



Medcare

SMART SLEEP SYSTEMS

Pathway ProgramsTM

Medcare Pathway Programs™

There is great demand for the diagnosis and proper identification of patients that could potentially have sleep disordered breathing. Physicians and medical professionals need efficient means to be able to properly determine the possibility of sleep disordered breathing (SDB). Medcare's unique Pathway Programs offer precise, yet easy to use systems for detecting SDB with flexible components to fit every environment.

- Detect Sleep Disordered Breathing
- Detect snoring
- Detect breathing instability
- Differentiate between central and obstructive apnea
- Use the activity and position sensor to estimate rest time
- Record oximetry optionally
- Simple and easy to use
- Minimize need for training
- Download, analyze and report in under 3 minutes

■ Components

Medcare knows one solution does not fit all. Pathway Programs feature a variety of components and options to suit your needs for detecting, diagnosing and controlling therapy of sleep disordered breathing. Plus, these components have all been designed to be comprehensive but incredibly easy to use. This means less time spent on training and using the system. The components come with a detailed written manual and a helpful hook-up card for patients. The software also simplifies the process with an intuitive user interface featuring familiar tasks. This makes it easy for anyone to use the software.

■ The Compass Software

The Medcare Compass Software is used to prepare the Compass recorders, download and analyze the study. It introduces a new type of user interface, designed for a simple and efficient workflow. By building on Medcare's strong software technology, this software frees up your time and lets you focus more on the patient. You can download, analyze, and make a report in less than 3 minutes. Plus, our proven analysis algorithms can analyze the recordings provided by the Compass recorder.

■ The Compass Recorder

The Compass lightweight recorder uses a quick, USB download and provides the most ergonomic solution for you and your patient. There are two models available.

Medcare
Compass

Sleep Clinic

Patient Information

Last Name:	Doe	Gender:	Male
First Name:	John	Date of Birth:	N/A
Patient ID:	123456789	Height:	1,78 m
Address:	Address 123	Weight:	95,0 kg
City:	53233 Large Town, TR	BMI:	30,0
Phone:	5433438098		

Recording Interval	Analyzed Interval
Date:	29.3.2003
Start Time:	22:22:27
Stop Time:	06:02:22
Duration:	459,9 minutes
	Start Time: 22:23:16
	Stop Time: 06:02:22
	Duration: 459,1 minutes
	Est. Rest Time: 448,5 minutes

Indices	Data Integrity
AHI: 7,4 Medium	Number of upright periods or device disconnections were 0 and accounted for 0,0 minutes
ODI: 37,1 High	Number of movement periods were 11 and accounted for 10,6 minutes that were excluded from analysis
Apnea Index: 0,9	Flow signal was valid for 100% of rest time
Hypopnea Index: 6,4	Oximetry signal was valid for 100% of rest time
RHI: 21,7%	
PBI: 5,9%	
Average Pulse Rate: 80,7 bpm	

Event Count

Apneas:	7
Obstructive Apneas:	5
Central/Mixed Apneas:	2
Hypopneas:	48
Desaturations:	128
RHI Periods:	169
Paradoxical Periods:	48
Breaths:	7247

Comments

Please note this patient's AHI.

Report Printed 19.3.2004 11:56:12

Example Report



The Compass Start Screen

■ Compass M10

This recorder is ideal for detecting Sleep Disordered Breathing, differentiating between central and obstructive apnea and using RMI to indicate patient breathing instability. The M10 is also a perfect fit for therapy control studies as flow is detected through the XactTrace RIP belts.

This device is based on respiratory movement acquired with Medcare's XactTrace RIP belts. It records thoracic and abdominal movement, position, activity, RMI and XFlow. Medcare's patent-pending RMI parameter gives an indication of a patient's breathing stability while XFlow is a semi-quantitative measure of inspiratory and expiratory flow derived from XactTrace.

■ Compass F10

This recorder is ideal for detecting SDB, snoring and using the flattening index to indicate flow limitation in the upper airway.

This device is based on nasal flow acquired with Medcare's nasal cannula. It also records snoring, position, and activity.



■ Extensions

- **Compass Oximeter Option:** Both devices offer the option of connecting an oximeter to complement the recording. The Compass oximeters also connect to ResMed ResLink technology.
- **Compass M10 Pediatric Option:** The Pediatric Option includes Medcare's disposable XactTrace belts to fit small individuals and children.
- **Compass M10 Custom-Fit Belt Option:** The Custom-Fit Belt Option includes Medcare's disposable XactTrace belts plus velcro straps to better suit patients of various sizes.

Recorded Signals from Compass M10 & Optional Oximeter

Abdominal Movement
Thoracic Movement
XFlow
Activity
Position
SpO2 Quality
SpO2 Beat-to-Beat
Plethysmograph
RD Quality
SpO2



Recorded Signals from Compass F10 & Optional Oximeter

Nasal Pressure
Nasal Flow
Flattening
Snore
Activity
Position
SpO2 Quality
SpO2 Beat-to-Beat
Plethysmograph
RD Quality
SpO2





SMART SLEEP SYSTEMS

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- Detect snoring
- Detect breathing instability
- Differentiate between central and obstructive apnea
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- Record oximetry optionally
- Simple and easy to use
- Minimize need for training
- Download, analyze and report in under 3 minutes

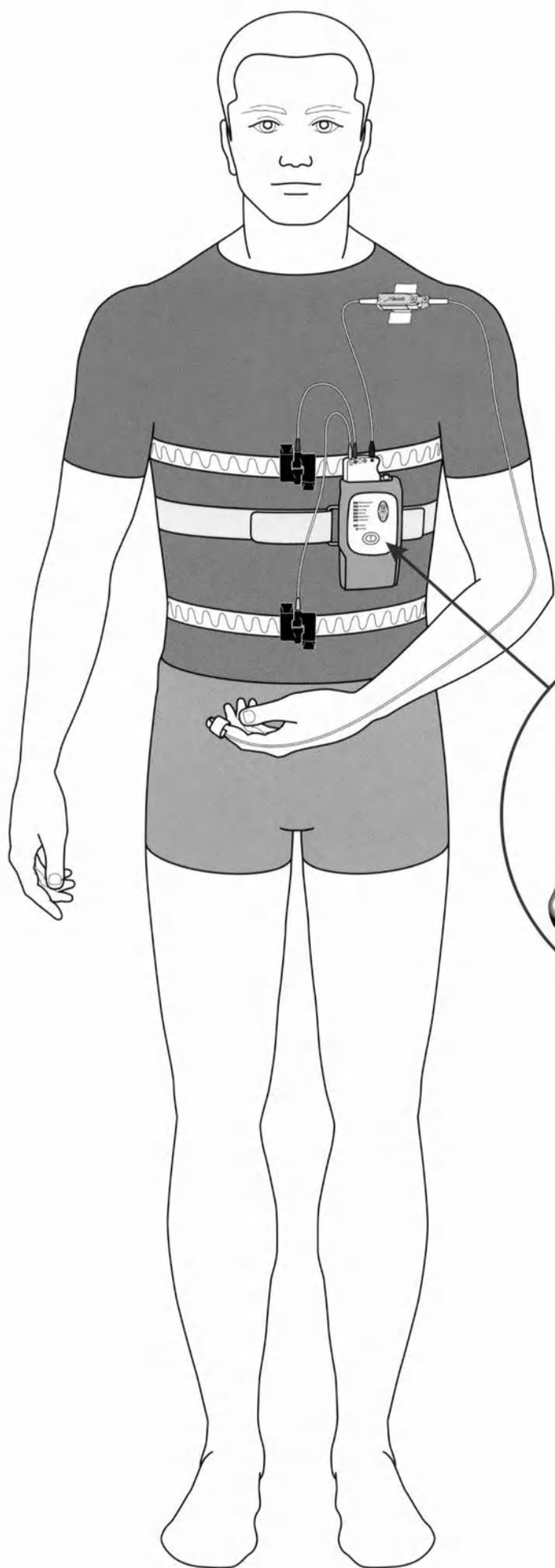
Compass systems are manufactured by Medcare Flaga, Reykjavik, Iceland. The manufacturer works in accordance with the EN ISO 9001 and EN ISO 13485 quality system and has the authority to mark the products with the CE mark. The CE mark is a declaration that the device is in compliance with the directives set forth by the European Union for medical devices, in particular the MDD annex VII. Compass is a Class IIa device according to Medical Device Directive (MDD), Annex V, "EC Directive" 93/42/EEC and Swedish implementation of the directive LVFS 2001:6, Certificate No. 41311838. Compass, XactTrace and Pathway Programs are trademarks of Medcare Flaga.

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D-0403-001

Medcare



SMART SLEEP SYSTEMS

Embletta®



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

■ Embletta: A Truly Flexible System

The Embletta offers unmatched diagnostic accuracy in a lightweight, compact design that is certainly 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. It can also be attached to flow generators 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. Embletta provides an outstanding SDB diagnostic solution. Exact nasal flow and pressure snore signals are obtained via a nasal cannula. Other signals that complete the diagnostic accuracy are position and activity, leg movement, oxygen saturation, pulse, oral flow, and last but not least, two respiratory effort signals through the XactTrace Respiratory Inductive Plethysmograph (RIP) sensors. The Embletta also features an event button.

■ Somnologica for Embletta

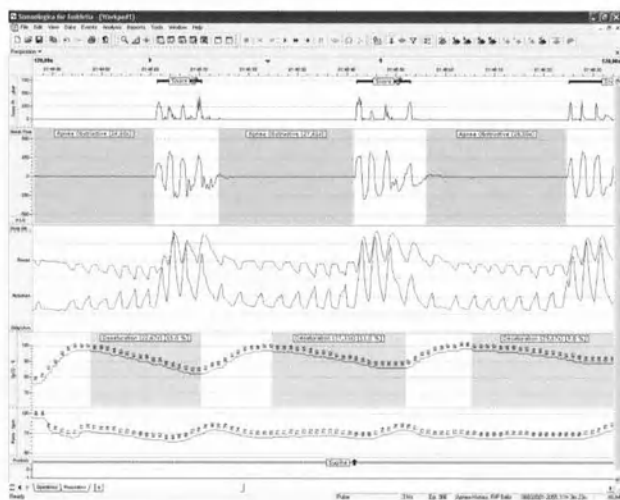
Somnologica for Embletta is a state-of-the-art software application that enhances the professional's ability to study and diagnose SDB more precisely. With its highly developed user interface, the software streamlines the steps in the sleep study process. Among its key features is an Operations Sheet that clearly guides you through preparing the device, downloading, analyzing recordings, and then creating reports. Somnologica for Embletta offers quality automatic respiration and Periodic Limb Movement (PLM) analysis. Somnologica for Embletta allows the analysis parameters to be set and reports customized. It even allows you to use 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 summarizes therapy results while PLM information is added to the Sleep Report. 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 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.

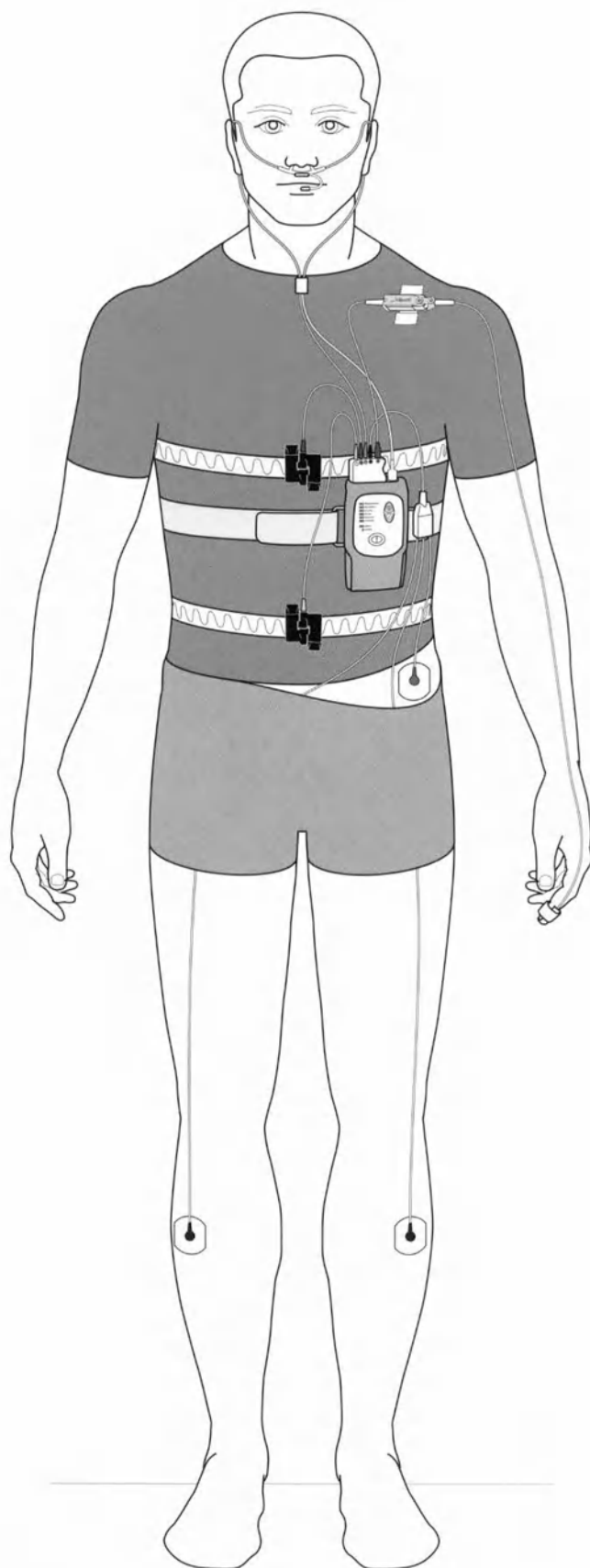
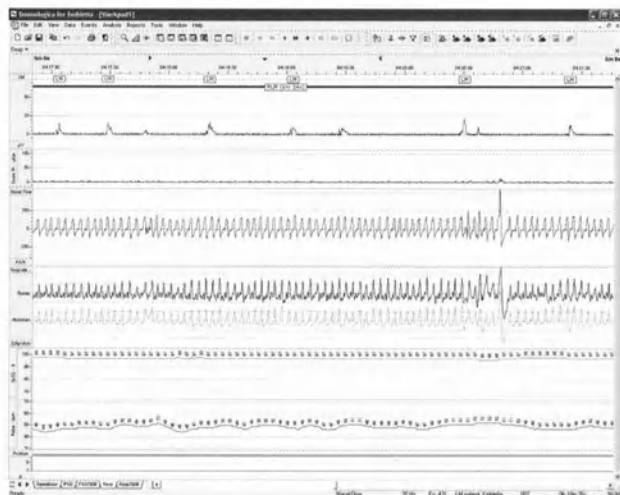
■ XactTrace™

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

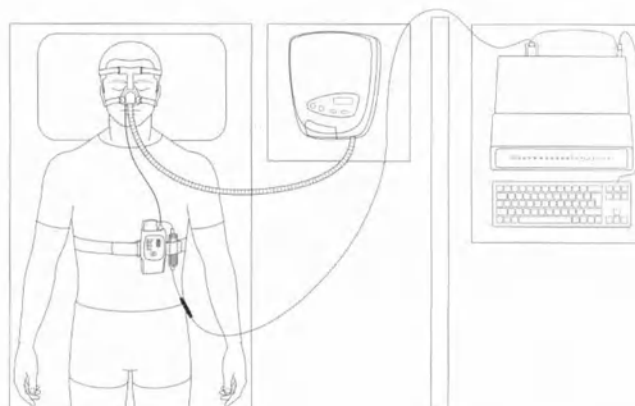
The Embletta can measure limb movement activity to help in the diagnosis of Periodic Limb Movement Disorder (PLMD). The Somnologica for Embletta software automatically analyzes the EMG signals and detects leg movements and PLM sequences. Information about PLM is added to the reports if this signal is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



Embletta Setup

■ Online Interface

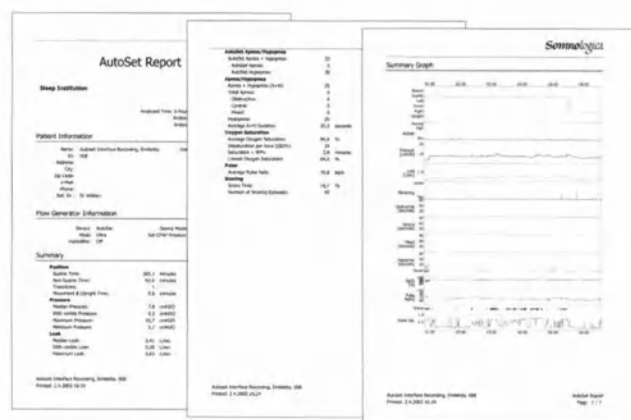
The Embletta Online Interface allows an attended, online study with the Embletta. The Online Interface connects the Embletta to a computer and has a quick-release connector which allows easy disconnection from the computer. The online solution provides the same parameters as the Embletta diagnostic studies.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



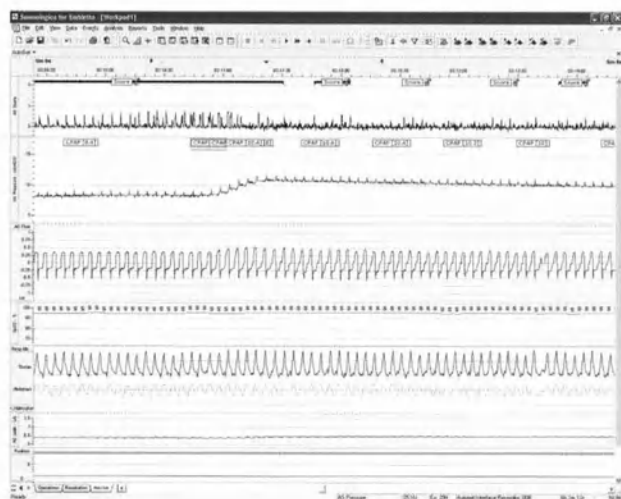
Online Interface

■ 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. These data are 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.

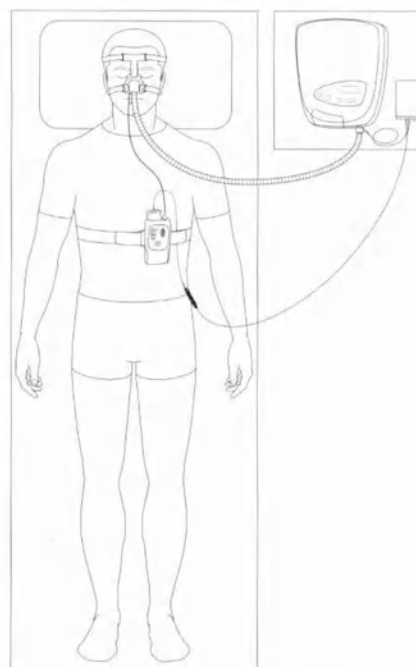


AutoSet Report

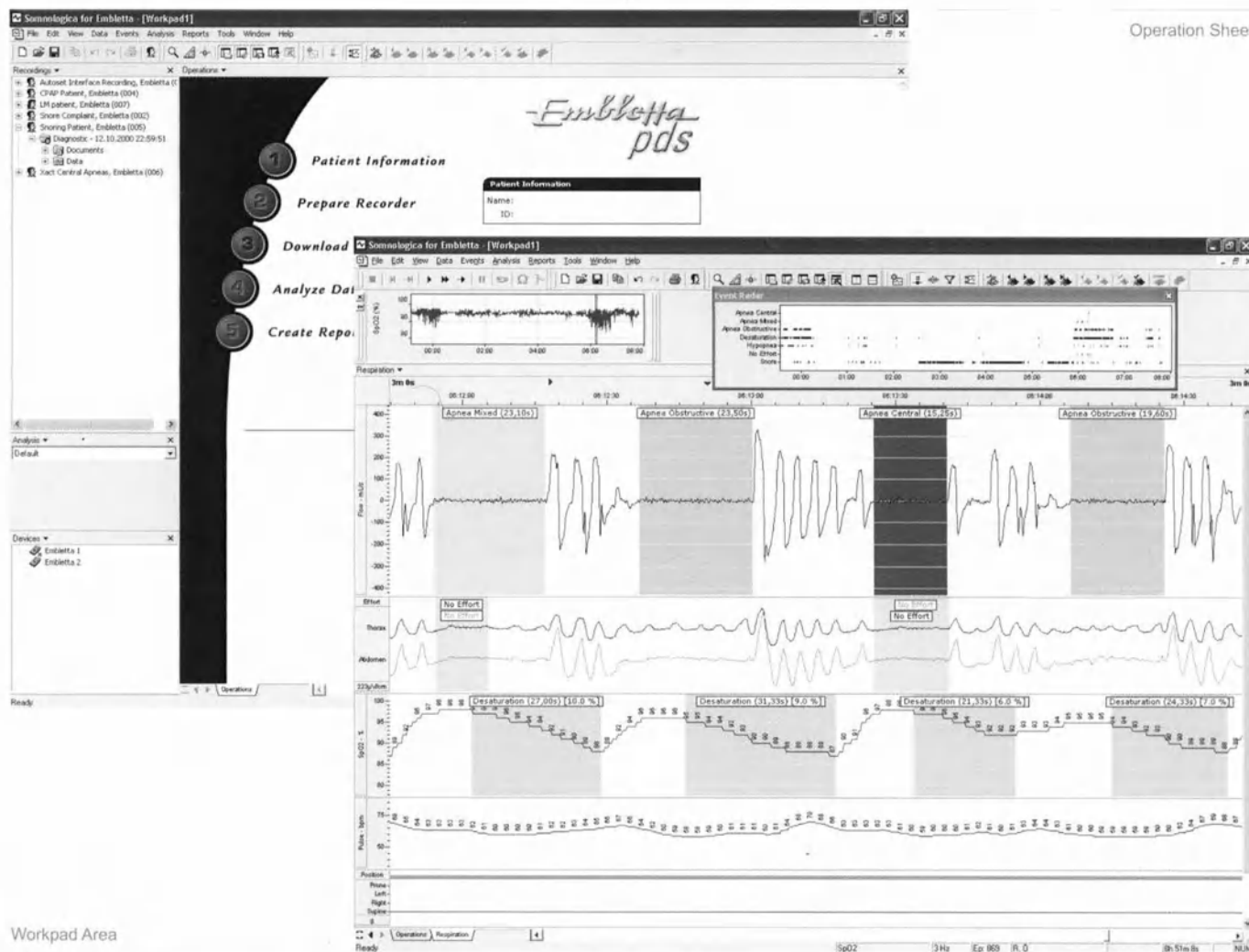


■ Flow Interface

With the Flow Interface the Embletta becomes an invaluable tool in determining the effectiveness of a CPAP or ventilation therapy. The Flow Interface is simply attached to the CPAP tubing and works with any type of flow generator. The Flow Interface also fits to all conventional mask types. No additional sensor is needed under the nasal mask, securing maximum patient comfort and the protection against leak.



Flow Interface



- 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 flow from thermistor
 - PLM Periodic Limb Movement (optional)
 - built-in 3D 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 design

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 the Flow Interface
- Quickly searches for patient groups or records of interest by using the Data Management Module



SMART SLEEP SYSTEMS

EMBLETTA MEASURES

- Flow/Pressure (nasal cannula/mask)
- Oral flow (thermistor)
- 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)
- SpO₂ average (oximeter)
- SpO₂ beat-to-beat (oximeter)
- Pulse rate (oximeter)
- Pulse waveform (oximeter)
- Body position
- Flow limitation
- Event marker
- Activity
- Limb Movement
- AutoSet information

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Embletta is Class IIa device according to Medical Device Directive (MDD), Annex V, "EC Directive" 93/42/EEC. Embletta has been tested and certified by SEMKO to comply with: EN 60601-1:1990 with A1 and A12:1993, A2:1995 and A13:1996, (IEC 60601-1, Second edition, 1988 with A1:1991 and A2, 1995), EN60601-1-2, 1993, EN55011:1990, EN 55 014-1:1993, EN60601-1-4, EN 865:1997, IEC 801-2, ed 2: 1991, IEC 801-3 draft 1992, IEC 801-4:1998, IEC 61000-4-5:1995, UL2601 2.Ed. 1997, CAN/CSA C22.2 No.601.1-M90.

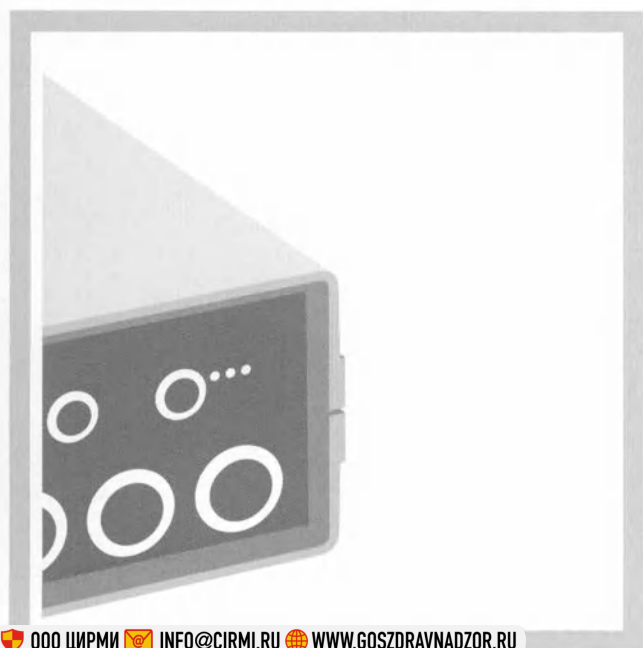
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For further information contact your local sales representative or contact sales@medcare.is

D-0305-022

Medcare



SMART SLEEP SYSTEMS

Embla®

The Embla® Recording Systems are developed and designed based on a decade of experience in the field of sleep technology. These systems offer a high degree of flexibility and signal quality to meet the highest demands of clinical work and research.



Embla Patient Unit



Embla S 7000 Bedside Unit

- The Embla recorders are indispensable in a wide range of clinical and research settings that require maximum flexibility and efficiency in data collection.
- By providing a comprehensive lab-based and portable application in one dynamic recorder, these devices maximize your investment.
- The Embla recorders all use the Somnologica™ software, which is designed to meet the needs for flexibility in research and ease-of-use in clinical work.

■ Embla Recording Systems

Embla Recording Systems represent an integration of advanced digital technology and precision engineering into ergonomically designed PSG and EEG systems.

- Embla is available in a number of different configurations: Designed for the dedicated high-performance sleep center. It offers a comprehensive array of patient, bedside and communication units to perform PSG and full EEG studies with ease.
- Offering extended referential recording capability, bipolar, respiratory and DC-level inputs. Suitable for both routine and extended sleep protocols, the Embla systems enable you to expand your services and record full EEG.
- Designed for EEG and polygraphic applications in clinical and research settings, the same recorder can be used in laboratory and ambulatory recordings. Its compact size allows the recorder to be easily carried by the patient.

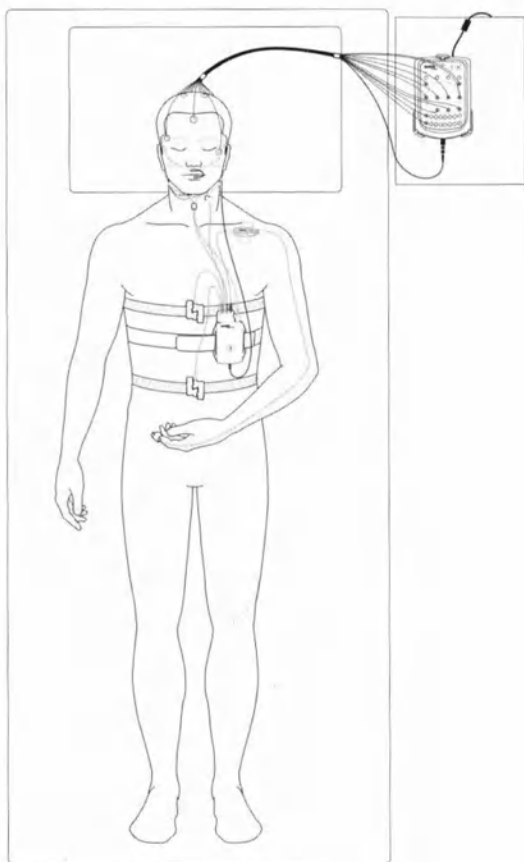
■ Streamlined Design

The patient interface of the Embla Recorder consists of the Bedside Unit and the Patient Unit. Both are lightweight and feature quick-disconnect for easy patient mobility.

- The clinically enhanced Patient Unit greatly reduces the cabling for signals such as respiratory effort, snoring, flow and SpO2. Worn by the patient, problems with tangled cables are eliminated.
- For routine EEG applications, the Patient Unit can be disconnected from the Bedside Unit and not used.
- The Bedside Unit is lightweight and can be comfortably worn by the patient with a strap attachment.
- A mobile stand or mounting bracket provides mobility and stability.

The Embla recorders share recording capabilities and performance-packed features.

- Featuring from 12 up to 32 referential channels (EEG, EOG, ...)
- Reference can be any single electrode or the common of any number of electrodes. Easily switched during acquisition.
- 8 bipolar channels for physiological signals such as EMG and EKG.
- 9 respiratory channels that include a built-in pressure transducer with steel luer lock, precise, 3-dimensional analysis of body



Patient Environment



Embla A10

position and movement, integrated oximetry with averaged SpO₂, beat-to-beat SpO₂, Pulse, Pulse waveform (Plethysmograph), Respiratory Inductive Plethysmography (RIP), snoring, patient event marker and more.

- 8 auxiliary DC channels for interfacing other critical signals, such as ETCO₂.
- Serial connectivity for devices with digital outputs, such as CPAP.
- Interface for electrode caps.

■ Built-In Functions that Make a Difference

- Device-integrated impedance function with illuminated display provides quick and easy bedside measurements.
- Easily accessible event buttons allow the caregiver or patient to enter time-stamped event entries.
- Integrated Ambient Light Detector registers ambient light changes in the patient environment.

■ The Connection that Counts

The Embla systems set the standard by utilizing an ethernet network to speed clean and reliable signals to the viewer in a variety of recording environments.

Using standard networking technologies changes the paradigm for delivery of services by opening a wide area of Ethernet connectivity options including your existing LAN, dedicated sleep lab LAN, wide area networks (WAN) and wireless networks. The Embla devices optimize facility operations and can be moved to new locations within the network environment with ease.

- Not tied to the limitations of cabling, the Embla Ethernet interface integrates more easily into even the most complex recording situations.
- Somnologica™ Studio will automatically detect Embla recorders regardless of where they are moved within the network.
- Somnologica Studio will automatically resume the recording if the recorder is moved in the middle of the recording.
- Ethernet is a very well established, reliable technology that is cost effective and easy to maintain.

■ Embla Ambulatory Systems

The Embla ambulatory recording systems are truly flexible. Designed for EEG and polygraphic applications in clinical and research settings, the same recorder can be used in laboratory and ambulatory recordings. Its compact size allows the recorder to be easily carried by the patient.

■ Designed for Optimal Flexibility

The Embla ambulatory recorders are customized in software. With configurable sensor settings, you can define custom

settings for almost any sensor available. This innovative design enables the recorder to be used in a variety of settings including on-line partial polysomnography, full polysomnography recording, or ambulatory EEG.

The Embla Ambulatory recorders can collect data from:

- 16 multipurpose channels
- Event button channel
- 2 oximeter channels
- 4 auxiliary channels

The data from the Embla is either recorded directly into Somnologica during on-line acquisition or downloaded to Somnologica from PC-Cards after ambulatory studies.

■ Somnologica Studio

Somnologica Studio is the performance powerhouse at the heart of all Embla systems and is designed for both clinical and research applications. Proven in hundreds of locations worldwide, Somnologica Studio provides solutions with a comprehensive array of tools that streamline workflow and improve patient data management.

- Work confidently with the proven and powerful capabilities of the Windows NT®, 2000® or XP® operating systems.
- Navigate easily and perform a sleep study in obvious steps using the Operation Sheet.
- Optimize your time by using tools that provide superior analysis power and scoring speed without compromising accuracy.
- Recording review is fast and easy with dynamic review tools that include montage reformatting, reference switching, re-filtering, and page comparison.
- Get the results you need with flexible report options that include customizable reports and versatile export tools.

■ Expand Your System Capabilities

To further enhance your system, you can add other options to create a complete and integrated system:

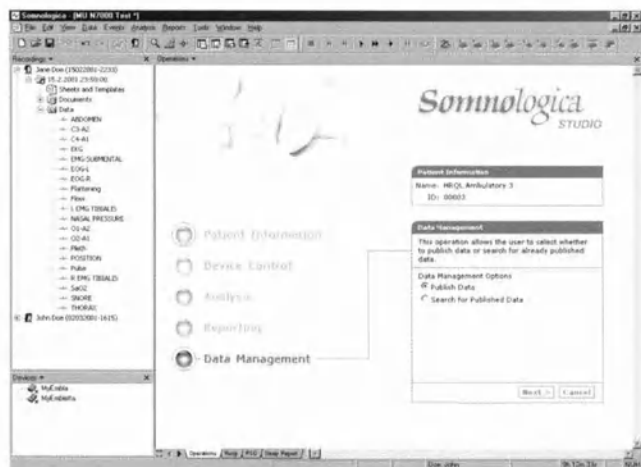
- Add the Data Management Module to help you keep track of your patients. It provides convenient access to patient information and flexible search features. This allows you to quickly locate patient groups or records of interest, enabling you to assess trends or target areas for intervention.
- Add Synchronized Digital Video to your Embla system for enhanced data analysis.
- Expand your services by adding the Embletta® PDS recorder for diagnosing sleep-disordered breathing.
- Take advantage of the latest technology with Xact products. The product line includes the XactTrace Respiratory Inductive Plethysmograph (RIP), the Embletta Xact AutoSet Interface and the Embletta Xact LM module.
- Expand to the Somnologica Science platform to meet your advanced research needs.

■ Future-Proof Your Investment

Embla's industry-leading engineering expertise makes the latest innovations in digital technology available with integrated, modular system components.

Embla systems represent the most comprehensive, multi-application array of sleep and sleep/EEG products available today. Designed with your success in mind, the Embla systems ensure that your needs are covered today and beyond with superior, proven products that work for you.

For more information on how Embla products can meet all of your PSG and PSG/EEG needs, contact your local representative.



Somnologica Operation Sheet

**Embla Communication Unit**

Controls the system and facilitates network communication.

Standard RJ45 Ethernet connection for connecting to your local network
8 isolated auxiliary channels, for external devices, such as ETCO2
2 isolated serial ports for external device communications, such as CPAP

**Embla Patient Unit**

Smart, efficient recording of respiratory parameters

9 respiratory channels
Oximetry
Flow/Pressure (nasal cannula/mask)
Flow limitation
Oral flow
Snore (by nasal pressure or by neck vibration sensor)
Abdominal movement (by XactTrace RIP belts or by Piezo element sensors)
Chest wall movement (by XactTrace RIP belts or by Piezo element sensors)
SpO2 averaged, SpO2 beat-to-beat, pulse rate, pulse waveform (oximeter)
Event marker
Body position / Activity

**Embla N 7000**

Polysomnography with extended EEG capabilities
Up to 60 channels

Bedside Unit

32 referential channels (EEG, EOG,...)
8 bipolar channels (EKG, EMG, Legs,...)
Amplifier re-referencing during acquisition
Integrated impedance test
Accessible event button
Integrated ambient light detector
Wide range of selectable sampling rates
Interface for electro-cap
Quick release

**Embla S 7000**

Polysomnography for sleep centers
Up to 40 channels

Bedside Unit

12 referential channels (EEG, EOG,...)
8 bipolar channels (EKG, EMG, Legs,...)
Amplifier re-referencing during acquisition
Integrated impedance test
Accessible event button
Integrated ambient light detector
Wide range of selectable sampling rates
Quick release

SMART SLEEP SYSTEMS

- Get what you need with a clinically streamlined design
- Use modular configurations of up to 60 channels
- Enjoy flexibility: sleep studies by night and EEG studies by day
- Simplify with ergonomically arranged system components
- Plug into existing network infrastructure to minimize installation costs
- Facilitate wireless networking with Ethernet connectivity
- Increase ease and comfort with minimal cabling and connections
- Detach smoothly and quickly when leaving bed
- Run a device-integrated impedance test effortlessly
- Acquire high quality signals
- Work with the industry-leading Somnologica Software



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