was to identify the effect that the joint presence of GE and Instrumentarium had on prices in past bidding rounds and, further, the price effect, if any, that the removal of Instrumentarium as an independent competitor would have.
- (278) The results of this empirical assessment were that the presence of Instrumentarium as an independent bidder in the auction and the number of bidders does not appear to have had any systematic influence over the size of the discount offered by GE in its bids. In none of the models that the Commission estimated was the coefficient of the

¹⁶³ The parties were able to gather the information necessary to carry out this type of analysis for [600-700]* tenders from 1998 through 2003. There are more than 15 observations in all countries (e.g. France: [300-400]*; Italy: [100-200]*; Germany: [0-100]*; the United Kingdom: [0-100]*; Spain: [0-100]*) but Ireland ([0-15]*).

¹⁶⁴ I.e. Siemens and Philips. Eventually, Philips' data set could not be used for the analysis because of the poor quality of the data.

dummy variable capturing the presence of Instrumentarium in the auction statistically significant. Such findings hold irrespectively of how the discount is computed or its proxy and whether the key European markets are considered collectively or individually (where data permit) or whether the focus is on winnings bids only or all bids (i.e. winning and losing bids).

Conclusion

(279) In the light of all the above elements, general market features, market shares and economic analysis, the Commission considers that the acquisition will not lead to the creation or strengthening of a dominant position in the market for analogue mammography devices as a result of which effective competition would be significantly impeded in the common market or substantial part of it.

B. Digital mammography

Emerging market - potential competition

(280) Demand for digital equipment is expected to grow substantially as digital mammography is generally seen to offer better contrast resolution and other image characteristics that will improve the capability for an early detection of cancer and reduce errors in detection process (so called false-positive). It is expected that in 2004 this market will represent 40% of the total revenues for mammography instruments, going up to 60% in 2006. This growth is also expected to result from other benefits offered by the digital technology such as a lower radiation dose and other functions generally connected with digital technology, for example, the suitability of user software, digital transmission and storage of imaging. It is further anticipated that digital technology will bring about new applications, such as 3D (tomosynthesis) and combination with ultrasound. All these factors will introduce new elements into the competitive situation.

(281) In digital mammography, GE is the leading company having been the first to introduce a digital equipment three years ago. The notifying party acknowledges that it has a [...] * however [...] *.¹⁶⁵ As there are no overlaps between the parties, the effects of the concentration in this market would arise from the reduction of potential competition because Instrumentarium has plans to enter this market.

(282) The market investigation has shown that all the actual suppliers of analogue mammography equipment are entering the digital market¹⁶⁶. In particular, Siemens, Hologic/Lorad and Fischer are already active in selling digital equipment, while Planmed, Giotto, Metaltronica have actively started marketing their digital appliances. All these companies have already made significant investments in R&D in the digital field in order to achieve a comparable or superior product to that of GE. It is also expected that new competitors will enter the market, such as Sectra and Kodak.

(283) More generally, entry in this market has been favoured by companies offering digital appliances comparable to those used by GE, in particular detector plates. In fact, many producers are acquiring digital detectors from third companies such as Anrad, or by

¹⁶⁵ [...] *

¹⁶⁶ Competitors' reply to the Commission's questionnaires on R&D in Mammography dated 28.5.2003.

competitors such as Hologic/Lorad. In this context, it has also to be considered that other branches of radiography enjoy full field digital capability and that many fields of R&D are common to the radiological sector.

- (284) Finally, the market investigation has shown that as far as R&D investments and achievements in the digital field are involved, Instrumentarium is generally not considered the most important and effective competitor to GE¹⁶⁷. In the 2002 Strategic Plan of Instrumentarium it is stated that [...] ¹⁶⁸.

Conclusion

- (285) Given the above elements, the Commission concludes that there is a sufficient number of actual and potential competitors that are in a position to compete with GE in the digital field also following the acquisition of Instrumentarium. The fact that many companies are currently entering the digital mammography market renders less likely the possibility that the merger between GE and Instrumentarium could reduce to a significant extent the actual or potential competition in this market or limit innovation in the digital field.
- (286) In the light of these elements, the Commission considers that the acquisition of Instrumentarium will not lead to the creation or strengthening of a dominant position in the market for digital mammography as a result of which effective competition would be significantly impeded in the common market or substantial part of it.

B. VERTICAL EFFECTS - SERIOUS DOUBTS DUE TO FORECLOSURE OF THE PATIENT MONITORS AND CIS MARKETS

1. Introduction

- (287) Apart from the horizontal effects in the market for perioperative monitors identified above, the Commission also identified serious doubts as to the compatibility of the concentration, as originally notified, in that it would be likely to have significant vertical effects on the markets for anaesthesia machines, perioperative and critical care patient monitors and Clinical Information Systems (CIS). The vertical effects of the concentration would be primarily due to Instrumentarium's significant market power in the "upstream" market for anaesthesia delivery machines and the technical interface (the need of the various devices to be integrated mechanically and/or exchange data electronically) between anaesthesia machines, perioperative and critical care monitors and CIS (areas in which the merged entity would be active). Such vertical concerns were also recently found by the Commission in its Article 8(2) decision in the Siemens/Draeger case¹⁶⁹ which presents similar characteristics with the present case.
- (288) Concerns were expressed that the merged entity would be able to prevent competing manufacturers of patient monitors, anaesthesia machines and CIS from having effective access to the merged entity's anaesthesia machine equipment, patient monitors and CIS systems and could thus result in foreclosure effects and hence higher prices and reduced choice for hospitals.

¹⁶⁷ Competitors' reply to the Commission's questionnaires on R&D in Mammography dated 28.5.2003.

¹⁶⁸ Instrumentarium Diagnostic Imaging - Strategic plan 2002.

¹⁶⁹ See case No COMP/M.2861 – Siemens/Draegerwerk/JV (not yet published), at point 149.

(289) It should be noted from the outset that, following the communication of the Commission's serious doubts in the Article 6(1)(c) decision initiating proceedings in this case, the parties offered a commitment in order to dispel the Commission's serious doubts relating to the above-mentioned vertical issues. The commitment was submitted formally on 11 June 2002 whilst the in-depth investigation was on-going. This commitment appeared to eliminate the serious doubts relating to the vertical issues and was therefore market tested in order to assess its viability and effectiveness and was further improved by the notifying party and re-submitted in a revised version on 4 July and then on 24 July 2003 as part of a revised package of commitments. In the light of the positive market test results and its assessment, it was concluded that the commitment was sufficient to eliminate the serious doubts relating to vertical issues in this case. As a result, no objections were raised as far as those vertical issues were concerned.

2. Background information

(290) The ability of the merged entity to foreclose would primarily arise from (i) its significant market power in anaesthesia machines and (ii) the technical interface between anaesthesia machines, monitors and CIS which requires co-operation between the anaesthesia machine manufacturer, the patient monitor manufacturer or CIS supplier.

(i) Instrumentarium's market power in the upstream market for anaesthesia delivery machines

(291) Anaesthesia machines, like other items of critical care equipment, are highly differentiated products with anaesthetists' preferences playing a key role in the choice of a clinic's anaesthesia equipment. As the Commission found in the Siemens/Draeger decision¹⁷⁰, customers have as a rule a preference for a specific item of equipment and would consider switching to a competing product only in the event of a fairly large price increase compared with the competition. Given the differentiated nature of the product in question and the fact that capacity restrictions are, on the other hand, of only minor importance to suppliers' decisions on prices and volumes, market shares provide a starting point from which to determine the relative market positions of the various competitors from the customer's point of view¹⁷¹.

(292) In order to assess the market power of Instrumentarium and its rivals in the anaesthesia machine market, the Commission looked first at the market shares of the various suppliers and then at other factors such as barriers to entry, switching costs, the differentiation of the products in question and customer preferences. The Commission based its findings on data provided by the parties, independent studies and the results of its market investigation. The Commission also had regard at its findings in the Siemens/Draeger decision where a similar analysis was performed.

(293) It is widely acknowledged that the anaesthesia machine market is highly concentrated both at an EEA and national level. Instrumentarium (Datex Ohmeda), Draeger, and to a much lesser extent Siemens, are the only suppliers with significant EEA-wide

¹⁷⁰ Point 125 of Decision in case No COMP/M.2861 – Siemens/Drägerwerk/JV.

¹⁷¹ Points 72-74 of Decision in case No COMP/M.2861 – Siemens/Drägerwerk/JV.

activities. An independent study by Frost & Sullivan¹⁷² (“the F&S Anaesthesia Report 2001”) puts Instrumentarium and Draeger on a par estimating their market shares at 38% and 39% respectively on an EEA basis. Apart from the two leading suppliers, there is also a number of suppliers such as Blease, Dameca, Penlon, Samed, Siare, Taema and Temel (“Others”) which have market shares in only a small number of Member States. At European level, the largest of these niche suppliers have market shares of 3% or less, according to the estimates by Frost & Sullivan.

(294) The market shares in the anaesthesia delivery machine market in the EEA and individual EEA countries, as provided by the parties in their notification, can be seen in the table below:

Anaesthesia delivery machines - National market shares

2002 % by value	EEA	EEA 173	A	BE	DK	DE	ES	FIN	FR	GR	IRL	IT	L	NL	PT	SW	UK	N
Instrumentarium	[30-40]*	[40-50]*	[50-60]*	[50-60]*	[0-10]*	[0-10]*	[40-50]*	[40-50]*	[20-30]*	[60-70]*	[60-70]*	[40-50]*	[40-50]*	[40-50]*	[50-60]*	[50-60]*	[40-50]*	[30-40]*
Draeger	[30-40]*	[20-30]*	[30-40]*	[30-40]*	[0-10]*	[70-80]*	[40-50]*	[30-40]*	[40-50]*	[10-20]*	[0-10]*	[20-30]*	[40-50]*	[40-50]*	[20-30]*	[10-20]*	[10-20]*	[30-40]*
Siemens	[10-20]*	[0-10]*	[0-10]*	[0-10]*	[0-10]*	[10-20]*	[0-10]*	[0-10]*	[0-10]*	[10-20]*	[0-10]*	[20-30]*	[20-30]*	[0-10]*	[20-30]*	[10-20]*	[0-10]*	[30-40]*
Others	[10-20]*	[20-30]*	[0-10]*	[0-10]*	[80-90]*	[0-10]*	[0-10]*	[20-30]*	[20-30]*	[20-30]*	[30-40]*	[10-20]*	[0-10]*	[10-20]*	[0-10]*	[10-20]*	[30-40]*	[0-10]*

Table 16 (Source: the parties)¹⁷⁴

(295) In addition to the above figures provided by the parties which, it should be noted, do not appear to contradict the findings of Frost and Sullivan at least on an EEA level, the Commission performed an exercise of reconstructing market shares on the basis of information it received through its market investigation¹⁷⁵. The table below relies on figures communicated by the parties, Siemens, and Draeger concerning their own turnover. The market shares of the remaining competitors are based on the data communicated by the parties in their notification¹⁷⁶.

2002 % by value	EEA	EEA 177	A	BE	DK	DE	ES	FIN	FR	GR	IRL	IT	L	NL	PT	SW	UK	N
Instru- men-	[25-30]*	[35-40]*	[25-30]*	[50-55]*	[0-5]*	[5-10]*	[45-50]*	[25-30]*	[20-25]*	[25-30]*	[50-55]*	[35-40]*	-	[45-50]*	[30-35]*	[60-65]*	[40-45]*	[45-50]*

¹⁷² Frost & Sullivan, European Anaesthesia and Respiratory Equipment Markets Report, 2001 “F&S Anaesthesia Report 2001”.

¹⁷³ Excluding Germany.

¹⁷⁴ Provided in the Notification.

¹⁷⁵ A similar exercise was performed in the Siemens/Draeger proceedings (see Siemens/Draeger decision at point 116). Due to the inability to obtain data from all competitors in the market, the reconstruction of market shares in the Siemens/Draeger decision remained incomplete (see point 116 in fine of the Siemens/Draeger decision). Therefore, a new reconstruction of market shares in the context of the current case was performed. It should, nonetheless be noted, that, according to the figures in the Siemens/Draeger decision, Instrumentarium would be the leading company in at least Ireland, Sweden and the United Kingdom. Draeger was found to be presumptively dominant in the following EEA countries (see point 153): *Denmark, Germany, Finland, France, the Netherlands and Norway*.

¹⁷⁶ Many smaller competitors were unable to provide precise turnover data on a national basis.

¹⁷⁷ Excluding Germany.

Instrumentarium ¹⁷⁸																		
Draeger ¹⁷⁹	[45-50]*	[30-35]*	[50-55]*	[35-40]* ¹⁸⁰	[50-55]*	[85-90]*	[40-45]*	[45-50]*	[45-50]*	[35-40]*	[5-10]*	[30-35]*	-	[30-35]*	[15-20]*	[5-10]*	[20-25]*	[45-50]*
Siemens ¹⁸¹	[5-10]*	[5-10]*	[15-20]*	[5-10]*	[0-5]*	[0-5]*	[0-5]*	[10-15]*	[10-15]*	[25-30]*	[15-20]*	[15-20]*	-	[0-5]*	[40-45]*	[15-20]*	[0-5]*	[0-5]* ¹⁸²
Others	[15-20]*	[20-25]*	[0-5]*	[0-5]*	[40-45]*	[0-5]*	[0-5]*	[15-20]*	[15-20]*	[5-10]*	[25-30]*	[10-15]*	-	[15-20]*	[0-5]*	[15-20]*	[35-40]*	[5-10]*

Table 17 (Source: Commission findings and information provided by the parties)

(296) The above tables show that Instrumentarium is one of two market leaders in anaesthesia delivery machines with an EEA market share, according to figures provided by the parties of at least [...] % (30-40% on the basis of the Commission's reconstruction) (sales of EUR [...]*) with Draeger having an EEA market share of [...] % (30-40% on the basis of the Commission's reconstruction)* (sales of [...]*). Almost [...] of Draeger's sales are achieved in Germany, the company's home market. If German sales are excluded, on the basis of the parties' data, Instrumentarium achieves a market share of [...] % (30-40% on the basis of the Commission's reconstruction) and Draeger only [...] % (30-40% on the basis of the Commission's reconstruction) on an EEA basis with respective sales of EUR [...] m and [...]*. According to the above tables, at national level, Instrumentarium's position on the market for anaesthesia delivery machines reaches levels indicative of a dominant position in a number of Member States where Instrumentarium has high market shares such as Belgium, Ireland, Sweden (above 50%), Spain, the Netherlands and the United Kingdom (above 40%).

(297) The above market shares should be considered in the light of additional relevant factors such as the existence of high entry barriers (market entry requires considerable sunk costs including a well developed distribution and service network as well as close commercial relations with hospitals and investment in R&D¹⁸³), the strong preference of customers for manufacturers with a proven track record and well-established products, the differentiated nature of the product and its critical importance for the life of the patient which increases the reluctance of doctors to switch suppliers of machinery, and the high brand recognition and quality of Instrumentarium's anaesthesia machines¹⁸⁴.

¹⁷⁸ Form CO.

¹⁷⁹ Business secret-confidential information: Reply to question 15, sent on 28.4.2003 referring to Answer No 2 of Article 11 request dated 27.1.2003, sent on 4.2.2003 (M.2861 Siemens/Draeger).

¹⁸⁰ Including Luxembourg.

¹⁸¹ Business secret-confidential information: Answer to Question 15 of Article 11 request, dated 11.4.2003 sent on 28.4.2003. “

¹⁸² No data provided for Norway.

¹⁸³ For example, Instrumentarium spent EUR 66.6 million on research and development in 2001 representing 7% of net sales for the anaesthesia and critical care business. (See Instrumentarium's annual report 2001, p. 19). The F&S Anaesthesia Report (2001) reports that “the market is fairly concentrated” and that there is “difficulty for new players to enter the market”, p.4-13.

¹⁸⁴ The overwhelming majority of respondents to the Commission's survey (anaesthesia questionnaire) stated that Datex-Ohmeda had “high” specifications and “high” quality respectively. Instrumentarium's leadership in anaesthesia machines vis-à-vis its smaller competitors is also evidenced by Instrumentarium's own documents. Instrumentarium's annual report of 2001 states that “with sales of EUR 714 million, it became clear during the year that we are now the largest supplier in the world of anaesthesia and critical care equipment and solutions. This position is highly advantageous for us in that it allows us to benefit from economies of scale in many areas, and hence it allows us to take carefully calculated risks in developing new businesses.” Instrumentarium's leadership is such that it is “the only company in the world to be able to offer a broad family of anaesthesia machines for varying applications”. See Instrumentarium Annual Report (2001), p. 4 and 8.

(298) In the light of the above information, it appears that Instrumentarium enjoys a significant degree of market power over its customer base throughout the EEA. The high market shares and the nature of the market (high concentration, high barriers to entry, differentiated nature of the products and strong consumer preferences), confirm the existence of serious doubts that Instrumentarium enjoys significant market power in at least the following national markets Belgium, Ireland, Sweden (above 50% with rivals being significantly smaller), and the United Kingdom (approximately [40-50]*% with rivals being significantly smaller).

(ii) Interoperability between anaesthesia machines, monitors and CIS

(299) Anaesthesia machines and perioperative monitors are used in the same area of the hospital, the perioperative area. As the parties state in the notification “*whilst a patient is undergoing anaesthesia, it is necessary to monitor the patient's vital signs to ensure his or her safety. This monitoring is undertaken by a Perioperative patient monitor*”¹⁸⁵. Given this use, anaesthesia machines and perioperative monitors are complementary products as both products are needed in order to perform surgery on a patient. The same applies to CIS systems which, without being necessary, are also used in conjunction with both anaesthesia machines and perioperative and critical care monitors in a number of EEA hospitals. Due to this simultaneous use in the same department of the hospital, there are commercial links in the marketing of those products to hospitals. The market investigation has shown that anaesthesiologists play an important role in influencing or actually deciding on purchases of both anaesthesia machines and perioperative monitors and, to a more limited extent, critical care monitors.

(300) In addition to the complementary use of the two products there is also a technical, vertical link or interface between anaesthesia machines and monitors. Even though both are necessary when a patient is undergoing surgery, the two products can be used completely separately, in the sense that the anaesthesia machine delivers gases to the patient and displays the delivery of gas on an anaesthesia display and the patient monitor connects via sensors to the patient and displays the patient's vital signs on the monitor display. However, as the market investigation shows, in practice, there is normally a connection between the two machines, either a mechanical (in the overwhelming majority of cases) or electronic connection or both. The market investigation also showed that co-operation by a device supplier such as an anaesthesia machine supplier is necessary so that independent suppliers of other devices such as patient monitors or CIS can integrate their devices mechanically or electronically with the anaesthesia machine.

Mechanical integration

(301) Mechanical integration, which is commonly used in EEA hospitals, requires that the monitor is mechanically integrated with the anaesthesia machine in that it stands on top of the anaesthesia machine (with clips and Velcro straps or mounting solutions) or is mounted onto the anaesthesia machine by means of a mobile “side arm”; the latter configuration is increasingly popular due to the popularity of flat panel displays which

¹⁸⁵ Form CO, p. 121.

are integrated in this way¹⁸⁶. Many different mechanical configurations are possible depending on the anaesthesiologist's needs. The parties' patient monitors and third-party patient monitors are mechanically integrated with Instrumentarium or other suppliers' anaesthesia machines.

(302) The reason for the desirability of mechanical integration is put clearly in a third party submission which explains that *“Because space in the operating room is limited and anaesthesiologists need constant access to the patient monitor and the anesthesia machine, a monitor must be securely attached to the anesthesia machine in a manner and location - “configuration” - which is fully compatible with the anaesthesiologist's workplace requirements¹⁸⁷”*. The F&S Anaesthesia Report (2001) also concludes that *“the market is moving towards a greater level of integration and computerisation which means a greater integration between the various equipment”¹⁸⁸*. Documentation submitted by third parties shows that there is clear demand for mechanical integration solutions by hospitals. This is also evidenced by the existence of dedicated mounting solution suppliers such as the major US mounting solutions supplier, GCX.

(303) Despite the parties claims that mechanical integration is very simple, third party documents and the parties' own internal documents show that mechanical interfacing is more complicated and requires co-operation between the anaesthesia machines supplier, monitor supplier and mounting solutions supplier¹⁸⁹. Different configurations of monitor-anaesthesia machine are tested and validated according to international standards. In their responses to the Commission's requests for information, both parties list relevant standards¹⁹⁰ such as the IEC 601-1. Whilst such standards are not obligatory, they are considered “best practices” and suppliers conform to them as there is increasing customer awareness and demand. Information provided by the parties, third party monitor suppliers and mounting solutions suppliers shows that tests are indeed habitually performed and the suppliers certify the validity of a given configuration before it is sold commercially to customers. GE acknowledges the need for co-operation by stating that *“mechanical integration is facilitated by using standard patient monitor mounts physically attached to the anaesthesia machine. The design is a cooperative effort between GE, the anaesthesia machine company and a*

¹⁸⁶ Instrumentarium's response to the Article 11 request dated 9 April 2003, Question 14: *“new monitors have an incorporated flat panel and LCD displays, which make it possible to mount monitoring elements on a side arm”*.

¹⁸⁷ Submission by third party dated 24 March 2003, p. 2.

¹⁸⁸ F&S Anaesthesia Report (2001), p. 4-31.

¹⁸⁹ A number of competitors stated that the completion of a validly tested configuration requires significant time of approximately 6 months and in some cases well over 6 months. (Third party responses dated 24.4.2003, 14.5.2003; 30.4.2003 and in particular third party response to Article 11 letter dated 11 April 2003, Question 4.) One third party stated that the minimum information and support required to achieve mechanical integration was *“Specification of the maximum weight that can be borne by the wheels; Specification of the channels and the weight they support, if channels are available; Location of fixing points for mounting hardware and their specified intended use; Information about possible places to adapt mounting solutions for the patient monitors; Information about all the possible set-ups, including all parts required in order to perform tests according IEC and UL; contact person for technical questions”*.

¹⁹⁰ Including, for example, the following standards: EN 740: 1998 and EN 12218: 1998 + A1: 2002 (harmonised standards related to medical devices under Council Directive 93/42/EEC); EN 740: 1998 (European standard relating to anaesthetic workstations).

manufacturer of patient monitor mounting systems"¹⁹¹. A third party stated that "*The development process requires access to detailed product specifications and other information available only from the manufacturers of both the monitor and the machines that are to be interconnected*"¹⁹². Instrumentarium also provided information showing that co-operation between the suppliers of the devices is necessary for an effective, validated mechanical integration; Instrumentarium claims that it has provided such co-operation in the past¹⁹³.

Electronic integration

- (304) In addition to mechanical integration, electronic integration between the anaesthesia machine and monitor is used by a number of hospitals. Electronic integration involves exchange of data between the anaesthesia machine and monitor or input of those devices' data into a CIS¹⁹⁴ or even a full integration of the anaesthesia machine, patient monitor and possibly CIS in one single device (such as Instrumentarium's ADU).
- (305) Electronic integration of anaesthesia machines and monitors or those devices with CIS systems appears to offer a number of significant clinical and administrative advantages to hospitals. Data generated by the anaesthesia machine can be displayed direct and in "real-time"¹⁹⁵ on the monitor's display in addition to appearing on the anaesthesia machine display. The market investigation showed¹⁹⁶ that those hospitals using electronic integration value the ability of displaying data generated by the anaesthesia machine and monitor in a single display as this enables the doctor to address the patient's needs more effectively. At the same time, the keeping of patient's clinical records is effortless, as data is generated automatically.
- (306) Despite the parties' claims that electronic integration is of limited use in the EEA, the Commission found that a significant number of hospitals responding to its market investigation actually interfaced their anaesthesia machines and monitors electronically. An additional number of hospitals, replied that they had plans to use CIS electronic interfaces in the next 2-3 years. For this reason major monitor suppliers

¹⁹¹ GE's response to the Commission's Article 11 request for information dated 9 April 2003, p.4. Emphasis added.

¹⁹² See third party submission of 24 March 2003, p. 2.

¹⁹³ In its response of 18 June 2003, Instrumentarium discussed its co-operation with monitor suppliers and mounting solution suppliers: "*it is important to note that the latest machine from Datex-Ohmeda, the S/5 Avance, due out in late June 2003, already has mounting solutions for Philips, Siemens, GE, Spacelabs and Datex-Ohmeda monitors developed and tested by GCX. This is due to Instrumentarium's proactive collaboration with GCX to develop the mounts. [...]*. Instrumentarium worked with the third-party mounting solution provider before the product launch.*"

¹⁹⁴ Electronic connection between anaesthesia machines and monitors can be achieved by means of small interface devices in which the machines are plugged. Each manufacturer has created its own solution (e.g. GE's "Octicomm" or Philips' "VueLink" device). Such physical components may be necessary for achieving an interface connection between an anaesthesia machine and patient monitor.

¹⁹⁵ "Real-time" transmission of data means that data generated by the anaesthesia machine are displayed alongside physiological data measured by the patient monitor on the patient monitor's display. This makes it easier for the physician to assimilate information on the patient's actual condition at any given point in time and to adjust the therapy accordingly.

¹⁹⁶ A significant number of respondents stated specific advantages arising from electronic integration. Results of responses to the Commission's questionnaire to customers show that a very large number of respondents stated convenience of displaying data on a single display and producing automated record as the main advantages of such electronic integration.

offer monitors that are already capable of electronic integration. Instrumentarium's electronically integrated ADU machine represents approximately 25% of Instrumentarium's total annual sales of anaesthesia machines¹⁹⁷. A third-party monitor supplier claimed that [20-25%]* of its monitor sales included interface modules in 2001. GE's "dear customer" letter of 4 April 2003, sent to all its customers on the occasion of its announcement of the bid for Instrumentarium, evidences GE's commitment to provide electronic integration.

- (307) As acknowledged by the parties, electronic integration requires the co-operation of both the monitor and the anaesthesia machine supplier as the output specification, protocol and other technical information needs to be known to a patient monitor manufacturer for an interface to be created. The parties have, however, claimed that Instrumentarium (and other anaesthesia machine manufacturers) practice an "open architecture" policy which enables other monitor manufacturers to develop quickly and at low cost the software needed for the anaesthesia machine and monitor to interface electronically. For example, Instrumentarium's specifications are publicly available in its machines' service manuals or on the internet¹⁹⁸.
- (308) Given that interfaces are proprietary, co-operation between the various suppliers appears to be necessary for a seamless exchange of electronic data between an anaesthesia machine and monitor. Third party suppliers of patient monitors produced documentation showing that efforts to produce electronic interfaces have not always met with effective co-operation by anaesthesia machine suppliers¹⁹⁹. A number of hospitals responding to the Commission's market investigation stated that they had faced problems of connectivity in the past and concluded that they needed assistance from the suppliers in order to achieve a seamless electronic interface²⁰⁰. GE acknowledges the need for co-operation by stating that *"developing, verifying and validating the protocol interpreter software generally requires co-operation between GE and the device vendor. The development process occurs in the following way. Based on an informal partnership with the anaesthesia machine vendor, the vendor provides protocol and operation manuals and technical assistance, and typically loans equipment (or provides for the use of equipment at their facilities) to develop the interface software. The monitor manufacturer defines the requirements, writes the software then performs the data mapping, as well as its verification and validation"*²⁰¹. In response to a direct question by the Commission on the ability of third party suppliers to create interfaces without co-operation by the anaesthesia machine supplier, Instrumentarium also acknowledges that this would not be possible²⁰². It is also to be noted that effective electronic integration requires

¹⁹⁷ [25-30]*% of sales in 2000 and [20-25]*% of sales in 2002.

¹⁹⁸ See Instrumentarium's response to question 28 of the Commission's Article 11 request for information dated 9 April 2003.

¹⁹⁹ Third party response to Question 15 of the Article 11 request for information dated 11/4/03 providing information on electronic interoperability problems.

²⁰⁰ Customers were asked to state whether they had faced difficulties in electronic connectivity and whether it was easy to connect a monitor and anaesthesia machine electronically without assistance from the supplier. A large number of customers responding to this question states that they had faced difficulties and that it was not easy to connect without supplier assistance.

²⁰¹ GE's response to the Commission's Article 11 request for information dated 9 April 2003, p. 6.

²⁰² See Instrumentarium's response to question 29 of the Commission's Article 11 request for information dated 9 April 2003 where it states that [...]*. [...]*.

adaptation to the relevant interfaces when the supplier of the anaesthesia machine upgrades or modifies the machine's protocol and output specifications.

Links between perioperative and critical care monitors and CIS- Standardisation

(309) Finally, standardisation (the need to use the same brand of devices throughout the various areas of the hospital) and increasing use of CIS systems and generally electronic connectivity of devices lead to an interface issue not only in the perioperative area but in the critical care area as well. A number of customers during the market investigation stated a number of standardisation benefits such as portability, no need to remove cables, training of staff, spare parts, compatibility with other equipment. Third party information also confirmed the existence of a standardisation trend. Standardisation advantages have been underlined by the European Society of Anaesthesiologists: *“In many hospitals across Europe, we see an increasing desire for standardisation of patient monitoring equipment across all acute care settings, since this offers the hospital benefits in terms of training, standardisation on cables and accessories, continuity of patient data and equipment maintenance”*²⁰³.

(310) Whist the parties submitted that standardisation benefits are outweighed by the disadvantage of being tied to a single supplier²⁰⁴, they acknowledge that such benefits exist including *“maintenance, in-house knowledge, system up-time, training, spare parts, suppliers one partner and solution provider, easy to improve the total system performance”*²⁰⁵. In addition, both parties acknowledge the desirability and trend towards the creation of a digital hospital environment with seamless and effective connectivity of various devices and the use of CIS in the perioperative and critical care areas. GE internal documents provided as an Annex to the Notification speak about the benefits of electronic connectivity throughout the OR with the aim being to create a *“digital cockpit for the OR” by offering “device integration, information convergence: monitor to anaesthesia, IT systems and equipment, OR and enterprise”*. GE also speaks of a trend for *“tighter integration with monitoring [and anaesthesia machines]*”* and *“integration into CIS” being the next step*²⁰⁶.

Conclusion on interfacing of relevant devices

(311) It is therefore reasonable to conclude that there appears to be an ever increasing need for anaesthesia machines and monitors to interface mechanically and electronically with one another as well as with CIS²⁰⁷. It is also reasonable to conclude that continued co-operation between anaesthesia machines suppliers and independent suppliers of patient monitors or CIS appears to be necessary in order to allow those independent suppliers to integrate their products mechanically and/or electronically with Instrumentarium anaesthesia machines and hence to meet their customers'

²⁰³ Professor [...]*, Industrial Liaison Officer, European Society of Anaesthesiologists quoted in a third party's response to Question 17 of the Article 11 request for information of 11 April 2003.

²⁰⁴ The market investigation also showed that a significant number of customers values the ability to “mix and match”.

²⁰⁵ See Annex 17 to GE's response to the Article 11 request of 9 April 2003, presentation “System Selling Go”.

²⁰⁶ See Annex 5.4 to the Notification, GEMS presentation on the rationale of the Instrumentarium deal.

²⁰⁷ A significant percentage of respondents to the Commission's market investigation stated that they had plans to connect their anaesthesia machines and monitors to CIS systems.

increasing need for interoperability. Integration of devices such as anaesthesia machines and monitors with CIS systems appears to be a desirable aim for hospitals in the EEA and that, in the light of this integration, seamless connectivity of devices is required for effective digitalised environments in the perioperative and critical care areas of the hospital.

3. Serious doubts that the merger may lead to foreclosure effects

- (312) The above information led the Commission to find serious doubts as to the compatibility of the concentration with the common market on the basis that the merged entity would have the ability to foreclose its rivals. This ability would arise from the merged entity's significant market power in anaesthesia machines and the need for co-operation between the anaesthesia machine manufacturer and the patient monitor manufacturer or CIS supplier²⁰⁸ as explained above.
- (313) If Instrumentarium so wishes, it can simply withhold its co-operation or, more likely, engage in subtler ways²⁰⁹ of degrading co-operation thus making it difficult for independent anaesthesia machine or monitor manufacturers or CIS suppliers to connect their devices or systems to those of the merged entity thus raising their costs.
- (314) When it initiated proceedings, the Commission also expressed serious doubts as to the compatibility of the concentration with the common market on the basis that the merger could change or enhance the incentives of the merged entity to use its ability to foreclose contrary to the parties' claims that the merger would not change anything in either the anaesthesia or the patient monitors markets compared to the incentives of Instrumentarium (an already vertically integrated company) before the merger.
- (315) It appears that, despite the parties' claims that such incentives could be excluded on the basis of limited extend of integration of the various devices, mechanical interoperability of anaesthesia machines and monitors is a relevant requirement for a significant number of hospitals due to the limited space of the OR and the need for ergonomics and patient safety. Even electronic interoperability, which is not as prevalent in the EEA today, is used by a significant number of customers with an even greater number of customers stating that they had plans of introducing electronic connectivity in the next two to three years.

²⁰⁸ As noted above, the parties do not deny that co-operation is necessary for effective and seamless mechanical and electronic integration nor that an anaesthesia machine supplier would have the ability to withhold necessary co-operation or to degrade co-operation.

²⁰⁹ There are many ways in which GE/Instrumentarium could attempt to achieve such foreclosure. Refusal of co-operation or "closure" of architecture could be an extreme measure that would immediately deprive independent monitor manufacturers from being able to sell monitors to customers using Instrumentarium anaesthesia machines. According to third party submissions a variety of more subtle and difficult to detect ways could be employed including for example frequent modifications and upgrades resulting in constant need for co-operation which the merged entity could delay or refuse, manipulation of the output to optimise performance when GE/Instrumentarium monitors are connected rather than another manufacturer's monitor; use of more proprietary protocols; provision of inferior connectivity to CIS systems; frequent changes in software code resulting in problems in the interoperability of rival monitors; manipulation of machine mounting brackets to reduce rivals' mechanical integration; refusal to loan equipment or co-operate in testing equipment for validation in accordance with international standards; delayed co-operation preventing competing manufacturers from showing their products in a timely way at important international trade fairs; etc. Third party and the parties' internal documents reveal certain co-operation problems with interoperability in the past.

- (316) In addition, it is to be noted that the merged entity would enjoy significant market power in anaesthesia delivery machines which could give GE/Instrumentarium the ability to exploit its anaesthesia market power, as described above, to the great benefit of its own perioperative monitors business as well as critical care monitor business and CIS. The merged entity's overall position in products for the perioperative and critical care areas of the hospital would be stronger than that of Instrumentarium alone before the merger²¹⁰. In patient monitors (combined sales of perioperative and critical care monitors,) the merged entity would be the leading company with a market share of [30-35]*%. In critical care monitors, the merged entity's market share would [...] from [10-15]* to [25-30]*% at an EEA level²¹¹ exceeding [30-35]*% in 8 EEA countries (Austria, Finland, the United Kingdom, Greece, Ireland, Netherlands, Spain, Sweden and Norway). In CIS, the merged entity would be able to combine its various solutions and to offer leading CIS solutions to perioperative and critical care customers²¹².
- (317) As regards the possible strategy of the merged entity, it should be noted that, even before the merger, it appears that Instrumentarium attempted to follow a strategy whereby it would *"leverage its franchise as the global leader in the anaesthesia market to become the global leader also in the related market for critical care systems and equipment"*²¹³. However, before the merger, Instrumentarium would appear to have had certain disadvantages which would limit the success of a potential foreclosure strategy and which have resulted in an acceptance of an "open" architecture policy by Instrumentarium²¹⁴ at least as far as technical interoperability is concerned. Instrumentarium's product range in critical care equipment was relatively

²¹⁰ In its Annex 5.4 documents (annex to the Notification), GE explains that one of the main reasons for the Instrumentarium deal was to combine the respective strengths of Instrumentarium and GE in the perioperative and critical care areas: *"Continuing GEMS IT commitment to clinical excellence at the point of care with a corresponding expansion of parameter base and core competencies: "expand presence in the perioperative area (Datex-Ohmeda: Global Leader)", "significantly enhance the perinatal care offering", "provide a significantly strengthened position and platform for growth in Europe", "expands non-invasive cardiology line-up", "provides additional building blocks for the convergence of devices and IT systems"*.

²¹¹ [20-25]*% taking into account the horizontal divestiture offered by the notifying party.

²¹² GE is active in the critical care and perioperative areas with its "Centricity Critical Care" and "Centricity Perioperative" products. Apart from the parties, the other main medical sector CIS suppliers are Siemens and Philips. Instrumentarium is present in the same care areas through its "Deio" and "Clinisoft" products. The notifying party has not provided market shares in CIS claiming that this is a fragmented, nascent and growing market. The notifying party, in the notification, also claims that their market share would remain below [25-30]*%. In subsequent responses both parties stated that their market share would be minimal and that, given the nascent nature of the market, market share calculation is not meaningful. Information collected by the Commission during its investigation by the main market players shows that in terms of 2001 and 2002 sales GE/Instrumentarium would be larger than Philips and Siemens and slightly smaller than Philips but much larger than Siemens in terms of installed base. In addition, in its web site GE speaks of its "leadership" in CIS: *"With over 700 Clinical Information Systems world-wide, GE Medical Systems Information Technologies proven leadership means we can deliver highly evolved systems for all your perinatal and critical care applications."* Instrumentarium also claims that its CIS product *"Deio is a world leader in the management of perioperative and critical care information through solutions that allow healthcare professionals offer better quality of care while conserving resources"* (See www.deio.com).

²¹³ This claim was included not only in Instrumentarium's internet site and in strategy documents of marketing advisers but also in Instrumentarium's Annual Report of 2001.

²¹⁴ In its response of 18 June 2003, Instrumentarium states that it *"has consistently supported open interfacing of anaesthesia machines and monitors. To support this effort, the company's long-standing policy has been to publish and support interfaces to its machines and monitors"*.

narrow²¹⁵. Hospitals (especially those wishing to standardise their monitors and CIS across the perioperative and critical care areas) had therefore a stronger incentive to insist on a “mix-and-match” policy in order to be able to obtain the monitor they preferred and to be able to use it with their anaesthesia machine of choice. As a result, Instrumentarium was only to a more limited extent able to use its market power in order to impose closed architecture policies or to increase its sales of critical care monitors and CIS. Instrumentarium's business strategists had acknowledged those problems²¹⁶. As suggested by internal documents, one commercial reason behind GE's acquisition of Instrumentarium was to exploit the merged entity's complementary strong positions in the perioperative and critical care areas.

(318) In the light of the above and in particular the strength of the merged entity in anaesthesia machines and the integration of devices and standardisation trends identified above the Commission therefore expressed serious doubts as to the compatibility of the concentration with the common market as it appeared that, by closing the architecture of its devices, the merged entity would have the ability and possibly the incentives to pursue a foreclosure strategy in the whole perioperative and critical care hospital spectrum: using its strength in anaesthesia machines to foreclose rivals and dominate or strengthen its dominance in anaesthesia machines, perioperative monitors, critical care monitors and CIS.

(319) Following the Commission's Article 6(1)(c) decision the parties claimed that the above-mentioned serious doubts would not be confirmed due to a number of arguments²¹⁷ (discussed to some extent above) and in particular the lack of incentives²¹⁸ of the merged entity to engage in foreclosure strategies on the basis that interfacing would not be an issue for the majority of patient monitor sales as electronic connectivity is not prevalent in the EEA, that Instrumentarium had been following an open architecture policy and the merger would not change the dynamics of competition in either the market for anaesthesia machines or perioperative monitors and that a foreclosure strategy would not be commercially reasonable or successful given that customers would resist it by turning to rivals which could satisfy their needs and which could engage in similar counter-strategies.

(320) However, in the light of the serious doubts as to the compatibility of the transaction with the common market due to the foreclosure issues identified in the 6(1)(c) decision, the notifying party submitted commitments in order to dispel the above-mentioned

²¹⁵ In its response of 18 June 2003, Instrumentarium explains that it had certain limitations in its product range, parameter capabilities and networking capabilities that did not allow it to adopt a standardisation strategy contrary to the major players such as GE, Philips and Siemens: [...]*

²¹⁶ In internal presentations submitted in response to the Article 11 questionnaire of 9 April 2003, Instrumentarium states that [...]*(see slide 4 of the presentation “ICU outside US strategy plan” of 18 August 1999). In its response of 18 June 2003, Instrumentarium explained that [...]*

²¹⁷ See Notification, p.122 et seq. and the parties' letter of 28 April 2003 with comments to the Art. 6(1)(c) decision in which they already suggested their willingness to offer a commitment to dispel the expressed foreclosure-related serious doubts. See also the parties' economic advisers', RBB, paper of 19 June 2003.

²¹⁸ The parties deny that Instrumentarium has market power in anaesthesia machines. This argument has been discussed above in the section describing Instrumentarium's market power in anaesthesia delivery machines in specific national countries where its market share exceeds 50%. The parties do not deny that an anaesthesia machine supplier could “close” the architecture of its machines or degrade interoperability and thus prevent or prejudice sales of rival patient monitor or CIS products that need to interface, mechanically or electronically, with anaesthesia machines.

serious doubts. This commitment appeared to eliminate the serious doubts relating to the vertical issues and was therefore market tested in order to assess its viability and effectiveness and was further improved by the notifying party and re-submitted in a revised version on 4 July and then on 24 July 2003 as part of a revised package of commitments. In the light of the positive market test results and its assessment, it was concluded that the commitment was sufficient to eliminate the serious doubts relating to vertical issues in this case. As a result, no objections were raised as regards the above-mentioned vertical issues.

V. COMMITMENTS

1. HORIZONTAL COMMITMENTS

(321) In order to remove the above-mentioned horizontal competition concerns on the market for perioperative monitors, GE has submitted a package of commitments. The commitments are attached to this Decision as Annex I.

1.1 Commitments submitted to the Commission

(322) As regards the market for perioperative monitors, the notifying party submitted on July 24 a package of remedies, based on the divestiture of Spacelabs (a division of Instrumentarium) in conjunction with a series of OEM supply agreements (Instrumentarium anaesthesia machines, Instrumentarium/Datex-Ohmeda perioperative monitor Cardiocap5 and Instrumentarium latest gas module model) aiming at making the divested business more appealing to potential purchasers and a more effective competitive force.

(323) The set of undertakings can be summarised as follows:

a) Divested Business

(324) Divestment of all assets, tangible and intangible (including proprietary know-how) and all businesses belonging to “Spacelabs”, a division of Instrumentarium, acquired by and incorporated into Instrumentarium in July 2002 and managed in conjunction with and through Datex-Ohmeda Inc. a fully owned subsidiary of Instrumentarium. The Spacelabs Divested Business comprises (*inter alia*) Datex-Ohmeda’s Spacelabs Medical manufacturing, distribution and research and development operations and sales channel operations for multi-parameter patient monitoring and associated equipment and services. The divested business is described in detail in Schedule 1 of the Undertakings and annexes thereto.

b) OEM Supply agreements

(325) As mentioned, the undertakings offered by GE include three OEM supply agreements aimed at rendering Spacelabs more competitive in the relevant market and thus allowing the Purchaser of Spacelabs to be present as a more viable competitor in tenders requiring both monitors and other pieces of equipment as part of perioperative monitor “systems”.

The OEM supply agreement for anaesthesia machines

This text is made available for information purposes only and does not constitute an official publication.

- (326) GE is committed to supplying on an OEM basis anaesthesia machines and related supplies, accessories and start-up kits, on a non-exclusive basis, to the Purchaser of Spacelabs for the purpose of resale to end-customers to whom the Purchaser supplies perioperative monitors for sale, and for the purpose of allowing the Purchaser to make combined perioperative monitor/anaesthesia machine bids and sales.
- (327) The OEM supply agreement will be in force for a duration of five years and will allow the purchaser of Spacelabs to supply the relevant products within the territory of the EEA and all future EU Member States (all accession countries). Moreover, the agreement also provides that successor and upgraded versions of the current products shall be supplied under the same terms and conditions. The products shall be priced at substantially similar conditions as those offered to GE distributors. The agreement also includes the supply of spare parts for a duration of 10 years after the expiration of the agreement and the supply of maintenance and repair services by GE, upon request by the purchaser, at favourable conditions. This supply agreement is described in detail in Schedule 2 of the Undertakings.

The OEM supply agreement for Cardiocap5/Gas monitor

- (328) GE is committed to supply the Cardiocap/5 perioperative monitors (including the Gas Monitors), and related supplies, accessories, leads and cables, to the Purchaser on an exclusive basis. The agreement shall be in force for a duration of 10 years and will allow the purchaser of Spacelabs to supply the relevant products within the territory of the EEA and all future EU Member States (all accession countries). Moreover, the agreement also foresees that successor and upgraded versions of the current products shall be supplied under the same terms and conditions. The products shall be supplied at “cost plus” pricing conditions, i.e. including GE direct production, distribution intellectual property and warranty and costs plus a margin of [20-30]*%. The agreement shall also include the supply of spare parts for a duration of 10 years after the expiration of the agreement and the supply of maintenance and repair services by GE, upon request by the purchaser, at favourable conditions. This agreement is described in detail in Schedule 3 of the Undertakings.

The OEM supply agreement for Gas Modules

- (329) GE is committed to supply to the Purchaser of Spacelabs the Datex-Ohmeda Gas Module. The agreement shall be in force for a duration of 10 years and will allow the purchaser of Spacelabs to supply the relevant products on a world-wide basis. Moreover, the agreement also foresees that successor and upgraded versions of the current products shall be supplied under the same terms and conditions. The products shall be supplied on pricing terms no less favourable than those offered to other third parties or, alternatively, on the basis of the same “cost-plus” terms foreseen for the supply of Cardiocap5. The agreement shall also include the supply of spare parts for a duration of 10 years and the supply of maintenance and repair services by GE, upon request by the purchaser, at favourable conditions. This OEM agreement is described in detail in Schedule 4 of the Undertakings.

c) Instrumentarium Commitment

- (330) It has to be mentioned that, in addition to the undertakings submitted by GE, on 17 July 2003 Instrumentarium submitted a commitment (“the Instrumentarium Commitment”) which is reproduced in Annex III to this Decision. The purpose of the

Instrumentarium Commitment is to ensure full compliance with the provisions of Section C and Section D of the Commitment Text, as submitted by GE, also prior to the Effective Date²¹⁹, when such commitments will be assumed by GE. In practice, most importantly the Instrumentarium Commitment will ensure the preservation of the viability and competitiveness of the divested business and the compliance with hold-separate and ring fencing obligations prior to GE effectively acquiring control of Instrumentarium. The Commission takes note of the Instrumentarium Commitment. However, this commitment does not constitute a condition for clearance.

1.2 Assessment of the notified concentration as modified by the undertakings

- (331) In the framework of the market test on the proposed undertakings, the Commission contacted approximately 200 third parties, including major hospitals in all Member States, the parties' main competitors and prospective purchasers of the divested business. Many respondents put forward concrete and substantial suggestions for amendments to the package proposed by the notifying party with a view to improving the overall package and making the divested business a more viable competitor. The most substantial suggestions related to the duration and the geographic scope of the OEM supply agreements; the need to ensure timely access to successor and upgraded versions; the spare parts supply provisions; and the pricing terms and conditions.
- (332) The final package of undertakings, submitted on July 24 and described above, incorporates the bulk of the suggestions and comments made by third parties in the context of the market test. The undertakings in their final form thus meet the concerns expressed by third parties as regards the need to ensure the greatest possible viability and competitiveness of the divested business.
- (333) The commitment relating to the divested business implies the transfer of all assets and activities belonging to Spacelabs. This company achieved, in 2002, global sales revenues of about EUR 180 million.
- (334) In terms of product range, the divestiture of the Spacelabs' business will more particularly comprise Spacelabs' patient monitoring platform known as the Ultraview Care Network. The Ultraview Care Network Monitors includes a variety of models²²⁰ and in particular, as confirmed by independent surveys²²¹, two high-end monitors which are equivalent to GE's high-end monitors (the Solars 9500 and 8000). Specifically, the Ultraview 1700 is Spacelabs' highest end patient monitor and is particularly suitable for use in high-end perioperative areas.
- (335) The Spacelabs' UCN system also comprises various modules that are available to meet specific monitoring needs, including in the perioperative area (e.g the Bispectral Index Module; the capnograph and EEG monitoring modules). Options are also available to mix-and-match screen sizes, display types (CRT or flat-panel), and networks (stand-alone, hard-wired or wireless). Clinicians are therefore enabled to

²¹⁹ As defined in the Undertakings: "Effective Date: the closing date as defined in the Combination Agreement dated 18 December 2002 between GE and Instrumentarium, whereby GE will acquire sole control of Instrumentarium.

²²⁰ The Ultraview 1030, 1050, 1500, 1600 and 1700.

²²¹ See T for G, Section 3.1 "Products and Markets", page 6.

customise monitor operation to specific patient preference and needs. Spacelabs Ultraview Care Network also supports seamless data acquisition and interfaces for access to the longitudinal patient record at the point of use, including hospital-based, clinic/physician office-based, and home-based healthcare. Spacelabs thus provides networking and connectivity solutions adapted to the needs on the market. In that perspective, Spacelabs' highest-end monitor can, for instance, provide access to clinical information systems at the point of care through different systems (Dynamic Network Access or Windows Dynamic Network Access) in order to give clinicians the ability to view and control information systems interfaced with the network. Finally, Spacelabs' offering includes information systems solutions which, in the near future, are expected to become critical for many hospitals. Specifically, a clinical information system for use throughout the perioperative environment ("Caremaster Plus OR Chart") has been designed for use by anaesthesia providers in order to address the needs of preoperative, operative and postoperative data management to provide the perioperative patient record. This CIS can be accessed in particular through Spacelabs' highest-end monitor. Finally, in 2003, Spacelabs will introduce the next generation networking infrastructure via its Intesys Clinical Database, providing an even opener network communication capability and enabling application via web services for remote information review.

- (336) In terms of product range and monitoring capabilities in the perioperative area, Spacelabs thus offers technical solutions similar to those of GE prior to the merger. The Commission notes that the divestiture of Spacelabs also includes the transfer of Spacelabs' intellectual property rights as well the current agreements concluded by Spacelabs with third parties as regards technology licences, some of which are particularly relevant for the integration of modules used in the perioperative area (e.g contract with Aspect Medical Systems with respect to BIS module, and licence under Nellcor's pulse oxymetry sensor coding patents).
- (337) As to the capability for the purchaser of Spacelabs to rely on effective sales forces and R&D, the Commission notes that, together with the requirement that the purchaser shall have, *inter alia*, the financial resources and proven expertise in order to develop the business, Spacelabs will also comprise distribution and research and development operations and sales channel operations for multi-parameter patient monitoring, currently managed through Datex-Ohmeda's Spacelabs Medical manufacturing. In addition, alongside the transfer of key personnel, the divestiture of the Spacelabs business would also include the creation of sales teams that are appropriate to the level of perioperative monitor business in each EU country to the extent the purchaser does not have distribution capacity in the country concerned. Moreover, in order to ensure that the sales personnel concerned has sufficient market experience, and can thus be expected to have an effective access to anaesthesiologists, this transfer would include distribution staff of Spacelabs currently employed by Instrumentarium and its affiliated undertakings.
- (338) With regard to the market presence of Spacelabs, the commitments are aimed at ensuring that the divestiture, together with the other commitments submitted by GE, will enable the purchaser of the business to be a competitive force of size, presence and strength similar to GE's prior to the-merger on the market for perioperative monitors.

- (339) First of all, whilst Spacelabs' installed base of perioperative monitors in Europe was on its own reported to be similar to that of GE in 2000 ([5-10]*% compared to [5-10]*% for GE)²²², with a market share then estimated at [5-10]*%, the subsequent integration of Spacelabs within Instrumentarium in 2002 has been accompanied by a slight decline in its sales of perioperative monitors. With the objective of fully restoring and enhancing Spacelabs' competitiveness in this area, the commitment package thus includes the undertaking by GE to supply to the purchaser, on an exclusive basis, Datex-Ohmeda's "Cardiopac5/gas monitor". This monitor, considered as equivalent to the UV 1500, has been offered with a view to ensuring that the sales of the divested business would on their own - i.e. without taking account of the possible sales of perioperative monitors by the purchaser - correspond, to the greatest possible extent, to GE's own sales of perioperative monitors pre-merger, in particular on markets where the transaction would lead to the creation of a dominant position.
- (340) The Commission notes, in this regard, that the EEA sales of Cardiopac/5 perioperative monitors during the year 2002 were, on their own, higher than the overall direct sales of GE's perioperative monitors, representing more than EUR [10-15]* million compared to EUR [5-10]* million for GE's direct sales. In the Member States where the Commission identified competition concerns, the combination of Spacelabs' own monitors and Cardiopac 5 perioperative monitors will eliminate or considerably reduce the overlap resulting from the merger. Thus, the overall 2002 direct sales of these monitors in France and Germany would have represented, respectively, a [5-10]*% and a [5-10]*% market share, compared to [5-10]*% and [5-10]*% for GE pre-merger. In other countries, on the basis of the 2002 figures, the corresponding market shares would even be substantially higher. In Spain, sales of Spacelabs and Cardiopac 5 perioperative monitors would thus represent a [15-20]*% market share compared to [10-15]*% for GE. In the United Kingdom, these sales would correspond to a [15-20]*% market share, compared to [5-10]*% for GE. Finally, in Sweden, where GE's market share was between [5-10]* and [5-10]*% in 2002, the overlap would be substantially reduced, down to only [0-5]*%. In view of the duration (10 years), the scope (the EEA including all Accession countries) and the exclusivity of the supply agreement for Cardiopac 5, the Commission considers that the purchaser will be in a position to maintain over time a significant market presence while also being in a position to develop its own manufacturing business. In that respect, the Commission further notes that the Cardiopac 5 perioperative monitor is indeed one of the best-selling products of Instrumentarium in the various EEA countries.
- (341) In addition to offsetting the overlaps resulting from the merger, the commitments submitted by the notifying party are aimed at ensuring that the purchaser is actually put in a position to exert, also in qualitative terms, an effective competitive constraint on the merging parties by offering products of comparable quality. In that regard, the Commission is of the opinion that the exclusivity foreseen by the commitment relating to the sale of Cardiopac 5 perioperative monitors, or any successor or upgraded versions, will ensure that the purchaser can be immediately perceived as offering close substitutes to Instrumentarium's patient monitors.

²²² T for G, Section 3.3.1, "Market Shares Monitors Europe" page 6.

- (342) In parallel, the purchaser will have access, for a considerable period of time (10 years), to Instrumentarium's renowned gas modules, on favourable pricing terms. The Commission considers that the commitment relating to the gas module, and its upgraded or successor versions, will enable the purchaser to further develop Spacelabs' own monitors by incorporating Instrumentarium's high-end technology in the field of gas monitoring, a feature which is crucial for effective and successful presence in the perioperative area. It also has to be underlined that, prior to the merger, GE did not have access to these gas modules. Spacelabs will thus be in a more advantageous position than GE pre-merger in this respect, by virtue of this specific commitment.
- (343) Finally, the Commission considers that, thanks to the commitment relating to the supply of Anaesthesia Machines and related supplies at favourable conditions, the Purchaser of Spacelabs, similarly to the merged entity, will be in a position to effectively and successfully participate in package bids, that is to say, tenders involving combined perioperative monitor/anaesthesia machine bids and sales, at competitive prices. Similarly to the case of gas modules, it has to be underlined also here that, prior to the merger, GE did not have access to these anaesthesia machines at the conditions set out in the OEM supply agreement. Moreover, Spacelabs will be in a position to offer a full range of patient monitors, not limited to the perioperative area, but also including the critical area, for which it has, already at this stage, a significant presence.

Conclusion on the commitments for perioperative monitors

- (344) The Commission is of the opinion that the undertakings can be regarded as sufficient to remove the competition concerns identified by the Commission as to the compatibility of the transaction with the common market. The final overall package offered by the notifying party incorporates to a very considerable extent the comments and reactions by third parties. In particular, these commitments will solve the competition concerns identified by the Commission by offsetting the overlap between the merging parties in the market for perioperative monitors and by restoring competitive conditions equivalent to those existing prior to the merger.
- (345) The Commission wishes nonetheless to emphasise that the identity of the Purchaser, which remains subject to the approval of the Commission, will be crucial to ensure the efficacy of the undertakings. As a matter of fact, in view of the specificities of the functioning of the relevant market, the "proven expertise" (such as being active in the market for perioperative or intensive care equipment and products) will be of particular relevance.
- (346) The commitments described above (the effective divestiture of the divestment business and the full compliance with the OEM supply agreements) constitute conditions of this Decision, as only through full compliance therewith (subject to any change pursuant to the review clause of the Annex), can the structural change on the relevant market be achieved. The remaining commitments constitute obligations (subject to any change pursuant to the review clause of the Annex), as they concern the implementing steps, which are necessary to achieve the sought structural change.

2. VERTICAL (INTERFACE) COMMITMENT

- (347) Following the communication of the Commission's serious doubts in the Article 6(1)(c) decision initiating proceedings in this case and whilst the in-depth investigation was ongoing, the notifying party, by letter of 11 June 2003, submitted commitments ("The Original Interface Commitment") pursuant to Article 8(2) and 10(2) of the Merger Regulation with a view to removing the Commission's serious doubts as to the interoperability between anaesthesia machines, patient monitors and CIS.
- (348) The commitment appeared to eliminate in principle the Commission's serious doubts relating to the vertical issues and was therefore market-tested in order to assess its viability and effectiveness. The commitment was revised by the notifying party on 4 July 2003 following comments received from market participants. Some further revisions were made following the market test of the "Horizontal Commitment". The final version of the Interface Commitment was therefore submitted on 24 July 2003 (the "Interface Commitment") and appears in Annex II to this Decision.

The market test of the Original Interface Commitment

- (349) The market test of the Original Interface Commitment produced largely positive results²²³. The majority of hospitals responding to the Commission's questionnaire appeared satisfied with the commitment and believed that it was sufficient to eliminate the vertical competition concerns identified above. A number of respondents, however, highlighted certain misgivings which were focused on a number of provisions which respondents felt could be improved in order to ensure the viability and effectiveness of the commitment.
- (350) In particular, some respondents thought that the obligation to keep interfaces open as defined in the Original Interface Commitment was not comprehensive as it excluded two-way exchange of data (from and to the merged entity's devices) and provided for open interfaces of the merged entity's patient monitors only as regards their connection with third party CIS and not with third party anaesthesia machines; open interfaces for CIS were not covered. The "open interface" definition in clause 3 of the original interface commitment was considered too vague (reference only to "industry practice") and ineffective by a number of respondents as it did not include a specific benchmark. It would not guarantee non-discriminatory treatment of third party devices and the merged entity's devices and therefore could still allow the merged entity to degrade interoperability of third party devices. The provisions relating to the obligation to provide interfacing information "without undue delay" and "from product development" were also considered rather vague. Information should be provided according to a principle of non-discriminatory treatment as soon as the information was sufficiently complete to enable third parties to achieve an open interfacing early enough so that third party suppliers could achieve interoperability of their devices in good time so as to be able to compete effectively with new products launched by the merged entity. The market test also highlighted some practical

²²³ Questionnaires were sent to approximately 200 hospitals which had participated in the Commission's in-depth investigation as well as to patient monitor, anaesthesia machine and CIS competitors of the parties. A significant number of responses were received by both competitors and customers. Overall, competitors were split fairly evenly as to the efficacy of the proposed commitment. Overall, a majority of customers expressed satisfaction that the commitment would eliminate the vertical concerns identified by the Commission. A minority of customers expressed certain concerns while others provided no or only unclear answers.

problems associated with the information and certification co-operation obligations of the Original Interface Commitment, namely that more specific procedures need to be included in the commitment and, in particular, that confidentiality of third party information not be compromised when co-operating with the merged entity. Finally, it was stressed that the Commission should ensure compliance with the commitment by closely monitoring its application through a trustee.

Assessment of the concentration as modified by the Interface Commitment

- (351) The positive results of the market test, the further improvements made by the notifying party and the Commission's assessment of the viability and effectiveness of the Interface Commitment, led to the conclusion that the Interface Commitment would dispel in an appropriate fashion the above-mentioned serious doubts relating to vertical, interoperability issues. As a result, no objections were raised as to the compatibility of the proposed concentration, as modified, with the common market as regards the above-mentioned vertical concerns.
- (352) The Interface Commitment aims at ensuring electrical and mechanical interoperability between the different relevant devices. According to the Interface Commitment, GE/Instrumentarium undertake to keep interfaces of existing and future therapy devices (anaesthesia machines and ventilators), patient monitors (including perioperative and critical care monitors), and CIS “open” by providing reasonable, safe, seamless and effective interface options in accordance with industry practice, accepted industry standards and relevant regulatory requirements. The commitment does not preclude GE/Instrumentarium from producing integrated machines (such as Instrumentarium's ADU) which are popular with a number of hospitals in the EEA provided that the interfaces of such machines remain open in order to allow interfacing of additional third party relevant devices. According to the commitment which took into account comments made by third parties during the market test, open interfaces should adhere to a principle of non-discriminatory treatment by providing third party devices with options as effective as those available to GE/Instrumentarium's own devices with the exception, of course, of situations where the third party device characteristics are such (for example inferior to those of GE/Instrumentarium's own devices) as not to permit such equivalent, open interfacing. GE/Instrumentarium will have an obligation to state in its product literature or web site that its devices have open interfaces. Customers would therefore have no reason to doubt that they could continue to “mix and match” GE/Instrumentarium devices with third party devices.
- (353) Further, GE/Instrumentarium would have an obligation to provide third party suppliers with the interfacing information and data, including for example the communication protocol and other specifications including necessary technical clarifications, which is necessary for third parties to develop open interfaces. Requisite interfacing information on modifications, upgrades or new devices would be provided automatically without further specific requests being necessary. Information would be provided on a non-discriminatory basis, free of charge or at cost and without undue delay. The information on upgrades and new devices would be provided at a sufficiently early stage having regard to a principle of non-discriminatory treatment and with the aim of providing third parties the opportunity to develop competing interfaces as early as GE/Instrumentarium. GE/Instrumentarium would therefore have to provide the requisite information immediately from the time that it is sufficiently developed to enable third parties to develop interfaces and in any event no later than

product development. Specific obligations are included ensuring that third parties would receive information or an adequate reasoned response explaining why the information is not available within twenty working days from making a request. Having considered comments by a third party stressing that early provision of information was paramount, the Commission believes that the commitment ensures such timely provision. The Commission considers that the commitments give adequate guarantees that competitors will receive such information in good time; in addition, in view of the relatively long product cycles of therapy equipment and patient monitors and the duration of tender procedures any foreclosure effects would be excluded.

- (354) In order to further ensure the efficacy of the commitment, GE/Instrumentarium undertook to provide technical assistance and consultation to enable third parties to use the interfacing information. Contact points would be advertised in its documentation or on its web site. Moreover, the commitment includes specific obligations for co-operation, lending of requisite equipment in order to perform interoperability tests and for certification purposes; third parties can therefore perform necessary tests in order to obtain certificates (such as the IEC 601 mechanical integration test) which they may find necessary. Confidentiality provisions are included in order to ensure that third party information provided to GE/Instrumentarium personnel in the context of the commitment would not be used by the merged entity for other purposes. Further, GE also accepted an obligation to provide third party suppliers with the necessary physical components and devices at reasonable and non-discriminatory market prices to enable them to achieve open Interfaces or to make demonstrations of interoperability to customers and at trade shows.
- (355) Finally, the commitment includes provisions designed to ensure its compliance. GE will have an obligation to report to the Commission upon request. The Commission will also have the ability to monitor compliance through the appointment of an independent trustee which will be appointed from the moment GE acquires control over Instrumentarium. The trustee will be assisted by an independent expert with knowledge of the relevant industry. In addition, third parties would have recourse to a fast track arbitration dispute resolution procedure (as set out in the Annex to the Interface Commitment) which would enable third parties to receive speedy and effective adjudication through independent arbitrators. Importantly, the Commission would retain control of the procedure as the arbitrators would have to seek and be bound by the Commission's interpretation of the Commitments where necessary.

Conclusion - The Interface Commitment eliminates the Commission's serious doubts relating to vertical issues

- (356) In addition and further to the horizontal commitments which reduce the merged entity's position in perioperative and critical care monitors, the Interface Commitment removes foreclosure-related serious doubts by ensuring that it will continue to be possible in the future to connect the patient monitors, anaesthesia machines and CIS of third-party manufacturers to the merged entity's devices and CIS. The merged entity would be under an obligation to provide safe, seamless and effective interface options, to provide interface information on a non-discriminatory basis and to co-operate with third parties where certification of a configuration is necessary. The monitoring and dispute resolution procedures included in the commitment would ensure the merged entity's compliance with the commitment by giving both the Commission and third parties adequate powers of monitoring and enforcement.

(357) In the light of the above, it is considered that the commitments would prevent the merged entity from engaging in foreclosure strategies. Hospitals in the EEA would benefit from continuing to enjoy the ability to mix and match devices and components from those suppliers they prefer on the merits of the supplier's product. This was confirmed by a number of specific positive customer responses in the market test of the commitment.

(358) It could therefore be concluded that, provided that the Interface Commitment entered into by the parties is complied with in full, the serious doubts identified by the Commission in relation to interoperability issues would be dispelled and the concentration, as modified by the Interface Commitment, could be declared compatible with the common market.

VI. CONDITIONS AND OBLIGATIONS

(359) Under the first sentence of the second subparagraph of Article 8(2) of the Merger Regulation, the Commission may attach to its decision conditions and obligations intended to ensure that the undertakings concerned comply with the commitments they have entered into vis-à-vis the Commission with a view to rendering the concentration compatible with the common market.

(360) Where a condition is not fulfilled, the Commission decision declaring the merger to be compatible with the common market no longer stands. Where the undertakings concerned commit a breach of an obligation, the Commission may revoke the clearance decision in accordance with Article 8(5)(b) of the Merger Regulation; the undertakings concerned may also be subject to fines and periodic penalty payments under Articles 14(2)(a) and 15(2)(a) of the Merger Regulation.

(361) In accordance with the basic distinction described above, the Commission makes its decision subject to the condition of full compliance with the following commitments:

- (a) the commitments set out in paragraphs 1 to 6, 15, 16, 17 and 20 of Annex I (the Spacelabs Commitment);
- (b) the whole of the Interface Commitment and its annex concerning interoperability issues which is attached as Annex II to the Decision except for the provisions regarding the specificities of the reporting obligations and of the trustee's appointment set out in clauses 8 and 9.

(362) In accordance with the basic distinction described above, the Commission makes its decision subject to the obligations on GE to comply in full with the commitments entered into in paragraphs 7 to 14, 18, 19, and 21 to 42 of Annex I (the Spacelabs Commitment), and with the provisions regarding the reporting obligations and the trustee's appointment set out in clauses 8 and 9 of Annex II (the Interface Commitment).

VII. CONCLUSION

(363) The Commission has concluded that the commitments submitted by the notifying party are sufficient to address the competition concerns raised by this concentration.

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Accordingly, subject to the full compliance with the commitments submitted by the notifying party, the Commission has decided not to oppose the notified operation and to declare it compatible with the common market and the functioning of the EEA Agreement. This Decision is adopted in application of Article 8(2) of the Merger Regulation and of Article 57 of the EEA Agreement.

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HAS ADOPTED THIS DECISION:

Article 1

The notified operation whereby General Electric Company would acquire sole control of Instrumentarium OYJ within the meaning of Article 3(1)(b) of Regulation (EEC) No 4064/89 is, as modified according to Annexes I and II to this Decision, hereby declared compatible with the common market and the functioning of the EEA Agreement.

Article 2

Article 1 is subject to full compliance with the conditions set out in paragraphs 1 to 6, 15, 16, 17 and 20 of the “Spacelabs Commitment” in Annex I to this Decision and with the whole of the “Interface Commitment”, including its annex, set out in Annex II to this Decision, except for clauses 8 and 9 of the Interface Commitment, which shall apply as obligations pursuant to Article 3.

Article 3

Article 1 is subject to full compliance with the obligations set out in paragraphs 7 to 14, 18, 19, and 21 to 42 of the Spacelabs Commitment in Annex I to this Decision and with clauses 8 and 9 of the Interface Commitment in Annex II to this Decision.

Article 4

This Decision is addressed to:

General Electric Company
3135 Easton Turnpike
Fairfield
Connecticut 06431
USA

Done at Brussels, 02.09.2003

For the Commission

Mario MONTI
Member of the Commission

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**Case No COMP/M.3083 -
General Electric Company/Instrumentarium OYJ
Commitments to the European Commission**

WITHOUT PREJUDICE

On 28 February 2003, General Electric Company ("GE") submitted a Form CO notification on a proposed concentration between GE and Instrumentarium OYJ (the "Parties") pursuant to Council Regulation (EEC) No. 4064/89 as amended by Commission Regulation (EC) No. 447/98 (the "Merger Regulation"). On 4 July 2003, the Commission issued a Statement of Objections in the case.

Pursuant to Article 8(2) and 10(2) of the Merger Regulation, GE hereby provides the following commitments (the "Commitments") in order to enable the European Commission (the "Commission") to declare the acquisition of Instrumentarium by GE compatible with the common market and the EEA Agreement by a decision pursuant to Article 8(2) of the Merger Regulation (the "Decision").

Any term used in these Commitments, unless otherwise defined, or unless the context indicates otherwise, shall be interpreted in the light of the Commission Notice on remedies acceptable under the Merger Regulation and under Commission Regulation (EC) No 447/98.

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SECTION A. DEFINITIONS

For the purpose of the Commitments, the following expressions shall have the following meaning:

Affiliated Undertakings: undertakings under the control of Instrumentarium and GE Medical Systems, whereby the notion of control shall be interpreted pursuant to Article 3 of the Merger Regulation and in the light of the Commission Notice on the concept of a concentration under Council Regulation (EEC) No 4064/89.

Anaesthesia Machine Supply Agreement: the agreement to be entered into between GE and the Purchaser as described in Section B and further described in Schedule 2.

Cardiopac/5 Gas Monitor: the Cardiopac/5 configured multiparameter patient monitor for anaesthesia use, which includes the Datex-Ohmeda gas bench measuring anaesthetic agents, respiratory gases and basic vital signs.

Cardiopac/5 Gas Monitor OEM Agreement: the original equipment manufacturer ("OEM") agreement to be entered into between GE and the Purchaser as described in Section B and further described in Schedule 3.

Closing: the transfer of the legal title of the Divested Business to the Purchaser(s).

Closing Date: the date on which the transfer of the legal title of the Divested Business to the Purchaser(s) occurs.

Combination Agreement: the agreement between GE and Instrumentarium dated 18 December 2002 concerning the acquisition of Instrumentarium by GE.

Commission Standard Trustee Mandate: the Commission's recommended model trustee mandate in the case of commitments accepted under the Merger Regulation.

Divested Business: the Spacelabs Divested Business as defined in Section B that GE commits to divest within the period provided for in Section D.

Divestiture Trustee: one or more than one natural or legal person(s), independent from the Parties, who is approved by the Commission and appointed by GE and who has received from GE the irrevocable and exclusive mandate to sell the Divested Business.

EEA: for the purpose of the Commitments, the European Economic Area (EEA) includes Iceland, Liechtenstein, Norway and all Member State countries of the EU as defined below.

Effective Date: the closing date as defined in the Combination Agreement dated 18 December 2002 between GE and Instrumentarium, whereby GE will acquire sole control of Instrumentarium.

EU: for the purpose of the Commitments, the European Union ("EU") includes the current Member State countries (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the United Kingdom) and all future Member State countries.

Extended Divestiture Period: the period from the date of expiry of the First Divestiture Period within which the Divestiture Trustee shall have an irrevocable and exclusive mandate from GE to sell the Divested Business.

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First Divestiture Period: the period within which GE may propose a Purchaser for the Divested Business.

Gas Module OEM Agreement: the agreement to be entered into between GE and the Purchaser as described in Section B and further described in Schedule 4.

GE: General Electric Company, a company incorporated under the laws of New York, USA, with its registered office at 3135 Easton Turnpike, Fairfield, Connecticut 06431, USA.

Hold Separate Manager: the person appointed to manage the day-to-day business of the Divested Business, as approved by the Commission, and acting under the supervision of the Monitoring Trustee.

Instrumentarium: Instrumentarium OYJ, a company incorporated under the laws of Finland, with its registered office at Kuortaneenkatu 2, 00510 Helsinki, Finland.

Interface Commitment: The interface commitment submitted by GE to the Commission on 4 July 2003.

Key Personnel: all personnel necessary to maintain the viability and competitiveness of the Divested Business.

Monitoring Trustee: one or more than one natural or legal person, independent from the Parties and of their Affiliated Undertakings, who is approved by the Commission and appointed by GE, and who has the duty to monitor the Parties' compliance with the conditions and obligations attached to the Decision.

Parties: GE and Instrumentarium.

Personnel: all personnel primarily employed by the Divested Business.

Purchaser: the sole entity approved by the Commission as acquirer of the Divested Business in accordance with the criteria set out in Section E.

Sale and Purchase Agreements: the binding agreements concerning the sale of the Divested Business to the Purchaser.

Spacelabs Divested Business: the monitoring and associated businesses of Instrumentarium as defined in Section B and further described in Schedule 1.

Trustee(s): the Monitoring Trustee and the Divestiture Trustee.

SECTION B. DIVESTMENT COMMITMENTS

Divested Business

1. GE commits to divest, or procure the divestiture of the Divested Business as a going concern to the Purchaser according to the procedure described in Section D.
2. The Spacelabs Divested Business comprises all of the assets and businesses described in more detail in Schedule 1. The Divested Business includes:
 - (a) tangible and intangible (including intellectual property rights) assets, which contribute to the current operation or may be necessary to ensure the viability and competitiveness of the Divested Business;
 - (b) licences, permits and authorisations issued by any governmental organisation for the benefit of the Divested Business; and
 - (c) contracts, agreements, leases, commitments and understandings of the Divested Business; all customer, credit and other records of the Divested Business (items referred to under (a)-(c) hereinafter collectively referred to as “Assets”); and
 - (d) the Personnel and Key Personnel.
3. In addition to the transfer of Personnel and Key Personnel referred to in paragraph 2(d) above, to the extent that the Purchaser does not have distribution capacity in any EU country for the Spacelabs Divested Business described in Schedule 1, GE will procure or facilitate distribution channels or the creation of sales teams that are appropriate to the level of the perioperative monitor business conducted in each such EU country, on terms agreed with the Purchaser, including the transfer of the former sales and distribution staff of Spacelabs still employed by Instrumentarium and its affiliated undertakings at the time of Closing. However, in no event shall GE be required to transfer, in addition to the Personnel and Key Personnel, an amount of sales and distribution staff in excess of GE's current sales staff specialising in the perioperative and critical care business in each such EU country.

Anaesthesia Machine Supply Agreement

4. GE commits to supply the Aestiva/5, Aestiva/5 7100, Aestiva/5 7900, S/5 Aespire, Aestiva/5 Compact/Induction, Aliseo and Aestiva/5 MRI and related supplies, accessories and start-up kits, on a non-exclusive basis, to the Purchaser for the purpose of resale solely to end-customers to whom the Purchaser supplies perioperative monitors for sale, and solely for the purpose of allowing the Purchaser to make combined perioperative monitor/anaesthesia machine bids and sales to end-user customers, in accordance with the terms and conditions set out

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in Schedule 2 and those other commercially reasonable terms agreed between GE and the Purchaser and approved by the Commission.

Cardiicap/5 Gas Monitor OEM Agreement

5. GE commits to supply the Cardiicap/5 Gas Monitor, and related supplies, accessories, leads and cables, to the Purchaser in accordance with the terms set out in Schedule 3 and those other commercially reasonable terms agreed between GE and the Purchaser and approved by the Commission.

Gas Module OEM Agreement

6. GE commits to supply the Datex-Ohmeda gas bench to the Purchaser in accordance with the terms set out in Schedule 4 and those other commercially reasonable terms agreed between GE and the Purchaser and approved by the Commission.

SECTION C. RELATED COMMITMENTS

7. GE undertakes from the Effective Date until Closing to fulfil the obligations in paragraphs 8 to 13 below, to the extent possible and reasonably practicable.

Preservation of Viability, Marketability and Competitiveness

8. To preserve the full economic viability, marketability and competitiveness of the Divested Business, in accordance with past commercial practice, and to reduce to the minimum any risk of loss of competitive potential of the Divested Business. In particular, until Closing, to undertake not to carry out any act upon its own authority that would foreseeably have a significant adverse impact on the economic value, or competitiveness of the Divested Business. Sufficient resources shall be made available for the development of the Divested Business, on the basis and continuation of the existing business plans, until Closing.

Hold-Separate Obligations of Parties

9. To keep the Divested Business separate from the businesses being retained.
10. To appoint a Hold Separate Manager, subject to the prior approval of the Commission, who shall be responsible for the management of the Divested Business, under supervision of the Monitoring Trustee. Prior to Closing, to assist the Monitoring Trustee in ensuring that the Divested Business is managed as a distinct and saleable entity separate from the businesses retained by GE. The Hold Separate Manager shall, to the extent possible and reasonably practicable, manage the Divested Business independently and in the best interest of the business with a view to ensuring its continued viability, marketability and competitiveness and its independence from the businesses retained by the Parties.
11. To ensure that the Divested Business is managed as a separate entity, the participation in central purchasing or marketing arrangements, the central information technology network and other central operational functions shall be severed, without compromising the full economic viability, marketability and competitiveness of the Divested Business.

Ring-Fencing

12. To implement all necessary measures to ensure that GE does not, after the date of the Decision, obtain any business secrets, know-how, commercial information, or any other information of a confidential or proprietary nature relating to the Divested Business, with the exception of information which is reasonably necessary for the divestiture of the Divested Business or whose disclosure is required by law.

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Due Diligence

13. In order to enable potential purchasers to carry out a reasonable due diligence of the Divested Business, to provide to potential purchasers sufficient information as regards the Divested Business as well as information and access with respect to the Personnel and Key Personnel, subject to customary confidentiality assurances and dependent on the stage of the divestiture process.

Non-Solicitation Clause

14. GE undertakes not to solicit, and to procure that Affiliated Undertakings do not solicit the Key Personnel transferred with the Divested Business for a period of [confidential]* after the Closing Date.

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SECTION D. THE DIVESTITURE PROCEDURE

The First Divestiture Period

15. GE undertakes to find one Purchaser for the Divested Business and to enter into a final binding Sale and Purchase Agreement with such Purchaser for the sale of the Divested Business within [confidential]* from the Effective Date.

The Extended Divestiture Period

16. Should GE be unable to enter into binding agreements for the sale of the Divested Business in the First Divestiture Period, the First Divestiture Period shall be extended by [confidential]* from the date of the expiry of the First Divestiture Period. GE undertakes to give the Divestiture Trustee an irrevocable and exclusive mandate to sell [confidential]* the Divested Business within the Extended Divestiture Period.

Closing

17. GE shall be deemed to have complied with this undertaking if, within a period not exceeding [confidential]* from the Effective Date, it has entered into a binding agreement for the sale in accordance with paragraphs 15 and 16, provided that the Closing takes place no later than [confidential]* after the execution of the Sale and Purchase Agreement.

Reporting

18. GE shall submit written reports in English on potential purchasers of the Divested Business and developments in the negotiations with such potential purchasers to the Commission and the Monitoring Trustee no later than 10 calendar days after the end of every month following the Effective Date (or otherwise at the Commission's request). These reporting obligations on GE shall continue until Closing.
19. GE shall inform the Commission and the Monitoring Trustee on the preparation of any data room documentation, information memorandum and due diligence procedure arranged by GE.

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SECTION E. THE PURCHASER

20. GE undertakes to ensure that the Purchaser shall be independent of and unconnected to the Parties, have the financial resources, proven expertise and incentive as appropriate to the nature of the Divested Business to maintain and/or develop the Divested Business as a viable and active competitive force in competition with GE and other competitors. In addition, the Purchaser must reasonably be expected to obtain all necessary approvals from the relevant competition and other regulatory authorities for the acquisition of the Divested Business. GE undertakes to demonstrate to the Commission that the Purchaser meets the requirements of these Commitments and that the Divested Business are being sold in a manner consistent with these Commitments.
21. When GE has reached or is about to reach an agreement with the Purchaser, it shall submit a fully documented and reasoned proposal, including a copy of the Sale and Purchase Agreement, to the Commission and the Monitoring Trustee. The proposal shall enable the Commission to verify that the requirements set out in paragraph 20 with regard to the Purchaser are fulfilled and that the Divested Business is being sold in a manner consistent with the conditions and obligations attached to the Decision.
22. Any final binding Sale and Purchase Agreements shall be conditional on the Commission's approval. The verification that a Divested Business is being sold in a manner consistent with the conditions and obligations attached to the Decision shall include the Commission's expeditious approval of the Purchaser and of the final binding Sale and Purchase Agreement.
23. The Commission may approve the sale of the Divested Business without one or more assets or parts of Personnel or Key Personnel, if this does not affect the viability and competitiveness of the Divested Business, taking into account the proposed purchaser.

SECTION F. TRUSTEE

I. Appointment Procedure

24. If GE has not entered into a binding Sales and Purchase Agreement [confidential]* before the end of the First Divestiture Period or if the Commission has rejected a purchaser proposed by GE at that time or thereafter, GE shall appoint a Divestiture Trustee. The appointment of the Divestiture Trustee shall take effect upon the commencement of the Extended Divestment Period.
25. GE shall appoint one or more Trustees, subject to the prior approval of the Commission as referred to in paragraph 27. The Trustee shall be independent of the Parties, possess the necessary qualifications to carry out its mandate, for example as an investment bank or consultant or auditor, and shall neither be nor become exposed to a conflict of interest. The Trustee shall be remunerated by GE in a way that does not impede the independent and effective fulfilment of its mandate.

Proposal by GE

26. GE shall propose a list of Trustees and the full terms of their mandates for the Commission's approval no later than [confidential]* after the date of the Decision in the case of the Monitoring Trustee and no later than [confidential]* before the end of the First Divestiture Period in the case of the Divestiture Trustee. The proposal shall contain sufficient information for the Commission to verify that the Trustee fulfils the requirements set out in paragraph 25. GE shall indicate to the Commission whether the proposed Trustees are to act as both Monitoring Trustee and Divestiture Trustee or whether different trustees are proposed for the two functions. The mandate submitted for approval shall be drawn up taking due account of the Commission Standard Trustee Mandate and shall include all provisions necessary to enable the Trustee to fulfil its duties under these Commitments.

Approval or rejection by the Commission

27. The Commission shall have the discretion to approve or reject the proposed Trustee(s) and to approve the proposed mandate subject to any modifications that the Commission deems necessary for the Trustee to fulfil its obligations. If only one name is approved, GE shall appoint or cause to be appointed, the individual or institution concerned as Trustee, in accordance with the mandate approved by the Commission. If more than one name is approved, GE shall be free to choose the Trustee to be appointed from among the names approved. The Trustee shall be appointed within [confidential]* of the Commission's approval, in accordance with the mandate approved by the Commission.

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New proposal by GE

28. If all the proposed Trustees are rejected, GE shall submit the names of at least two more individuals or institutions within [confidential]* of being informed of the rejection, in accordance with the requirements set out in paragraph 25 for approval in accordance with paragraph 27.

Trustee nominated by the Commission

29. If all further proposed Trustees are rejected by the Commission, the Commission shall nominate a Trustee, whom GE shall appoint, or cause to be appointed, in accordance with a Trustee mandate approved by the Commission.

II. Functions of the Trustee

30. The Trustee shall assume its specified duties in order to ensure compliance with the Commitments. The Commission may, on its own initiative or at the request of the Trustee or GE, give any orders or instructions to the Trustee in order to ensure compliance with the conditions and obligations attached to the Decision.

Duties and obligations of the Monitoring Trustee

31. Following its appointment, the Monitoring Trustee shall:
- (i) propose in its first report to the Commission a detailed work plan describing how it intends to monitor compliance with the obligations and conditions attached to the Decision;
 - (ii) monitor compliance by the Parties with the conditions and obligations attached to the Decision;
 - (iii) assume the other functions assigned to the Monitoring Trustee under the conditions and obligations attached to the Decision;
 - (iv) propose to the Parties such measures as the Monitoring Trustee considers necessary to ensure the Parties compliance with the conditions and obligations attached to the Decision;
 - (v) review and assess potential purchasers as well as the progress of the divestiture process and verify that potential purchasers receive sufficient information;
 - (vi) provide to the Commission, sending GE a copy without any confidential information at the same time, a written report within 15 calendar days after the end of every month. The report shall cover the operation and management of the Divested Business so that the Commission can assess whether the business is held in a manner consistent with the Commitments and the progress of the divestiture process as well as potential purchasers. In addition to these reports, the Monitoring Trustee

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shall promptly report in writing to the Commission, sending GE a non-confidential copy at the same time, if it concludes on reasonable grounds that GE is failing to comply with any of the conditions or obligations under these Commitments;

- (vii) once GE has proposed to the Commission a Purchaser, within [confidential]* after receipt of the proposal, assess the independence and suitability of the proposed purchaser and the viability of the Divested Business after the sale to the Purchaser and give its opinion to the Commission as to whether the Divested Business is sold in a manner consistent with the conditions and obligations attached to the Decision.

Duties and obligations of the Divestiture Trustee

- 32. Within the Extended Divestiture Period, the Divestiture Trustee shall sell the Divested Business to a Purchaser independent of the Parties, provided that the Commission has approved that Purchaser and the final binding Sale and Purchase Agreement in accordance with procedures laid down in paragraphs 20 to 23. The Divestiture Trustee shall include in the Sale and Purchase Agreement such terms and conditions as it considers appropriate for an expedient sale. In particular, the Divestiture Trustee may include in the Sale and Purchase Agreement such customary representations and warranties and indemnities as are reasonably required to effect the sale. The Divestiture Trustee shall protect the legitimate interests of the Parties, subject to the Parties' unconditional obligation to divest [confidential]* in the Extended Divestiture Period.
- 33. Following the expiration of the First Divestiture Period (or otherwise at the Commission's request) the Divestiture Trustee shall provide the Commission with a comprehensive monthly report written in English on the progress of the divestiture process. Such reports shall be submitted within 15 calendar days after the end of every month. The Monitoring Trustee and GE shall be provided a simultaneous non-confidential copy of these reports.

III. Duties and obligations of the Parties

- 34. GE undertakes from the Effective Date until Closing to provide the Trustee with all such assistance and information, including copies of all relevant documents, as the Trustee may reasonably require to perform its tasks. The Trustee shall have full and complete access to any of the Parties' books, records, documents, personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments. GE shall make available to the Trustee offices, and a representative of GE shall be available for meetings in order to provide the Trustee with all information necessary for the performance of its tasks.
- 35. GE undertakes from the Effective Date until Closing to provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request on behalf of the management of the Divested Business. This shall include

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all administrative support functions relating to the Divested Business that are currently carried out at headquarters level. The Parties shall provide the Monitoring Trustee, on request, with access to the information submitted to potential purchasers, in particular to any data room documentation and all other information granted to potential purchasers in the due diligence procedure.

36. GE shall grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee for the sale, the Closing and all actions and declarations which the Divestiture Trustee considers reasonably necessary or appropriate to achieve the sale and the Closing, including the appointment of advisors to assist with the sale process. Upon request of the Divestiture Trustee, GE shall cause the documents required for the sale and the Closing to be duly executed.
37. At the expense of GE, the Trustee may appoint advisors (in particular for corporate finance or legal advice), incurring reasonable fees and other expenses, subject to GE approval (this approval not to be unreasonably withheld) if the Trustee considers the advisors reasonably necessary or appropriate for the performance of its duties. Should GE refuse to approve the advisors proposed by the Trustee the Commission may approve the appointment of such advisors instead. Only the Trustee shall be entitled to issue instructions to the advisors. In the Extended Divestiture Period, the Divestiture Trustee may use advisors who served GE during the First Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient Sale.

IV. Replacement, Discharge and Reappointment of the Trustee

38. The Commission may, after hearing the Trustee, order GE to remove the Trustee if the Trustee has not acted in accordance with the Commitments or for any other good cause.
39. The Trustee may also be removed by GE with the prior approval of the Commission and after the Commission has heard the Trustee if the Trustee has not acted in accordance with the Commitments or for any other good cause.
40. The Trustee may be required to continue in its function until a new Trustee is in place to whom the Trustee has effected a full hand over of all relevant information. The new Trustee shall be appointed in accordance with the procedure referred to in paragraphs 24 to 29.
41. The Trustee shall cease to act as Trustee only after the Commission has discharged it from its duties, following a request from the Trustee or GE after all the Commitments with which the Trustee has been entrusted have been implemented. However, the Commission may at any time require the reappointment of the Monitoring Trustee if it subsequently appears that the relevant remedies might not have been fully and properly implemented.

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SECTION G. THE REVIEW CLAUSE

42. The Commission may, where appropriate, in response to a request from GE showing good cause and accompanied by a report from the Monitoring Trustee:
- (i) Grant an extension of the Divestiture Periods, or
 - (ii) Waive or modify, in exceptional circumstances, one or more of the conditions and obligations in the Commitments.

Where GE seeks an extension of a time period, it shall submit a request to the Commission no later than one month before the expiry of that period, showing good cause. Only in exceptional circumstances shall GE be entitled to request an extension within the last month of any period.

24 July 2003

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duly authorised for and on behalf of GE

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LIST OF SCHEDULES

- 1 Spacelabs Divested Business
- 2 Main Terms of Anaesthesia Machine Supply Agreement
- 3 Main Terms of Cardiocap/5 Gas Monitor OEM Agreement
- 4 Main Terms of Gas Module OEM Agreement

SCHEDULE 1

Spacelabs Divested Business

1) LEGAL AND FUNCTIONAL STRUCTURE OF THE SPACELABS DIVESTED BUSINESS

The Spacelabs Divested Business currently is conducted through Datex-Ohmeda, Inc., a fully owned subsidiary of Instrumentarium. The Spacelabs Divested Business comprises Datex-Ohmeda's Spacelabs Medical manufacturing, distribution and research and development operations and sales channel operations for multiparameter patient monitoring and associated equipment and services. The business also includes the Spacelabs ambulatory blood pressure business, which supplies blood pressure monitoring equipment to a variety of care settings; and Spacelabs clinical information system business, which includes the design, production, distribution, research and development operations for clinical information systems for perioperative, critical care, neonatal critical care and perinatal care areas. See Annex 1 to this Schedule for details of the Spacelabs products and services.

Spacelabs has subsidiaries in Austria, Australia, China, Guam, France, Hong Kong, India, Italy, Mexico, Singapore, Spain, Sweden, UK, USA and Taiwan [confidential]*.

2) ASSETS TO BE DIVESTED

Subject to a transfer being required by a Purchaser and GE being permitted to do so, the Spacelabs Divested Business includes, but is not limited to:

(a) Main tangible assets:

i) *Plant, equipment and other tangible assets related to manufacturing, distribution and research and development for the Spacelabs Divested Business located at*

(1) 5150 220th Ave SE, Issaquah, WA, 98029, USA

(2) 925 Sherman Ave, Hamden, CT, 06514, USA²²⁴

(3) 1200 East Campbell Road, Suite 104, Richardson, TX, 75081, USA

(b) Main intangible assets:

²²⁴ [Confidential]

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i) Intellectual property rights

Provided that it is entitled to do so, GE shall transfer the Spacelabs intellectual property rights to the Purchaser. [Confidential Annex]*

ii) Licences, permits & authorisations

All necessary licences, permits and authorisations of the Spacelabs Divestment Business required by governmental authorities, including CE markings, which shall be transferred to the Purchaser provided that GE is entitled to do so. These include:

- (1) Permits required by the City of Issaquah for the operation of certain equipment used in the development, manufacturing and repair of the products of the Spacelabs Divestment Business, including:
 - (a) Mechanical Permit: BLD02-00253MEC03-00008 – Manufacturing and Factory Repair Gas Systems (building A)
 - (b) Mechanical Permit: MEC02-00107 – R&D Lab Gas Systems (building B)
 - (c) Permits to operate compressed-air vessels for use in the manufacturing process.
- (2) Active business licence #BUS03-01777 from the City of Issaquah.
- (3) Certification #Q1Z 02 10 12238 002 from TUV Product Service certifying that the company meets the requirements of EN 46001: 1996, ISO 13485 : 1996 and ISO 9001: 1994
- (4) Certification # G1 02 10 12238 001 from TUV Product Service certifying that the company maintains a quality system which ensures that the products conform with the essential requirements of the Directive 93/42EEC.
- (5) Certificate No 1140-12-2002 - Certificate to Foreign Government from the U.S. Department of Health and Human Services – the Food and Drug Administration to certify that the specified products manufactured and distributed by the company may be marketed in, and legally exported from, the United States of America.
- (6) FDA approval for Birthnet perinatal clinical information system.

iii) Contracts, agreements, leases etc.

(1) Building lease contracts:

- (a) Real property leases for Buildings A and B at 5150 220th Ave SE, Issaquah, WA, 98029, USA [confidential]*.
- (b) Real property lease for 925 Sherman Ave, Hamden CT 06514, USA [confidential]*.
- (c) Real property lease for Spring Creek Business Park, 1200 Campbell Ste 104, Richardson, TX, 75081, USA [confidential]*.

(2) Equipment Lease Contracts:

- (a) Leases of various operating and administrative equipment with terms over 36 months from Archive Group, 1800 112th Ave NE, Suite 250W, Bellevue, WA 98004, USA and from NCF Financial, Inc., 12911 NE 126th Place, Kirkland, WA 98034, USA
- (b) Leases of fleet vehicles on terms up to 50 months from Automotive Rentals, Inc., P O Box 5039, Mt. Laurel, NJ 08054, USA

(3) Distribution and Licence Agreements:

- (a) Distribution and Licence Agreement, dated July 24, 1996, by and between Spacelabs Medical, Inc. and [confidential]* with respect to [confidential]* module.
- (b) Licence and Development Agreement, dated May 23, 1995, by and between Spacelabs Medical, Inc. and [confidential]* with respect to ECG interpretive algorithms.
- (c) Licence Agreement, dated March 26, 1990, by and between [confidential]* and Spacelabs, Inc. for a licence under [confidential]* pulse oximetry sensor coding patents.
- (d) Licence Agreement, dated May 30, 2001 between Spacelabs Medical, Inc. and [confidential]* with respect to RF printed circuit boards used in telemetry transmitters.
- (e) Licence Agreement, dated August 27, 1991, between Spacelabs Medical, Inc. and [confidential]* for a source code licence to the [confidential]* operating system.

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- (f) Distribution Agreement, dated December 31, 2002, by and between Spacelabs Medical, Inc. and [confidential]* for [confidential]* to act as a distributor of specified ABP products and accessories on a private-label basis.
- (g) Licence Agreement, dated April 1, 1999, by and between Spacelabs, Inc. and [confidential]* for [confidential]* to grant a licence to Spacelabs to incorporate an infrared locator system into patient monitoring and clinical information system products.

(4) OEM and Manufacturing Agreements:

- (a) OEM Agreement, dated January 23, 1997, by and between Spacelabs Medical, Inc. and [confidential]* with respect to sensor cable connectors.
- (b) Amended and Restated OEM Development, Purchase and Sale Agreement, dated April 19, 2002, by and between Spacelabs Medical, Inc. and [confidential]* with respect to development and licence of capnography products
- (c) Manufacturing Agreement, dated July 31, 2001, by and between Spacelabs Medical, Inc. and [confidential]* with respect to development and licence of portable antennas and access points
- (d) OEM Agreement, dated June 30, 2000, by and between [confidential]* and Spacelabs Medical, Inc. for the licence of development kits and right to imbed [confidential]* products into Spacelabs products
- (e) OEM Agreement, dated May 18, 1995, by and between [confidential]* and Spacelabs Medical, Inc. with respect to purchase and sale of [confidential]* gas boards.
- (f) Software Licence and OEM Purchase Agreement dated as of March 30, 1995 between Spacelabs Medical, Inc. and [confidential]* with respect to wireless LAN software and products.
- (g) ABPM Private Label Distribution Agreement dated as of December 31, 2002 between Spacelabs Medical, Inc. and [confidential]* with respect to the manufacture and distribution of ABPM equipment and related products.
- (h) Technology Cross-Licence Agreement, dated December 31, 2002, by and between Spacelabs Medical, Inc. and [confidential]*. Under this agreement, Spacelabs grants [confidential]* perpetual, royalty-free, non-exclusive licences to use certain ECG-related technology.

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- (i) Licence Agreement, dated April 12, 2000, by and between Spacelabs, Inc. and [confidential]* for certain development/consulting work in connection with network connectivity.
- (j) Licence Agreement, undated (but with attached letter dated September 25, 1987), by and between Spacelabs, Inc. and [confidential]* for the use of certain software to use for research and development of customer software.
- (k) Licence Agreement, dated September 14, 1995, by and between Spacelabs, Inc. and [confidential]* for a non-exclusive reseller licence to use certain [confidential]* clinical information and management system software for development and marketing purposes.
- (l) Development Agreement, dated September 8, 1984 and amended on August 12, 1985, by and between Spacelabs, Inc. and [confidential]* for [confidential]* to design and develop a network communication service software package utilizing the [confidential]* Ethernet hardware and supporting the [confidential]* application requirements for Spacelabs.
- (m) Licence Agreement, dated September 14, 2000, by and between Spacelabs, Inc. and [confidential]* for [confidential]* to provide certain software on a non-exclusive basis.
- (n) Licence Agreement, dated March 18, 1999, by and between Spacelabs, Inc. and [confidential]* for [confidential]* to provide a worldwide, exclusive, transferable perpetual licence to use its [confidential]* technology in Spacelabs products.
- (o) Licence Agreement, dated January 20, 1984, by and between Spacelabs, Inc. and [confidential]* for [confidential]* to provide a non-exclusive, worldwide, perpetual and transferable licence for Spacelabs to use its computer software programme for the accumulation, display and storage of data.
- (p) Licence Agreement, dated September 4, 1999, by and between Spacelabs, Inc., [confidential]* and [confidential]* whereby [confidential]* provide Spacelabs with certain [confidential]* technology to develop and licence the [confidential]* to allow for the connectivity of [confidential]* cardiology carts.
- (q) Licence Agreement, dated April 10, 2001, by and between Spacelabs, Inc. and [confidential]* for the assignment of royalties to [confidential]* charting software to be developed for Spacelabs.
- (r) Licence Agreement, dated June 24, 1999, by and between Spacelabs, Inc. and [confidential]* whereby [confidential]* grants Spacelabs a non-exclusive, worldwide licence to install [confidential]* cardiology software in Spacelabs products.

(5) Distribution Arrangements:

Distribution arrangements with independent distributors. [Confidential Annex]*

(6) Principal Purchase Agreements:

List of Spacelabs Committed Volume Agreements with certain customers. [Confidential Annex]*

(7) Principal Supply Agreements:

- (a) [confidential]* (printed circuit board assemblies)
- (b) [Confidential]* (printed circuit board assemblies)
- (c) [Confidential]* (paper)
- (d) [Confidential]* (printers and recorders)
- (e) [Confidential]* (computer hardware)
- (f) [Confidential]* (displays)
- (g) [Confidential]* (cables)
- (h) [Confidential]* (cables)
- (i) [Confidential]* (cuffs)
- (j) [Confidential]* (cuffs)
- (k) [Confidential]* (displays)
- (l) [Confidential]* (displays)
- (m)[Confidential]* (cables)
- (n) [Confidential]* (software development/R&D)
- (o) [Confidential]* (injection moulding and metal fabrication)
- (p) [Confidential]* (power supplies)
- (q) [Confidential]* (monitors for UCW and UV 1500)
- (r) [Confidential]*

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(s) [Confidential]*

(c) Existing Customer Records and Record-keeping Systems

All existing customer records of the Divested Business, in both hard copy and electronic formats, and computer systems used to access this information, including:

Current Systems

- i) For transactions after January 1, 2003, data from the MFGPRO computer system maintained by the Datex Ohmeda, Inc.*
- ii) For transactions after October 1, 2002, data from the international subsidiaries of Datex Ohmeda concerning Spacelabs customers.*

Legacy Archiving Systems

- iii) The MAXCIM computer system containing customer master record data, detailed booking, shipment, invoicing and returns history records, customer payment history and account balance status data.*
- iv) The ORACLE Applications database containing customer master record data, detailed booking, shipment, and invoicing history records, customer payment history and account balance data for customers of the Spacelabs Medical International subsidiaries.*
- v) The ORACLE marketing database containing sales history data on net bookings and shipments, together with any internally developed systems containing customer data.*
- vi) The CLARIFY computer system containing customer data on installed base and service call history for both field service and technical support.*
- vii) The GET PAID computer system containing customer collection correspondence data.*
- viii) Any hard copy records, including quote and sales order customer files, field service call reports, equipment depot repair records and customer invoicing.*

(d) The Personnel and Key Personnel

Personnel and Key Personnel who are to be transferred to the Purchaser either automatically by law or by virtue of contractual agreements with the Spacelabs Divested Business.

(e) Transitional Arrangements

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The Spacelabs Divested Business shall be entitled to benefit from service or supply arrangements, which were previously provided by Instrumentarium or Affiliated Undertakings, for a transitional period after Closing, including:

- (i) Certain Financial Services – including accounts payable, tax and treasury services and financial reporting.*
- (ii) HR, payroll, benefits, employee training*
- (iii) Corporate IT systems & support – e.g. Mfg Pro ERP, Lotus Notes email, telephones.*
- (iv) Field Service, Customer Support, Product Support, Technical Support and Training, Order Fulfilment, International Distribution*
- (v) International Distributor Management and Support*
- (vi) Corporate Accounts*
- (vii) Regulatory Support – in particular for transitioning registrations, complaint management (SONAR) and other regulatory requirements.*

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Annex 1

SPACELABS MEDICAL PRODUCTS AND SOLUTIONS

INTRODUCTION

Spacelabs' principal products include networkable patient monitoring products, network and information communication products and clinical information systems. In addition, the company sells disposable medical supplies, such as patient electrodes, specialty graph paper, sensors and connecting lead wires that are used with medical devices.

Introduced in 1998, Spacelabs' patient monitoring platform, the Ultraview Care Network (UCN), offers clinicians streamlined access to patient information across the entire healthcare enterprise. The Ultraview Care Network incorporates a range of patient monitors connected to information systems via a monitoring network to provide a comprehensive interactive network that supports a powerful clinical workcentre. The workcentre provides desktop integration of patient monitoring and information systems data. In addition, network gateway and web-based application technologies provide information systems with data collected on the network.

The system includes a number of options that enable it to be adapted for specific needs of healthcare organisations. Options are available to mix-and-match screen sizes, display types (CRT or flat-panel), and networks (stand-alone, hard-wired or wireless). UCN also incorporates Spacelabs' monitoring features, which integrates data from bedside monitors into a clinical data repository, and the integration of auxiliary devices via its Flexport interfaces.

A wide variety of single and multiparameter modules for Ultraview Care Network monitors provide flexibility to meet specific monitoring needs in the perioperative and critical care areas.

Spacelabs Ultraview Care Network supports seamless data acquisition and exchange across the enterprise, addressing clinicians' continuing need for decision-support information management. It supports interfaces for and provides quick access to the longitudinal patient record at the point of use, including hospital-based, clinic/physician office-based, and home-based healthcare. Spacelabs' strategic vision is the capability to integrate patient information among disparate systems and networks and make it available to local and remote users.

In 2003, Spacelabs will introduce the next generation networking infrastructure via its Intesys Clinical Database, providing an even opener network communication capability and enabling application via webservices for remote information review.

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PATIENT MONITORING PRODUCTS

Ultra view Care Network Monitors

Ultraview 1030

(Note: this product has not been available for sale since the first quarter of 2003 but it continues to be maintained and serviced)

The Ultraview 1030 patient monitor is a lightweight, compact and portable patient monitor that can be used in the perioperative or critical care areas. It shares the same touchscreen controls as other Ultraview Care network and PCMS²²⁵ monitors of appropriate levels. The 1030 has a 10.4" TFT display with a 140° viewing angle.

Ultraview 1050

The Ultraview 1050 patient monitor combines the advanced features of stationary monitors with the lightweight, compact design and portability of a transport monitor. It is also adaptable for use in the critical care or perioperative care areas. The 1050's 10.4" (26.4cm) active matrix TFT colour LCD displays 4 to 6 waveforms and has a 140° viewing angle. The advanced battery management system maximises its transport capability and illustrates the current power-level status.

Ultraview 1500

(Note: this product has not been available for sale since the first quarter of 2003 but it continues to be maintained and serviced)

The Ultraview 1500 is designed for hospitals which want a large 6-waveform display, but do not require the availability of hospital information systems at the patient bedside. The 1500 provides a 15" colour display, XVGA touchscreen and interactive networking, standard trends, up to 6 waveforms, arrhythmia analysis, and an optional calculations package.

Ultraview 1600

The Ultraview 1600 integrates flexible display choices with a complete range of bedside capabilities, including a user-friendly touchscreen interface and Data Shuttle and Expanded Network options. The 1600 offers 18 parameters utilising Ultraview and PCMS modules, as well as Flexport interfaces, and can be adapted for the perioperative and critical care areas. It accommodates two single-high modules or one double-high printer module. Modules may be inserted or removed without disconnecting the power supply. Mounting options allow the addition of incremental module housings.

Ultraview 1700

The Ultraview 1700 combines an independent display with bedside and central station capabilities. The Ultraview 1700 offers the WinDNA feature that provides the ability to window into other information systems, integrating multiple care resources at the point-of-care. The 1700 is Spacelabs' highest end patient monitor and is suitable for use in high-end perioperative and critical care areas.

²²⁵ Patient Care Management System.

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Ultraview Foetal Monitoring Ultraview Maternal Obstetrical Monitor (MOM)

Spacelabs sells Labour & Delivery monitors in the U.S. but does not actively sell these in the EEA. In January 2000, Spacelabs introduced its Ultraview Maternal Obstetrical Monitor (MOM) in the U.S., a combined foetal and maternal vital signs monitor which is designed to present comprehensive data on a single display. MOM features a touchscreen, multiple waveforms, a colour option, battery backup and the ability to print maternal ECGs on an integrated printer.

Ambulatory Blood Pressure Monitoring (“ABP”)

Spacelabs ambulatory blood pressure monitors include the 90217 Ultralite and 90207 ABP monitors. Both monitors feature a compact and lightweight design to optimise patient comfort. Comfort helps ensure patient compliance and, consequently, may decrease the number of artifactual readings.

Patient Monitor Modules

A wide variety of single and multiparameter modules is available for Ultraview Care Network monitors to meet specific monitoring needs. All Spacelabs’ Ultraview Care Network modules incorporate a microprocessor so that processing takes place in the module, not just in the monitor.

Ultraview Command Module

The Ultraview Command Module provides a variety of vital signs monitoring in a single package, including Multiview arrhythmia analysis, 12-lead ECG and ST segment analysis, diagnostic reports, adult/neonatal NIBP, cardiac output, pulse oximetry, 4 invasive pressures, 2 temperatures, Varitrend (OCRG), and respiration.

MultiView Arrhythmia Analysis

The MultiView Arrhythmia analysis system provides simultaneous analysis of two ECG leads for arrhythmias, offering greater accuracy and more information than conventional single lead systems. MultiView Arrhythmia operates with Spacelabs Ethernet-based PCMS network and full disclosure capabilities are possible using the 90845 Multi Disclosure Review Station which stores up to 384 hours of data for as many as 16 patients and provides for hourly hard-copy printouts.

12 Lead EGG and ST Segment Analysis

The 90492, 12 lead ECG and ST segment module offer continuous 12 lead EGG and ST segment information in a bedside monitor. Respiration and MultiView arrhythmia analysis capabilities are available as options.

The 90492 module is designed for continuous monitoring, display and documentation of 12 lead information. This is suitable for monitoring patients with transient or a symptomatic cardiac abnormalities. It also facilitates observation of EGG changes in response to evolving clinical conditions or therapeutic interventions. The module is

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capable of detecting, alarming and storing both transient and sustained ST segment deviations for all 12 leads. Heart rate and arrhythmia trends are also available in the same bedside module.

Pulse Oximetry

Spacelabs' pulse oximetry modules are suitable for use in adult, paediatric and neonatal applications and are compatible with Spacelabs, Nellcor and Novametrix sensors. The Sensorwatch signal strength indicator provides visual aid on the monitor for optimal sensor application.

SvO₂

The SvO₂ module has used the Oximetrix technology from Abbott Critical Care Systems to provide continuous measurement of mixed-venous oxygen saturation. This module represents an invasive approach to oxygen saturation measurement and employs direct infrared technology. Abbott supplied the multilumen catheters and disposables needed to work with the unit. The catheter is normally inserted during high risk surgery for postoperative monitoring in the ICU. The SvO₂ module was recently discontinued by Abbot Laboratories, but Spacelabs is seeking an alternative supplier. Spacelabs does not foresee any difficulties in securing such an alternative supplier.

Cardiac Output

Up to five cardiac output curves are displayed on the monitor screen. After averaging, the current average is displayed on the screen, with the date and time obtained, until the next cardiac output determination. Calculations provide systemic vascular resistance and index, right and left ventricular stroke work and index, cardiac index, stroke volume and index, and pulmonary vascular resistance and index. Up to 30 sets of cardiac output and associated vital sign measurement values are held in module memory.

NIBP

Spacelabs' NIBP modules derive pressure values by the oscillometric technique. Systolic, diastolic and mean pressures are displayed. Up to 120 measurements are held in module memory for review. Microprocessors control the inflation/deflation of the patient cuff through its internal pump.

EEG Monitoring Module

Introduced in April 1995, the two or four channel 90481 EEG Modular was designed for use in head injuries, anaesthesia monitoring and displaying seizure activities. It is compatible with Spacelabs Medical monitors and allows access to EEG data from anywhere on the monitoring system network.

Mainstream 90515 Capnograph

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Spacelabs mainstream 90515 capnograph module provides EtCO₂, minimum CO₂, O₂ and respiration rate monitoring. The mainstream 90515 capnograph module can be used with all Spacelabs' modular monitors, monitoring the respiratory rate of the patient while being transported from one area to another. The module is self-calibrating. Its design incorporates a rapid warm-up rate, lightweight sensors and a disposable airway adapter.

Sidestream 90513 Capnograph

The sidestream 90513 capnograph module measures and analyses EtCO₂, O₂ and N₂O respiratory gas values and monitors respiratory rate. The 90513 has an internal-reference gas cylinder that allows the unit to automatically self-calibrate. The cylinder provides accurate calibration for up to a year before it needs to be replaced. The 90513, like the 90515, interfaces with the Ultraview Care Network and PCMS bedside monitors and 90600A/906151A monitors.

Bispectral Index (BIS) Module

The Bispectral Index is a processed EEG parameter giving anaesthesia providers a non-invasive, direct means of quantitatively measuring the effects of anaesthetics on the brain. The BIS is designed to aid in monitoring the effects of certain anaesthetic agents, allowing anaesthesia providers to optimise the delivery of anaesthetic and sedative agents to patients requiring anaesthesia.

Module Configuration Manager

Module Configuration Manager allows clinicians to tailor the patient monitor to unit protocols or user preferences. Alarms for EGG, arrhythmia, ST segment, pulse oximetry, respiration, invasive pressure and temperature can be configured for high, medium, low or no severity, and to selectively produce recordings. User-defined default settings allow clinicians to further customise monitor operation, setup and alarms to specific patient or user preferences and needs.

Varitrend 3 for Neonatal OCRG

Varitrend 3 event storage enables users to specify their own definitions of oxycardiopulmonary (OCRG) events based on three criteria - apnoea duration, heart rate, and SPO₂ value - independent of alarm conditions. Varitrend 3 captures a window of data surrounding events, which can be reviewed, edited and documented at the bedside monitor.

NETWORKING , CONNECTIVITY SOLUTIONS AND OPEN SYSTEMS SOLUTIONS

Introduction

The Ultraview 1700 can perform three functions: operate as a bedside monitor, central terminal, clinical terminal and/or PC. Its ability to perform three functions in one monitor enables both cost and space savings. The Ultraview 1700 with Dynamic Network Access (DNA) or Windows Dynamic Network Access (WinDNA) provides access to clinical information systems at the point of care. WinDNA gives clinicians the ability to view and control information systems interfaced with the network and having MS Windows

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functionality available at the bedside. This opens at the bedside the world of applications as the Spacelabs Medical Caremaster Plus clinical information system, clinical information systems from other manufacturers, laboratory, pharmacy, order entry, or general hospital information systems. Device and interface familiarity is designed to enhance integration and exchange from connected systems.

Ultraview Digital Telemetry System

Spacelabs' modular Ultraview Digital Telemetry System provides both ECG-only and multi-parameter monitoring of ambulatory patients. The system operates between 608 and 614MHz, a band not used for private land mobile radio, business radio services or broadcast analogue and digital television. The modular system offers a flexible approach that allows telemetry and step-down units to configure systems to meet their current and future telemetry requirements.

Ultraview Digital Telemetry offers a lightweight and compact transmitter that enables monitoring of heart rate, ST-segment, arrhythmia and continuous SpO₂. The multi-parameter transmitter also integrates with the Spacelabs Ultralite ambulatory blood pressure monitor for the transmission of non-invasive blood pressure values to a central station, as well as to multi-disclosure and information systems. Ultraview Digital Telemetry's multi-parameter capability is designed to help support a hospital's changing census by extending telemetry monitoring to patients across a wider range of acuity.

Ultraview Web Source

The Ultraview Web Source is a telemedicine-based product that forms part of the Ultraview Care Network. Web Source CM is designed to give remote caregivers internet access to information such as cardiac arrhythmia events that was previously available only locally or in printed format. Web Source also provides the ability to remotely access electronic patient records and other software applications used in patient care, such as previous medical encounters, treatment information, vital signs, streaming waveforms and ECG records.

A Java-based user interface running inside a standard web browser collates data and presents it to clinicians in a consistent, easy-to-use format.

Ultraview Clinical Messenger

(Note: this product is today only available in US. For EU, it requires local radio frequency approval)

In January 2000, Spacelabs obtained FDA clearance to market its Ultraview Clinical Messenger, a multi-parameter waveform wireless paging system. Unlike traditional pagers, which only notify caregivers when an alarm occurs, the Ultraview Clinical Messenger is designed to provide additional information, including up to 12 seconds of graphic waveforms for any monitored parameter. By displaying the actual patient waveform, in addition to numeric patient information, the Ultraview Clinical Messenger system enables caregivers to provide a flexible response to alarm conditions. For example, if a nurse is not in the patient's room when a cardiopulmonary event sets off an alarm, the nurse can still see that patient's waveforms and other vital signs. Viewing the waveform that initiated the alarm enables the caregiver to evaluate the alarm.

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The Ultraview Clinical Messenger can be expanded to support over 85 bedside medical devices from other manufacturers via the Spacelabs Flexport system interface. The Flexport system interface enables the Ultraview system to forward alarm notification and waveforms from stand-alone devices, such as ventilators, to a mobile caregiver's pager.

Connectivity Solutions

Spacelabs Medical has made connectivity a design criteria for its Ultraview® Care Network™ system architecture. The Ultraview Gateway provides communication between patient monitoring and information systems. Flexport® interfaces provide integration of device data at the patient bedside. WinDNA® allows the use of Windows applications on the patient monitoring system. This can provide integration with other information systems from throughout the hospital.

System connectivity via Ultraview Gateway

The Ultraview Gateway is a network interface that provides communication between healthcare information systems and Spacelabs Medical's Ultraview monitoring products, PCIS monitoring products, and/or other vendors' monitoring products. Through its use of open standards, the Ultraview Gateway provides healthcare organizations with the flexibility to select a best-of-class solution.

The Ultraview Gateway communicates all real-time numeric data, include Flexport interface data and physiological calculations, synchronizes the time and system data from multiple networks, stores clinical data, supports the open HL7 v2.3 standard, thereby preserving a hospital's choice among an extensive list of vendor options and provides waveforms to external systems.

Quicknet Interface

Spacelabs QuickNet interface allows portable Ultraview monitors to be used temporarily at the bedside as part of the network when permanently installed monitors are not available.

Device connectivity via Flexport System Interfaces

Clinicians today have more sources of information than ever before; yet these different sources of information can be a hindrance at the bedside if the data cannot be correlated, compared, documented and responded to in the event of an alarm. Spacelabs Medical's Flexport system interfaces allow clinicians to interface any compatible device, e.g. monitoring, ventilator, anesthesia machine, infusion devices, with the patient monitor and monitoring system, unifying information, easing documentation, and enhancing alarm response. Flexport system interfaces also facilitate the use of automated patient charting systems by providing integration of data including respiratory therapy from the patient's bedside. Spacelabs Medical's Flexport System Interfaces integrate data from more than 85 different third-party peripheral devices, such as multigas analysers, pulse oximeters, NIBP monitors, IV pumps, incubators, capnographs, etc., with data from Spacelabs Medical Ultraview Care Network monitors. This integration provides centralised alarms, display, trending and documentation of all vital sign numeric and alarm status for each patient on a single monitor. The Universal Flexport interface can integrate any device that uses Spacelabs Medical's Universal Flexport Protocol (UFP). Spacelabs Medical provides manufacturers with a free licence to use its UFP. This allows manufacturers

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with devices that are not currently Flexport-compatible, or are under development, to design their equipment to be compatible with Ultraview Care Network monitors.

Open systems solutions

Dynamic Network Access (DNA)

Dynamic Network Access (DNA) gives clinicians the ability to view and control information systems interfaced with the Ultraview Care Network and having X-windows functionality. The 1700 is compatible with character-mode emulations such as VT220, which includes many information systems currently installed in hospitals.

X-windows and VT220-compatible systems include the X-Windows based clinical information system, clinical information systems from other manufacturers, laboratory, pharmacy, order entry, or general hospital information systems.

WinDNA

The WinDNA (Windows Dynamic Network Access) feature for the Ultraview 1700 allows clinicians to view and access Microsoft Windows applications on the same display as patient waveforms and other vital signs data. With the WinDNA feature, Windows applications are available at any bedside or central Ultraview 1700 monitor on the Ultraview Care Network. WinDNA also minimises cost and space requirements by eliminating the need for multiple terminals in the patient's room.

INFORMATION SYSTEM SOLUTIONS

Open Access to hospitalwide information systems in the Ultraview 1700

Enabled by the Ultraview Gateway and WinDNA, clinicians can view and control Windows applications right on the patient monitor's display, eliminating the need for separate terminals in the patient's room. Nurses can check lab results and other reports, enter orders, review protocols, and do charting right at the patient's bedside. Input can be done using the mouse, keyboard and touchscreen. This way, hospitals can give access to their hospitalwide applications from administrative systems, laboratory system, electronic patient system, medical record system, radiology systems, etc. while the user can use all these applications in one and the same place, the Ultraview 1700 with ergonomic controls as touchscreen...

Departmental Clinical Information Systems

Spacelabs provides a suite of departmental clinical information systems with access to whatever data is required to manage a patient's care. At the same time, clinicians from remote locations can access up-to-date, comprehensive patient information.

Caremaster Plus

The Caremaster Plus system has been designed to be interfaced with other hospital information systems. The Ultraview 1700 or another computer workstation at the patient bedside or elsewhere in the hospital on the network can function as a workstation to enter and review data on the Caremaster Plus record. Spacelabs offer Caremaster Plus departmental charting solutions for the anesthesia department, adult, pediatric and neonatal intensive care units. Caremaster Plus applications are run in MS Windows environment, using Microsoft SQL Server database platform.

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Caremaster Plus ORchart

The ORChart is a clinical information system for use throughout the perioperative environment. Designed for use by anesthesia providers and perioperative clinicians, ORChart is designed to address the needs of preoperative, operative and postoperative data management to provide the perioperative patient record. ORChart is a flexible application which accommodates the hospital's existing patient care process, as well as future changes to the process. A tab paradigm provides the information in a manner which relates to the flow of clinical information throughout all phases of the perioperative anesthesia process. Steps in the anesthesia process are presented as easily identified icons arranged in an order appropriate to the perioperative procedure.

Information from OR Chart can be accessed at a dedicated computer or on a Spacelabs Ultraview 1700. When vital signs and clinical information are consolidated on the Ultraview 1700, anesthesia providers can view overall patient status at one display. OR Chart supports automatic capture of vital signs and other information to speed input and enhance data consistency. The application's Autonote function minimizes the need for keyboard entry.

Case configurations are provided at both the institutional level and at clinician specific level. Each specific case configuration includes a selection list of appropriate supplies and drugs.

Caremaster Plus Critical Care Chart

Caremaster Plus Critical Care Chart has been designed specifically for the data-intensive, fast-paced critical care environment. Critical Care Chart includes automatic patient record, linking elements to facilitate clinical decision making. It covers complete audit trail and system security, required in the critical care. Using the Ultraview 1700 and its interfacing capabilities, the Critical Care Chart helps automate the patient record in ICU via automated data acquisition from monitors and other bedside devices. The user interface has been especially designed for nursing and clinicians ease of use. The colour-coded cells show numerical data that violate user-defined ranges. Patient management functions include the ability to automatically or manually document lab results, medications, IV fluids and blood administration. Retrospective view of information enables users to have a complete view over the patient's assessment.

Caremaster Plus NeoChart

Caremaster Plus Critical Care Chart has been designed specifically for the neonatal critical care unit. Besides the overall critical care charting needs, neochart includes specific neonatal demographics, such as foetal and maternal histories, specific parameters and drug calculations, tuned for neonatal environment.

Birthnet Labour and Delivery data management

(Note: this product is sold in the US only)

The Birthnet obstetric data management system provides computerized charting and information management, designed specifically for the labour and delivery environment. The system documents data for mothers and new babies and may be used for both hospital and physicians office documentation. Birthnet offers single-screen chronological

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charting, reprints for foetal monitoring strips, annotations, such as FHR baseline, uterine activity.... The key patient data are automatically verified and incoming information is checked with the range of normal, known limits. Birthnet's modular design allows users to purchase only the functions they require, segmented in documentation, surveillance, archival, reporting and statistical configurations.

THE NEW INTESYS CLINICAL SUITE – LAUNCH 2003

Vision

The launch of the Intesys Clinical Suite takes Spacelabs one step closer to the Intesys vision of creating an *integrated system* that provides clinical information when and where you need it.

In the evolution from the ICW to the Intesys Clinical Suite, Spacelabs steps from the departmental to the enterprise perspective. Spacelabs begins offering solutions that benefit the hospital's monitoring investment on a hospital-wide basis. It begins looking at solutions the way hospitals do, in the entirety of the organization. Spacelabs offers interfaces that are higher performance and standards-based and software that is secure to help them meet their privacy needs. Spacelabs offers products that can scale from the first department to the entire hospital.

The Intesys vision is to provide integrated solutions for the clinical information Spacelabs manages. Its goal is to integrate that information with the hospitals work and information flow to improve the quality and efficiency of healthcare. The Intesys Clinical Suite provides clinical information to healthcare providers when and where they need it on an enterprise scale that our competitors cannot match.

Future Direction

As stated above, the launch 2003 is a step toward the vision. The Intesys Clinical Suite will continue to evolve with more integrated applications and enterprise access capabilities. Applications will talk directly to the database rather than to monitors. The result will be stronger security, easier implementation and greater integration of information.

The next step will be the integration of full disclosure data into the central database to give enterprise-wide access to this information. As well, browser-based waveform viewing and printing services will all become enterprise applications, highly accessible and inclusive of all patients on the network. "Monitors loaders" will concentrate exclusively on getting monitor data into the database, and there will be monitor loaders for Ultraview, Datex-Ohmeda S/5 and future networks. The Intesys Clinical Suite is a dynamic platform, designed for growth and added capability. Most importantly, customers who buy today will be able to enjoy the future capabilities along a smooth upgrade path.

- Intesys – The brand for Spacelabs information management software products. The name indicates our vision of an *integrated system*. These products offer additional value to

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Spacelabs monitoring customers.

- ICW (Intesys Central Workstation) – A central workstation running Intesys applications. In the original ICW release (2002) all applications were installed on the workstation. With the Intesys Clinical Suite launch, all information can be accessed at the ICW, though the database itself may be on a central server.
- ICS (Intesys Clinical Suite) – A set of software applications that uses the information from Spacelabs monitor products to create superior healthcare solutions for our customers.
- Express Chart – The name originally applied to the electronic flowsheet in the Clinical Browser. However, “Express Chart” implied greater charting capability than the flowsheet was designed to deliver. The name is no longer used.
- Clinical Browser –The common user interface for navigating the web-based applications in the Intesys Clinical Suite. The Clinical Browser is comprised of menus, the patient list, web-links and navigation controls. Today it includes patient demographics, the Electronic Flowsheet and access to the Vital Signs Viewer.
- Monitor loader – A technology currently in development. A monitor loader is computer software that collects data from a monitor network and puts it into the Intesys Clinical Database. Similar in concept to an Ultraview Gateway, but simpler. Its job is to load the database. It does not interface with clinical information systems or any other applications. The Intesys Clinical Database may have multiple monitor loaders and even mixed monitor loaders for different monitoring networks in a hospital, for example, an Ultraview monitor loader and an S/5 monitor loader.

The NEW Intesys Clinical Suite

The Intesys Clinical Suite (ICS) is a set of products that complement Spacelabs monitoring products. These products collect, organize and present clinical information when and where the user needs it. The architecture is flexible to allow customers to buy what they need today, and grow into a hospital-wide system over time. Following is the structure for each of the ICS products.

New 91810 ICW Full Disclosure

ICW Full Disclosure is installed in a clinical unit such as ICU, ED or telemetry. The software is installed on a typical workstation-grade personal computer in an enterprise configuration or on a server in a single-computer departmental implementation. The computer is connected to the Spacelabs monitoring network via an Ethernet connection utilizing the Spacelabs protocol. Ultraview Gateway software is included with ICW Full Disclosure to communicate with the monitors, to get census information, alarms and waveforms. A second network interface card (NIC) is recommended in the PC hardware so that the Gateway can easily interface to other networks.

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The ICW Full Disclosure software license can be purchased with options to support up to 32 patients. These can be hardwired or telemetry patients, or a combination of both. 24 hours of full disclosure recording is standard; 72 hours of full disclosure is optional. Customers can now purchase an option to use the included Ultraview Gateway to implement an HL7 interface to send vital signs to their clinical information system (CIS). It is possible to implement several ICW Full Disclosure systems on the same network

New 91875 Clinical Browser

The 91875 Clinical Browser is built around a powerful clinical database. The system can be implemented in a single department, multiple departments or for an enterprise of hundreds of monitored patients. The Clinical Browser is a server product and the size of the server computer is scaled to the number of patients sending data to it. The Clinical Browser gets its data from the Ultraview Gateway, either in a 91810 ICW Full Disclosure or a standard 91816 Ultraview Gateway. The Clinical Browser can be viewed from the ICW Full Disclosure computer or virtually any other PC workstation with a browser (Internet Explorer 6.0 or higher).

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**SCHEDULE 2:
ANAESTHESIA MACHINE SUPPLY AGREEMENT
MAIN TERMS**

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Anaesthesia Machine Supply Agreement Main Terms

(to the extent required by any Purchaser)

Date	To be entered into contemporaneously with Closing.
Parties	General Electric Company, a New York corporation (“GE”) and [PURCHASER]* (the “Purchaser”)
Purpose	Under this Agreement, GE agrees to supply the Purchaser with the Products (as defined below) and related supplies, accessories and start-up kits on a non-exclusive basis, for the purpose of resale in the EEA by the Purchaser solely to end-user customers to whom the Purchaser supplies perioperative monitors and solely for the purpose of allowing the Purchaser to make combined perioperative monitor/anaesthesia machine sales to end-user customers.
Term	Non-renewable term of 5 years or as agreed between the Purchaser and GE.
Territory	The Purchaser will be entitled to supply the Products to end users in the territory of the EEA only. The Purchaser shall not sell the Products outside the EEA. GE retains the right to sell the Products to end users in the EEA or the rest of the world, either directly or through third parties.
Products	<p>The Aestiva/5 7100, Aestiva/5 7900, S/5 Aespire, Aestiva/5 Compact/Induction, Aliseo, Aestiva/5 MRI (each the “Product”, and together the “Products”) or any successor and upgraded versions of each Product as they become available. Once the manufacture of the Product is discontinued and the successor version is manufactured, GE will not be under the obligation to supply the discontinued version.</p> <p>Upon request by the Purchaser, GE commits to provide the Purchaser, with spare parts and service manuals required for the Purchaser's installed base of Products at non-discriminatory prices for the term of the Agreement and for a period of ten years after the expiration of the Agreement, subject to the parts continuing to be produced by GE or capable of being sourced from third Parties in accordance with GE's own policy of providing the same spare parts to GE customers.</p>
Pricing	GE agrees to provide the Products to the Purchaser on pricing terms substantially similar to, and in any event not less favourable than, those given to distributors in countries where sales are made through distributors, and in countries where sales are made directly by GE with a discount off the national list price equivalent to the average discount granted to GE distributors within the EEA.
Purchases	The Purchaser shall order the Products and GE shall supply the Products in quantities which take account of customary economic considerations and in any case sufficient to satisfy the Purchaser's needs.

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	<p>The Purchaser agrees to negotiate with GE purchase orders covering requirements for a period to be agreed upon between the Purchaser and GE on a basis that is commercially reasonable. The Purchaser will provide a non-binding rolling twelve (12) month forecast to GE on a monthly basis. GE will advise the Purchaser of any long lead time items and their costs. The Purchaser will authorise GE to purchase those items, at the Purchaser's own risk, as necessary to ensure continuity of supply of Products.</p> <p>The purchase forecast and the updates thereof shall be provided in good faith. GE shall use its best efforts to inform the Purchaser of any anticipated problems regarding deliveries in accordance with the purchase forecast.</p>
Interface	<p>GE undertakes to provide output data and related information and to cooperate with the Purchaser in developing their interface to enable the possibility to electronically transmit data generated by the product for the purpose of combining with the Purchaser's patient monitors or clinical information systems, in accordance with the Interface Commitment.</p>
Labelling	<p>The Purchaser shall cause the Products to be labelled and provided with necessary and appropriate signs, instructions and/or warnings and to be otherwise put into a form acceptable for sale and use. The Purchaser shall also obtain and conduct registrations and/or approvals as necessary. The Purchaser shall inform GE of the requirement for such labelling, registration, testing and/or approvals and the results thereof. Upon the Purchaser's request GE will at the Purchaser's cost assist the Purchaser in labelling the Products and in obtaining registrations, tests and/or approvals where necessary.</p>
Quality Assurance; Records; Recall	<p>The Purchaser shall fully comply with all applicable laws and regulations of the competent jurisdiction in the territories in which the Purchaser sells the Products. In particular, the Purchaser shall ensure that the Products as well as the Purchaser's activities in relation thereto conform with all legislation, rules, regulations and statutory requirements existing from time to time. GE shall manufacture the Products in full compliance with all applicable laws and regulations of its competent country in which it manufactures.</p> <p>The Purchaser agrees that the appropriate labelling of the Products or any products containing the Products and the obtaining of registrations, tests and/or approvals from relevant authorities where necessary, is the responsibility of the Purchaser and will be done at the Purchaser's cost.</p> <p>The Purchaser shall maintain serial and/or lot number and date of shipment records for each Product and shall cause its local distributors and sales representatives to maintain serial and/or lot number and date of shipment records for each product of the Purchaser so that, if necessary for tracing or recall purposes, the name and address of each end-user purchaser of a product containing a Product can be identified to the serial and/or lot number of the Product. The Purchaser shall give its assistance to GE in tracing or recall situations by making the records</p>

	<p>available or alternatively by contacting the end-user itself. The Purchaser shall promptly make such records available to GE if any authority in any country requests such records from GE.</p> <p>The Purchaser shall forward to GE within five (5) business days from the receipt of the complaint, any complaints received relating in any way to the Product during the prior month including, without limitation, situations when the Product fails when first used, frequent or persistent product reliability issues or when the customer expresses dissatisfaction with product performance. If the Purchaser becomes aware of an incident where the Product has or may have contributed to or caused a death or injury or an event where a unit of the Product has or may have malfunctioned and, if that malfunction occurred again, it could cause or contribute to death or injury or a customer expresses concern about patient safety, the Purchaser shall notify GE as soon as possible and shall use its best efforts to give such notice to GE orally within twenty-four (24) hours from the receipt of such complaint or becoming aware of such event and shall use its best efforts to confirm such notice by telefax within six (6) hours after giving oral notice. In all circumstances the Purchaser shall fully cooperate with GE in relation to investigating any such complaints and/or incidents.</p> <p>In the event GE should be required or should voluntarily decide to initiate any preventive or corrective action, such as product shipment hold, notification, field correction and recall, the Purchaser agrees to cooperate fully with GE. In carrying out preventive or corrective action, GE shall be responsible for (i) the investigation to determine the cause and extent of the problem (ii) all regulatory authority contacts, as applicable (iii) overall coordination of any corrective activities involving the Product.</p> <p>The Purchaser shall be responsible for promptly (i) locating the unit of the Product in question (ii) notifying the end-user (iii) in the event of recall, requiring that the recalled Products are returned (iv) in the event of product shipment hold initiating a shipment hold immediately upon notice by GE and (v) requiring and performing field upgrades and/or repairs when requested by GE.</p> <p>In the event that GE deems it necessary to take any corrective action (including notifications, field corrections or recalls) with respect of any of the Products sold to the Purchaser, regardless or whether such action is initiated to comply with applicable laws or regulations or for other reasons, the costs incurred by the Purchaser that are reasonably linked to the corrective action that GE deems is necessary shall be borne by GE.</p> <p>The Purchaser shall have the right to audit GE's facility of manufacture for the Products upon a mutually agreed time.</p>
<p>Brochures, Catalogues</p>	<p>GE agrees to supply the Purchaser at reasonable cost with samples of existing brochures and catalogues related to the Product to enable the Purchaser to make its own brochures and catalogues. In order to ensure the accuracy of any statements concerning the Product and compliance with regulatory requirements, the Purchaser will obtain GE's approval for all brochures, catalogues and other sales promotional material which it produces to promote the Product.</p>

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<p>Trademarks and Intellectual Property</p>	<p>The Purchaser shall be entitled to sell the Product under its own brand and product name. The Purchaser shall not be entitled to use the DATEX-OHMEDA brand name or any of the Product names. The Purchaser shall not reverse engineer any of the Products supplied under the Agreement.</p>
<p>Promotion of the Product</p>	<p>It is understood and agreed that all expenses incurred by the Purchaser in marketing, selling, promoting and servicing the Product shall be borne by the Purchaser, and GE shall be under no obligation to make any payments to the Purchaser for such expenses.</p>
<p>Warranty</p>	<p>GE agrees to remedy any defect in the Product resulting from faulty materials or workmanship.</p> <p>GE's sole obligation shall be to repair or replace. GE's obligation shall apply only to defects appearing and notified to GE within a period of twelve (12) months from the date of delivery of the Product by the Purchaser to the end-user customer or fifteen (15) months from the date of invoice of the Product by GE to the Purchaser, whichever occurs first. The said period is limited to three (3) months as from the date of delivery by GE in respect of the accessories and spare and replacement parts. Defects in a repaired or replaced Product or part shall be covered to the extent of the unexpired term of the applicable warranty period.</p> <p>In no event shall GE be liable to the Purchaser for any special, consequential, incidental or indirect damages, including but not limited to loss of profit or revenues, cost of capital or increased expenses.</p>
<p>Maintenance and Repair</p>	<p>GE or GE's distributor shall be responsible for repair services to end-user customers during the warranty period in accordance with GE's warranty obligations.</p> <p>At the Purchaser's option, GE or GE's distributor shall be responsible for providing all maintenance and repair services to end-user customers after the expiration of the warranty period. These maintenance and repair services shall be provided on a non-discriminatory basis and commercial terms substantially similar to those provided to GE's other customers.</p> <p>The Purchaser shall maintain adequate records of all service provided to end-user customers with respect to Products in such level and detail as may be necessary to enable the parties to determine the complete service history of each Product.</p> <p>At the Purchaser's option, GE will train at its designated training facilities a limited number of the Purchaser's service and clinical training personnel who will, in turn, be the designated trainers for all other service personnel and end-users. The Purchaser will be charged GE's standard training fees and pay the out-of pocket travel and living expenses of the personnel attending the training sessions. The Purchaser shall periodically conduct training sessions for its clinical trainers and service personnel to enable it's service capabilities with respect to Products and it's clinical training provided to end-users to be</p>

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	<p>maintained at all times at the state of the art.</p> <p>GE will provide to the Purchaser, at reasonable prices, any written materials it utilizes for training of service personnel and end-users with respect to the GE Products. The Purchaser shall be entitled to use these materials as the basis for creating its own materials, in its own name. GE will assist in developing and conducting training sessions when and as reasonably requested by the Purchaser, at GE's regular established rates for such services.</p>
Confidentiality	<p>The parties undertake to treat as strictly confidential, even after this Agreement has terminated, each other's trade secrets and non-public information.</p> <p>The Purchaser shall not, and shall use its best endeavours to ensure that its officers and employees will not, whether during the term or after the termination of the Agreement, use or disclose to any person any information relating to GE or any of its affiliates or their products, affairs or business, including the terms and conditions agreed in the Agreement or in connection therewith.</p>
Termination	<p>Termination shall be possible in accordance with standard commercial terms to be negotiated between the Parties, such as a material breach or failure by the Purchaser to perform its obligations or comply with the requirements of the Agreement, liquidation etc.</p> <p>In the event that GE wishes to terminate the Agreement in advance of its agreed termination date, GE shall obtain the prior approval of the Commission.</p>

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**SCHEDULE 3:
CARDIOCAP/5 GAS MONITOR
OEM AGREEMENT MAIN TERMS**

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Schedule 3:

Cardiocap/5 Gas Monitor OEM Agreement Main Terms

(to the extent required by any Purchaser)

Date	To be entered into contemporaneously with Closing.
Parties	General Electric Company, a New York corporation (“GE”) and [PURCHASER]* (the “Purchaser”)
Purpose	Under this Agreement, GE will agree to supply the Purchaser with the Cardiocap/5 Gas Monitor (the “Product”), and related supplies, accessories, leads and cables, and grant the Purchaser the right to be the sole and exclusive supplier of the Product in the territory of the EEA
Term	Non-renewable term of 10 years.
Territory	The Purchaser will be entitled to supply the Product in the territory of the EEA only. The Purchaser shall not promote or sell the Product outside of the EEA. During the term of the Agreement GE will not sell or supply the Product in the EEA other than to the Purchaser. GE will retain the right to supply the Product outside the EEA.
Product	<p>This Agreement applies to the Cardiocap/5 Gas Monitor (or any future successor or upgraded versions of this Product as they become available) only, i.e. the Cardiocap/5 configured multiparameter patient monitor for anaesthesia, which includes the Datex-Ohmeda gas bench measuring anaesthetic agents, respiratory gases and basic vital signs. The Purchaser will not be entitled to receive from GE, or supply to end users, any versions of the Cardiocap/5 other than the Cardiocap/5 Gas Monitor. Once the manufacture of the Product is discontinued and the successor version is manufactured, GE will not be under the obligation to supply the discontinued version.</p> <p>Upon request by the Purchaser, GE commits to provide the Purchaser with spare parts and samples of service manuals required for the Purchaser's installed base of the Product at non-discriminatory prices for the term of the Agreement and for a period of ten years after the expiration of the Agreement, subject to the parts continuing to be produced by GE or capable of being sourced from third Parties in accordance with GE's own policy of providing the same spare parts to GE customers.</p>
Pricing	GE agrees to supply the Product to the Purchaser on Cost Plus Terms – i.e. the total of GE's Product Costs (defined as direct materials, direct labor, and full manufacturing overhead both variable and fixed portions), Distribution Costs (in transit freight, customs, duties), Intellectual Property Costs (engineering development cost recovery) and Warranty Costs (defined as [confidential])* of total cost from previous

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	items), plus [confidential]*.
Purchases	<p>The Purchaser agrees to negotiate with GE purchase orders covering requirements for a period to be agreed upon between the Purchaser and GE on a basis that is commercially reasonable. The Purchaser will provide a non-binding rolling twelve (12) month forecast to GE on a monthly basis. GE will advise the Purchaser of any long lead time items and their costs. The Purchaser will authorise GE to purchase those items, at Purchaser's risk, as necessary to ensure continuity of supply of Products.</p> <p>The purchase forecast and the updates thereof shall be provided in good faith. GE shall use its best efforts to inform the Purchaser of any anticipated problems regarding deliveries in accordance with the purchase forecast.</p>
Labelling	<p>The Purchaser shall cause the Product to be labelled and provided with necessary and appropriate signs, instructions and/or warnings and to be otherwise put into form acceptable for sale and use. The Purchaser shall also obtain and conduct registrations and/or approvals as necessary. The Purchaser shall inform GE of the requirement for such labelling, registration, testing and/or approvals and the results thereof. Upon the Purchaser's request GE will assist the Purchaser in labelling the Product and in obtaining registrations, tests and/or approvals where necessary. All registrations and/or approvals shall be deemed to be owned by GE. Unless prohibited by local law, all registrations and/or approvals obtained by the Purchaser shall be in the name of GE.</p>
Brochures, Catalogues	<p>GE agrees to supply the Purchaser at reasonable cost with samples of existing brochures and catalogues related to the Product to enable the Purchaser to make its own brochures and catalogues. In order to ensure the accuracy of any statements concerning the Product and compliance with regulatory requirements, the Purchaser will obtain GE's approval for all brochures, catalogues and other sales promotional material which it produces to promote the Product.</p>
Trademarks and Intellectual Property	<p>GE shall provide the Product to the Purchaser on an original equipment manufacturer ("OEM") basis. The Purchaser shall be entitled to sell the Product under its own brand and product name. The Purchaser shall not be entitled to use the DATEX-OHMEDA brand name or the Cardiacap product name. The Purchaser shall not reverse engineer any of the Products supplied under the Agreement.</p>
Promotion of the Product	<p>The Purchaser shall actively market, promote and support sales of the Product throughout the EEA. It is understood and agreed that all expenses incurred by the Purchaser in marketing, selling, promoting and servicing the Product shall be borne by the Purchaser, and GE shall be under no obligation to make any payments to the Purchaser for such expenses.</p>
Quality Assurance; Records; Recall	<p>The Purchaser shall fully comply with all applicable laws and regulations of the competent jurisdiction in the territories in which the Purchaser sells the Products. In particular, the Purchaser shall ensure that the Products as well as the Purchaser's activities in relation thereto</p>

	<p>conform with all legislation, rules, regulations and statutory requirements existing from time to time. GE shall manufacture the Products in full compliance with all applicable laws and regulations of its competent country in which it manufactures.</p> <p>The Purchaser agrees that the appropriate labelling of the Products or any products containing the Products and the obtaining of registrations, tests and/or approvals from relevant authorities where necessary, is the responsibility of the Purchaser and will be done at the Purchaser's cost.</p> <p>The Purchaser shall maintain serial and/or lot number and date of shipment records for each Product and shall cause its local distributors and sales representatives to maintain serial and/or lot number and date of shipment records for each Product of the Purchaser so that, if necessary for tracing or recall purposes, the name and address of each end-user purchaser of a Product can be identified to the serial and/or lot number of the Product. The Purchaser shall give its assistance to GE in tracing or recall situations by making the records available or alternatively by contacting the end-user itself. The Purchaser shall promptly make such records available to GE if any authority in any country requests such records from GE.</p> <p>The Purchaser shall forward to GE within five (5) business days from the receipt of the complaint, any complaints received relating in any way to the Product during the prior month including, without limitation, situations when the Product fails when first used, frequent or persistent product reliability issues or when the customer expresses dissatisfaction with product performance. If the Purchaser becomes aware of an incident where the Product has or may have contributed to or caused a death or injury or an event where a unit of the Product has or may have malfunctioned and, if that malfunction occurred again, it could cause or contribute to death or injury or a customer expresses concern about patient safety, the Purchaser shall notify GE as soon as possible and shall use its best efforts to give such notice to GE orally within twenty-four (24) hours from the receipt of such complaint or becoming aware of such event and shall use its best efforts to confirm such notice by telefax within six (6) hours after giving oral notice. In all circumstances the Purchaser shall fully cooperate with GE in relation to investigating any such complaints and/or incidents.</p> <p>In the event GE should be required or should voluntarily decide to initiate any preventive or corrective action, such as product shipment hold, notification, field correction and recall, the Purchaser agrees to cooperate fully with GE. In carrying out preventive or corrective action, GE shall be responsible for (i) the investigation to determine the cause and extent of the problem (ii) all regulatory authority contacts, as applicable (iii) overall coordination of any corrective activities involving the Product.</p> <p>The Purchaser shall be responsible for promptly (i) locating the unit of the Product in question (ii) notifying the end-user (iii) in the event of recall, requiring that the recalled Products are returned (iv) in the event of product shipment hold initiating a shipment hold immediately upon notice by GE and (v) requiring and performing field upgrades and/or repairs</p>
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	<p>when requested by GE.</p> <p>In the event that GE deems it necessary to take any corrective action (including notifications, field corrections or recalls) with respect of any of the Products sold to the Purchaser, regardless of whether such action is initiated to comply with applicable laws or regulations or for other reasons, the costs incurred by the Purchaser that are reasonably linked to the corrective action that GE deems is necessary shall be borne by GE.</p> <p>The Purchaser shall have the right to audit GE's facility of manufacture for the Products upon a mutually agreed time.</p>
Warranty	<p>GE agrees to remedy any defect in the Product resulting from faulty materials or workmanship.</p> <p>GE's sole obligation shall be to repair or replace. GE's obligation shall apply only to defects appearing and notified to GE within a period of twelve (12) months from the date of delivery of the Product by the Purchaser to the end-user customer or fifteen (15) months from the date of invoice of the Product by GE to the Purchaser, whichever occurs first. The said period is limited to three (3) months as from the date of delivery by GE in respect of the accessories and spare and replacement parts. Defects in a repaired or replaced Product or part shall be covered to the extent of the unexpired term of the applicable warranty period.</p> <p>In no event shall GE be liable to the Purchaser for any special, consequential, incidental or indirect damages, including but not limited to loss of profit or revenues, cost of capital or increased expenses.</p>
Maintenance and Repair	<p>GE or GE's distributor shall be responsible for repair services to end-user customers during the warranty period in accordance with GE's warranty obligations.</p> <p>At the Purchaser's option, GE or GE's distributor shall be responsible for providing all maintenance and repair services to end-user customers after the expiration of the warranty period. These maintenance and repair services shall be provided on a non-discriminatory basis and commercial terms substantially similar to those provided to GE's other customers.</p> <p>The Purchaser shall maintain adequate records of all service provided to end-user customers with respect to Products in such level and detail as may be necessary to enable the parties to determine the complete service history of each Product.</p> <p>GE or GE's distributor shall be responsible for repair services to end-user customers during the warranty period in accordance with GE's warranty obligations.</p> <p>At the Purchaser's option, GE or GE's distributor shall be responsible for providing all maintenance and repair services to end-user customers after the expiration of the warranty period. These maintenance and repair services shall be provided on a non-discriminatory basis and commercial terms substantially similar to those provided to GE's other</p>

	<p>customers.</p> <p>The Purchaser shall maintain adequate records of all service provided to end-user customers with respect to Products in such level and detail as may be necessary to enable the parties to determine the complete service history of each Product.</p> <p>At the Purchaser's option, GE will train at its designated training facilities a limited number of the Purchaser's service and clinical training personnel who will, in turn, be the designated trainers for all other service personnel and end-users. The Purchaser will be charged GE's standard training fees and pay the out-of pocket travel and living expenses of the personnel attending the training sessions. The Purchaser shall periodically conduct training sessions for its clinical trainers and service personnel to enable it's service capabilities with respect to Products and it's clinical training provided to end-users to be maintained at all times at the state of the art.</p> <p>GE will provide to the Purchaser, at reasonable prices, any written materials it utilizes for training of service personnel and end-users with respect to the GE Products.</p> <p>GE will provide to the Purchaser a sample of any written materials it utilizes for training of service personnel and end-users with respect to the GE Products. The Purchaser shall be entitled to use these materials as the basis for creating its own materials, in its own name. GE will assist in developing and conducting training sessions when and as reasonably requested by the Purchaser, at GE's regular established rates for such services.</p>
Confidentiality	<p>The parties undertake to treat as strictly confidential, even after this Agreement has terminated, each other's trade secrets and non-public information.</p> <p>The Purchaser shall not, and shall use its best endeavours to ensure that its officers and employees will not, whether during the term or after the termination of the Agreement, use or disclose to any person any information relating to GE or any of its affiliates or their products, affairs or business, including the terms and conditions agreed in the Agreement or in connection therewith.</p>
Termination	<p>Termination shall be possible in accordance with standard commercial terms to be negotiated between the Parties, such as a material breach or failure by the Purchaser to perform its obligations or comply with the requirements of the Agreement, liquidation etc.</p> <p>In the event that GE wishes to terminate the Agreement in advance of its agreed termination date, GE shall obtain the prior approval of the Commission.</p>

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**SCHEDULE 4:
GAS MODULE OEM AGREEMENT MAIN TERMS**

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Gas Module OEM Agreement Main Terms

(to the extent required by any Purchaser)

Date	To be entered into contemporaneously with Closing.
Parties	[General Electric Company, a New York corporation (“Manufacturer”) and [PURCHASER]* (the “Company”)]
Purpose	For the term of this Agreement, the Manufacturer agrees to sell and the Company agrees to purchase Datex-Ohmeda gas benches.
Term	10 years.
Territory	The Company will be entitled to supply the Product on a world-wide basis. The Manufacturer retains the right to sell the Products to end users, either directly or through third parties.
Product	<p>Gas Module consisting of the Datex-Ohmeda Compact Airway, mains power supply and enclosure (hereinafter referred to as “the Product”), upgraded versions of this Product, and any successor to this Product with the same parameters as this Product to ensure continuity, as they become available. The functional specifications of gas measurements and the parameters are specified in the Datex-Ohmeda S/5 Compact Airway Module Customer Specifications. Once the manufacture of the Product is discontinued and the successor version is manufactured, the Manufacturer will not be under the obligation to supply the discontinued version.</p> <p>(The Company may choose, before entering into this Agreement, to purchase only the measurement technologies and software of the Datex-Ohmeda S/5 Compact Airway Module, and not the complete module including mains power supply and enclosure)</p> <p>The Manufacturer shall use its best efforts to ensure that the compatible spare parts, required for the installed base of the Product, will be available at non-discriminatory prices for a period of at least ten years from the delivery by the Manufacturer of the Product in question, subject to the parts continuing to be produced by GE or capable of being sourced from third Parties in accordance with GE's own policy of producing the same spare parts to GE customers.</p>
Independent Trader	The Company shall act as independent trader and buy and sell in its own name and for its own account. The Company is not authorised to act in the name of the Manufacturer, and nothing in this commitment shall be construed to constitute either Party the agent of the other Party for any purpose.
Estimated Purchase; Reports; Minimum Purchase Requirement	The Company agrees to negotiate with the Manufacturer purchase orders covering requirements for a period to be agreed upon between the Company and the Manufacturer on a basis that is commercially reasonable. The Company will provide a non-binding rolling twelve (12) month forecast to

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	<p>the Manufacturer on a monthly basis. Manufacturer will advise the Company of any long lead time items and their costs. The Company will authorise the Manufacturer to purchase those items, at Company's risk, as necessary to ensure continuity of supply of Products.</p> <p>The purchase schedule and the updates thereof shall be provided in good faith. The Manufacturer shall use its best efforts to inform the Purchaser of any anticipated problems regarding deliveries in accordance with the purchase schedule.</p> <p>The Purchaser shall order the Products and GE shall supply the Products in quantities and modalities which take account of customary economic considerations and in any case sufficient to satisfy the Purchaser's needs.</p>
<p>Sales under this Agreement; Prices and Other Terms</p>	<p>GE agrees to provide the Products to the Purchaser on pricing terms similar to, and in any event not less favourable than, those given to other third parties, in particular Datascope. In case current supply agreements with such third parties lapse or are terminated, GE agrees to supply the Product to the Purchaser on Cost Plus Terms – i.e. the total of GE's Product Costs (defined as direct materials, direct labor, and full manufacturing overhead both variable and fixed portions), Distribution Costs (in transit freight, customs, duties), Intellectual Property Costs (engineering development cost recovery) and Warranty Costs (defined as [confidential]* of total cost from previous items), plus [confidential]*.</p>
<p>Warranty and Liability; Division of Liability</p>	<p>The Manufacturer agrees to remedy any defect in the Products supplied by the Manufacturer resulting from faulty materials or workmanship.</p> <p>The above shall apply only to defects appearing within a period of eighteen (18) months from the date of delivery by the Manufacturer. The Manufacturer's sole obligation shall be to repair or replace. The said period is limited to four (4) months in respect of other reusable accessories and to six (6) months in respect of spare parts, the said periods being calculated, in each case, as from the date of delivery by the Manufacturer. The same periods are applied in respect of any defects in a repaired or replaced Product or part.</p> <p>In no event shall the Manufacturer be liable to the Company for any special, consequential, incidental or indirect damages, including but not limited to loss of profit or revenues, cost of capital or increased expenses.</p>
<p>Trademarks and Other Industrial Property Rights</p>	<p>The Company certifies that it is an Original Equipment Manufacturer and that each Product purchased under this Agreement will be incorporated by the Company as part of a product to be distributed by the Company under the Company's trademarks or trade names. The Company agrees not to distribute, sell, promote or advertise the Products as separate items without obtaining the Manufacturer's prior written approval thereto. Notwithstanding the above the Company may sell spare parts or accessories as separate items.</p> <p>The Company shall not use or refer to the Manufacturer's name or trademarks in any other form or manner or for any purpose except as set forth below or otherwise agreed by Manufacturer.</p>

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	<p>The Company agrees not to use any trademarks of the Manufacturer, such as DATEX-OHMEDA or GE, in marketing, selling or promoting the Products or in any other way, without obtaining the Manufacturer's prior written approval. Such approval shall, however, not be required in the case of deliveries of spare parts or accessories supplied by the Manufacturer and bearing the Manufacturer's trade mark.</p>
<p>Competition; Trade Secrets; Confidentiality</p>	<p>The Parties hereby undertake to treat as strictly confidential, even after this Agreement has terminated, each other's trade secrets and non-public information.</p> <p>The Company shall not, and shall use its best endeavours to ensure that its officers and employees will not, whether during the term or after the termination of this Agreement, use or disclose to any person any information relating to the Manufacturer or any of its affiliates or their Products, affairs or business, including the terms and conditions agreed in this Agreement or in connection herewith.</p>
<p>Regulatory Requirements / Quality Assurance</p>	<p>The Company shall fully comply with all applicable laws and regulations of the competent jurisdiction in the territories in which the Company sells its products containing the Products. In particular, the Company shall ensure that the Products as well as the Company's activities in relation thereto conform with all legislation, rules, regulations and statutory requirements existing from time to time. The Manufacturer shall manufacture the Products in full compliance with all applicable laws and regulations of its competent country in which it manufactures.</p> <p>The Company agrees that the appropriate labelling of the Products or any products containing the Products and the obtaining of registrations, tests and/or approvals from relevant authorities where necessary, is the responsibility of the Company and will be done at the Company's cost.</p> <p>The Company shall maintain serial and/or lot number and date of shipment records for each Product and shall cause its local distributors and sales representatives to maintain serial and/or lot number and date of shipment records for each product of the Company containing a Product so that, if necessary for tracing or recall purposes, the name and address of each end-user purchaser of a product containing a Product can be identified to the serial and/or lot number of the Product. The Company shall give its assistance to the Manufacturer in tracing or recall situations by making the records available or alternatively by contacting the end-user itself. The Company shall promptly make such records available to the Manufacturer if any authority in any country requests such records from the Manufacturer.</p> <p>The Company shall forward to the Manufacturer within five (5) business days from the receipt of the complaint, any complaints received relating in any way to the Product during the prior month including, without limitation, situations when the Product fails when first used, frequent or persistent product reliability issues or when the customer expresses dissatisfaction with product performance. If the Company becomes aware of an incident where the Product has or may have contributed to or caused a death or injury or an event where a unit of the Product has or may have malfunctioned and, if that malfunction occurred again, it could cause or contribute to death or injury or a</p>

	<p>customer expresses concern about patient safety, the Company shall notify the Manufacturer as soon as possible and shall use its best efforts to give such notice to Manufacturer orally within twenty-four (24) hours from the receipt of such complaint or becoming aware of such event and shall use its best efforts to confirm such notice by telefax within six (6) hours after giving oral notice. In all circumstances the Company shall fully cooperate with the Manufacturer in relation to investigating any such complaints and/or incidents.</p> <p>In the event the Manufacturer should be required or should voluntarily decide to initiate any preventive or corrective action, such as product shipment hold, notification, field correction and recall, the Company agrees to cooperate fully with the Manufacturer. In carrying out preventive or corrective action, the Manufacturer shall be responsible for (i) the investigation to determine the cause and extent of the problem (ii) all regulatory authority contacts, as applicable (iii) overall coordination of any corrective activities involving the Product.</p> <p>The Company shall be responsible for promptly (i) locating the unit of the Product in question (ii) notifying the end-user (iii) in the event of recall, requiring that the recalled Products are returned (iv) in the event of product shipment hold initiating a shipment hold immediately upon notice by the Manufacturer and (v) requiring and performing field upgrades and/or repairs when requested by the Manufacturer.</p> <p>In the event that the Manufacturer deems it necessary to take any corrective action (including notifications, field corrections or recalls) with respect of any of the Products sold to the Customer including Products that have been incorporated in any of the Customer's products and distributed by the Customer, regardless or whether such action is initiated to comply with applicable laws or regulations or for other reasons, the costs incurred by the Company that are reasonably linked to the corrective action that the Manufacturer deems is necessary shall be borne by the Manufacturer.</p> <p>The Company shall have the right to audit the Manufacturer's facility of manufacture for the Products upon a mutually agreed time.</p> <p>The Manufacturer will provide to the Company, at its list price, any written materials it utilizes for training of service personnel and end-users with respect to the Manufacturer's Products. The Company shall be entitled to use these materials as the basis for creating its own materials, in its own name. The Manufacturer will assist in developing and conducting training sessions when and as reasonably requested by the Company, at the Manufacturer's regular established rates for such services.</p>
<p>Maintenance and Repair</p>	<p>The Manufacturer or the Manufacturer's distributor shall be responsible for repair services to end-user customers during the warranty period in accordance with the Manufacturer's warranty obligations.</p> <p>At the Company's option, the Manufacturer or the Manufacturer's distributor shall be responsible for providing all maintenance and repair services to end-user customers after the expiration of the warranty period. These maintenance and repair services shall be provided on a non-discriminatory basis and commercial terms substantially similar to those</p>

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	<p>provided to the Manufacturer's other customers. The Company shall maintain adequate records of all service provided to end-user customers with respect to Products in such level and detail as may be necessary to enable the parties to determine the complete service history of each Product.</p> <p>At the Company's option, the Manufacturer shall provide to the Company training and training materials with respect to the Products on a non-discriminatory basis and commercial terms substantially similar to those provided by Instrumentarium to Datascope.</p>
Termination	<p>Termination shall be possible in accordance with standard commercial terms to be negotiated between the Parties, such as a material breach or failure by the Company to perform its obligations or comply with the requirements of the Agreement, liquidation etc.</p> <p>In the event that GE wishes to terminate the Agreement in advance of its agreed termination date, GE shall obtain the prior approval of the Commission.</p>

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**Case No COMP/M.3083 - GE/Instrumentarium:
Interfacing Commitment to the European Commission**

Without Prejudice

On 28 February 2003, General Electric Company ("GE") submitted a Form CO notification on a proposed concentration between GE and Instrumentarium OYJ (the "Parties") pursuant to Council Regulation (EEC) No. 4064/89 as amended by Commission Regulation (EC) No. 447/98 (the "Merger Regulation").

Pursuant to Article 8(2) and 10(2) of the Merger Regulation, the Parties hereby provide the following Commitments (the "Commitments") in order to enable the European Commission (the "Commission") to declare the acquisition of Instrumentarium by GE compatible with the common market and the EEA Agreement by a decision pursuant to Article 8(2) of the Merger Regulation (the "Decision").

Any term used in this text, unless otherwise defined, or unless the context indicates otherwise, shall be interpreted in the light of the Commission Notice on remedies acceptable under the Merger Regulation and under Commission Regulation (EC) No 447/98.

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SECTION A. DEFINITIONS

- Effective Date:** The Closing Date as defined in the Combination Agreement dated 18 December 2002 between GE and Instrumentarium, whereby GE will acquire sole control of Instrumentarium.
- GE:** General Electric Company, a company incorporated under the laws of New York, USA, with its registered office at 3135 Easton Turnpike, Fairfield, Connecticut 06431, USA.
- Instrumentarium:** Instrumentarium OYJ, a company incorporated under the laws of Finland, with its registered office at Kuortaneenkatu 2, 00510 Helsinki, Finland.
- GE/Instrumentarium:** The merged entity including both GE and Instrumentarium and all subsidiaries of those two companies.
- Therapy Devices:** Anaesthesia machines (including ventilator components) and ventilators.
- Patient Monitors:** Patient monitors for use in clinical critical care areas of the hospital, the operating room (OR) area and the adjacent clinical areas of the hospital. The term Patient Monitor shall include the parts necessary for the operation of the patient monitor, including data acquisition components, displays and input/output components.
- Clinical Information Systems (CIS):** Information systems, used in hospitals, for capturing clinical information and documenting activity at the point-of-care.
- Interface:** The possibility to either (1) electronically exchange data generated by (i) Therapy Devices for the purpose of combining with Patient Monitors or CIS or (ii) Patient Monitors for the purpose of combining with Therapy Devices or CIS or (2) physically mount monitors or CIS on Therapy Devices.
- Working Days:** "Working days" within the meaning of Article 23 of Commission Regulation (EC) No 447/98 of 1 March 1998 (the Implementing Regulation).

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SECTION B. THE COMMITMENT

Open Interfaces

1. GE undertakes that
 - i. GE/Instrumentarium will keep the existing and future Interfaces of GE/Instrumentarium's existing and future Therapy Devices open, with respect to their combination with third party Patient Monitors or CIS.
 - ii. GE/Instrumentarium will keep the existing and future Interfaces of GE/Instrumentarium's existing and future Patient Monitors open, with respect to their combination with third party Therapy Devices or CIS.
 - iii. GE/Instrumentarium will keep the existing and future Interfaces of GE/Instrumentarium's existing and future CIS open, with respect to their combination with third party Therapy Devices and/or Patient Monitors.
2. *These Commitments do not, however, prevent GE/Instrumentarium from developing integrated systems, provided that their Interfaces will remain open to additional third party devices, in accordance with Sections 1(i)-(iii) above.*
3. An Interface shall be considered as "open" in accordance with Section 1(i)-(iii) above, if it provides third party suppliers of Therapy Devices, Patient Monitors or CIS with reasonable, safe, seamless and effective Interface options in accordance with regulatory requirements applicable in the EEA, industry practice and accepted industry standards.

The Interface options provided to third party suppliers of Therapy Devices, Patient Monitors or CIS, in accordance with Sections 1(i)-(iii), should adhere to a principle of non-discriminatory treatment and should be, as far as possible, given the characteristics of the third party Therapy Device, Patient Monitor or CIS respectively, equivalent to the options available to GE/Instrumentarium's own Therapy Devices, Patient Monitors or CIS.

For the avoidance of any doubt, GE shall not be required to provide an electronic Interface to third party products that do not have an ability to exchange information electronically.

Duty to Provide Interfacing Information

4. GE also undertakes that:
 - i. GE/Instrumentarium will make available to all Therapy Device, Patient Monitor or CIS suppliers or mounting solutions suppliers, which have made a request to receive such Interfacing information in relation to a

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product which they wish to Interface with a GE/Instrumentarium product in accordance with Sections 1(i)-(iii) above at any time following the adoption of the Decision, the Interfacing information and data, including for example the communication Interface protocol and other specifications, as well as any reasonably necessary ancillary technical clarifications, which are necessary to ensure an open Interface between GE/Instrumentarium's existing and future Therapy Devices and third party Patient Monitor(s) or CIS, between GE/Instrumentarium existing and future Patient Monitors and third party Therapy Devices or CIS and between GE/Instrumentarium 's existing and future CIS and third party Therapy Devices and/or Patient Monitors. This shall include the provision of any new Interfacing information relating to an Interface modification or upgrade of existing or future GE/Instrumentarium Therapy Devices, Patient Monitors or CIS without further request being necessary.

- ii. GE/Instrumentarium will provide this Interfacing information in English without undue delay. In particular as regards future or upgraded GE/Instrumentarium Therapy Devices and/or Patient Monitors, GE/Instrumentarium shall, having regard to the principle of non-discriminatory treatment and with the aim of providing third parties the opportunity to develop competing interfaces as early as GE/Instrumentarium, provide any new Interfacing information and data immediately from the time that the Interface information is sufficiently developed to enable a third party to develop an Interface and, in any event, no later than completion of product development. Further, GE/Instrumentarium shall respond to all written requests by third party suppliers for the receipt of Interfacing information pursuant to this Commitment within a period of 20 Working Days either providing the information or explaining why the information is not available.
- iii. GE/Instrumentarium will provide Interfacing information free of charge or at documentation cost, and on a non-discriminatory basis. Contact details for the provision of Interfacing information pursuant to this commitment should be advertised in GE/Instrumentarium's documentation and/or on its website, and reasonable technical assistance/consultation provided where necessary and at reasonable prices to enable third parties to understand and be able to use the Interfacing information to achieve an Open Interface in accordance with clause 1 above.
- iv. With respect to the commitments set out in Sections 1(i) and 1(ii), GE/Instrumentarium will, if requested, make available, either at a GE/Instrumentarium location or on loan (whichever the third party requests) for a reasonable period which in any event should not be less than 3 months, the new device or the upgrade, as applicable, or a

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reasonable facsimile thereof, at cost, so that the third party can conduct necessary interoperability tests.

- v. GE/Instrumentarium will, if requested by a third party, keep all information received from a third party in the context of this commitment confidential and shall use this information only to discharge its obligations under this commitment and for no other purpose.
- vi. GE may request that a third party receiving information according to this provision be bound by a confidentiality agreement obliging that party to use the information for purposes directly related to this commitment and for no other purpose. In case of disagreement concerning the terms of the confidentiality agreement, the Commission shall have the power to decide its terms and GE undertakes that GE/Instrumentarium will enter into such agreement as required by the Commission.

Interface Certification Cooperation

5. GE undertakes that GE/Instrumentarium will, if the certification of a combination of GE/Instrumentarium Therapy Devices with third party Patient Monitors or CIS is requested by the third party supplier (including mounting solutions suppliers) or the customer, carry out reasonably necessary cooperation with this third party upon request, on a non-discriminatory basis and free of charge or at cost, and without undue delay. The cooperation will include examination and testing with original components of both suppliers, which may take place, for instance, at a GE/Instrumentarium location or by means of lending equipment. Records of the examination and testing will be available for both suppliers. GE/Instrumentarium's product literature or website will state that GE/Instrumentarium's relevant products have open Interfaces. The certification relates to the mechanical and electronic interoperability of devices according to the standards commonly used in the EEA or any EEA-country.

6. The above principles shall apply *mutatis mutandis* to a certification cooperation (if at all required) relating to the combination of GE/Instrumentarium's Patient Monitors and a third party Therapy Device or CIS.

Duty to Provide Devices and Components

7. GE undertakes that GE/Instrumentarium will, if necessary to achieve an Open Interface in accordance with clause 1, provide third party suppliers of Patient Monitors, Therapy Devices or CIS with the necessary physical components at reasonable and non-discriminatory market prices.

GE further undertakes that GE/Instrumentarium will sell to third party suppliers of Patient Monitors, Therapy Devices or CIS GE/Instrumentarium Therapy Devices, Patient Monitors or CIS at reasonable and non-discriminatory market prices where this is necessary for demonstrations of interoperability to customers or at trade shows.

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Monitoring of Compliance and Review

8. GE/Instrumentarium shall report to the Commission any matters which the Commission reasonably requests in order to determine whether GE/Instrumentarium has complied with this Commitment. Any such report shall be sent to the Commission within 15 Working Days from the date the Commission makes a request.

9. GE/Instrumentarium will appoint an independent trustee with sufficient expertise and powers to monitor compliance with the commitments. The appointment shall take place in time so that the trustee is appointed on the Effective Date or within 15 Working Days following a subsequent request by the Commission. The trustee and its mandate, terms and conditions shall be subject to the Commission's prior written approval. If GE/Instrumentarium fails to appoint a trustee within 15 Working Days following a request by the Commission, the Commission shall have the right to choose a trustee and GE/Instrumentarium shall appoint the trustee in accordance with terms and conditions as requested by the Commission. The trustee shall have the power to appoint an expert with expertise of the anaesthesia, ventilation and patient monitor industries including information technology aspects of those industries to assist the trustee in the discharge of its duties. Before appointing the expert, the trustee shall obtain the Commission's approval in writing. The trustee's and expert's remuneration shall be borne by GE/Instrumentarium.

10. In the event that a third party supplier has reason to believe that GE/Instrumentarium is failing to comply with the requirements of these Commitments vis-à-vis this third party supplier, the fast track dispute resolution procedure set out in Annex I shall apply.

11. The Commission may, in exceptional circumstances and where appropriate, in response to a request from GE/Instrumentarium showing good cause, waive, modify or substitute, one or more of the provisions of these Commitments at any time.

24 July 2003

Signature

duly authorized for and on behalf of General Electric Company

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ANNEX I

FAST TRACK DISPUTE RESOLUTION

1. In the event that a third party supplier has reason to believe that GE/Instrumentarium is failing to comply with the requirements of the Commitments vis-à-vis this third party supplier and, in particular, has reason to believe that:
 - i. GE/Instrumentarium refuses or fails to provide an open Interface in accordance with paragraphs 1 - 3 of the Commitments; or
 - ii. GE/Instrumentarium refuses or fails to provide interfacing information in accordance with paragraph 4 of the Commitments; or
 - iii. GE/Instrumentarium refuses or fails to provide interface certification cooperation in accordance with paragraphs 5 and 6 of the Commitments;the fast track dispute resolution procedure below will apply.
2. Any third party supplier who wishes to avail itself of the fast track dispute resolution procedure (a “requesting party”) must notify GE/Instrumentarium in writing specifying the reasons leading that party to believe that GE/Instrumentarium is failing to comply with the requirements of the Commitments (the "Notice"). The requesting party and GE/Instrumentarium will use their best efforts to resolve all differences of opinion and to settle all disputes that may arise through co-operation and consultation within a reasonable period of time not to exceed fifteen (15) Working Days after receipt of the Notice.
3. Should the requesting party and GE/Instrumentarium fail to resolve their differences of opinion through cooperation and consultation as provided for in paragraph 2, the requesting party shall nominate an arbitrator.
 - i. GE/Instrumentarium shall, within two weeks of receiving a notification in writing from a requesting party of the appointment of an arbitrator, nominate its arbitrator and provide to the requesting party in writing detailed reasons for its challenged conduct.
 - ii. The arbitrators nominated by GE/Instrumentarium and the requesting party shall, within one week from the nomination of the former, agree to appoint a third arbitrator. If the arbitrators nominated by GE/Instrumentarium and the requesting party cannot agree on the nomination of a third arbitrator, they shall request that the President of the London Court of Arbitration appoint the third arbitrator.
 - iii. The arbitrators shall be instructed to establish an arbitration tribunal and to make a decision within one month of the appointment of the third arbitrator as to the compliance by GE/Instrumentarium with its obligation under the Commitments;
 - iv. In their decision, the arbitrators shall also decide the action to be taken by GE/Instrumentarium in order to ensure compliance with the Commitments vis-à-vis the requesting party;
 - v. Any of the arbitrators will be entitled to request any relevant information from GE/Instrumentarium or the requesting party in order to enable the arbitrators to reach a decision.
 - vi. The burden of proof in any dispute under this fast track dispute resolution procedure is as follows: i) the requesting party must produce evidence of a prima facie case,

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- and ii) if the requesting party produces evidence of a prima facie case, the arbitrator must find in favour of the requesting party unless GE/Instrumentarium can produce evidence to the contrary.
- vii. The arbitrators shall be instructed not to disclose confidential information. Throughout the Commitments the standard attributed to confidential information and business secrets are those as set out in accordance with European Community competition law.
 - viii. The arbitration shall be in English and shall be conducted in accordance with the rules of the London Court of Arbitration and the rules of the London Court of Arbitration will be amended accordingly. In the event of disagreement between the parties to the arbitration regarding the interpretation of the Commitments, the arbitrators shall seek and be bound by the Commission's interpretation of the Commitments before finding in favour of any party to the arbitration.
 - ix. All notices provided under the fast track dispute resolution procedure shall be in English and delivered between 09:00 and 17:00 on a Working Day.
 - x. The arbitration award shall, in addition to dealing with the merits of the claim, impose the fees and costs of the prevailing party upon the party that is unsuccessful.