

Embletta™ pds

SMART

SLEEK

COMPACT

CONVENIENT



Embletta™ pds

The Embletta PDS is a digital recorder offering researchers and clinicians a complete system from diagnosis to treatment. This recorder's diagnostic features and its software, Somnologica for Embletta, is an unbeatable combination that allows users to study Sleep Disordered Breathing (SDB) with unparalleled precision and ease. The Embletta helps users determine the efficacy of treatment with the ResMed's AutoSet™ Interface and provides greater convenience with the Embletta Go for Palm™. Unlike any other product, the Embletta is a high quality system pursuing highly sensitive, specific and yet cost effective methodology for diagnosing SDB.



Embletta PDS is a Truly Flexible System

Embletta can be adapted to a variety of studies with variable proxy connections all depending on the users' needs. Beyond its adaptability with proxies it can be combined with a Palm™ and an AutoSet.

Embletta provides the user with an outstanding solution in SDB with the Respiratory Inductive Plethysmograph (RIP) technology and the exact nasal flow, pressure and snore signals via a nasal cannula pressure transducer. Other signals that complete Embletta's diagnostic precision are position and activity, LM, oxygen saturation, pulse and oral flow. It also features an event button. The Embletta can also be connected to the AutoSet to measure flow, pressure, leak and tidal volume.

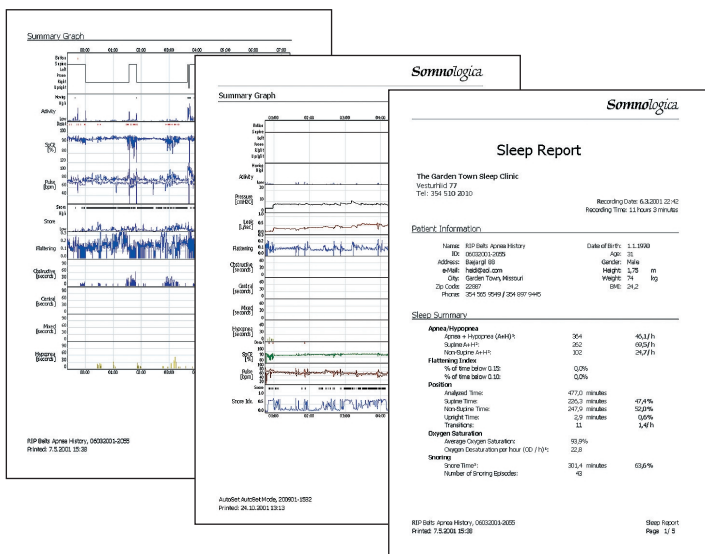
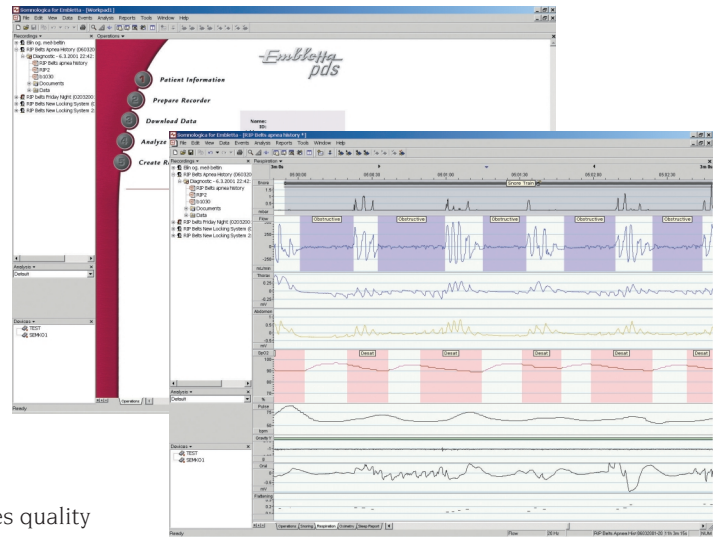
The Embletta PDS is a pocket sized digital recording device designed to diagnose SDB. This recorder offers unmatched diagnostic acuity in a lightweight, compact design that is truly easy to use. Powered by two alkaline or rechargeable batteries, the Embletta has an internal flash memory that can store a full night's comprehensive respiratory data. One of Embletta's benefits is that the patient can easily prepare for a sleep study in the comfort of his home.

XactTrace

The XactTrace Respiratory Inductive Plethysmograph (RIP) is an important addition to the Embletta system for increased quality of respiratory effort measurement. The XactTrace sensor generates a high quality signal that is a measure of the chest/abdomen circumference. This signal gives a qualitative measure of ventilation and flow. The XactTrace delivers a highly sensitive and reliable tracing. Conveniently, they can be custom fit to each patient. These hygienic, single use belts can be custom fit to each patient and no effort goes into cleaning and maintenance.

Somnologica for Embletta

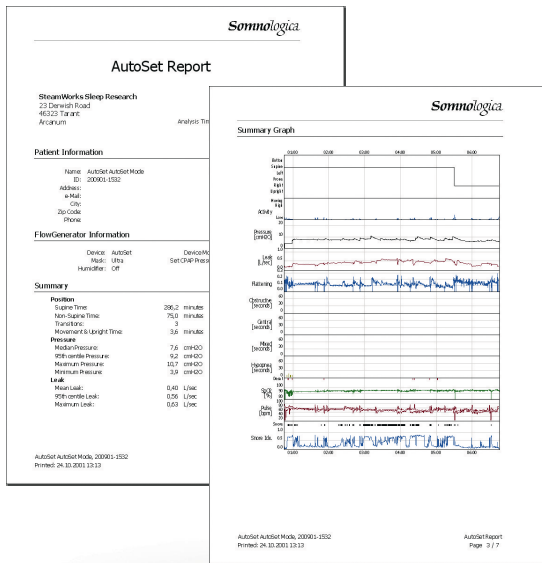
Somnologica for Embletta is a state of the art software application that perfectly complements the clinician or the researcher. While enhancing the professional's ability to study and diagnose SDB more precisely, this ingenious software streamlines the steps in the sleep study process and offers a highly developed user interface. Among its key features is an Operation Sheet that clearly guides you through preparing the device, downloading, analyzing recordings, and then creating reports. Somnologica for Embletta has been praised by numerous satisfied customers for its automatic respiration and PLM analyzer. This software uses quality analysis that calculates more signals than are recorded such as nasal flow and snore pressure. Somnologica allows users to set the analysis parameters and to customize reports. It even allows the use of hot keys to manually score and edit a study. The report function summarizes the analysis and includes descriptive graphics of the night's events. The sleep report gives detailed information on respiration events, including statistics, graphs and tables. The AutoSet report is used to summarize therapy results while the PLM report shows limb movement patterns. The Recording Manager organizes your patients and studies, while the Device Manager detects individual devices and their status. Embletta recordings can also be analyzed with the Somnologica 3 Embla software, offering additional capability and flexibility.



Embletta Go for Palm™

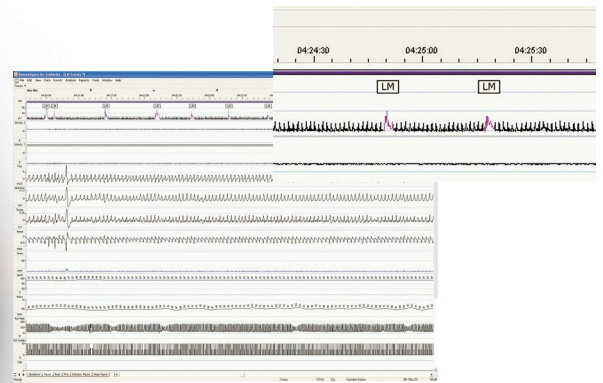
Embletta Go for Palm allows you to prepare an ambulatory Embletta study in the palm of your hand. Embletta Go for Palm is a standalone application that features pre-installed Embletta Go for Palm software on a Palm™ handheld device. As well as guiding you through the steps in preparing the Embletta, Embletta Go for Palm also has real-time signal visualization that enables users to monitor signal quality during start-up and make any sensor placement adjustments.





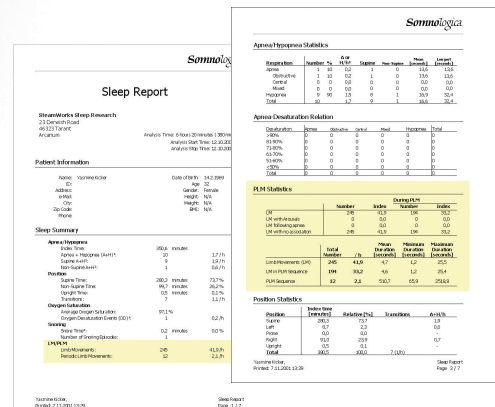
AutoSet Interface

The Embletta AutoSet Interface connects the Embletta to ResMed's AutoSet generator. The AutoSet is an automatic titration device for the treatment of Obstructive Sleep Apnea (OSA). The AutoSet technology is a patented algorithm that responds to a variety of parameters including the inspiratory flow-time curve, the most reliable way to detect impending upper airway collapse. The Embletta AutoSet Interface reads the digital information about the inspiratory flow-time curve as well as pressure, snore, and leak to the Embletta. This is then stored with the other signals Embletta records, including respiratory effort, body position and saturation. The AutoSet Report in Somnologia for Embletta summarizes the data acquired from both devices.



Limb Movement

The Embletta can measure limb movement activity to help in the diagnosis of Periodic Limb Movement Disorder (PLMD). The Somnologia software automatically analyzes the EMG signals and detects leg movements and PLM sequences. Information about PLM is added to the reports if this signal is recorded.



Embletta Measures

- Flow/Pressure (nasal cannula/mask)
- Oral Flow (thermistor)
- SpO₂ average (oximeter)
- SpO₂ beat-to-beat (oximeter)
- Pulse rate (oximeter)
- Pulse waveform (oximeter)
- Body position
- Snore (by nasal pressure or by neck vibration sensor Piezo element)
- Abdominal movement (by XactTrace RIP Belts or by Piezo element sensors)
- Chest wall movement (by XactTrace RIP Belts or by Piezo element sensors)
- Activity
- Flow limitation
- Event marker

Embletta Specifications

Dimensions (H x W x D)	0.8" x 2.5" x 4.9" / 20 x 65 x 124 mm
Weight	Embletta 0.24lb/110g, batteries: 0.1lb/46g
Batteries	2 AA alkaline batteries (12 hours duration) 2 AA rechargeable batteries (12 hours duration)
Housing construction	Injection molded plastic, covered with aluminium shields.
Number of channels	7 sensors, 14 derived signals
Recording capacity	Up to 12 hours (16MB memory)
Maximum patient leakage current	10 μ A, complying with EN6060-1
Operating temperature	40°F to 120°F (+5°C to +50°C)
Storage temperature	0°F to 120°F (-20°C to +50°C)
Humidity	90% non-condensing
IEC 601-1 Classifications	Class IIa, Type BF

Somnologica for Embletta™, minimal system specifications Windows® XP, Windows® 2000 SP1, Windows® NT4 SP6a, Windows® 98, Windows® ME, Pentium II 350MHz, 128MB memory, 6GB IDE disk, CD-ROM, one serial port, 16MB graphics adapter, 17" monitor.

Somnologica for Embletta™, optimal system specifications Windows® XP, Windows® 2000 SP1, Pentium III 1GHz, 256MB memory, 18GB SCSI disk, CD-ROM, CD-Writer, two serial ports, 64MB graphics adapter, 21" monitor.

Embletta PDS is manufactured by Flaga hf. Medical Devices, Reykjavik, Iceland, and distributed by ResMed. The manufacturer works in accordance with the ISO 9002 quality system and has the authority to mark the products with the CE mark (CE 0413). The products comply with the following standards: EN 60601, ISO 9002 / EN 46002 and fulfill the MDD annex VII. Embletta, Embla, and Somnologica are trademarks of Flaga hf. AutoSet is a trademark of ResMed Ltd. Palm is a trademark of Palm Computing Inc.



- Diagnose more accurately with Embletta's exceptional SDB diagnostic features:
 - Nasal Flow and Snoring from Cannula (pressure transducer)
 - 2 Respiratory Effort Signals (XactTrace or Piezo)
 - Oxygen Saturation and Pulse
 - Oral Thermistor
 - PLM (optional)
 - Built-In 3-D Body Position and Activity Sensor
 - 9 Physiological Channels to 16 Traces in total
- Simplify data collection and data download with Embletta's large internal flash memory
- Maximize resources with Embletta's full ambulatory capability
- Enhance patient comfort with the lightweight, easily worn design

Embletta's complete system:

- Allow the highly developed Somnologica for Embletta user interface to guide you through the sleep study process with its unique Operation Buttons
- Employ Somnologica for Embletta's Automatic Respiration Analyzer to support manual analysis and editing
- Benefit from a more exact respiratory effort trace with the XactTrace
- Detect your patient's leg movements with the PLM sensor
- Confirm the efficacy of treatment using the AutoSet Interface
- Experience the flexibility of preparing sleep studies on the Embletta Go for Palm™