infoscan
telemedical systems

Infoscan MED Recorder
User Manual

Producer:

Infoscan S.A.
17 Rejtana St. apt. 16
02-516 Warsaw, Poland

phone: +48 22 188 18 63
e-mail: info@infoscan.pl

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Before starting to use this device the user is required to familiarize him or herself with the instructions including warnings and precautions.

Read this user manual carefully. It contains important information about safe and proper installation, use of the device and how to maintain it.

Table of Contents

Glossary 5
Safety Information 6
Statements 7
Introduction 7
Indications for Use 8
How to Use this Manual 9
Device Description 9
Device Elements Description 11
Charging the Battery 12
Sensors 13
Fitting 14
Main Menu 16
Using the Device 16
Data Saving 17
Data Transmission 17
System Description 17
Principles of Operation 19
Cleaning and Maintenance 19
Cleaning 19
Maintenance 20
Directive for Waste Disposal 21
Troubleshooting 21
Specifications 21
Range and Accuracy of Measurements 22
Technical Parameters 22

Compatibility 22
Electromagnetic Compatibility Declaration 22
Symbols 23
Guidance and Manufacturer's Declaration –Electromagnetic Emissions 23
Guidance and Manufacturer's Declaration –Electromagnetic Immunity 24
Accessories/Additional Materials 24
Service and Technical Support/Service Guarantee 26

Table of Figures

Figure 1. The MED Recorder Device after opening the transport case. 9
Figure 2. Main display: Buttons and symbols 10
Figure 3. Infoscan MED Recorder Device – Home screen 10
Figure 4. Examination screen 11
Figure 5. Sensor connectors and indicators 12
Figure 6. Packed sensors 13
Figure 7. Diagram of placement of airflow sensors 14
Figure 8. Placement of body position sensors 14
Figure 9. Reusable pulse oximeter sensor 15
Figure 10. Patient ready for registration 15
Figure 11. MED. Recorder System logging window 17
Figure 12. Recorder System data access window 18
Figure 13/14. Recorder System schedule registration window. 18

Glossary

Device – Infoscan MED Recorder

SpO2 subsystem – Measurement module recording pulse and blood oxygen saturation

SpO2 sensor – Pulse oximeter sensor, reusable finger clip, soft tip or adhesive wrap sensor

Sensor module – Multi-measurement module, plug-in unit for different types of intelligent sensors

Airflow sensor – Thermistor sensor that detects nasal and oral airflow

Body movement sensor – Electronic motion sensors record movement in all directions using two separate 3-axis accelerometers. They sense changes in body position and can detect back (supine), front (prone) or side and chest and abdominal movements

Snoring detector (built in microphone) - Records sound levels including snoring noise during sleep

OLED display – Displays parameters and waveforms measured by the device. The screen will turn off after going into standby mode Keypad – Set of buttons used to operate the recorder

GSM/GPRS module – Communication module used for data transmission to the online web server, over an unlimited distance.

Storage/memory card – Secure Digital (SD) memory card formatted for use in portable devices to store measurement data. The card is installed in this device.

Safety information

WARNING symbols indicate a potential hazard or unsafe practice that, if ignored, could result in death or serious injury to the patient or user.

WARNING: Accessories have to be used in accordance with the user manual because their length generates a risk of strangulation or asphyxiation

WARNING: The device should be used only during the recording to avoid skin irritation from prolonged contact with the accessories

WARNING: DO NOT USE the device when charging the battery. Remove/unplug all sensors from the patient's body prior to charging.

WARNING: This device uses an internal date and timer. Precision of the date and time depends on the accurate setting of the internal clock.

WARNING: Explosion hazard. Do not use this equipment in the presence of flammable anesthetics, vapors or liquids

WARNING: Magnetic and electrical fields are capable of interfering with the proper performance of the equipment. For this reason, make sure that all external devices operated at less than 1 meter from the equipment comply with the relevant Infoscan MED Recorder requirements. Mobile phones, X-ray equipment or MRI devices are possible sources of interference as they may emit higher levels of electromagnetic radiation.

WARNING: The usage of accessories, sensors or cables other than those provided by Infoscan may have a negative impact on device performance and may affect measurement accuracy. Disassembly and repair of this product should be carried out by qualified Infoscan authorized personnel only.

WARNING: This device is not defibrillator proof.

WARNING: Before connecting the equipment to the mains, check that the voltage and frequency ratings of the power line are the same as those indicated on the label affixed to the equipment or in this manual.

WARNING: Protect the equipment from exposure to high humidity (such as rain), which may cause damage or affect its performance.

⚠ **WARNING:** Do not use the device, sensors, leads or cables that appear damaged or are defective.

⚠ **WARNING:** Protect the equipment from damage caused by unintentional drop, collision, strong vibration or other mechanical force during servicing. Do not lift the device by its sensors or cables; they might get disconnected from the device and as a result the device might fall on the patient.

⚠ **WARNING:** Follow the applicable waste control regulations to dispose of the package material and keep well out of the reach of children. This device uses a lithium polymer battery.

⚠ **WARNING:** This device uses a GSM module, emitting electromagnetic waves during operation. This device interferes with the use of a pacemaker!

⚠ **WARNING:** The device has to be used only in the supplied belt.

⚠ **WARNING:** Keep and use the device away from particulate and do not expose it to intense sunlight

⚠ **WARNING:** Store and use the device away from pets, pests and children, their action can cause damage to the device or accessories.

Statments

- This device is not intended to provide automated clinical decisions.
- This device is not intended for emergency calls.
- This device is not intended to provide real time data.
- Clinical judgment and experience are required to check and interpret the measurements collected and transmitted.

Introduction

⚠ **WARNING:** Do not make a diagnosis based solely on the parameters displayed by the device. Infoscan MED Recorder gathers data, which should be reviewed in terms of symptoms and clinical signs.

⚠ **WARNING:** A qualified clinician is needed to assess all Infoscan measurements. An interpretation of Infoscan recorded data is only significant if it is reviewed by a qualified clinician.

WARNING: Changes or modifications not expressly approved by Infoscan S.A. could void the user's authority to operate the equipment

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help

Indications for Use

The Infoscan MED Recorder is indicated for use by Health Care Professional (HCP), where it may aid in the diagnosis of sleep disordered breathing for adult patients. The Infoscan MED Recorder records the following data: patient respiratory airflow, snoring, blood oxygen saturation, pulse and body position during sleep. The device uses these recordings to produce a report for the HCP that may aid in the diagnosis of sleep disordered breathing for further clinical evaluation. The device is intended for home and hospital use under the direction of a HCP.

How to Use this Manual

Before using the Infoscan MED Recorder Device please read the following instructions thoroughly.

Device Description

Infoscan MED Recorder Device is a modular, digital recorder of physiological parameters. This device combines multiple measurement modules in a compact package. The user operates the device with press buttons and views the parameters and waveforms on a built-in color OLED display.

Figure 1. The MED Recorder Device after opening the transport case.

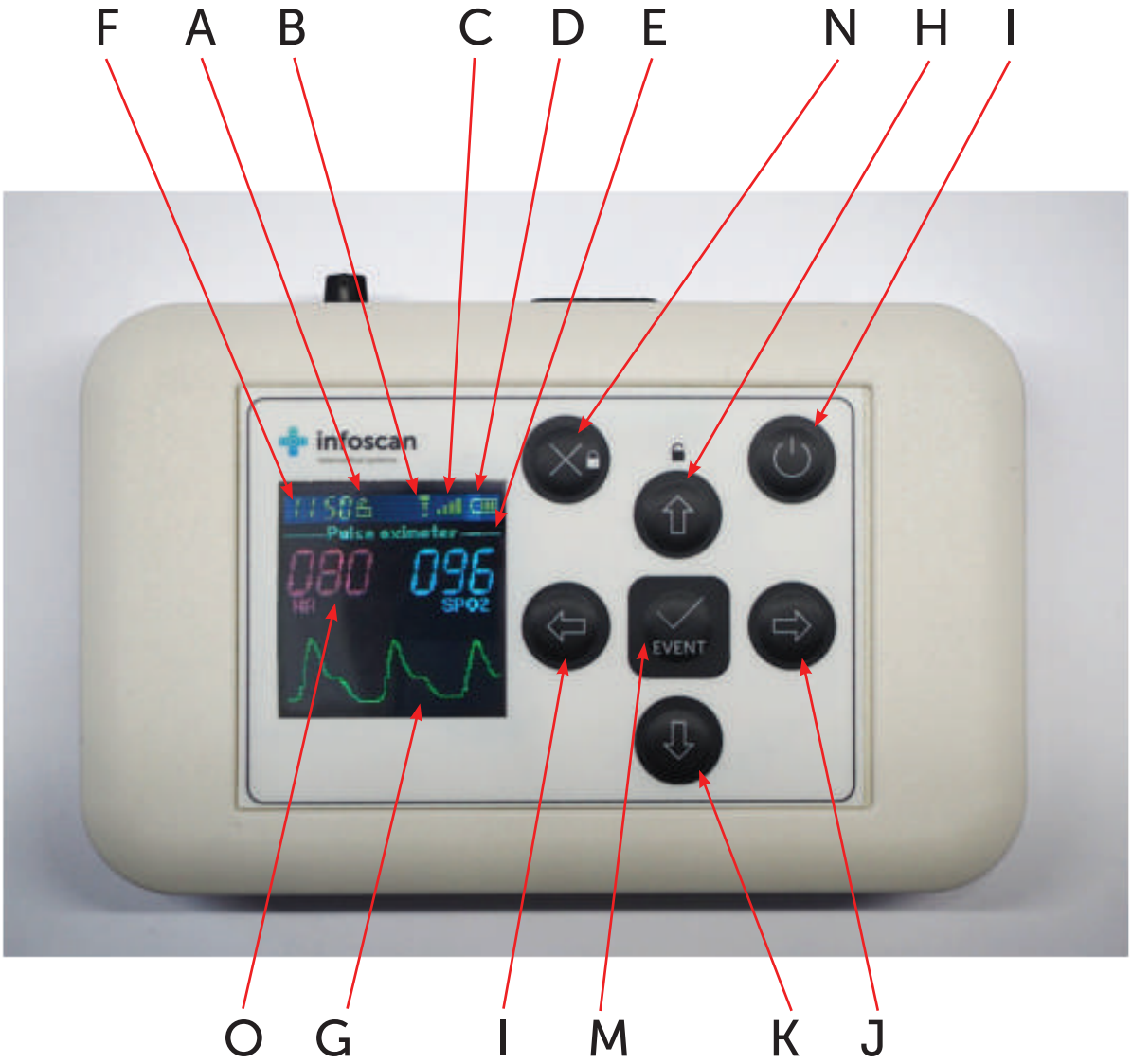


Figure 2. Main display: Buttons and symbols

Figure 3. Infoscan MED Recorder Device – Home screen

Description of Buttons and Symbols

A. Keypad locking symbol (open/closed padlock). Keypad should be locked after setting the device, before starting wthe examination process. To lock the device press and hold the [N] button, which serves to cancel.
B. Data transmission symbol
C. GPRS/GSM network coverage symbol
D. Battery level indicator
E. Operating mode
F. Current date and time synchronized with a central server
G. Pulse waveform
H. Up arrow button
I. Power on/off button
J. Right arrow button
K. Down arrow button
L. Left arrow button
M. Accept button
N. Cancel button
O. Pulse rate index and blood saturation index

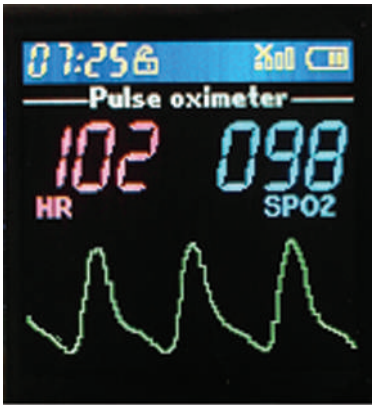


Figure 4. Examination screen

P. Socket for airflow and body movement sensors
Q. Micro USB connector for AC charger (on the side wall)
R. LED indicators (on the side wall)
S. Socket for the Nonin pulse oximeter sensor

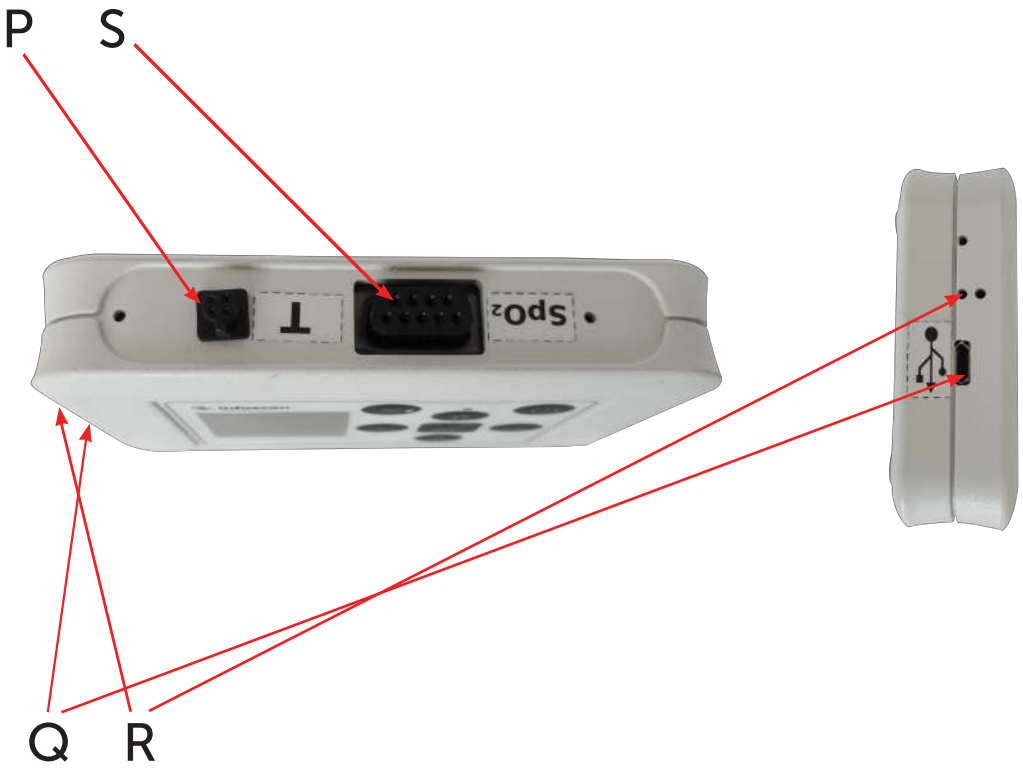


Figure 5. Sensor connectors and indicators

Charging the Battery

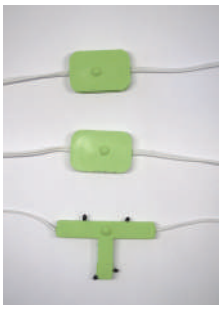
When you connect the charger to the device a lightning stamp appears on empty battery icon. After charging the battery icon will fill up but the lightning stamp remains visible. The device is now ready for operation, fully charged internal battery allows you to perform one registration. Actual operating time depends on strength of the GSM network signal and it is up to 24 hours (the minimum value is 14 hours).
The device can be powered with standard 5V 2A micro USB charger.

⚠ WARNING: DO NOT USE the device when the battery is charging. Remove/unplug all sensors from patient's body before charging.

Sensors

After unpacking the accessories you must wait at least 60 minutes before usage if the device has been transported or stored in order to stabilize its temperature.

Figure 6. Packed sensors

	Nonin pulse Oximeter soft sensor
	Body position and airflow sensors (Infoscan accessory) **Warning:** sensor's cable (outer shell) contains DEHP

Before starting a recording session and turning the device on check that the appropriate manufacturer specified sensors are fitted and connected.

When the appropriate sensors have been connected to the main unit press (and hold for 2 seconds) to switch it on. The welcome home screen will be displayed. Press the right arrow button to go to the menu and settings.

Nonin pulse Oximeter soft sensor is intended for multiple-patient reuse. Remember to clean the sensor after the registration. Body position and airflow sensors are single patient use only.

Fitting

1. Fit the oral and nasal air flow sensor so that the two small open sensors point toward patient's nostrils while the third open tube points towards his/her mouth. You can make minor adjustments to the sensor to comfortably fit the face. Fit the loop around the patient's ears and then back around the neck. Avoid pulling it over the head.

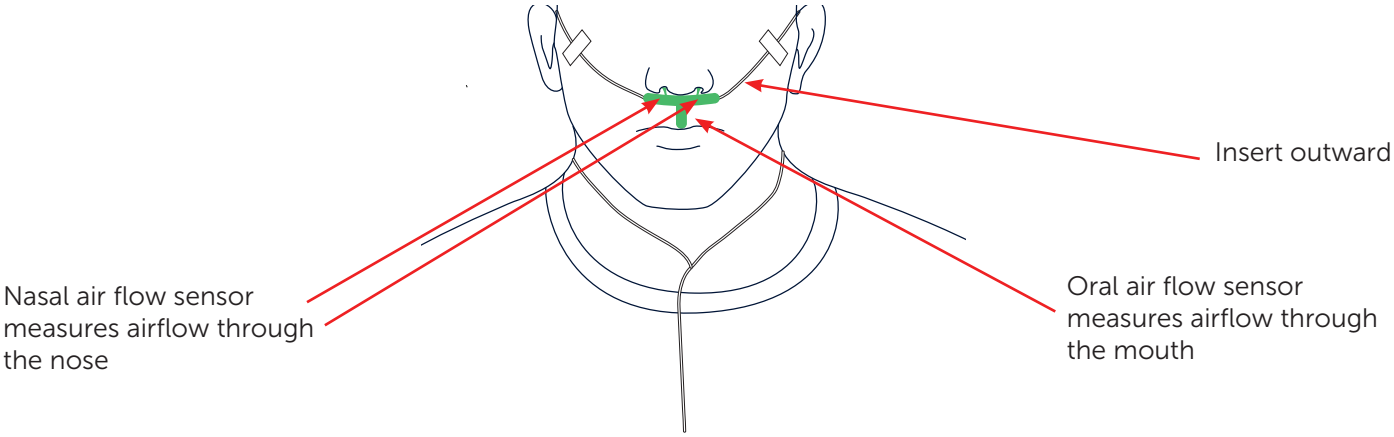


Figure 7. Diagram of placement of airflow sensors

2. Make sure the sensor is placed on the chest (in the middle of sternum) and secure it with medical tape. The body movement sensor should be placed and secured below the diaphragm (in the middle of abdomen - 2 cm over the navel). Remove chest hair if necessary.

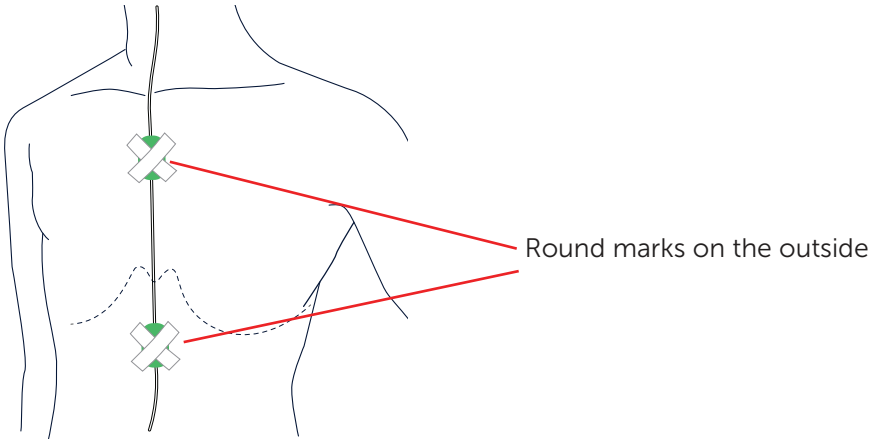


Figure 8. Placement of body position sensors

Warning: Make sure the sensors are placed with the round marks pointing outward.

3. Insert your index finger into the pulse oximeter sensor. Note that for proper operation of the sensor the tip of the finger must remain in contact with the end sensor.

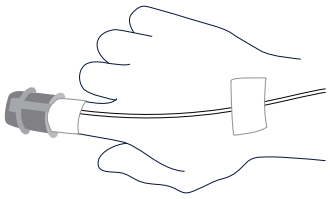


Figure 9. Reusable pulse oximeter sensor

4. Put on belt and put in its pocket the MED Recorder Device.

Figure 10. Patient ready for registration

Main Menu

Select a menu option by pressing the 

button. Change parameters by using the left and right arrows. To exit press  .

Device menu:

1. The system displays the following:
   a. System log – allows the current system log entries to be checked, message contains action name and its status code
   b. FW version – contains information about the version of the Firmware installed on the Device
   c. SysStatus – allows the internal status data to be checked

2. Settings displays the following:
   a. System log – allows the current system log entries to be checked, message contains action name and its status code
   b. Clock – allows manual adjustment of the built-in real time clock
   c. Display – allows a time delay to be set after which the screen will be dimmed to conserve energy
   d. Language – allows a language to be set for the user interface, the available languages are English (EN) and Polish (PL)
   e. RSSI – changes the minimum threshold for GSM network reception required to start data transmission
   f. Reset RD/RW – resets the registers that store information about the use of the internal SD card

Using the Device

After switching on the device, the system logo will appear for a few seconds followed by the home screen displaying the data and time. Press and hold the right arrow for 2 seconds to select the system menu.
Pressing the right arrow button again you will display the pulse oximeter screen. If there is no sensor attached the “No finger” symbol will be shown. The screen shows the saturation and pulse data of the patient.
The different parameters are color-coded. : blue color for blood oxygen saturation, red color for pulse rate. The other screens present: data from the first accelerometer, data from the second accelerometer, data from air flow sensors and snoring sound registered by internal microphone.

During testing the device screen will be turned off (or turned on) according to the device settings. Before starting the test, the keypad can be locked by pressing the button for a few seconds. (Note: This will be indicated by the locked "padlock" symbol in the status bar). To unlock the keyboard press the and buttons together.
(Note: The open "padlock" symbol will appear in the status bar. This protects the unit from children and unintentional pressing of buttons).

WARNING: Do not disassemble the device, only the Infoscan authorized service can do it.

Data Saving

The measured data are continuously saved on a memory card that is built into the device and sent to be MED Recorder ServSoft during and after the test.

Test results are accessible for the physician via a web interface.

Data Transmission

The device uses GSM/GPRS communication technology to transmit data, which enables data to be sent directly to the Infoscan MED Recorder ServSoft where the results are storaged. The data transmission is dependent network bandwidth and availability. It is accompanied by the display of data transmission symbol on the screen.

System Description

User interface provided by MED Recorder ServSoft is available via Web Browser and allows exporting previously transferred data. Access to the system is possible after logging on servsoft.infoscan.eu site.

Figure 11. MED. Recorder System logging window

After verification of the user data access window appears. User can set up new registrations, view registration details and download selected registrations in HL7 format. The registrations have one of four statuses: "New" (no data), "Pending" (data transfer in progress), "Generating HL7" (data transfer is complete and HL7 file is being prepared) and "Ready" (HL7 is prepared). Only registrations with the status "Ready" can be exported by clicking export buttons.

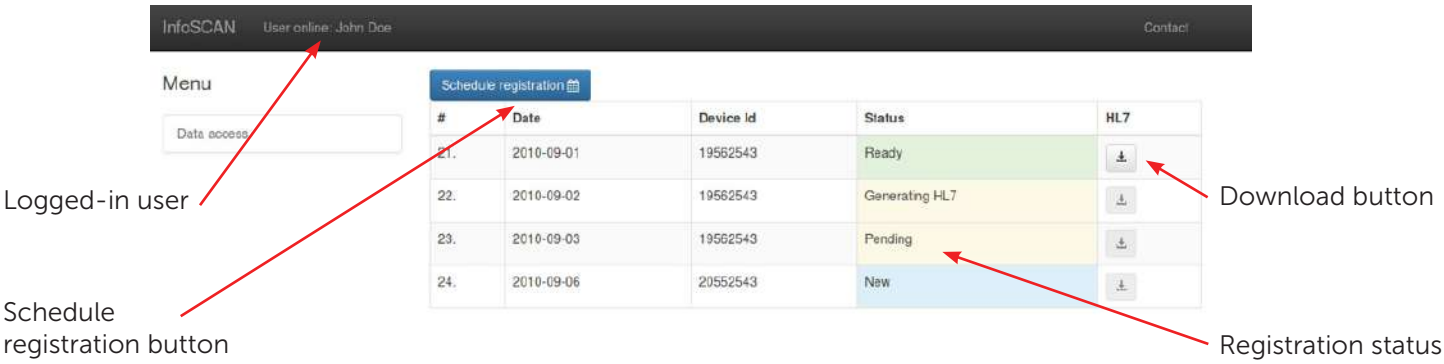


Figure 12. Recorder System data access window

Clicking the Schedule registration button causes the appearance of schedule registration window.

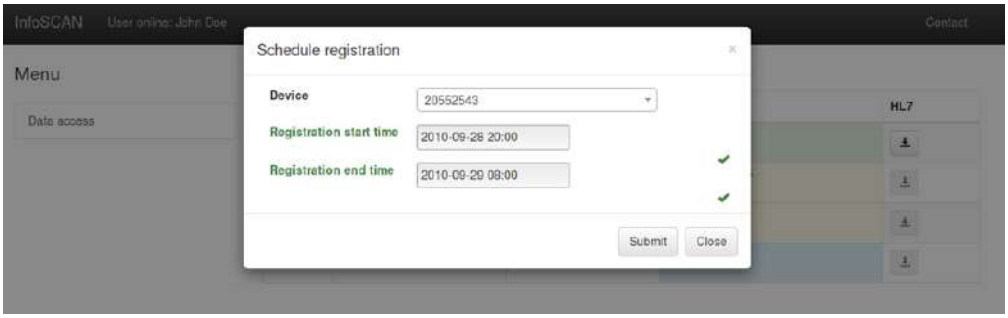


Figure 13. Recorder System schedule registration window.

Clicking the row in registrations table causes the appearance of registration detail window. Blue progress bar shows the theoretical progress of registration (based on time). Green progress bar shows the actual progress of registration (based on transferred data).

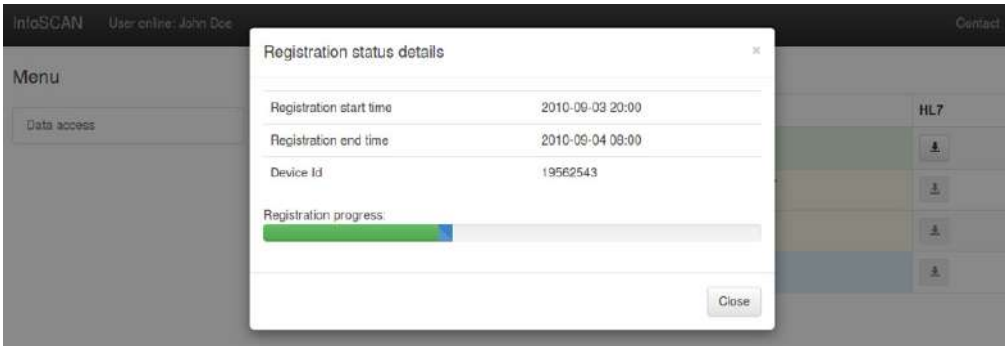


Figure 14. Recorder System schedule registration window.

Principles of Operation

The following sensors are available for used with the Infoscan MED Recorder Device:

Pulse Oximeter: A pulse oximeter estimates the level of oxygen in the blood using visible and infrared light. A clip, provided with the Infoscan MED Recorder, is placed on the tip of a finger and red and infrared light are shone through one side of the finger; the detector measures the light that passes through the other side. Hemoglobin, present in the blood, absorbs different amounts of the light depending on whether, or not, it is oxygenated. Blood cells are bright red when they are loaded with oxygen, and they change to a bluish color when they are no longer carrying a full load. Note that measurements may be affected by excess light or the presence of nail polish for which blocking the light or removing the nail polish/switching the probe to a different finger may suffice to remedy the issue.

Nasal and oral airflow is measured using a thermistor sensor, which is sensitive to the temperature differences in exhaled (cold) and inhaled (warm) air. The sensors determine, in a qualitative manner, the presence, or absence, of airflow through the nose or mouth. Using 3 separate sensors airflow in each passage may be measured independently.

Body position sensors (3D accelerometers placed per instructions) determine the relative movements of the abdomen and chest by recording sensor acceleration relative to the constant speed of Earth. Recording this data from the sensors permits patient body position [back (supine), front (prone) or side] to be determined remotely.

Cleaning and Maintenance

Cleaning

Infoscan MED Recorder Device and pulse oximeter sensor should be cleaned after each use following the instructions below. Cleaning shall be performed by the physician or healthcare provider or another healthcare professional.

⚠ CAUTION:
- Unplug pulse oximeter sensor from the device before cleaning.
- Do not sterilize, autoclave or immerse the device or the sensors in liquid of any kind.
- Do not use caustic or abrasive cleaning agents on the device or sensors; do not use cleaning agents containing ammonium chloride.
- Clean the device and pulse oximeter sensor before applying it to a new patient.

MED Recorder device includes the automatic offset correction. An annual calibration service is not necessary.

Cleaning procedure for healthcare professional:

1. Take the device out of the carrying case.
2. Make sure that the device is switched off.
3. If the device is still in a belt case, remove it.
4. If still attached, detach the Pulse Oximeter Sensor from the Device.
Note: Need to pull the connector out from the connector nest.
5. If still attached, detach the Air Flow and Body Position Sensor from the Device.
Note: Need to pull the connector out from the connector nest.
6. Clean the device with a dump cloth and a mild detergent.
Note: Do not dip the device into detergent container.
Note: Allow the device to dry thoroughly before reusing.
7. To clean the Pulse Oximeter Sensor, wipe all patient contacting surfaces with a soft cloth dampened with a mild detergent.
8. Clean the Pulse Oximeter Sensor cable, gently wipe the cord from the plug towards the sensor. Wipe the grey sensor inside and outside.
Note: Do not pour or spray any liquids onto the sensor.
Note: Allow the sensor to dry thoroughly before reusing.
9. Leave the cleaned parts to dry.

Manufacturer recommends cleaning the belt after each 25 uses.

1. Wash the belt by hand or in a regular washing machine at 86°F (30°C).
2. Allow the belt to dry. Do not tumble dry or dry clean.

Maintenance

- Replace the reusable belt every 500 uses
- Replace the Pulse Oximetry Sensor every 5 years

MED Recorder device includes the automatic offset correction. An annual calibration service is not necessary.

NOTE: It is also acceptable to carry out other cleaning procedure than recommended by Infoscan if its effectiveness has been confirmed.

NOTE: Infoscan MED Recorder Device cannot be sterilized.

Directive for Waste Disposal

WARNING: All electrical and electronic products should be disposed of separately from the municipal waste stream via designated facilities appointed by the government or the local authorities.
This symbol stands for the 2012/19/EU Directive of Waste Electronic and Electrical Equipment (WEEE).

Troubleshooting

If Nonin pulse Oximeter does not detect a finger it is necessary to ensure that the sensor is connected properly to socket. If "Data Unavailable" message is still displayed check whether the sensor is shining. If you see red light and none of your fingers can catch measurement contact with Infoscan service.
If body position and airflow sensors do not record data is necessary to ensure that they are connected properly to socket. If they are but no movement or airflow data are registered contact with Infoscan service.
If you notice that one of the pieces of medical tape is coming off secure it with additional medical tape.

Specifications

Range and Accuracy of Measurements

Pulse Oximetry

- SpO2: 0 to 100%
- Pulse rate range: 18 to 321 beats per minute

- SpO2 accuracy (70-100%) +/- 2 digits
- Pulse rate accuracy (18-300 BPM): +/- 3 digits

Airflow
- Data sampling rate: 45 times/second, qualitative measurement determining airflow in different passages of the respiratory system.

Body movement (accelerometers)
- Data sampling rate: 45 times/second, qualitative measurement.

Technical Parameters

- Operating temperature: 5°C to 40°C (41°F to 104°F)
- Temperature of storage: -25°C to 70°C (-13°F to 158°F)
- Humidity: 15% to 90% non-condensing
- Maximum altitude: 2000m a.s.l.
- Power requirements: 170 mW (screen off), 350 mW (screen on)
- Power supply: Internal battery Li-Polymer, constant voltage 3.6-4.2V
- Dimensions (without sensors): 120 mm (depth) × 75 mm (width) × 32 mm (height) (4.72" × 2.95" ×1.26")
- Weight: 135 g (with battery)
- Accuracy of internal timer < ±1 s/day
- Blood saturation sensor specifications: in accordance with NONIN® PureLight® series 8000
- Airflow and body movement sensors: provided only by Infoscan
- Fully charged battery life is sufficient for up to 24 hours continuous operation
- Life of battery: up to 12 months
- Technical inspection recommended: every 12 months

Compatibility

Safety Standards: IEC 60601-1:2005, IEC 60601-1-2-2007 modified, ISO 80601-2-61:2011
Quality standard: ISO 13485:2012

- Applied part type: BF
- Medical device class: II a

- FCC ID: 2ALKP-MED-RECORDER
- Mode of Operation: continuous
- Power Supply: Internally powered (battery)
- Product and accessories life: 36 months (except of Air Flow and Body Position Sensor)

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Electromagnetic Compatibility Declaration

The Infoscan MED Recorder is indicated for use in electromagnetic environment, where RF radiation interference is limited. To ensure compliance with RF exposure guidelines the device must be used with a minimum separation (1 meter) from portable radio communications.

Symbols

A number of symbols are used throughout this manual in order to draw attention to safety items and other important information.
The following section contains a description of symbols that may be located on either the Infoscan MED Recorder or in documentation accompanying the device.

	Warning! Consult accompanying text or documents
	**User manual** (please read)
	Follow the instruction manual
	Serial number of product
	Class II a
	Type BF applied part
	GSM module
	Date of production
	Manufacturer
	European CE conformity marking (in accordance with MDD 93/42/EEC)
	Directive for disposal of electrical and electronic equipment
	Store at specified temperatures

	Do not expose the unit to rain or moisture
Rx	Prescription only

Guidance and Manufacturer's Declaration –Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Radiated Emissions according IEC 61000-4-3 CISPR 11	Range 30 –1000MHz Group 1 Class B	This Device uses RF energy only for its internal functioning. Therefore, its RF radiated emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Conducted Emissions CISPR 11	Not applicable- Device is battery operated;	
Harmonic Emissions IEC 61000-3-2	Not applicable - Device is battery operated;	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Not applicable - Device is battery operated;	

Guidance and Manufacturer's Declaration –Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV ±8 kV Contact ±6 kV Air Contact ±6 kV Air	±6 kV ±8 kV Contact ±6 kV Air Contact ±6 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	Not applicable- This is a battery operated device and has no patient-coupled cables nor I/O cables which are longer than 3 meters	
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable- This is a battery operated device;	
Power frequency (80MHz – 2.5GHz) electromagnetic field IEC 61000-4-8	3 V/m	Not applicable- This is a battery operated device;	
Radiated, radio-frequency electromagnetic field immunity test. Test procedure IEC 61000-4-3	Frequency range: 80MHz – 2.5GHz	Subrange: 80 – 1000MHz	Power frequency electromagnetic fields should be at levels characteristic of a typical location in a typical home or hospital environment.
		Subrange: 1 –2.5GHz	Power frequency electromagnetic fields should be at levels characteristic of a typical location in a typical home or hospital environment.

Immunity to conducted disturbances, inducted by radio-frequency fields. Test procedure IEC 61000-4-6	3Vrms in the range 150 kHz - 80 MHz; Amplitude modulated at 80% with modulation frequency 2 Hz	Not applicable- This is a battery operated device;	
IEC 55011 – Magnetic Field Strength Measurement	Range 30MHz – 1000MHz:	Range 30MHz – 1000MHz	The measured emissions of the Device below the specified limits.

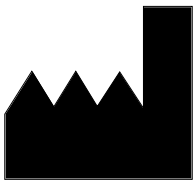
Accessories/Additional Materials

- Blood saturation sensor (in accordance with NONIN® PureLight® series 8000): 1 piece
- Airflow and body movement sensors (by Infoscan MED): 1 piece
- User Manual: 1 piece
- Patient Manual: 1 piece
- Belt (material, for use above garment) with case for the device: 1 piece
- Transportation case: 1 piece

Service and Technical Support/Service Guarantee

Type of device	
Model	
Serial number	
Date of purchase	

Contact



Infoscan S.A.
17 Rejtana St. apt. 16
02-516 Warsaw, Poland
phone: +48 22 188 18 63, Service Center +48 22-101-09-32
e-mail: serwis@infoscan.pl, www: http://www.infoscan.eu

Authorized US representative

Liberty Management Group Ltd,
2871 Coastal Dr,
Aurora, IL-60503, USA
Phone: (630) 270-2921
Fax: (815) 986-2632
e-mail: info@fdahelp.us
www.fdahelp.us

Warranty Repairs

In case of malfunction or damage of the Recorder or when battery is used and change of the battery is required, please contact **Authorized US representative**:

Liberty Management Group Ltd,
2871 Coastal Dr,
Aurora, IL-60503, USA
Phone: (630) 270-2921
Fax: (815) 986-2632
e-mail: info@fdahelp.us
www.fdahelp.us

The claim will be registered and the Recorder will be replaced by a new device.
Please follow the instructions of the Authorized Dealer for the return of the claimed Recorder.

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