

Annex I: Project Final Summary

Project Final Summary

<u>Section 1: PROJECT IDENTIFICATION</u> CRAF 70716	NOT CONFIDENTIAL
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Title of the project		
Programmable air wave generator with controlled temperature, pressure, humidity and air wave frequencies for calibration		
Acronym of the project		
PAWG		
Type of contract		Total project cost
CRAFT		€1.515.400.00
Contract number	Duration	EU contribution
QLK4-CT-2002-70716	24 Months	€757.360.00
Commencement date		Period covered by the progress report
1 June 2002		1 June 2002 – 31 May 2004
<u>PROJECT COORDINATOR</u>		
Name Anton F.P. van Putten	Title prof. dr. ir.	Address Aquariuslaan 62, 5632 BD Eindhoven, The Netherlands
Telephone	Telefax	E-mail address
31 40 242 7877	31 40 242 5205	Anton37.putten@wxs.nl
Key words		
Calibration standard, European Standard Pr CEN 13826, dynamic flow generator		
World wide web address		
Web page is under construction (hollandpromote.com)		

List of participants					
Type of organization	Tel	Fax	Email	Partner address	
				Name of authorised Representative	
The Contractors					
A1	SME 1 Coordinator ARL	31 40 2427877	31 40 2425205	Anton37.putten@wxs.nl	AnMar Ingenieursburo bv Prof. dr.ir. A.F.P. van Putten P.O. Box 1200 5602 BE Eindhoven, The Netherlands
A2	SME 2 JAEGER	49 93149 72700	49 931 49 72300	RL@Jaeger-Toennies.com	JAEGER GmbH (Viasys) Dipl. Ing. Ralf Lothar Leibnissstrasse 7, 97201 Höchberg, Germany
A3	SME 3 QIC	351 239 982044	351 239 982012	Rui@quantific.pt	Quantific-Instrumentacao Cientifica, Rui Machado, M.Sc. Lda IPN Rua Pedro Nunes, 3030- 199 Coimbra, Portugal
The Subcontractors					
B1	RTD 1 NMi	31 15 2691500	31 15 2612971	MCharite@NMi.nl	NMi, Van Swinden Laboratorium b.v. Mr. Rien Charité Schoenmakerstraat 97, 2600 AR Delft, The Netherlands
B2	RTD 2 VTT	358 94566342	358 9 456 6390	KariLarjava@VTT.FI	Technical Research Centre of Finland, VTT, Dr. Kari Larjava Vuorimiehentie 5. 02044 ESPOO, Finland
B3	RTD 3 TUD	31 15 278 5610	31 15 2784717	O.H.Bosgra@wbmt.tudelft.nl	Delft University of Technology, Drs Ing. A.L. Loos Julianalaan 134, 2628 BL Delft, The Netherlands.
B4	RTD 4 ADDF	351 239 410650	351 239 9829158	Correia@berta.fis.uc.pt	ADDF / University of Coimbra, Prof. Carlos Correia Electronics and Instr. Lab. Dept. de Fisica, 3004-516 Coimbra, Portugal
X1	PTB	49 30 3481 287	49 30 3481 507	Riedel@PTB.DE Assistant contractor To NMI	Physikalisch Technische Bundesanstalt Berlin Dr. Stephan Mieke Abbestrasse 2-12 10587 Berlin, Germany
X2	VPI	31 15 2787969	3115 278 6758	Info@vpinstruments.com Assistant contractor to ARL	VPIstruments, Ir. Pascal F. A. M. Van Putten Prins Bernardlaan 6 Delft

Annex I: Project Progress Summary

Objectives:

Existing calibration equipment for lung diagnostic equipment does not comply with latest European standards and calibration requirements. The trace-ability for calibration and testing of new flow measurement equipment, primarily for medical pulmonary and resuscitation equipment is of utmost importance for improved diagnostics, quality, reliability and more efficient drug consumption. To meet latest standards, a new physical calibration standard has been realized, based upon the written European standard Pr CEN 13826 in close collaboration with two National institutes of Metrology, i.e. NMI in the Netherlands and PTB, Berlin Germany. Viasys as manufacturer of medical lung diagnostic equipment and other RTD institutes have also participated in this project. This new standard will also comply with the requirements of the American Thoracic Society Standards (ATS) and will offer also BPTS calibration outcomes.

Simultaneously, to calibrate under controlled environmental conditions with a continuous airflow, the need for a second calibration facility has been observed. This wide range calibration facility covers pressure, temperature and Relative Humidity (RH) conditions, which were also retrieved from the CEN 13 826 standard.

Results and Milestones:

As is common practice the project has been divided into milestones and deliverables (=results) complying with the project flow chart, such as has been laid down in the project proposal description.

The **first milestone result** reveals a firm scientific background. For this reason a comprehensive report has been produced, in which all relevant data, definitions, requirements, specifications and known calibration standards for lung diagnostic equipment has been compiled. Attached to the Pr CEN 13826 standard, two basic expiratory flow calibration curves A and B have been reported which must be met. The ATS standard is also included, revealing the 26 different calibration curves to be reproduced with calibration equipment.

The **second milestone result** is devoted to the research, simulation and evaluation of potential implementations for this new calibration standard. VTT and PTB have performed a comprehensive study, calculations and simulations in which the essential physical, geometric, and technical parameters have been investigated. From the different possibilities, for flow generation it is decided to apply the piston cylinder principle. Critical parameters to investigate are flow curve rise time, length to width ratio of the piston cylinder and the pneumatic resistances involved. This has resulted in a number of reports.

The potential of a conventional open loop configuration is considered. Secondly, a closed loop configuration is investigated, keeping in mind that four physical parameters, Pressure, Airflow velocity, Temperature and Relative Humidity, must be controlled in the new standard. As a first step, the open loop configuration is chosen as proposed by Jaeger. For practical reasons, the closed loop configuration as proposed by ARL is temporarily put aside. **Design and simulation results** are reported. TUD and PTB have investigated the performance of existing calibration systems.

For testing purposes under *continuous* flow conditions, a closed loop flow calibration tunnel has been designed and built by ARL in close collaboration with VPI. With help of this closed loop calibration tunnel all four parameters can be controlled, in particular airflow velocities from 0 up to 100 m/s, pressure from 0 – 16 bar, temperature and RH. Further it is envisaged that this calibration tunnel will be automated and extended with a controllable RH facility between 40 and 100 % and a temperature control facility ranging from 0 to 40°C. Calibration procedures will be automated. **Results** are available and reported. ARL has also built a closed loop scale model with which the closed loop configuration principle is demonstrated, offering easy control of pressure, temperature and RH.

Finally, Jaeger has built a first fully operational prototype of the dynamic airflow generator in an open loop configuration. First experiments have shown already a large improvement with the existing state of the art of dynamic airflow generators. First test results are obtained and reported.

Benefits and Beneficiaries:

The benefits and beneficiaries are obvious. Ultimately, the new standard with the performances outlined previously is unique and so far known does not exist. The impact on the manufacture of lung diagnostic equipment may be substantial when better calibration facilities become available giving more insight in COPD and Asthma diseases, ultimately also resulting into more efficient drug consumption and patient treatment.

Future Actions (if applicable):

The continuous airflow calibration tunnel will be optimized and will become a fully automated calibration facility for airflow, pressure, temperature and RH control, in the widest ranges possible.

The dynamic airflow calibration PAWG standard will also be expanded with pressure, temperature and RH control. This requires the design and construction of a second prototype with built-in features as predefined. The piston drive will be equipped with a linear motor instead of a stepper motor. Further actions to be taken are the investigation and implementation of an airflow velocity device with high dynamic performances of at least 25 Hz. It is intended to realize a third and final prototype for testing and final evaluation purposes.

