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Specifications for equipment used for infant pulmonary function testing

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Specifications for equipment used for infant pulmonary function testing. U. Frey, J. Stocks, A. Coates, P. Sly, J. Bates, on behalf of the ERS/ATS Task Force on Standards for Infant Respiratory Function Testing. ©ERS Journals Ltd 2000.
ABSTRACT: The aim of this position paper is to define minimal performance criteria for the separate items comprising equipment used to measure respiratory function in infants together with overall performance criteria for the assembled pieces of such equipment.

These guidelines cover numerous aspects including: 1) safety, 2) documentation and maintenance of equipment, 3) physical characteristics of mechanical parts and signal transducers, and 4) data acquisition. Further, validation procedures for individual components as well as for the integrated equipment are recommended.

Adherence to these guidelines should ensure that infant lung function measurements can be performed with an acceptable degree of safety, precision and reproducibility. They will also facilitate multicentre collection of data and performance of clinical investigations.

Manufacturers of infant respiratory function equipment should make every effort to comply with these guidelines, which represent the current standards of paediatric health professionals in this field.
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The present document represents one of a series [1–6] that is being produced by the European Respiratory Society/American Thoracic Society Task Force on standards for infant respiratory function testing. The aim of this task force is to summarize what is currently seen to be good laboratory practice, and to provide recommendations for both users and manufacturers of infant lung function equipment and software. These recommendations have been developed after widespread communication on an international level and are directed towards future developments in this field, including the use of more automated equipment than has been used in many research centres in the past.

As the technology for assessing respiratory function expands and progresses, it will become increasingly necessary to be able to compare results between systems in a coherent fashion. The feasibility of performing multicentre trials to investigate infant respiratory physiology or study the effects of disease and therapeutic interventions on the developing lung has, to date, been limited by the wide range of equipment that has been used. The lack of standardized equipment and test procedures has also made it difficult to establish normative values for the various parameters of interest that are independent of the measurement device used, or to use these tests as reliable clinical tools.

The aim of the present position paper is to define minimal performance criteria for the separate items comprising the equipment, together with overall performance criteria for an assembled piece of equipment. The effectiveness of these guidelines will obviously depend on the extent to which manufacturers comply with them and the willingness of the end-user to adhere to the standards that are developed. These guidelines are not mandatory with respect to equipment that is currently in use, since it is recognized that it will take time to adapt software and equipment. It is recommended that any apparent limitations be stated in potential publications, to assist interpretation of data collected with different systems.

Full details regarding specific techniques such as plethysmography, analysis of tidal breathing and the rapid thoracoabdominal compression technique can be found in the current relevant accompanying documents in the current series. Further documentation will be required in the near future to address specific problems when assessing

For editorial comments see page 579.

respiratory function in infants and young children in the intensive care unit and during assessment of bronchial responsiveness. These are thus only briefly alluded to here, together with those techniques associated with measurement of oscillation mechanics, oesophageal manometry, gas mixing, *etc*., position papers on which subjects are still to be developed. The present document is limited to the general principles of measuring, analysing and reporting infant lung function. Its purpose is to facilitate quality control by ensuring adequate documentation and assessment [7] of both equipment and algorithms. This will reassure the end-user that the purchased system can be used with a degree of confidence.

General issues

Infant pulmonary function test (PFT) equipment is a complex construct of individual technical components, which have to be characterized regarding their individual as well as their overall performance. For any infant PFT equipment, it is not sufficient to state the characteristics of the individual components in isolation. The manufacturer must also state the characteristics of the integrated equipment as a unit in terms of frequency response, dead space, resistance, *etc*.

Safety aspects and documentation

1) Infant lung function equipment including software must meet the current safety requirements for medical equipment (International Medical Device Directive (International Electrotechnical Commission (IEC) (MDD) 93/42/European Economic Community (EEC) (see *Appendix 1*)) as well as specific national safety requirements (*e.g*. the Food and Drug Administration in the USA, the Medical device Certification (CE) in Europe and the Max Planck Gesalschaft (MPG) in Germany). 2) The maintenance, calibration and use of the equipment must be clearly documented in a manual, and adequate on-site training and ongoing support provided, so that the user is fully aware of its capabilities and limitations. 3) All systems must have printed specifications to define the performance requirements described below (see MDD 93/42/EEC). This is important for both interpretation of results and comparison of data between different systems. 4) Pneumatic valves near the infant′s face need to meet the highest security standards. High-pressure valves must be guaranteed not to burst or release any pressure towards the infant′s face or airway opening. In case of malfunction, the infant′s face must never be endangered. Pressure circuits of pneumatic valves must be physically separated from the airway opening. 5) The performance of the equipment must be tested regularly according to the requirements of the manufacturer. In addition to thorough assessment prior to release, manufacturers of integrated infant lung function systems should carry out an on-site validation protocol at the time of initial installation, whenever any major amendments to equipment or software are made, and at regular 6–12 monthly intervals thereafter. Primary users of the equipment should be present throughout such validation procedures, the results of which should be carefully documented and stored.

Careful use of the equipment provided to ensure patient safety remains the responsibility of the operator. Routine safety measures in the PFT laboratory include: 1) full resuscitation equipment, including suction, being available at the site of infant lung function testing, plus a suitable alarm system; 2) Two individuals (other than parents) being present during testing, one of whom has prime responsibility for the infant′s well being; the infant must never be left unattended; 3) continuous monitoring (and ideally recording) using at least pulse oximetry; 4) transparent face masks for monitoring of the infant; and 5) adherence to the hospital-specific protocol for sedation or anaesthesia.

Further details regarding measurement conditions which may influence infant safety or the accuracy and reproducibility of results have been published previously [8 - ch. 3].

Hygiene: cleaning of equipment

1) All measuring devices must be capable of undergoing rapid thorough disinfection. If reusable flow sensors are used, these should be disinfected between subjects and recalibration performed. The information from the manufacturer must include complete instructions on the appropriate cleaning techniques and solutions. 2) The use of disposable sensors is recommended *in situ*ation in which infection risk of nosocomial infection or cross-contamination exists, particularly in intubated infants. 3) Valves should be changed between subjects. Nondisposable valves must have cleaning and disinfection instructions specified in the operator′s manual. 4) Parts of the lung function equipment which are only in indirect contact with the patient′s airway opening and which are difficult to clean (*e.g*. loudspeakers) should ideally be separated from the breathing circuit by viral/bacterial filters. However, very little is currently known about the influence of such filters on the static and dynamic behaviour of the equipment. Furthermore, some filters may not provide an effective barrier against agents such as *Pseudomonas* and should therefore be used with extreme caution. Such factors need further investigation.

Mechanical components of the lung function equipment

Total apparatus dead space

Many investigators have found that application of a face mask or nasal prongs and a flowmeter changes the breathing pattern [8–10]. This may not only alter the very parameters being measured but also place an undesirable load on the infant, especially those that are very small or sick. In ventilated preterm infants, the dead space of the apparatus ($V_{D,app}$) is the most important determinant of this load and changes in arterial carbon dioxide tension can occur within minutes of attaching the device. The defilution of $V_{D,app}$ is particularly difficult as, even with the same piece of apparatus, it may vary according to the precise application. During measurements of respiratory mechanics and tidal breathing, the relevant $V_{D,app}$ is the additional volume through which the infant must breathe while attached to the equipment, which is not ventilated

by any bias flow of gas. By contrast, during measurements of lung volumes, whether by plethysmography or gas dilution methods, the entire volume of the equipment proximal to the occlusion or switching valve (including any tubing used to connect transducers or provide a bias flow) needs to be subtracted from the calculated values. This may be a considerably greater volume than that through which the infant has to breathe. In addition, the physiological effect of any equipment dead space depends not only on absolute magnitude but also on its configuration, long narrow tubes or complex valves being more likely to result in carbon dioxide retention and stimulation of breathing than short wide appliances such as masks.

Although the ultimate goal would be to eliminate dead space in all devices, this is not practical during many of the currently available measurements unless a flow through technique is employed [10]. There are limits to how low the $V_{D,app}$ can be made when performing measuring in infants, due to the requirements for connection to external devices (*e.g.* masks, and endotracheal (ET) tubes) and the need to minimize the resistance of the device. There are also practical difficulties in assessing the effective $V_{D,app}$. The method by which $V_{D,app}$ has been assessed should be specified (volumetric, dimensional, W.S. Fowler's dead space method, *etc.*). Manufacturers should also describe exactly what has been included in the $V_{D,app}$ calculations for each type of test, so that the user can check this. The following recommendations refer specifically to the "effective" $V_{D,app}$, *i.e.* that which the infant will breathe through. Since it is impossible for manufacturers to know what size mask will be used with their apparatus, the guidelines refer to target $V_{D,app}$ without the mask. When reporting $V_{D,app}$, the user must, however, include the additional dead space of the mask, which is often $\geq$2 mL·kg body weight^{-1} in small infants. (see *Face masks* section). In addition, the manufacturer must ensure that the $V_{D,app}$ (including any relevant tubing, *etc.*) is subtracted from calculations of lung volume *etc.*

Ideally any device that is used continuously should have an "effective" $V_{D,app}$ when *in situ* of <1 mL·kg body weight^{-1}. Since this may be impractical in very small babies, a system with negligible $V_{D,app}$ (such as the flow through technique [2, 10] or a face-out body plethysmograph [9]) would be preferable. For a device that is used intermittently, *i.e.* in tests of short duration, the maximum recommended $V_{D,app}$ is 1.5–2 mL·kg body weight^{-1}.

Face masks

Since infants are preferential nose breathers, the use of a face mask that covers nose and mouth is obligatory in many infant PFTs. Consensus regarding the effective dead space of any particular face mask is important since, for many PFTs, the dead space of the face mask has to be subtracted (*e.g.* during lung volume measurements). Furthermore, the size and compliance of the face mask may contribute to measurement errors during certain tests. For example, a very firm mask is required during any technique involving airway occlusions, whereas a mask with minimal dead space is required to avoid errors due to parallel shunts during respiratory input impedance measurements. The brand and size of the face mask should therefore be reported. 1) Depending on the application, reduction of the face mask dead space by filling with silicone putty should be considered. 2) The effective dead space of the face mask can be measured *in vitro* by water displacement and 50% of the value obtained subtracted to take into account the space occupied by the infant's face and the putty ring (unpublished data from the present task force). Thus a Rendell Baker mask (Soucek, Ambu International, Brøndby, Denmark) size 0 (for use in 2–4 kg infants) has a total dead space of 10 mL by water displacement but only 5mL when *in situ* on the infant's face. Similarly the "effective" dead space of size 1 (4–6 kg) and 2 (6–12 kg) Rendell Baker masks have been shown to be ~10 and ~15 mL respectively. These recommendations have been recently confirmed by direct measurements of mask dead space [11].

It is recognized that this can only represent an approximation since face shape, amount of putty used or pressure applied to an air-filled cushion will vary within and between centres. Nevertheless, adoption of these guidelines would help to minimize the gross discrepancies currently occurring, wherein some centres ignore the dead space of the mask completely and others subtract the total volume. In practical terms, this could account for systematic differences in lung volume between centres of up to 4 mL·kg body weight^{-1}.

Resistance

Minimizing the resistance of the infant lung function equipment is important since the overall resistance of the equipment may not only dramatically change the respiratory pattern in spontaneously breathing babies but could also interfere with triggering devices in those who are ventilated. Any significant increase in resistance increases the expiratory time constant and potentially influences the end-expiratory level. This, in turn, affects any measurements that are volume-dependent, including forced flow manoeuvres, respiratory mechanics measurements and various tidal breathing parameters. Bearing in mind the wide within- and between-subject variability of resistance according to age, body size, clinical status, measurement technique, *etc.*, it is only possible to suggest broad guidelines that need to be interpreted according to the measurements being undertaken. However, the need to design future apparatus with as low a resistance as possible within the constraints of simultaneously attaining a low dead space and high resolution cannot be overemphasized. 1) The combined resistance of the apparatus (including any valves, capnographs, *etc.*) should be <20% of the infant's intrinsic resistance at the mean flows likely to be encountered. Thus, as a rough guide (see above), the combined apparatus resistance should not exceed 1.2 kPa·L^{-1}·s at 50 mL·s^{-1} in spontaneously breathing preterm infants, 0.7 kPa·L^{-1}·s at 100 mL·s^{-1} in term neonates and 0.5 kPa·L^{-1}·s at 300 mL·s^{-1} in infants and young children. It should be noted that much higher flows ($\dot{V}$) may be encountered at any given age during special manoeuvres and ventilatory assistance [8 - p. 77]. The manufacturer and user should therefore determine the $\dot{V}$ range over which the device is likely to be used and ensure that excessive resistance does not occur at higher $\dot{V}$. 2) Manufacturers should provide the user with details of the resistance of their equipment over

the full range of $\dot{V}$ likely to be encountered, in graphic and/or tabular form or as Rohrer's equation indices. 3) Particular attention must be paid to the potential resistance of the ET tube during measurements in ventilated infants [8 - ch. 17]. Apparatus resistance (or impedance, where relevant) must always be subtracted before reporting infant resistance. In ventilated infants, accurate *in vivo* assessments of ET tube resistance are difficult to obtain and reported resistances, therefore, usually include that of the ET tube. Although this may be acceptable for monitoring changes within a baby, the potential impact of this added resistance (particularly with tubes of ≤3 mm inside diameter) must be taken into account by both manufacturers, when designing equipment for use in the intensive care unit (ICU), and the user, when interpreting results.

Valves

Valves, in particular computer-driven valves, must meet high security standards (see *Safety aspects and documentation* section). 1) Valve position must be detectable by the investigator at all times. This can be achieved by using transparent components in cases in which this is feasible or by on-screen display. Alternatively, airway opening pressure can be monitored continuously as a safety measure. 2) Unintended closure of the airway opening by the valve system must be instantly detected by an alarm system. 3) Valve malfunction must never cause an occlusion, the default position always being that ensuring airway opening. 4) Valves should operate as quietly as possible. Noisy valves disturb sleeping infants, causing arousal or change in sleep stage, and may also concern parents. 5) The volume displacement by the valve and resistance of the open valve should be minimal and not alter pressure measurements. 6) Systems which use differential pressure-measurements in ventilated infants and periodically "purge" the pressure sensing lines in order to keep them clear and assure good measurements must ensure that the pump and solenoids operate in a fail-safe manner and do not deliver excessive volume into the circuit. 7) Valves used for testing infants and children have special requirements that vary depending upon whether they are used continuously or intermittently. The mode of action is particularly important for the dead space requirement of valves. The additional dead space of a valve should be minimized and be no greater than that of the flow sensor when used continuously and no more than double that of the flow sensor when used intermittently. In cases in which it is an integral part of the measurement equipment, the $V_{D,app}$ and resistance of the equipment must meet the criteria described in the *Total apparatus dead space* and *Resistance* sections. 8) The shutter closure time (as defined as the period between the onset and end of the occlusion movement (*i.e.* excluding any delay due to signal processing, such as the reaction time of magnetic valves, *etc.*)) is critical in some test measurements. For measurements of the interrupter resistance (R_{int}) and multiple occlusion resistance, closure time must be <10 ms. The closure times for passive respiratory mechanics measurements, determination of plethysmographic lung volumes and other occlusion tests are required only to be of sufficient speed to close at the appropriate volume. 9) Measurements using valves are usually highly sensitive to measurement errors induced by air-leaks through the valve system (see below). 10) Postocclusion oscillatory pressure transients are influenced by not only the elastic and inertive properties of the respiratory system but also valve closure speed, the distance between the shutter and valve and valve closure characteristics [12–14]. Since these postocclusion pressure transients influence many lung function measurements (*e.g.* curve fitting algorithms during R_{int} measurements), the dynamic characteristics of the shutter valve should be characterized by the manufacturers.

Leaks, connectors and the mechanical time constant of the equipment

The airtightness of infant lung function testing equipment, including the face mask seal, is critical during all measurements. This is particularly true if gases of low viscosity (*e.g.* in gas dilution techniques) or high pressures (*e.g.* in the raised volume rapid thoracoabdominal compression (RVRTC) technique or measurements in ventilated infants) are used. 1) Connectors should be constructed so that multiple use and repeated cleaning does not alter their leak properties. 2) If O-rings are used for connectors, recommendations for the replacement and maintenance of the connector must be provided. 3) Recommendations regarding the best types of face mask and sealing procedure (*e.g.* putty ring) to use are described elsewhere [2–6]. 4) When measurements are made in intubated infants, any leak around the ET tube will significantly affect the accuracy of lung function measurements [8 - ch. 17]). It is, therefore, essential that a clear display of the magnitude of the leak (calculated as the relative difference between the inspired and expired volumes) should be available during both recording and analysis of data. 5) The extent to which infant lung function equipment needs to be airtight depends upon the specific application and the pressures likely to be encountered during testing. Thus equipment used for any technique involving airway occlusions must be pressure-tight to ≥±2 kPa (20 cmH_2O), whereas that used for passive inflations or the RVRTC technique (including the face seal) may need to withstand pressure changes at the airway opening of up to 5 kPa. By contrast, valves used during jacket inflations for the squeeze technique must withstand pressures of up to 15–20 kPa. Specific details are provided in the relevant articles of the current series [2–6]. 6) Airtightness should be defined by leak measurements in open systems or by time constants in closed systems. The time constant in a closed system can be measured using a calibration chamber with similar capacitive properties to those found under normal measurement conditions. If an acceptable error of the pressure measurements of <1%, a minimal respiratory frequency of 10 $breath \cdot min^{-1}$ and linear behaviour of the leak are assumed, the time constant of the leak must be >300 s. However, it should be noted that leaks usually behave in a nonlinear manner. 7) Manufacturers should provide the necessary adapters and software to allow the operator to check the airtightness of the equipment at the time of calibration and prior to infant measurements. Spare parts for any components that are likely to need intermittent replacement should also be provided.

Measurement of pressure

Pressure measurements in infants and children vary not by patient size but by pressure source and disease state.

Location of pressure transducers. Sample ports for pressure measurements should not be located where eddies of gas at orifice entry or exit points may artificially alter the pressure. Effects of eddies currents on pressure measurements have been reported in the literature [8 - pp. 99–102], but are not the only potential problem for lateral pressure measurements. The major issue is the Bernoulli effect that occurs to a significant degree when the diameter of the tube is small [15]. The latter might be, therefore, particularly important for measurements in infants.

Baseline stability (equipment only). Typical reasons for baseline instability of the equipment include intrinsic drift of transducers and sensitivity to temperature, position (gravity, *e.g.* solid-state pressure transducers) and other changes in environmental conditions. 1) Baseline instability may be crucial for calibration and measurement procedures (*e.g.* when using catheter tip transducers for oesophageal manometry) and must be specified by the manufacturer. 2) Frequent automated rezeroing (*e.g.* by software) is recommended for concurrent differential pressure transducers (*e.g.* in flowmeters), using a brief disconnection of the pressure transducer by electromechanical valves.

Ranges. Pressure ranges vary depending upon whether the system is used in ventilated infants, when airway pressure swings are usually greater than those in spontaneously breathing subjects, and the specific application. The recommended pressure ranges for infant lung function tests are given in table 1.

Linearization. Pressure measurements should be linear to within ±1% of the reading or 0.1 kPa, whichever is greater.

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Frequency response. Newer pressure transducers, particularly solid-state piezoresistive transducers, usually have flat frequency responses up to very high frequencies. However, as discussed below (Frequency response of the entire equipment section), they may be degraded by attachment to the equipment.

Table 1. – Pressure ranges normally encountered during pulmonary function tests in infants and young children

Pressure transducer	Pressure range kPa
Oesophageal pressure	-5–5
Airway opening pressure	-10–10
plethysmographic box pressure (100 L)	-0.1–0.1
Jacket pressure (forced flows)	0–15

The ranges shown above over all possible applications including raised volume and passive inflation techniques and measurements in ventilated infants. The usual range of oesophageal and airway opening pressures encountered during tidal breathing and occlusions within the tidal range tend to fall within the range 1.5 kPa. Similarly, the pressure changes encountered during infant plethysmography are usually of the order of 2–40 Pa, but the pressure range of the transducer needs to be consideraly greater than this in order to cope with the marked thermal drift of the plethysmographic signal during the equilibration period.

Measurement of flow

A variety of devices can be used for the measurement of $\dot{V}$ The flowmeter should be a low-resistance low-dead space device. Currently, most flowmeters are pneumotachometers (PNTs) which are based on a screen resistance, although hot wire anemometers have been favoured in some ventilator circuits. Recently the use of ultrasonic flowmeters has also been reported [16].

Placement of the flowmeter. The placement of the device within a breathing circuit remains somewhat controversial but should be such that errors due to condensation, applied pressure or flow-generated Venturi forces are avoided. For further details, see [8, ch 5]. In the special situation in which flowmeters are implemented in ventilator circuits, particular caution is required depending on the specific application. Thus, although flow sensors can be placed within the ventilator circuit and "in-line" with the subject′s airway for measurements of passive mechanics using multiple regression in fully ventilated infants, those for measurement of passive respiratory mechanics using the occlusion techniques should be external to the ventilator circuit. [5, 8 - ch. 17].

Dead space. The dead space of the PNT/flowmeter will be governed by the recommendations regarding $V_{D,app}$ given in the *Total apparatus dead space* section. Bearing in mind the need to attach a face mask and possibly an occlusion valve, the dead space of the isolated flowmeter should ideally be <1 mL·g body weight^{-1}. However, this may not be achievable in infants of <5 kg, particularly when tests that require a large linear range of $\dot{V}$ are being used. In these circumstances, the smallest suitable device should be employed. Modern technology has allowed the introduction of devices that have a linear $\dot{V}$ range of 0–10 L·min^{-1} and a dead space in the order of 1 mL, rising to ~5 mL if linearity to ≥35 L·min^{-1} is required. Depending on the size of the 14 individual, even this reduced dead space may not be acceptable for long-term measurements, thereby necessitating the use of dead space-free or indirect methods (see *Total apparatus dead space* section).

Resistance of flowmeters. 1) The upper limit of the resistance of flowmeters is governed by the recommendations for the total flow resistance of the equipment as described in the *Resistance* section. 2) The resistance is dependent upon the measurement principle used, and gas composition and viscosity/gas density. If room air is not used during the PFT, kinematic viscosity resistance of the PNT has to be considered (based on Hagen-Poiseulle′s law). Resistance is dependent on gas density. In this case, the flow-sensing devices need either to be calibrated at the appropriate gas concentration or corrected through an algorithm for the change in gas composition. If the latter approach is used, the manufacturer′s documentation must include the algorithm, the gases for which it is valid and the range of concentrations included. The potential effect of gas interaction must also be documented.

Temperature correction. 1) For standard screen and capillary PNTs, heating is required to prevent water vapour condensation from altering the resistive characteristics. It has been shown that significant errors in volume measurement can occur within minutes of placing an unheated screen PNT in a ventilator circuit. 2) The recommended heating temperature of the tube ranges 30–37°C. For new sensors using materials with a low thermal conductivity, the problem of condensation may be reduced. As the time course of gas within the PNT is probably too short for temperature changes to be equilibrated, the heat selection should simply be that required to minimize water accumulation. 3) The software should compensate for changes in environmental temperature or the temperature of the inspired gas as necessary.

Linearization and linear range. The physical properties of most flowmeters usually cause a nonlinear relationship between the applied and measured signals. Most devices have built in hardware or software linearization algorithms. 1) The method of determining the linearity must be specified and, if a linearization table is applied, the method of calculation and application to measured events specified in the operator's manual. 2) The linearization procedure must ensure that all sensors of the same type yield comparable results. This requires a high precision of production or some means of identifying individual characteristics (*e.g.* coded plugs). 3) As described in the *Frequency response of the entire equipment* section, the extent to which a device gives a linear output when attached to various types and sizes of ET tube must also be specified. 4) After linearization, flowmeters must be linear to within ±2.5% of the applied signal (or to within ±2 $mL \cdot s^{-1}$ for flows of ≤100 $mL \cdot s^{-1}$). 5) The linearity of the flowmeters should be checked with the standard connectors used during measurements *in situ*.

Because there is a wide range of $\dot{V}$ found in infants according to age, test (tidal or forced manoeuvres) and disease state, the use of several different sensors may be necessary in order to obtain accurate measurements. The linear range of any flowmeter will need to exceed that generally observed during tidal breathing, particularly if any special manoeuvres or measurements are performed. Thus, even when undertaking a range of tests in any given infant, it may be necessary to use several differently sized flowmeters to maximize the accuracy of recordings under different measurement conditions. The flow ranges normally encountered are given in table 2.

Common mode rejection. During certain tests (*e.g.* during occlusion or RVRTC techniques), or when studying ventilated babies, the differential pressure transducers in pneumotachographs may become pressurized depending on the circuitry used. Any differential measurements (*e.g.* $\dot{V}$) must have a common mode rejection such that, in the absence of a differential signal, a common mode signal of nominal full scale amplitude changes the differential signal output by <±5% of its nominal full scale. In other words, any signal from the transducer in response to a pressure that is common to both sides of the device must be minimal compared to the response to an applied differential signal [8 - p. 98].

Table 2. – Flow ranges normally encountered

Infant weight kg	Flow range $mL \cdot s^{-1}$		
	Tidal breathing	RTC/SBT	RVRtc
<2	0–100	0–200	0–400
2–4	0–200	0–300	0–600
4–10	0–300	0–600	0–2000
>10	0–500	0–1000	0–3000

RTC: rapid thoracoadominal compression technique; SBT: Single breath technique; RVRtc: raised volume RTC.

Frequency response. The frequency response of $\dot{V}$ measurement devices is usually critical to their performance. They are expected to have flat frequency responses up to 10 Hz (*Measurement of pressure* section), *i.e.*, under operating conditions, flowmeters are expected to have a response error of ±0.5 dB at 10 Hz (*i.e.* within ±6%). Although most commercially available devices can achieve this when assessed in isolation, considerable degradation can occur when attached, for example, to an ET tube [17].

Calibration of flow.. 1) Calibration or verification of the accuracy of a flow-measuring device should be performed before testing each patient. 2) Any flow-sensing device must undergo physical calibration throughout its full range of use. This should be a minimum of a three-point calibration: maximum positive and negative flow and a zero-point calibration. 3) Flow measuring devices that are subject to influence from humidity, temperature, changing gas composition, *etc.* need calibration or verification prior to every test and ideally on an hourly basis if being used "in-line" for continuous monitoring in the ICU. 4) Calibration may be performed either with known flows using a precision flow system (rotameters) or, more commonly nowadays, with a calibrated syringe. 5) Calibrated values can be checked using a known volume. Each device must be able to be volume-calibrated to a precision of within ±2.5% except for the neonatal sensor, for which the accuracy should be within 1 mL using a precision syringe. 6) If the volume calibration method with a precision syringe is used then the test volumes should be checked at different frequencies to simulate the range of $\dot{V}$ likely to be encountered during testing, taking care not to exceed the linear $\dot{V}$ range of the device (see *Calibration procedures* section).

Table 3. – Recommended ranges of target parameters during assessment of the overall performance of infant pulmonary function test equipment

	Range	Minimum*	Accuracy %
Respiratory frequency breaths·min^{-1}	10–80	1	±2^{+}
Tidal volume mL	10–100	1	±2.5
Lung volume mL	50–300	2	±5
Compliance $mL \cdot kPa^{-1}$	2–200	0.5	±2.5
Forced flow $mL \cdot s^{-1}$	See table 2	2	±2.5
Resistance $kPa \cdot L^{-1} \cdot s$	0.5–10	0.01	±5

*: greatest acceptable error in the presence of small signals; $^{+}$: data are presented as $L \cdot min^{-1}$ and not %.

Frequency response of the entire equipment

The frequency response of a measurement device is defined as the ability to accurately convert a physiological signal to an electrical signal, being faithful with respect to both the magnitude (attenuation) and temporal relationship (phase lag) to dynamic events over a defined frequency range [12–15]. The required frequency response of the pressure and flow transducers is given below. However, since the pressure and flow transducers are connected to the face mask *via* ports, valve systems or tubes that may influence their performance at different frequencies, the frequency response of the entire integrated system must also be assessed. This is particularly important when assessing equipment for use in intubated infants as the ET tube may have a major impact on the frequency characteristics. Furthermore, since it is likely that the equipment may be attached to different sizes of ET tube according to age and weight of infant studied during clinical use, it is essential to carry out these assessments using the full range of relevant tubes. The smaller the tube, the greater the impact usually is. The way in which such assessments can be performed is described elsewhere [7, 17–21]. 1) The frequency response of the equipment as an integrated unit must be characterized and documented by the manufacturer, with details given of individual components if appropriate. Adequate documentation includes the method of determination and the frequency response expressed as a Bode plot. The equipment, under operating conditions, is expected to have a response error of within ±0.5 dB at 10 Hz (*i.e.* within 7±6%). The frequency response of the equipment should be regularly checked based on procedures described elsewhere [7, 17–21]. 2) Equipment for newer techniques including oscillation mechanics may require higher fidelity. However, the important factor for such measurements is that the frequency response of pressure and flow transducer systems be matched over the frequency range of interest, *i.e.* it is not essential that they both be flat so long as they are the same. This is because impedance is calculated by dividing pressure by $\dot{V}$ in the frequency domain, so, in principle any imperfections in the frequency responses will cancel out so long as they are identical. 3) In order to optimize, the frequency response of the whole equipment, tube connectors should be as short and stiff as possible and the frequency response of the signal transducers should be tested with the connecting tubes in place.

Assessment of the performance of infant pulmonary function test equipment

Manufacturers should not only state the physical characteristics of the integrated equipment as a unit (see above), and the appropriate individual components (*e.g.* signal transducers (see below)), in terms of frequency response, dead space and resistance but also document the overall performance. Thus they should demonstrate that the target measurement parameter (*e.g.* airway resistance, lung compliance, lung volume or forced flows) can be determined with a specified accuracy [7] over the full physiological range of values for the parameters in question and at various respiratory frequencies. The ranges that usually occur in infants are summarized in tables 1–3. Table 3 gives some recommendations regarding how accurately equipment should be able to measure selected parameters of respiratory function in infants. These limits depend not only on the PFT equipment but also who on the ability of an infant lung model to reproduce given volumes, $\dot{V}$ and resistance accurately [7].

Since relatively few centres have the expertise or necessary equipment to undertake a full equipment assessment, it is recommended that all commercially available systems should be validated by an independent source and the results presented in a published format. Mechanical infant lung models capable of testing infant pulmonary function equipment are extremely difficult to build. Their performance has to be validated and described in detail before they can be used to test the overall performance of infant PFT equipment. Recommendations regarding equipment assessment [7, 8 - pp.77–79], together with a description of a validated infant lung model [7], have been published recently.

Calibration procedures

Although an essential part of daily quality control, errors can easily occur during the calibration procedure, thereby invalidating subsequent measurements. It is, therefore, important to remove the variability of user calibration from infant PFTs in as far as is possible. Some recommendations can be summarized as follows. For further details of calibration techniques, the reader is referred to previous recommendations [8 - p. 77–79]. 1) Provision of a computer-driven calibration system is recommended provided there is also the facility for the user to apply test standards for the purpose of verification. 2) The use of electrical calibration is to be discouraged since the majority of factors (temperature, ambient conditions, position, *etc.*) affect the transducers but not the analogue-to-digital (A/D) converter or analogue electronics. Furthermore, electrical calibration does not allow any leaks in transducers or their tubing to be detected. 3) Although disposable flowmeters are usually supplied in "precalibrated" form, it is essential that the user regularly verifies the accuracy of the recordings using a precision syringe over the full range of $\dot{V}$ likely to be encountered. Although users often tend to check such devices using a range of volumes, it should be stressed that, if the linearity of the device is to be assessed, a calibrated syringe pumped at different speeds to cover low, medium and high $\dot{V}$ across the linear range gives the best guide to accuracy of performance. As mentioned in the *Frequency response of the entire equipment* section, it is essential that such verification is performed while the flowmeter is attached to an appropriately sized ET tube if it is to be used in intubated infants. 4) Factory calibrations should occur over many data points. A three-point calibration will not reveal alinearities or hysteresis. Sophisticated techniques that use continuous waveforms, including impulse response techniques, swept frequency response techniques, etc. now exist for calibration. 5) Daily calibration is sufficient for the latest technology in pressure measurement devices, as changes in ambient conditions simply need to be referenced. However, this is not sufficient for $\dot{V}$ measuring devices that are subject to influence from humidity, temperature, changing gas composition *etc.* Such devices need calibration or verification prior to every

test and ideally on an hourly basis if being used "in-line" for continuous monitoring in the ICU. 6) Pressure manometers are usually very stable but should be checked on a regular basis using a certified electronic manometer. The use of water manometers is to be discouraged due to their potential for misuse [8 - p. 78].

Data acquisition

Lung function equipment is mostly computer-driven *via* digital-to-analogue (D/A) outputs. Electrical signals from pressure and flow transducers are collected *via* an A/D board. The specifications of A/D conversion are critical for accurate lung function measurements. Computer control may also be achieved through digital intake/output lines.

Sampling rate

1) A sampling rate of 200 Hz should generally be used during infant PFTs (recommendation: ≥40 dB at any frequency exceeding half the sampling rate. This ensures that the sampling theorem is nominally met (see *Appendix 2*, [8 - p. 58]. 4) If anti-aliasing (low-pass) filters are used [8 - p. 63], the filter characteristics should not influence the amplitude or phase of the measured signal in the range specified above. It must be remembered that it is crucial to pass the analogue signal through anti-aliasing filters with appropriate frequency cut-offs prior to sampling in order to satisfy the Shannon sampling theorem and avoid the potentially insidious problem of aliasing (see *Appendix 2*). 5) The numerical and analytical integrals over a half period of a 10-Hz sinusoid should not differ by >0.1%. The trapezoidal method can be used successfully at high sampling rates such as 200 Hz. At substantially lower rates, a more sophisticated method such as Simpson′s rule may be necessary.

Resolution and accuracy

In order to digitize analogue voltage signals from a signal transducer, data are sampled by an A/D converter that maps a specified voltage range into a number of equally spaced values (bins). The number of bins depends on how many bits the A/D converter has. A 12-bit A/D converter (currently the most common type) has 4,096 bins so that it can, for example, resolve a range of -10–10 V into ~5-mV steps. A/D converters with greater numbers of bits (*e.g.* 14, 16 or 20) are also readily available and possess commensurately greater resolution. It is crucial to make sure that the incoming voltage signal from the transducer occupies as much of the allowable voltage range of the A/D converter as possible so that discretization error is minimized. For example, if a 12-bit A/D converter is used to sample a flow signal varying between -100 and 100 $mL.s^{-1}$, the maximum resolution that the stored samples can have is 0.049 $mL{\cdot}s^{-1}$ (200/4,096) provided the flow signal is amplified so that -100 and 100 $mL{\cdot}s^{-1}$ correspond to the lowest and highest voltages that the A/D converter can handle. By contrast, if the flow signal varies between -2,000 and 2,000 $mL{\cdot}s^{-1}$ (as is required, for example, during the RVRTC technique for measuring forced expired flows in infants), the best resolution that can be hoped for is ~1 $mL{\cdot}s^{-1}$. This may introduce problems with obtaining a true zero flow, and hence drift of the volume baseline. In such circumstances, special software to stabilize the volume signal (*e.g.* the use of a dead band in the flow signal) may be required. If greater resolution is required, an A/D converter with >12 bits must be used. The ratio of the largest to the smallest voltage change that the A/D converter can resolve thus becomes a critical issue. In summary, for infant PFTs, the task force currently recommends minimal specifications as follows: 1) the minimum resolution of the A/D converter should be ≥12 bits; 2) a greater dynamic range and/or rezeroing option should be available in cases in which signals are at risk of saturating electronic circuits; and 3) the smallest detectable signal should be ≤0.1% of the specified full scale, *i.e.*, if a flowmeter with range of 0–1,000 $mL{\cdot}s^{-1}$ is used, it must be possible to measure with a resolution of 1 $mL{\cdot}s^{-1}$.

Output

External provisions for handling raw data enable the user to verify the system by other means and to compare the various algorithms used by different systems. This is an invaluable means of detecting systematic errors and improving overall quality control and an essential part of any infant lung function testing system. 1) There should be an output of either raw or processed signals. These may be analogue or digital (serial or parallel). Type, format, voltage range, raw or processed signal, *etc.*, must be specified in the operator′s or service manual. 2) Although this facility is becoming increasingly available, it is often a relatively complex and time-consuming procedure that requires simplifying for more general use. Without the ability to make direct comparisons of data analysis between different systems, highly significant discrepancies and errors in the algorithms and signal processing may go undetected for years [22].

Signals to computer interfacing (digital-to-analogue outputs)

Most PFT measurement procedures are computer-driven. Valve closures or the start of signal acquisition are usually regulated through D/A outputs. These D/A-regulated valves are highly critical with regard to safety, especially if they occlude the airway opening, modulate the gas concentration of the inspired air or regulate rapid chest compression. D/A-regulated valves must meet the safety regulations of the IEC (see also *Valves* section). D/A outputs are usually triggered by measured and processed analogue signals. Triggering algorithms such as inspiratory or expiratory efforts, thresholds and pressure plateaux are specified in the various other articles in the current series that describe the individual techniques [2–6]. However, some general issues are stated here. 1) Equipment should have the ability to override automation. However manual configuration of the D/A outputs or thresholds should be limited such that IEC safety standards are still met. For example, airway opening occlusion time should not exceed 3 s during respiratory mechanics measurements but may need to be up to 10 s during plethysmographic measurements of lung volume. 2) If lung function tests require passive inflation of the lung, this needs to be in accordance with the individual breathing pattern of the spontaneously breathing infant.

Conclusions

In this position paper, recommendations have been made regarding the minimal technical requirements for infant PFT equipment such that measurements can be performed with an acceptable degree of safety, precision and reproducibility. Minimal criteria for safety, documentation, hygiene, and testing and calibration procedures of PFT equipment have also been defined. Regarding the mechanical components of the PFT equipment, recommendations on $V_{D,app}$ face masks, frequency response, resistance, valve performance, leaks and connectors have been given. With respect to pressure and flow transducers, criteria have been proposed for location of transducers, baseline stability, the ranges necessary for measurements in infants, the linearization algorithm, frequency response, dead space, resistance, temperature correction and calibration procedures. For A/D conversion, the minimal sampling rate, accuracy and filtering have been defined, whereas for D/A outputs, minimal safety aspects and performance criteria have been discussed.

It is important to emphasize that the recommendations presented here do not necessarily invalidate previously published data collected with less automated systems or without all the proposed quality control. Nevertheless, manufacturers of infant respiratory function equipment should make every effort to comply with these guidelines in the future, since they represent the standards of paediatric health professionals in this field.

It is recognized that this document will need regular updating in response to advances in both technology and knowledge regarding the application and interpretation of these tests under different circumstances. In the meantime, every attempt has been made to avoid being too prescriptive in order to allow for future developments while at same time offering guidance as to minimum standards for those developing equipment and performing tests. These standards should facilitate international collaboration, the exchange of clinical Pulmonary function test data for second opinions and training.

Appendix 1: Safety aspects

For further information regarding the security of programmable electrical devices, contact the national representative of the IEC in the relevant country or the IEC, 3 rue de Varembé, P.O. Box 131, CH 1211 Geneva 20, Switzerland, Tel: 41 229190211; Fax: 41 229190300.

Appendix 2: The sampling theorem and aliasing

In addressing the question "How rapidly should a continuous signal be sampled?", one might intuitively suspect the answer to be "As rapidly as possible", given that the intention is to select a finite number of points from a curve that itself consists of an infinite number of points. Fortunately, however, this is not the answer for a continuous signal that is band-limited, which means that some frequency exists ($f0$) exists above which the signal has no power. (This is equivalent to saying that the magnitude of the signal's Fourier transform is 0 above $f0$).) Sampling frequency depends critically on the frequency content of the signal that is being sampled and hence on respiratory frequency. Typical tidal breathing data is band-limited to ~10 Hz, although this, of course, varies with respiratory frequency according to the size, age and health status of the infant.

The rule that "All the information in a signal band-limited to frequency $f0$ can be captured in its samples taken at a rate of greater than $2f0$" is known as Shannon's sampling theorem. The critical frequency $2f0$ is known as the Nyquist rate.

If has been established above how fast a band-limited signal should be sampled. An important question now arises, namely "What happens if sampling is not performed at twice the Nyquist rate $2f0$?" Obviously the highest frequencies in the signal cannot be properly captured by the samples. However, these high frequencies do not simply disappear. Instead, they reappear as artefactual lower frequencies in the sampled signal, a phenomenon known as aliasing. Aliasing is a particularly insidious problem because its presence can not be determined from the sampled data points once they have been collected, yet it may result in the appearance of significant components in the sampled data that were not present in the original continuous signal.

In order to demonstrate how aliasing works, a continuous sine wave of period T is shown in figure 1. An appropriate sampling of this signal would be with a period $<T/2$. However, if the signal were sampled with a period of $3T/4$, as shown in figure 1, and with only these samples available, it would be concluded that a much slower sine wave with a period of $3T$ as also shown, had been sampled. In general, if a signal is band-limited to $f0$ and sampled at a rate of $2(f0\text{-}g)$, then only those frequencies up to $f0$- g are properly characterized in the samples and any components in the original signal at a frequency of $f0\text{-}g+h$ appear in the sampled signal as a component of equal power at a frequency of $f0\text{-}g\text{-}h$, where g and h are positive quantities and $h<g$.

The only way to avoid aliasing is to sample above $2f0$. Practically, it is usually most convenient to impose a particular $f0$ in the continuous signal being sampled by first passing it through an analogue low-pass filter with appropriate frequency cut-off. Such filters are called anti-aliasing filters. It is important to note that antialiasing filters can never have an infinitely sharp cut-off. That is,

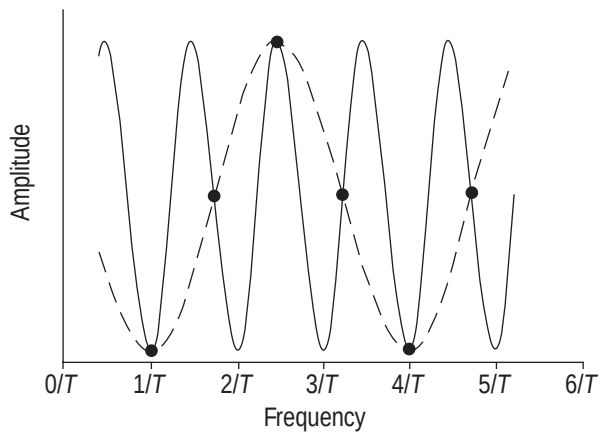

Fig. 1. – Aliasing. If a sine wave of frequency $1/T$ (———) is sampled at a rate of $4/3T$ (●), sample of a sine wave of frequency $1/3T$ (– – – –) are otained.

they can never simply let through all frequencies in the pass-band unattenuated while blocking all higher frequencies completely. In reality, such filters have a finite roll-off. The pass-band is defined as that frequency region over which the attenuation of the filter is <3 db (*i.e.* >50% of the original signal power is allowed to pass), whereas, above the pass-band, the attenuation falls off at a rate determined by the filter design. Thus, in practice, the sampling theorem can never be satisfied absolutely and so choices have to be made as to how much signal above the nominal pass-band can be tolerated. This then dictates the choice of anti-aliasing filter design and data sampling rate. Since it is difficult for the general user to recognize aliasing problems, it is important that manufacturers check their systems prior to release and offer reassurance on this subjects. However, if aliasing is suspected in any particular situation, a relatively easy way of testing for its presence is to resample the original continuous signal using a variety of different sampling rates and examine the frequency content of each sampled record. If aliasing is occurring, it would be expected that a frequency-dependent shift in the structure of the signal′s power spectrum would be seen as the aliased components move to different places according to the relationships between their true frequencies and the data sampling rates.

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