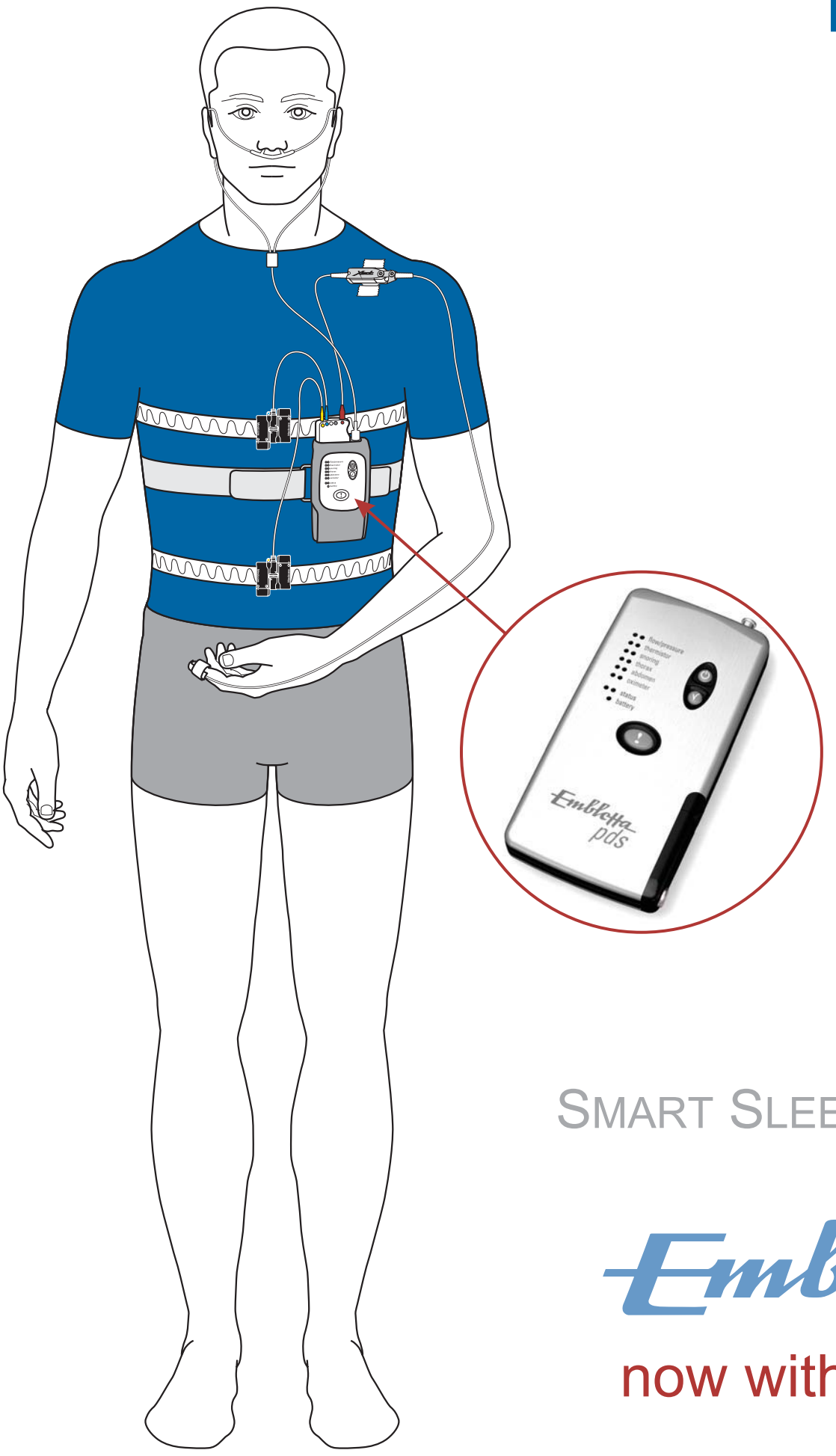
Medcare



SMART SLEEP SYSTEMS

Embletta®

now with ♡ EKG

The Embletta® is a pocket-sized digital recorder that is a complete system for diagnosis of sleep disordered breathing (SDB) in the sleep clinic, hospital, or home. With its advanced diagnostic features and the Somnologica for Embletta software, the Embletta is a highly sensitive, yet cost effective, method for diagnosing SDB.

Embletta: A Truly Flexible System

The Embletta offers unmatched diagnostic accuracy in a lightweight, compact design that is easy to use. Powered by two alkaline or rechargeable batteries, the Embletta has an internal flash memory that can store comprehensive respiratory data. The Embletta can be adapted to a variety of ambulatory and online studies by using its variable proxy connections. Embletta's diagnostic signals include position and activity, leg movement, oxygen saturation, pulse, oral flow, event button and two respiratory effort signals through the XactTrace Respiratory Inductive Plethysmograph (RIP) sensors. Optional signals include leg movement, EKG and EEG. Not only an outstanding SDB diagnostic solution, it can also be used to determine the efficacy of treatment. The Embletta can be directly connected to a ResMed AutoSet® flow generator where flow, pressure, leak, and events from the AutoSet are added to the signals recorded by the Embletta. Exact nasal flow and pressure snore signals are obtained via a nasal cannula.

Embletta

Somnologica for Embletta

Somnologica for Embletta software helps professionals study and diagnose SDB more precisely. With its highly developed user interface, the software streamlines the steps in the sleep study process. The main Operations Sheet clearly guides you through preparing the device, downloading, analyzing recordings, and creating reports. Somnologica for Embletta also features a proven automatic respiration and Periodic Limb Movement (PLM) analysis that allows the analysis parameters to be set and detailed reports customized. It includes easy scoring and editing tools plus managers for recordings and devices. Embletta recordings can also be analyzed with Somnologica Studio, the Embla software, offering additional capability and flexibility.

Data Management Module

The Data Management Module helps you maintain and manage your patient records. The module enables you to store and easily access clinical outcomes and patient information. Flexible search features allow you to quickly locate patient groups or records of interest, enabling you to assess trends or target areas for intervention.

EKG and Embletta

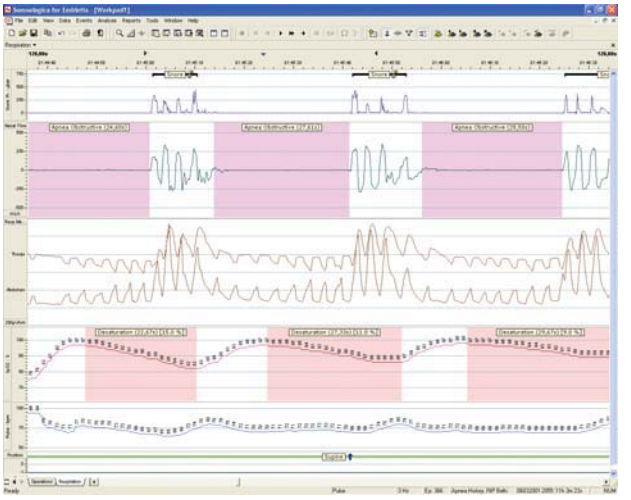
The Embletta EKG Extension solution measures EKG and can be used to help identify cardiac arrhythmia using disposable electrodes, snap-on cables, and a special EKG Extension proxy. The X30 EKG proxy is used with XactTrace respiratory effort sensors.

EEG and Embletta

The Embletta EEG Extension solution measures a single channel EEG and can be used to identify Respiratory Related Arousals (RERA) and to help verify when the patient is asleep. The X50 EEG solution uses electrodes, a special EEG Extension proxy and XactTrace respiratory effort sensors.

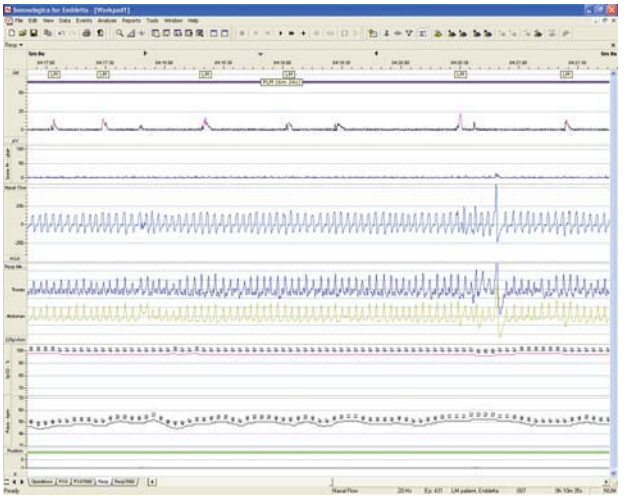
XactTrace™

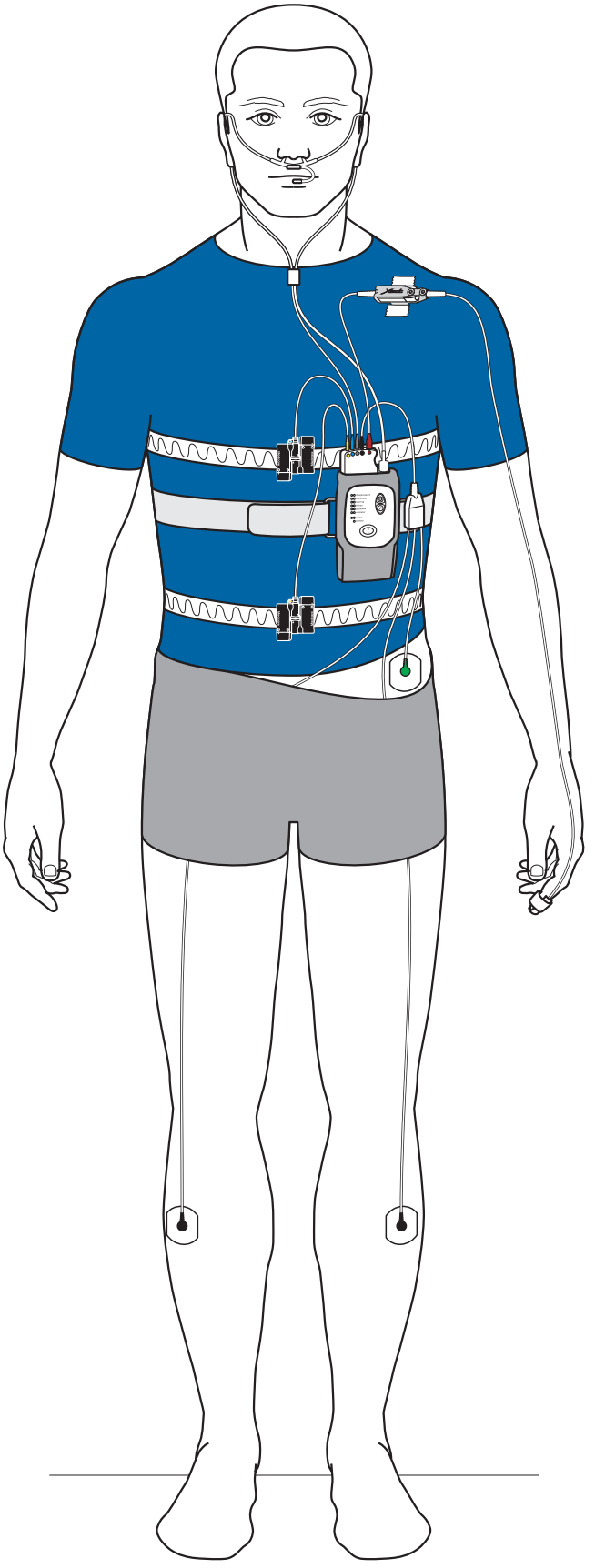
The XactTrace Respiratory Inductive Plethysmograph (RIP) is an important addition to the Embletta system for increased quality of respiratory effort measurement. The XactTrace sensor generates a high quality signal that is a measure of the chest/abdomen circumference. This signal gives a qualitative measure of ventilation and flow. The XactTrace delivers a highly sensitive and reliable tracing. Conveniently, the XactTrace belts can be custom fit to each patient. These belts are very hygienic and user friendly and are available both in single use and reusable versions.



Limb Movement

The Embletta can measure limb movement activity to help in the diagnosis of Periodic Limb Movement Disorder (PLMD). The Somnologica for Embletta 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.

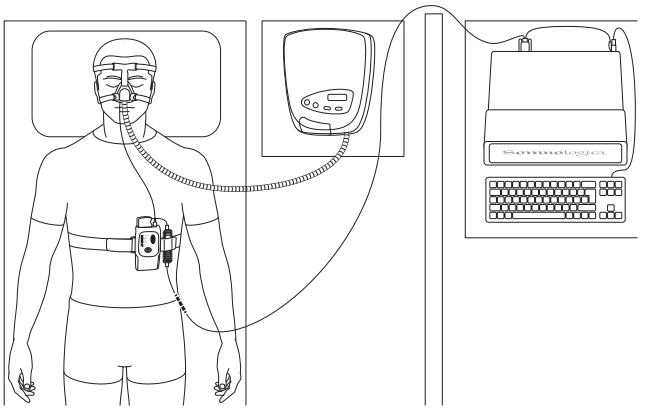




Embletta Setup

Download in Under 3 Minutes

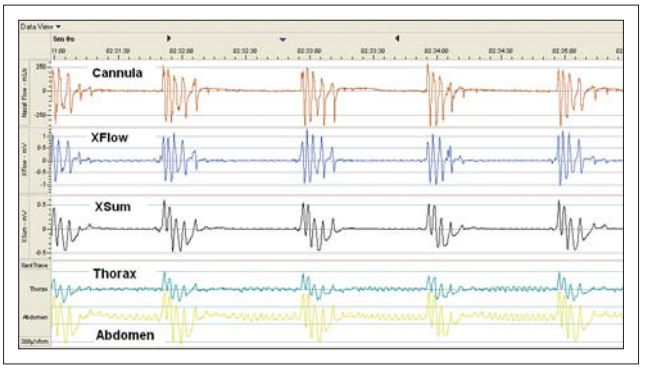
Now, your work is more efficient than ever before. Reduce the Embletta download time of a regular sleep study to only 2 - 3 minutes for a full night's study. The USB Download Cable for the Embletta uses USB technology to connect the system to your computer. It's also more convenient, as USB technology has become the most common method for connecting computers to all types of devices.



Online Interface

Online Interface

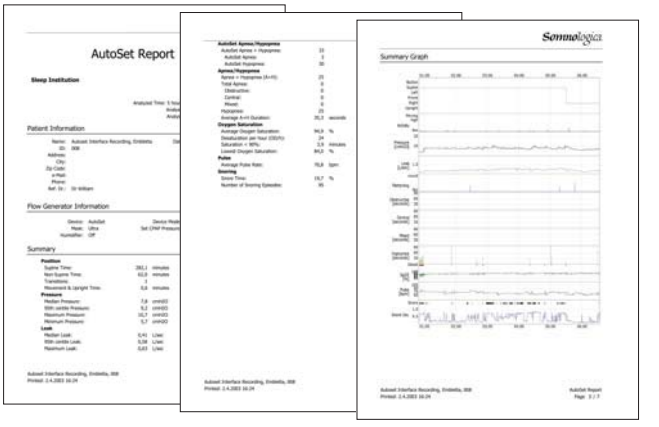
The Embletta Online Interface allows an attended, online study with the Embletta. The Online Interface connects the Embletta to a computer and has a quick-release connector which allows easy disconnection from the computer. The online solution provides the same parameters as the Embletta diagnostic studies. With the Online Interface it is possible to view the signals online while recording and to monitor mask pressure during a CPAP study.



XFlow compared to cannula Flow signal

XFlow

XFlow is an efficient and unintrusive way to get the flow information you need. When the output of the abdominal and thoracic signals measured by XactTrace is combined, the patient's inspiratory and expiratory flow can be measured. This semi-quantitative XFlow signal is comparable to linearized airflow signals acquired from nasal pressure transducers and a pneumotachograph signal.
Plus, XFlow optimizes patient comfort. Derived from the two respiratory signals, alone it can fully represent the patient's ventilation patterns without interfering with the CPAP mask or headgear. Combining the XFlow values with CPAP mask pressure measurements means you can assess flow and therapy pressure in the least intrusive way.



AutoSet Report

AutoSet Interface

The Embletta AutoSet Interface connects the Embletta to ResMed's AutoSet flow 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 sends the digital information about the inspiratory flow-time curve, as well as AutoSet pressure, snore, and leak to the Embletta. This data is stored with the other signals Embletta records and help verify the effectiveness of treatment. The AutoSet Report in Somnologica for Embletta summarizes the data acquired from both devices.

Operations Sheet

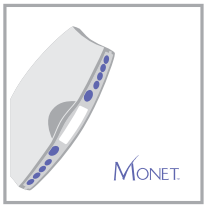
Workpad Area

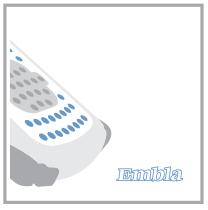
- Diagnose more accurately with Embletta's SDB diagnostic features:
  - nasal flow and snoring from cannula (pressure transducer)
  - 2 respiratory effort signals (XactTrace or Piezo)
  - oxygen saturation and pulse
  - oral flow from thermistor
  - XFlow from XactTrace
  - Periodic Limb Movement (optional)
  - EKG (optional)
  - EEG (optional)
  - built-in 3D body position and activity sensor
  - acquires up to 26 traces
- Maximize resources with Embletta's full ambulatory capability
- Enhance patient comfort with the lightweight design
- Fast USB download

EMBLETTA'S COMPLETE SYSTEM:

- Features the highly developed Somnologica for Embletta interface that guides you through the sleep study process
- Employs Somnologica for Embletta's automatic respiration analyzer and allows manual analysis and editing
- Benefits from a more exact respiratory effort with the XactTrace Respiratory Inductive Plethysmograph (RIP)
- Detects your patient's leg movements with the PLM sensor
- Confirms the efficacy of treatment using the AutoSet Interface
- Determines the effectiveness of a CPAP or ventilation therapy using XFlow
- Quickly searches for patient groups or records of interest by using the Data Management Module
- Measure EKG and relate it to the respiratory parameters
- Measure EEG and relate it to the respiratory parameters

Embletta®





SMART SLEEP SYSTEMS

EMBLETTA MEASURES	X10	X20	X30	X50
Flow/Pressure (nasal cannula/mask)	■	■	■	■
Oral flow (thermistor)	○	○	○	○
XFlow (by XactTrace RIP belts)	■	■	■	■
Snore (by nasal pressure)	■	■	■	■
Snore (by neck vibration sensor Piezo element)	○			
Flow limitation	■	■	■	■
Abdominal movement (by XactTrace RIP belts)	■	■	■	■
Chest wall movement (by XactTrace RIP belts)	■	■	■	■
SpO_2 average (oximeter)	■	■	■	■
SpO_2 beat-to-beat (oximeter)	■	■	■	■
Pulse rate (oximeter)	■	■	■	■
Pulse waveform (oximeter)	■	■	■	■
Body position	■	■	■	■
Activity	■	■	■	■
Event marker	■	■	■	■
Limb Movement		■		
AutoSet information	■	■	■	■
EKG			■	
EEG				■

○ = Optional

The Embletta systems are manufactured by Medcare, Reykjavík, Iceland. The Medcare Quality Management System complies with SS-EN ISO 9001:2000 and SS-EN ISO 13485:2003. Medcare certifies that the development, manufacture, sales and service of the Embletta systems are in conformity with Annex II of the Directive 93/42/EEC on medical devices.
The Embletta systems are certified to carry the CE mark (notified body number 0413). The CE mark is a declaration that the medical device is in compliance with the directive set forth by the European Union for medical devices.
For further information on the Embletta systems, please contact support@medcare.com.

Medcare Sidumuli 24, 108 Reykjavik, Iceland Tel: +354 510 2000 Fax: +354 510 2010 • Medcare GmbH Argelsrieder Feld 11, 82234 Wessling, Germany Tel: +49 (0) 8153 9066 30 Fax: +49 (0) 8153 9066 31 • Medcare Kon. Wilhelminaplein 13, 1062 HH Amsterdam, The Netherlands Tel: +31 20 346 0130 Fax: +31 20 346 0121 • Medcare Systems, Inc 55 Pineview - Suite 100, Buffalo, NY 14228 U.S.A. Tel: +1 (716) 691 0718 Fax: +1 (716) 691 1004

For further information, see www.medcare.com or contact sales@medcare.com

D-0305-022