



Infant body composition through Air Displacement Plethysmography for Research and Clinical applications

- ▶ Gold Standard accuracy using whole-body densitometric principles
- ▶ Excellent test-to-test repeatability
- ▶ Fat and Fat-Free Mass measurements
- ▶ Fast test time (about 7 minutes total test time)
- ▶ Safe, non-invasive, and ideally suited for frequent testing
- ▶ Accommodates most infant behaviors (crying, movement, etc.)



Researchers widely recognize that the accurate assessment and tracking of body composition in the critical period immediately following birth and throughout early life can provide key information in both clinical and research settings. This includes developing nutrition guidelines, NICU release criteria, dosage requirements, and acquiring normative growth data.

The PEA POD is the world's only Air Displacement Plethysmography system using whole body densitometry to determine body composition (Fat and Fat-Free Mass) in infants weighing between 1 and 8 kg.

Each PEA POD is a complete turnkey system based on the same Gold Standard operating principle as hydrostatic (underwater) weighting.

The PEA POD is extremely simple to use and does not require a license to operate. It is also completely non-invasive and ideal for frequent, longitudinal tracking of body composition.

Applications

The PEA POD is an important tool that enables a better understanding of fetal programming, the assessment of efficacy of nutritional therapies, and the development of normative body composition data among other applications. It is used in a wide variety of segments:

- ▶ Academic and Medical Research
- ▶ Neonatology Departments
- ▶ Nutrition Assessment Centers

Proven Accuracy

The PEA POD uses the principles of whole-body densitometry to determine body composition. In this technique, body mass and body volume are measured (both performed within the unit). Once body density ($\text{Density} = \text{Mass}/\text{Volume}$) is determined, the PEA POD uses known (or user customized) densitometric equations to calculate percent Fat and Fat-Free Mass. The accuracy of the PEA POD has been shown to be very high against reference techniques in a number of research publications.

Test Sequence

The PEA POD is extremely simple to operate, with software prompts guiding the operator through each step of the process. From start to finish, a PEA POD test takes about 7 minutes:

- ▶ Basic information is entered into the software program while the automatic volume calibration takes place
- ▶ Body mass is measured with a high precision electronic load cell scale embedded in the unit (accuracy is assured by calibrations at regular intervals)
- ▶ Infant is placed in the PEA POD test chamber tray and enters the warmed test chamber for a 2-minute volume measurement. During the entire period the infant is clearly visible at all time through the unit window.
- ▶ Test results are computed, displayed and printed



The infant is easily placed in the warmed test chamber



High precision scale embedded in the unit



The PEA POD is a complete turn-key system and can be rolled to various locations

Software Features

- ▶ Longitudinal reports of body composition changes
- ▶ Customizable body composition ranges
- ▶ Customizable density models based on ethnicity and gender
- ▶ Data export capability

Maintenance

The PEA POD is designed for durability over time. Each PEA POD has an internal diagnostic test function to analyze system performance and provide feedback to service personnel. Extended service agreements are available to insure optimal performance for long term use.

Safety

The PEA POD is designed and manufactured in compliance with the strictest quality standards required for medical devices.

The PEA POD uses a combination of electronic, temperature, and carbon dioxide sensors to activate visual and audible alarms to alert the user of any abnormal function. The PEA POD has a HEPA filter to protect against airborne disease transmission.

The PEA POD has also a redundant safety system, consisting of a Cancel Test button and an Emergency STOP knob the operator can use to immediately stop/cancel a test and remove the subject.



The infant is clearly visible at all time through the unit window



The operator can use an Emergency STOP knob to interrupt a test and to immediately open the test chamber

User-friendly and straightforward software interface

TEST DATE	DATA	MEAN	+1 SD	-1 SD
11/10/2003 12:21:19 PM	9.9	---	---	---
11/12/2003 1:15:00 PM	9.8	---	---	---
11/19/2003 12:36:00 PM	9.7	---	---	---
11/19/2003 12:42:00 PM	10.1	---	---	---
11/21/2003 11:47:00 AM	9.5	---	---	---
11/24/2003 12:36:00 PM	9.9	---	---	---
12/1/2003 1:47:00 PM	10.5	---	---	---
12/8/2003 11:36:00 AM	10.4	10.9	20.5	1.2
12/19/2003 11:15:19 AM	10.3	12.5	21.8	3.1
12/22/2003 11:02:00 AM	12.8	14.1	23.1	5.1
12/29/2003 1:22:00 PM	14.2	15.7	24.4	7.0
1/5/2004 10:31:00 AM	17.5	17.3	25.7	8.9
1/19/2004 11:19:00 AM	20.1	20.5	28.2	12.7
2/2/2004 11:41:00 AM	23.5	23.6	30.8	16.5
2/16/2004 12:23:00 PM	27.6	28.8	33.4	20.3
3/1/2004 11:23:00 AM	31.1	30.0	35.9	24.1
3/15/2004 10:57:00 AM	34.6	31.5	37.0	28.0
3/29/2004 11:02:00 AM	36.4	31.6	36.9	28.3
4/12/2004 11:20:00 AM	35.4	31.7	36.8	28.6
4/26/2004 12:02:00 PM	34.2	31.8	36.7	28.8

Reports can be created showing longitudinal changes in body composition over time with reference values for comparison

Validation studies

- *Body-composition in infancy: air-displacement plethysmography compared with a reference 4-compartment model* [K. Ellis, at al. *American Journal of Clinical Nutrition*, 85(1):90-95, 2007]
- *Validation of a new pediatric air-displacement plethysmograph for assessing body composition in infants* [G. Ma, at al. *American Journal of Clinical Nutrition*, 79(4):653-660, 2004]
- *A new air displacement plethysmograph for the measurement of body composition in infants* [A. Urlando, at al. *Pediatric Research*, 53:486-492, 2003]

Longitudinal Body Composition Studies

- *Longitudinal Body Composition Data in Exclusively Breast-Fed Infants: A Multicenter Study* [DA Fields, JM Gilchrist, PM Catalano, ML Gianni, PM Roggero, F Mosca. *Obesity (Silver Spring)*. 2011 Feb 10. [Epub ahead of print]
- *Quality of growth in exclusively breast-fed infants in the first six months of life: an Italian Study* [P Roggero, ML Gianni, A Orsi, P Piemontese, O Amato, N Liotto, L Morlacchi, F Taroni, DA Fields, PM Catalano, F Mosca. *Pediatric Research*. Aug 24, 2010 [Epub ahead of print]
- *Body composition from birth to 4.5 months in infants born to non-obese women* [A Carberry, P Colditz, B Lingwood. *Pediatric Research*. 68(1):84-8, 2010]

Nutrition and Growth Studies

- *Influence of protein and energy intakes on body composition of formula-fed preterm infants after term* [P Roggero, M Gianni, O Amato, A Orsi, P Piemontese, F Mosca. *Journal of Pediatric Gastroenterology and Nutrition*, 47(3):375-378, 2008]
- *Postnatal growth failure in preterm infants: recovery of growth and body composition after term* [P Roggero, ML Gianni, O Amato, A Orsi, P Piemontese, B Cosma, L Morlacchi, F Mosca. *Early Hum Dev*. 2008 Aug;84(8):555-9].

Technical Specifications

Tests

Total Weight, Fat Mass, Fat-Free Mass, Body surface area, Thoracic Gas Volume (TGV) estimate

Hardware

Dimensions	156x80x122 cm
Weight	141 kg
Temperature	20-27°C (operating); -21-75°C (storage)
Humidity	20%-70% (non-condensing)

Standard Packaging Includes

PEA POD unit, calibration kit, user manual

Electrical requirements

Voltage 110-240V ±10%; 50/60Hz

Safety and Quality Standards

Class I Equipment, Type BF. Equipment has received FDA 510(k) clearance and complies with MDD (93/42 EEC), EN 60601-1 (Safety) and EN 60601-1-2 (EMC)

The COSMED USA, Inc. quality management system is certified to the ISO13485:2003 standard



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