Bittium Respiro™

Operating Instructions for healthcare professionals

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Bittium Biosignals Ltd.
Pioneerinkatu 6
70800 Kuopio
Finland
Phone: +358 40 344 2000
www.bittium.com

Notice

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Summary of Changes

Version	Date	Changes Between Releases	Status
2.0.0	2023.12.11	New layout. Categorized notes and warnings.	Approved
3.0.0	2024.08.26	Cleaning and disinfection instructions updated.	Approved
4.0.0	2024.12.17	Device Manager instructions updated.	Approved
5.0.0	2025.03.27	General update.	Approved

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1 CONVENTIONS

The following conventions are used in these user instructions:

WARNING: Warning statements describe conditions or actions that can result in personal injury or loss of life.

CAUTION: Caution statements describe conditions or actions that can result in damage to the equipment or loss of data. Caution statements alert the user that the clinician has the responsibility of determining significance of results due to actions and varying factors present with each case.

NOTE Notes contain additional information on using this product.

TIP Tips contain additional information on how to make use of the features and functions of the device.

CE 0537

The CE Mark and Notified Body Registration Number signify that the product meets all essential requirements of European Medical Device Regulation 2017/745.

1.1 Terminology

Table 1 Terms used in the document

Term	Description
ECG	Electrocardiogram
EDF	European Data Format
HSAT	Home sleep apnea testing
IP	Ingress Protection
MDR	Medical Device Regulation

2 GENERAL WARNINGS AND CAUTIONS TO REVIEW BEFORE USE

Do not operate Bittium Respiro™ device without first reviewing the following notices.

WARNING: Do not use a broken device or a RIP belt, ECG adapter, ECG electrode or cannula for which the packing has been damaged or opened. Contact nursing staff if the devices and sensors are damaged.

WARNING: Nasal cannula, ECG adapter, ECG electrodes and RIP belts are for single-use only. Reuse between patients is strictly prohibited. The reuse of single-use products may lead to contamination.

WARNING: RIP belts must not be worn against skin.

WARNING: Respiro is not intended to be used at the same time with high frequency (HF) surgical equipment or with a defibrillator.

WARNING: Position the nasal cannula carefully. Use medical tape for securing the cannula. Make sure that the cannula length is optimal for each patient. Avoid using too long cannulas to ensure patient safety.

WARNING: Do not open and/or modify the equipment.

WARNING: Risk of lethal electric shock if fluid leaks into the power supply. Do not use fluids or chemical cleaning agents for cleaning. Disconnect power supply before cleaning.

CAUTION: Use only the included power supply and the charging dock when charging Respiro™.

CAUTION: Respiro device's internal pressure sensor is very sensitive. Do not produce excessive pressure to nasal cannula's pressure hose.

CAUTION: Use only mild detergents and disinfectants approved by the manufacturer when cleaning and disinfecting the devices. Immersing the devices in liquids is prohibited.

CAUTION: Nail polish and artificial nails must be removed before recording as they interfere with the pulse oximeter.

CAUTION: Do not use the devices in shower or sauna. IP67.

CAUTION: EMC disturbances may cause interference and/or noise to recording data.

CAUTION: Respiro device should not be used adjacent to or stacked with other electrical equipment. If adjacent or stacked use is necessary, the device should be observed carefully to verify normal operation.

CAUTION: Use the device only with medical device components and other system parts provided by Bittium Biosignals Ltd. Other medical device components and system parts may negatively affect the device performance or cause non-recognized issues and non-conformities or break the device.

CAUTION: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Respiro device, including cables specified by Bittium Biosignals Ltd. Otherwise, degradation of the performance of this equipment could result. Examples of such devices include: mobile phone, laptop computer, activity band, smart ring.

CAUTION: Before operating Respiro device, please read this manual thoroughly and keep it for future reference. Failing to follow the operation instructions in this manual may result in improper analysis of the data. The manufacturer accepts no liability for damages resulting from improper use.

CAUTION: You must ensure that the operating system in the computer you are using is up-to-date and secure

CAUTION: Respiro is not suitable for use in MRI environment.

CAUTION: Do not store cannulas in direct sunlight. Store cannulas in dry conditions.

CAUTION: Respiro device contains a magnet. Do not place it directly next to a medical device (e.g. pacemaker) during use.

NOTE The connector for the pulse oximeter is a push-pull connector. Do not twist or bend the connector when connecting the pulse oximeter sensor.

NOTE Do not use excessive force when connecting the nasal cannula

NOTE Keep the devices, medical device components and other system parts out of reach for children and pets.

NOTE Body and hand creams as well as sunscreens can damage the device

NOTE Skin must be intact, clean, and dry in the area where the ECG electrode is attached (applicable only in ECG use case).

NOTE Body-worn components (e.g. medical tape) may irritate skin, but there are no other known adverse events due to using the Respiro device. If the patient has lots of body hair it must be shaved from the area where the ECG electrode is attached (applicable only in ECG use case).

NOTE Any serious incident that has occurred in relation to the device must be reported to the manufacturer and the competent authority of the country in which the user and/or patient is established.

NOTE We recommend changing the batteries of the Nonin 3150BLE pulse oximeter after each recording night or at the latest every two recording nights to ensure that the pulse oximeter's battery capacity is sufficient for the entire recording period.

NOTE The screenshots shown in the document may not represent the latest software User Interface views.

3 INTRODUCTION

These instructions cover the correct and safe use of the Respiro™ sleep apnea device. Respiro provides reliable recordings of selected sleep apnea-related bio signals in home sleep apnea testing (HSAT).

CAUTION: Before operating Respiro device, please read this manual thoroughly and keep it for future reference. Failing to follow the operation instructions in this manual may result in improper analysis of the data. The manufacturer accepts no liability for damages resulting from improper use.

3.1 Respiro intended use

The device is intended to be used as a screening device for brief overnight polygraphy, which is always carried out by doctor's prescription. Use of Respiro for any other purpose is prohibited. Respiro is used either in a hospital or at patient's home. The device records patient's biosignals. The device does not actively monitor the patient's status, make diagnoses or treat the patient and it cannot be used as a life-sustaining device. Device does not record EMG, EOG, or EEG signals required in an extensive sleep study (polysomnography). Device is not designed to be used with children. The device is operated by healthcare professionals (hospital), the patient or another person at the patient's home. A healthcare professional gives instructions to the patient or the device operator on using the device and starting the recording before using it at home. The patient is provided with an illustrated quick guide for home use.

Image below gives an overview of the device and its interfaces.

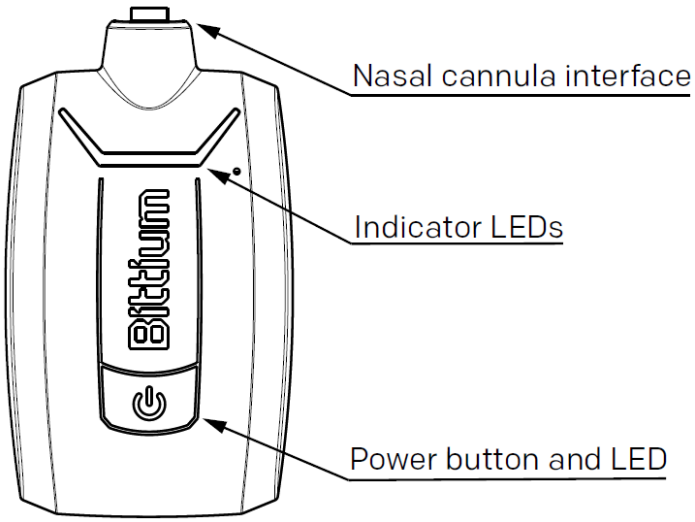


Figure 1 Respiro device interfaces

Figure below presents the pulse oximeter and the sensor.

Figure 2 Pulse oximeter and sensor

See also pulse oximeter's operator's manual: Operator's Manual Model 3150 WristOx2® Pulse Oximeter BLE and USB: https://www.nonin.com/support/3150-ble/. Operator's Manual can also be found from device's memory.

NOTE The screenshots shown in the document may not represent the latest software User Interface views.

Table below lists the biosignals and sensors used in Bittium Respiro:

Table 2 Signals and sensors

Signal	Sensor
Airflow	Nasal cannula and air pressure sensor
Respiratory effort (abdominal)	Respiratory inductance plethysmography (RIP) belt (abdominal)
Respiratory effort (thorax)	Respiratory inductance plethysmography (RIP) belt (thorax)
Oxygen saturation & pulse rate	Wrist-worn pulse oximeter with finger sensor
ECG monitoring	1-channel ECG electrode
Body position	Integrated accelerometer
Snoring	Integrated microphone for audio volume

3.2 Adverse events

Body-worn components (eg. medical tape) may irritate skin, but there are no other known adverse events due to using the Respiro device.

3.3 Indications

- Suspected sleep-related breathing disorder (obstructive sleep apnea, central sleep apnea, mixed sleep apnea, Cheyne-Stokes breathing)

3.4 Contraindications

- The product is not intended for pediatric patients. Age limit 18 years.
- Outstandingly big physical size. Sensor adjustment out of control.
- Amputation – missing fingers / both hands (SpO2 measurement not possible).
- Unfeasible to use sensors for any reason (sensitive skin).
- Artificial nails / thick fingernail painting prevents SpO2 measurement.
- Acute respiratory infection, which might be a confusing factor in symptoms and interpretation.
- A person who is unable to perform self-directed / independent recordings at home.

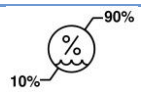
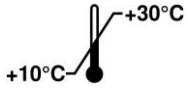
A doctor always assesses the requirement for a night polygraphy and whether the patient is suitable for home recording. Only an expert can interpret and analyze the results of night polygraphy recording and be responsible for the given statements and care.

3.5 Security

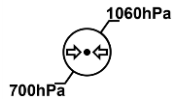
System applications are recommended to be used with computers with proper anti-virus protection installed. Use of firewall is also recommended. With any concern related to security please contact medical.support@bittium.com for additional recommendation and support.

3.6 Symbols and Labels

Symbol	Description
CE	The device complies with the requirements of the Medical Device Regulation 2017/745 or Medical Device Directive 93/42/EEC
CH REP	Swiss authorized representative.
EC REP	Authorized representative in the European Community/European Union.
CE 0123	CE Marking indicating conformance to EC directive No. 93/42/EEC concerning medical devices.
	Type BF applied part (electrically isolated).
	Do not reuse.
	Consult Instruction for use.
LOT	The Lot number.
	For EU only: This symbol indicates that this device shall be disposed according to European Union directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE).
	During transportation: keep package dry, protect from rain.
MD	Medical device.
IP67	Ingress protection rating. Device is dust-protected and protected against the effects of immersion in water between 15 cm and 1 m for 30 minutes.
IP31	Ingress protection rating. Device is protected against small objects (≥2,5 mm) and condensation.
	Wireless Transmission Symbol.

	A relative humidity range of 10 % to 90 %, non-condensing.
	Transport and storage conditions +10 °C to + 30 °C (transport) +10 °C to + 30 °C at a relative humidity up to 90 %, non-condensing (storage).
	Product number. Indicates the catalogue number so that the medical device can be identified.
	Manufacturer.
	For Devices and other medical device components and system parts Data matrix (GS1) is a two-dimensional barcode consisting of black and white modules arranged in either a square or rectangular pattern, also known as a matrix. The data to be encoded can be text or numeric data. GS1 data matrix includes GTIN and production identifier (PI). • GTIN (01) • Serial number (21) • Date of manufacture (11) • LOT (10)

	For software products:
	
	UDI code in human readable and machine-readable format, accompanied with symbol “Unique Device Identifier”
	
	• UDI code shall consist of the following attribute:
	  ○ UDI-DI AI(01) GS1 GTIN
	  ○ UDI-PI AI(8012) software version no. A.B.C

	Atmospheric pressure limitation. Indicates the range of atmospheric pressure to which the medical device can be safely exposed. An atmospheric pressure range of 700 hPa to 1 060 hPa.
	Use-by date.
	Date of manufacture.
	Keep away from sunlight.

	Single patient multiple use.
	Serial number.

3.7 User responsibility and warranty

This product shall be assembled, operated, maintained, and repaired in accordance with the instructions provided.

A defective product must not be used. Parts that are broken, worn, missing, incomplete, distorted or contaminated must be replaced immediately. Should any repair or replacement become necessary, the device shall be delivered to your local distributor or Bittium Biosignals Ltd for service.

The user of the product is solely responsible for any malfunction resulting from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than Bittium Biosignals Ltd or their authorized service personnel.

The device has been tested to work with the following cannulas:

- CNSAC Nasal Pressure monitoring cannula (adult), 0.3m tube, male luer connector (NC-002/30c)

The use of medical device components or system parts other than those approved by the manufacturer may break the device, decrease its performance, or cause other issues.

Shelf life of the medical device components and other system parts shipped with Respiro can be seen from the product packing markings.

Warranty: 12 months for Respiro and pulse oximeter. Service interval is max. 2 years.

3.8 Device disposal

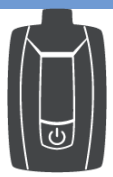
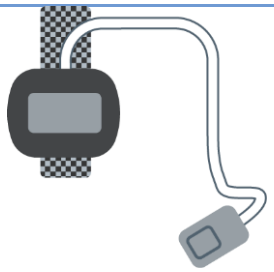
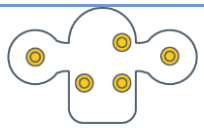
If the product or its documentation bears this mark, it must not be disposed of with other household waste at the end of its life. The device contains electronics that require it to be recycled in an appropriate manner. Take care of the environment and dispose of the device according to the disposal instructions. You can check the location of the nearest recycling point with your local waste disposal authority.

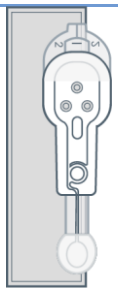
4 USING RESPIRO

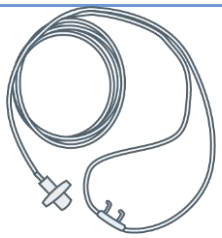
4.1 Respiro Carry case contents

Table below lists the carry case contents as illustrations.

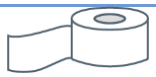
Table 3 Carry case contents

Item	Image
Bittium Respiro™ device (applied part)	
Charger dock	
Medical Power Supply 5V 1400mA (same power supply is used with the charger dock)	
Pulse oximeter Nonin 3150 with batteries (type AAA), 2 pcs (inserted)	
RIP (Respiratory inductance plethysmography) belt(s) for attaching Respiro to body (applied part). Two sizes are available, short and long. • Size Short: Length approx. 80 cm, recommended range of use 80 - 120cm. Default size. • Size Long: Length approx. 120 cm, recommended range of use 120 - 180 cm	
Respiro patch for 1 RIP belt (Applied part), 2 pcs	

Respiro patch for 2 RIP belts (Applied part), 2 pcs	
Respiro ECG Adapter (applied part, single use)	
Bittium OmegaSnap™ ECG electrode (applied part, single use)	
Bittium Respiro Quick Guide	
Bittium Respiro Notes and Warnings	

Cannula (applied part, single use).	

In addition, recommended to use. Not provided by Bittium

Medical tape (applied part, single use)	

WARNING: Do not use a broken device or a RIP belt, ECG adapter, ECG electrode or cannula for which the packing has been opened.

WARNING: Position the nasal cannula carefully. Use medical tape for securing the cannula. Make sure that the cannula length is optimal for each patient. Avoid using too long cannulas to ensure patient safety.

4.2 Carry case packing

Figure below shows the Respiro carry case contents in HSAT™ recording.

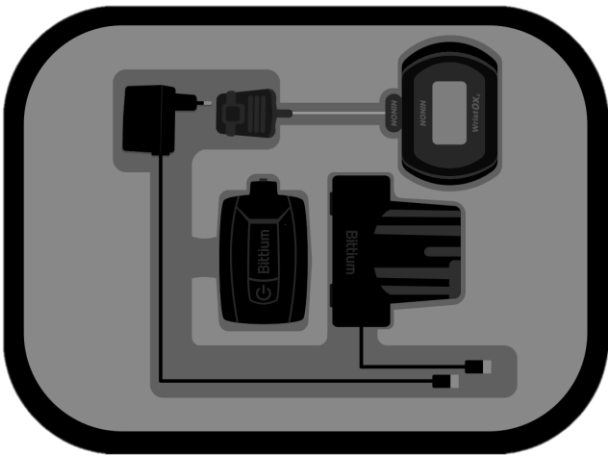
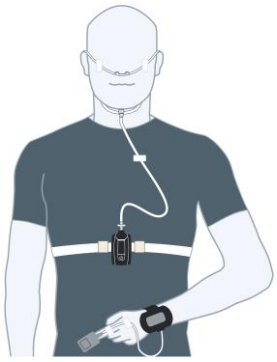


Figure 3 Carry case packing, HSAT

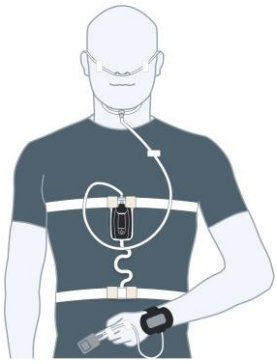
4.3 Configuration options

Respiro polygraphy recording can be carried out as an HSAT™ recording with three sensor configurations. Respiro device (integrated accelerometer and microphone), pulse oximeter with a finger sensor and nasal cannula are used in every setup options. Instead, the **number of RIP belts** and the inclusion of **ECG (electrocardiography) electrode** are dependent on the used setup option. All three setup options are illustrated in the Figure 4.



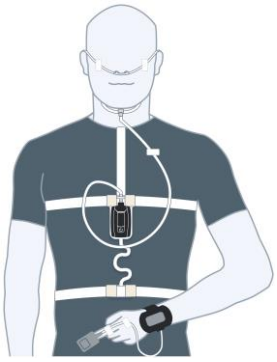
1 RIP belt configuration

- Respiro device
- Pulse oximeter with a finger sensor
- Nasal cannula
- **1 RIP belt**



2 RIP belts configuration

- Respiro device
- Pulse oximeter with a finger sensor
- Nasal cannula
- **2 RIP belts**



2 RIP belts configuration with ECG

- Respiro device
- Pulse oximeter with a finger sensor
- Nasal cannula
- **2 RIP belts**
- **ECG**

Figure 4 Bittium HSAT service setup options

4.4 Equipment needed in recording

See chapter 4.1

4.5 Respiro indicator LEDs and power button functions

LED indications are shown as viewed from the front of Respiro.

4.5.1 LED indications in idle state

Respiro LED indications in idle state are as shown in the figure below:

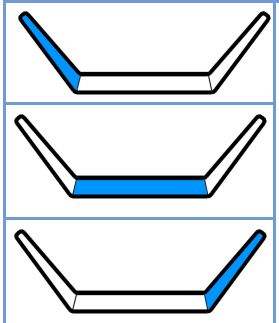
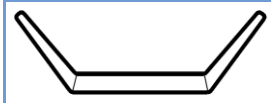
Figure 5 Respiro indicator LEDs in idle state

In this state there is no recording ongoing, and the device is idle. This is the basic state. If no activity occurs in 5 minutes Respiro will shut down. In that state Respiro has no LED indications.

4.5.2 LED indicators during recording

Respiro LED indicators show recording status as described in Table 4 during recording. For potential error situations refer to Chapter 6.

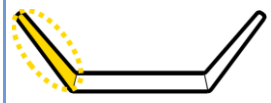
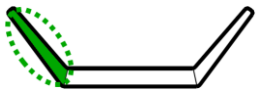
Table 4 LED indicators during recording

Color	Meaning
	Cycling blue lights: Respiro vibrates once, recording start ongoing When recording is ended, Respiro vibrates 3 times and the LEDs flash once.
	Green LEDs on after recording start for 30 seconds: All sensors ok. Indication is same if patient stands up during recording or if patient has first entered a patient marker indication.
	No LEDs on: Respiro in sleep mode, recording ongoing. Patient not standing.
	Middle LED blue for 3 seconds: Patient marker indication when power button is pressed once.

4.5.3 LED indicators while charging Respiro

Respiro LED indicators blink as described in Table 5 when Respiro is charged in its charging dock.

Table 5 LED indicators during charging

Color	Meaning
	Leftmost LED blinking yellow: Battery charge 0-29 %.
	Leftmost LED blinking green: Battery charge 30-49 %.
 	Two leftmost LEDs turn successively green, rightmost LED off: Battery charge 50-89 %.
  	All three LEDs turn successively green: Battery charge 90-94 %.
	All LEDs static green: Battery charge 95-100 %.

4.5.4 Power button functions

Respiro device's power button has the following functions:

- A press of approx. 3 seconds: Respiro power on and idle state (blue LED).
- After power on a press of approx. 8 seconds after which Respiro vibrates once: Recording start.
- A press of approx. 3 seconds during recording: Recording end. Respiro vibrates 3 times.
- Short press (<3 seconds): Patient event marker set indication during recording.
- A press of approx. 12 seconds: Respiro hardware force shutdown.

TIP After the registration is finished, the device switches itself off within approx. 5 minutes if it is not used.

See also chapter 4.5.2 for corresponding UI indications.

4.6 Before recording

Before performing Bittium HSAT recording, Respiro device is charged, and batteries are inserted to the pulse oximeter to check the battery state. Make sure that the Respiro device's battery charge status is sufficient (at least two green LEDs are blinking successively according to Table 5 while charging. Note! If scheduled recording is used all three indicator LEDs must be blinking successively to ensure sufficient battery charge for the recording) for the planned recording.

Contrast to Respiro, a pulse oximeter contains replaceable batteries. After inserting batteries check the state of the battery indicator. The battery indicator (Figure 6) shows one of three states: full, half, and low. **Replace batteries to a pulse oximeter when it reaches less than three segments on the screen.** Different types of batteries (alkaline, lithium, rechargeable) can have an effect on the pulse oximeter's operating time. We recommend changing the batteries of the Nonin 3150BLE pulse oximeter after each recording night or at the latest every two recording nights to ensure that the pulse oximeter's battery capacity is sufficient for the entire recording period. Remove the batteries and disconnect the sensor if the pulse oximeter is to be stored for more than 1 month.

Figure 6 Battery charge symbol

Respiro battery life is approx. 20 hours of HSAT recording with the largest configuration and Bluetooth® use. It is recommended that Respiro is always fully charged between patients.

TIP If the recording type is 2 RIP belts configuration with ECG and it is necessary to perform a recording for two nights, the patient must be instructed not to remove the ECG electrode after the first night. The electrode can remain attached also while having a shower, but the electrode's snap connectors must be carefully dried after the shower.

4.6.1 Charging Respiro

Set Respiro in the charging dock while making sure that the charging dock is connected to the power supply.

TIP Connect the charging dock only to the USB port of the supplied power supply. Do not connect it anywhere else for charging.

TIP If a recording state is accidentally on in Respiro device, it is ended automatically when the Respiro device is set in the charging dock

Respiro device's battery is at least 95 % full when all 3 indicator LEDs are green. See chapter 4.5.3.

4.6.2 Attaching the pulse oximeter's wristband

Attach the pulse oximeter's wristband as shown in the images below.

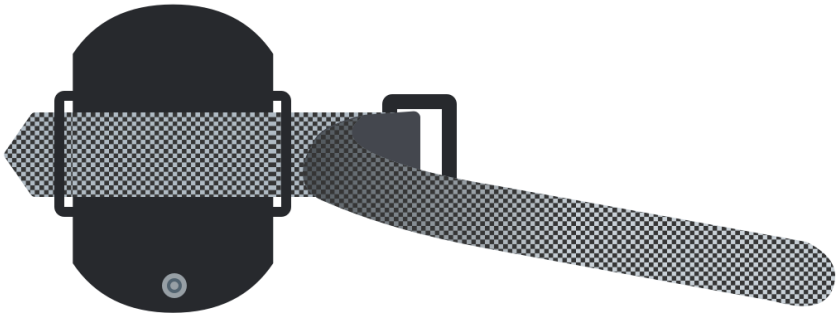


Figure 7 Threading the short part

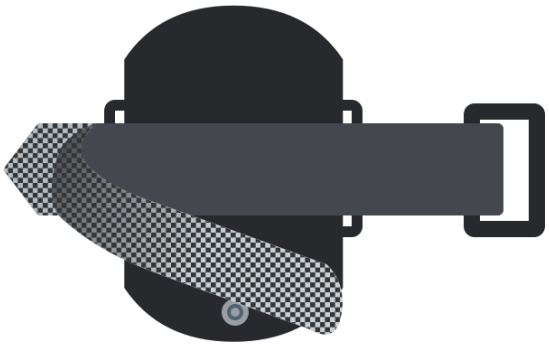


Figure 8 Threading the long part

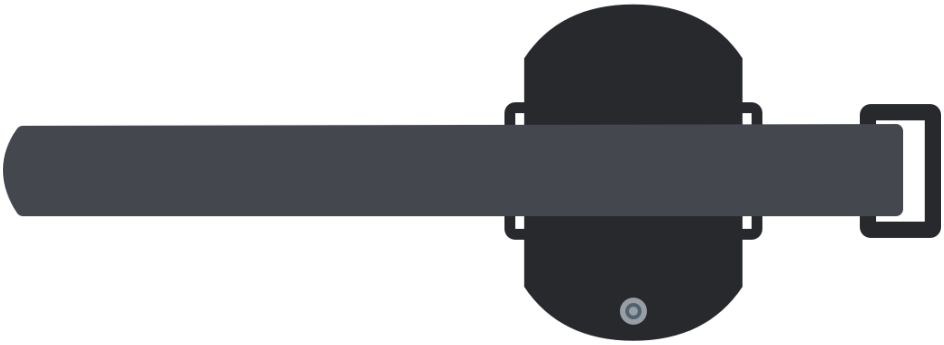


Figure 9 Attached wristband, back view

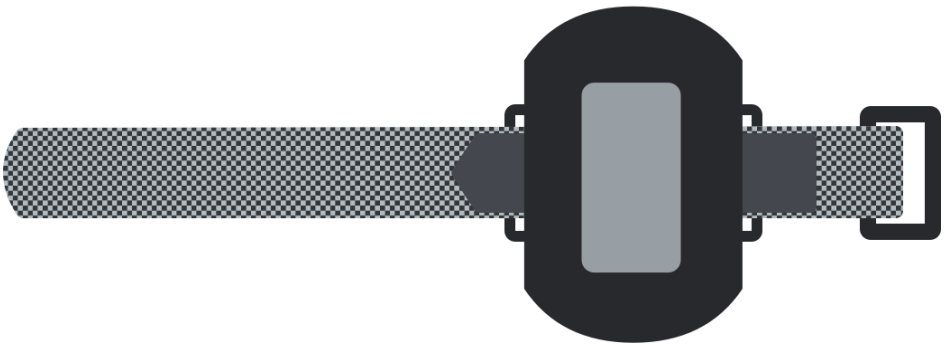


Figure 10 Attached wristband, front view

4.6.3 Checking the device pairs

The carry case equipment (Respiro, pulse oximeter) is already connected by the manufacturer. Note, however that when for example cleaning several devices at the same time these device pairs may get mixed with other devices. It is possible to find out the device pairs following the instructions below.

TIP	Make sure that Respiro is not in the charger dock or connected to a computer when checking the device pairs.

Respiro and pulse oximeter:

1. Start the Respiro devices by pressing the power button approx. 3 seconds. All 3 indicator LEDs are blue.
2. Press the power button again approx. 8 seconds until Respiro vibrates once and all 3 indicator LEDs are blinking blue.
3. Bluetooth connection is formed automatically between Respiro and the pulse oximeter. Press the pulse oximeter's power button with eg. your fingernail to start it if it does not start automatically.

Figure 11 Pulse oximeter power button

4. After Respiro has activated the recording state all 3 indicator LEDs will be blinking blue for few seconds. Then, after the pulse oximeter is started, Respiro device's left LED indicator will be green, if the finger is inserted in the sensor and yellow if it is not. Respiro is not connected to the pulse oximeter in question if the left LED indicator is red.
5. Switch off the Respiro device by pressing the power button. Press the power button for approx. 3 seconds to stop the activated recording state.

TIP It is not necessary to switch off the pulse oximeter separately from its power button. It switches off automatically after 10 minutes when there is no Bluetooth connection and when the finger is removed from the sensor

You can also find out the device pairs via Respiro Device Manager by comparing the serial number information in Respiro Device Manager with that shown on the pulse oximeter.

4.7 Respiro Device Manager

Bittium Respiro Device Manager is a software that is used for setting up Respiro device in HSAT recordings. Bittium Respiro Device Manager works in Windows based operating system, and it includes the following functionalities:

- Updating firmware
- Synchronizing device time with PC time
- Language selection
- Selecting sensor configuration
- Connecting Respiro and pulse oximeter
- Scheduling recording (start and end times)
- Saving recording files
- Deleting recording files
- Reset recorder

4.7.1 Starting Respiro Device Manager

1. Connect the Respiro device's charging dock to a computer with the USB cable.
2. Set Respiro in the charging dock. Respiro indicator LEDs will be blue for a moment until the charging cycle begins and the LEDs blink green cycling from left to right.
3. Start Respiro Device Manager application via Windows File Explorer by double-clicking first the Respiro device icon. You can open the File Explorer by clicking the yellow folder icon at the bottom of the desktop view.
    a) Double-click Respiro device icon.

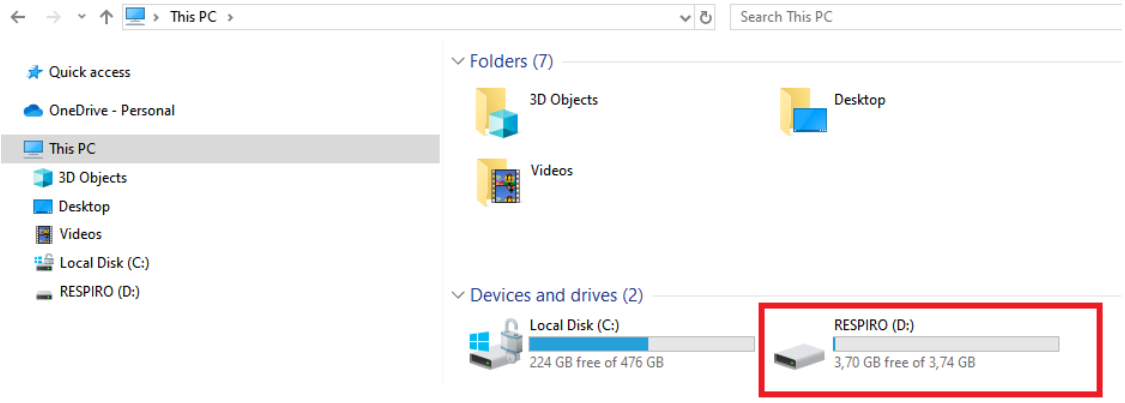


Figure 12 Opening Respiro Device Manager from PC

b) Double-click Respiro Device Manager folder.

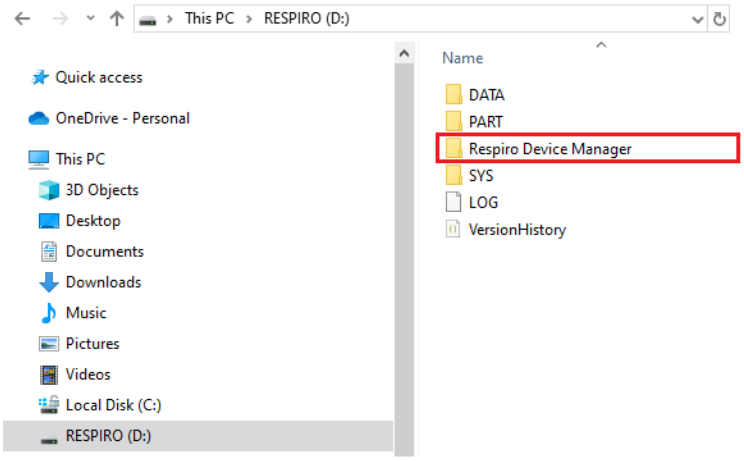


Figure 13 Opening Respiro Device Manager from the Respiro Device Manager folder

c) Double-click Respiro Device Manager file. A desktop shortcut is created when using Respiro Device Manager for the first time.

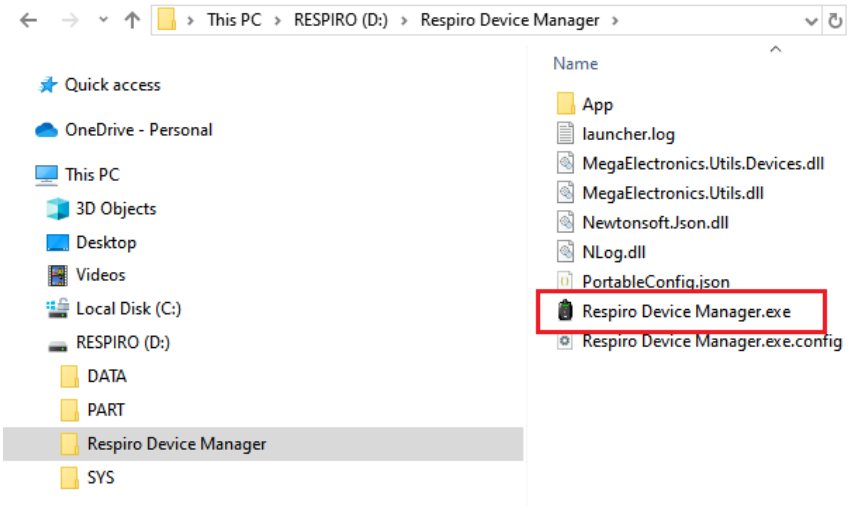


Figure 14 Opening Respiro Device Manager.exe

4. Wait for the application to detect Respiro. Make sure that Respiro is inserted in the charger dock and that the charger dock is connected to the computer.
5. After the home view is opened, the Respiro Device Manager installs a Bittium Root certificate to the PC. The online update mentioned in chapter 5.3 requires this. Press “Yes” in the following Security Warning window:

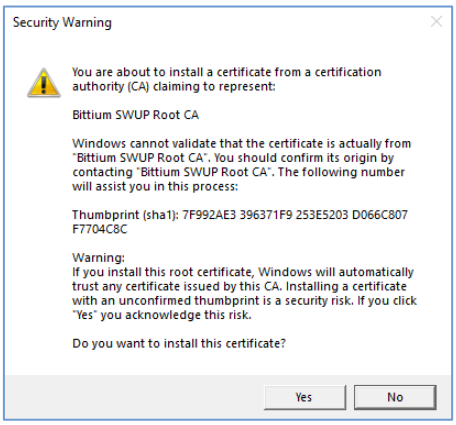


Figure 15 Certificate installation window

TIP The certificate installation window is asked only once in the first time when the Respiro Device Manager is installed.

6. The Home view of Respiro Device Manager opens.

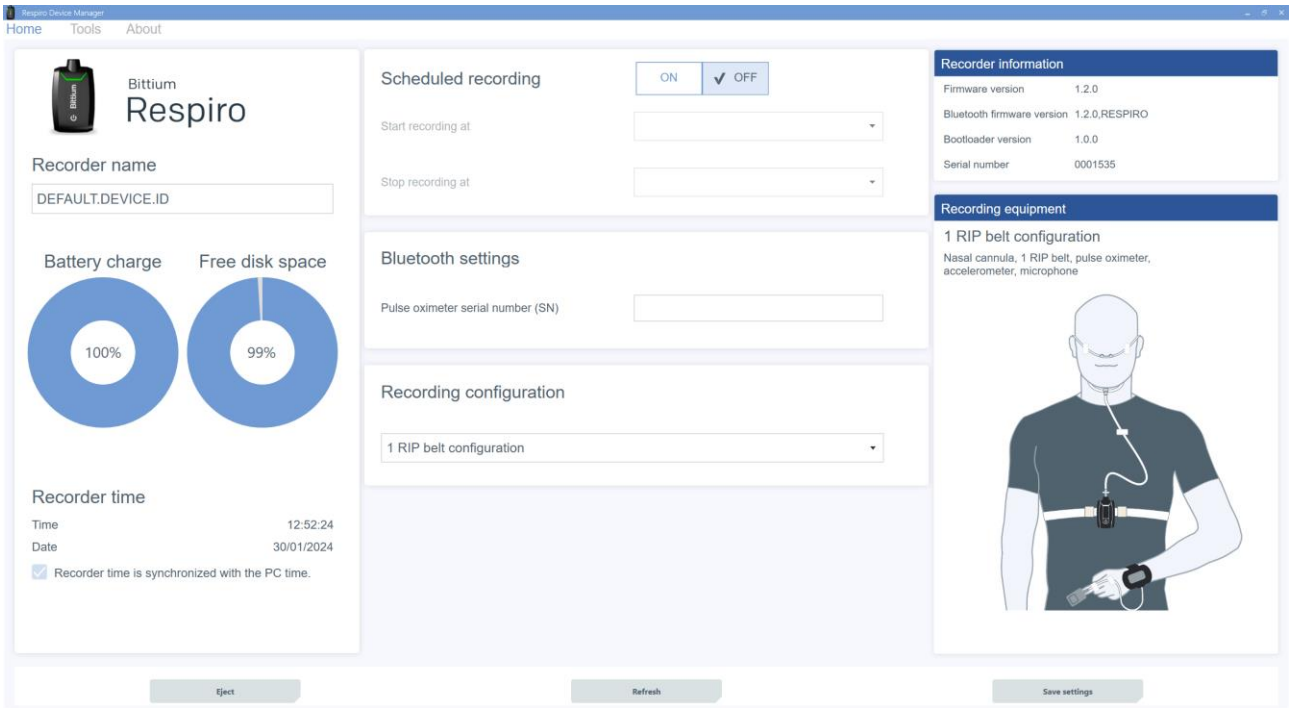


Figure 16 Respiro Device Manager Home view

4.7.2 Connecting Respiro and the pulse oximeter

Follow these instructions if you need to connect Respiro and the pulse oximeter again due to e.g. a device failure:

1. Open Respiro Device Manager as instructed in the earlier chapter 4.7.1.
2. Enter the pulse oximeter's serial number, found on the back cover of the pulse oximeter, in the "Pulse oximeter serial number" field in the Respiro Device Manager home view and click "Save". If you want to add a name for the Respiro device, you can enter it in the "Recorder name" field.

TIP Do not use patient information when re-naming Respiro device. Allowed characters when re-naming Respiro device are: letters a-z, numbers 0-9, dot (.) and comma (,).

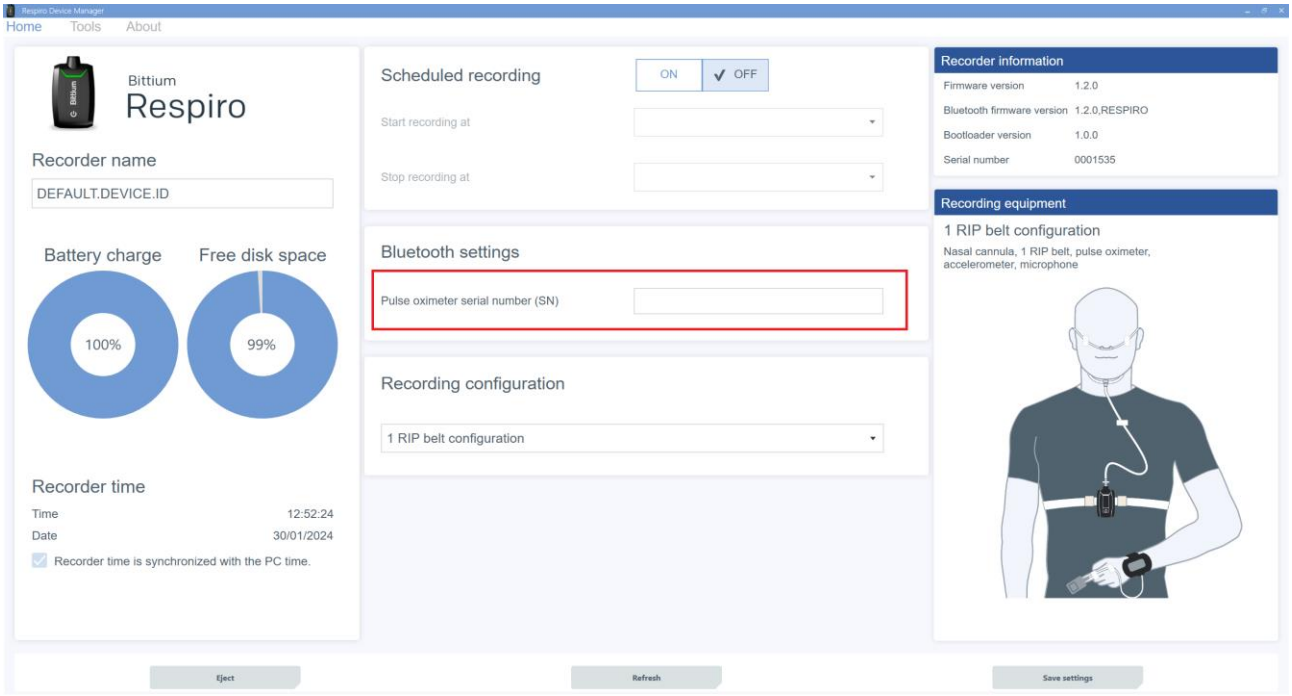


Figure 17 Respiro Device Manager Home view

3. Start the pulse oximeter by pressing its power button (see chapter 4.6.3) with e.g. your fingernail when the application requests you to do so and click OK. Connecting starts.

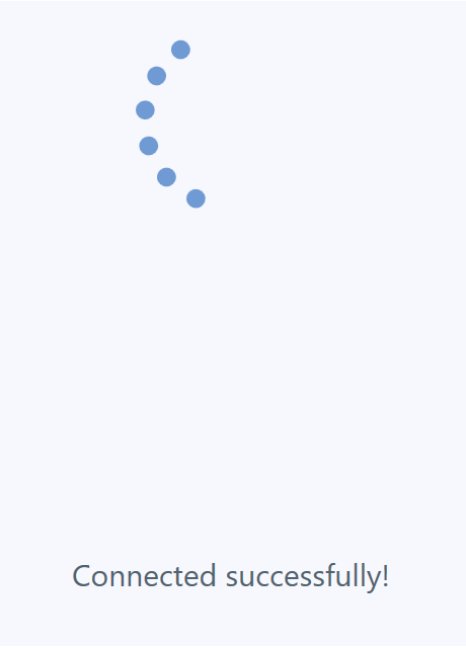


Figure 18 Pulse oximeter has connected to Respiro successfully!

Respiro Device Manager application notifies you if the connecting process was successful. If it was not successful, try again and follow the on-screen instructions. See Figure 19. Note that it is also possible that the pulse oximeter is already connected with another Respiro device, and this is why the connecting process fails. In this case enter the oximeter's serial number in the Pulse oximeter device name field in the Respiro Device Manager home view and click Save. This replaces the old device pair with this new one.

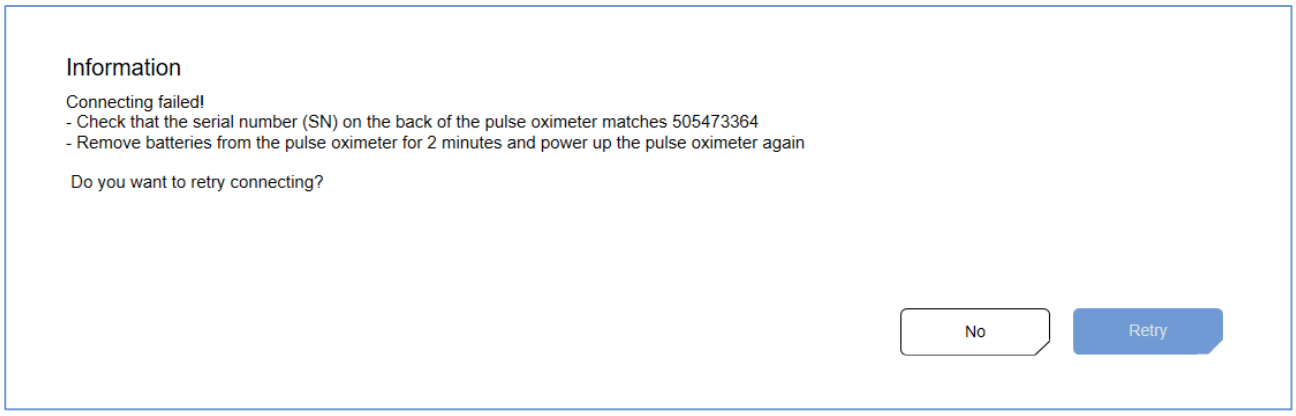


Figure 19 Pulse oximeter connecting failed information window

TIP The Pulse oximeter serial number field must contain 9-digits. Non-digit characters are not allowed.

TIP If the registration is scheduled the above instructions do not apply. In this case the scheduled registration must be first removed using the Respiro Device Manager.

Ensure that Nonin pulse oximeter is not already connected to another device by following the pulse oximeter's Bluetooth indicator light (see Nonin Pulse Oximeter Operator's Manual). If the pulse oximeter is connected to another Respiro, find this Respiro and turn it off.

Remember to always detach Respiro safely from the computer using the Windows Safely remove hardware function or via Respiro Device Manager's Eject function.

4.7.3 HSAT recording mode

In HSAT recording mode the recording is saved directly to Respiro's internal memory. After the recording in HSAT recording mode, Bittium Respiro™ is returned to clinic / hospital and the device is connected to PC with USB cable and the recording data is uploaded locally from the device's internal memory card and stored to the Bittium MedicalSuite™ service platform.

4.8 Starting recording

Before starting a recording, you must select the configuration from Bittium Respiro Device Manager that will be used from the drop-down list under Recording configuration. The options are:

- 1 RIP belt configuration
- 2 RIP belts configuration
- 2 RIP belts configuration with ECG

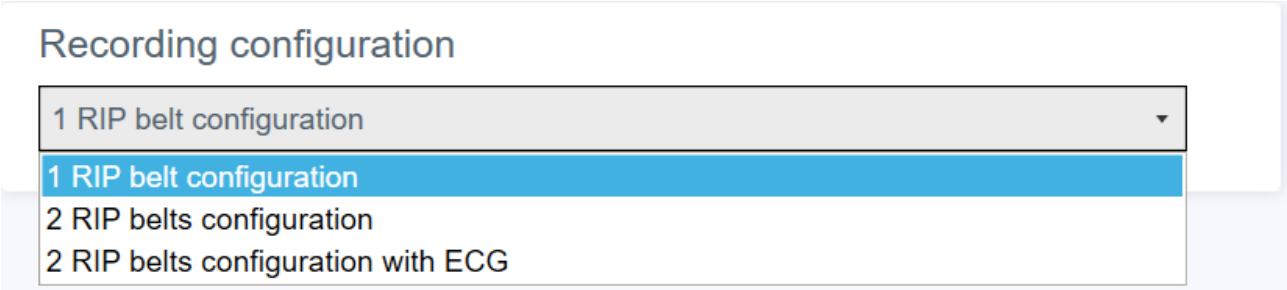


Figure 20 Recording configuration

The selected option is shown in the figure on the right. The selected configuration is valid until it is changed in Device Manager. Click “Save” after the configuration is selected.

4.8.1 Scheduled recording

In HSAT recording it is possible to set the recording to start and stop at a predefined time in cases where the patient may not be able to start it by himself/herself. The function is activated in the Respiro Device Manager main screen. See chapter 4.7.1 for information on how to start the Respiro Device Manager application. Respiro turns automatically on at the selected starting time and starts to record data from the sensors. Starting the recording is indicated by a short vibration in Respiro.

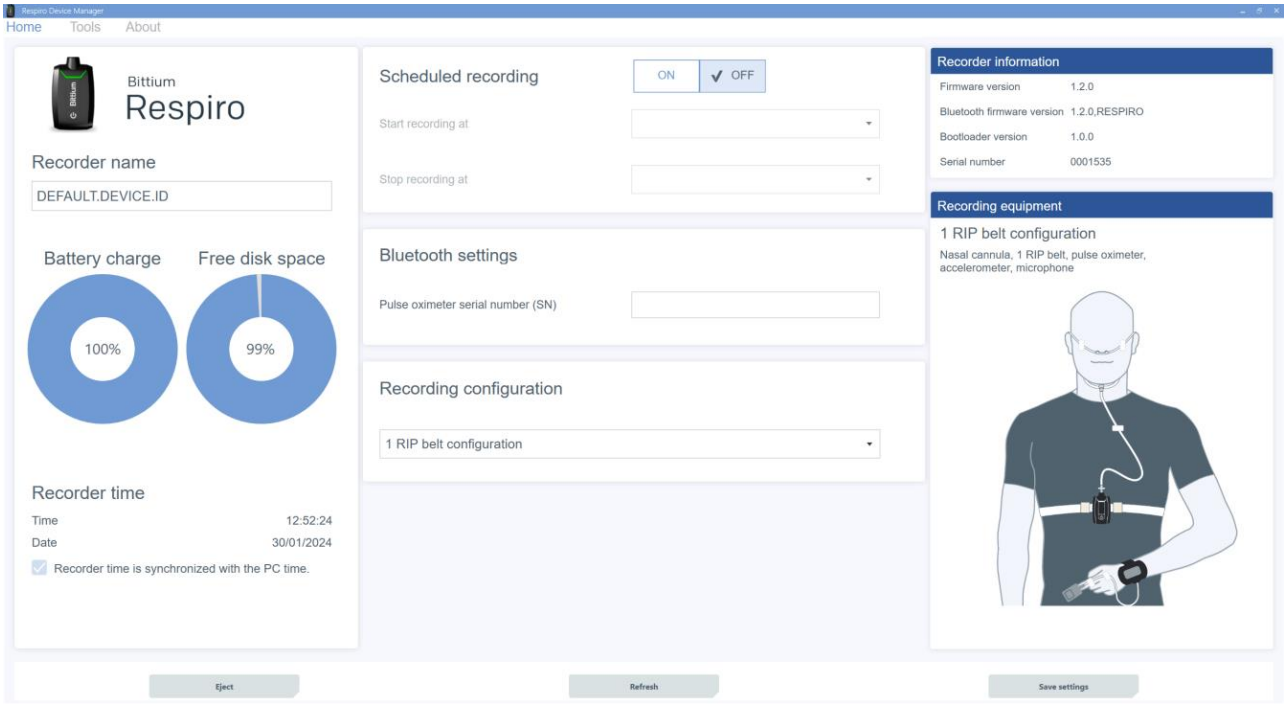


Figure 21 Respiro Device Manager home view

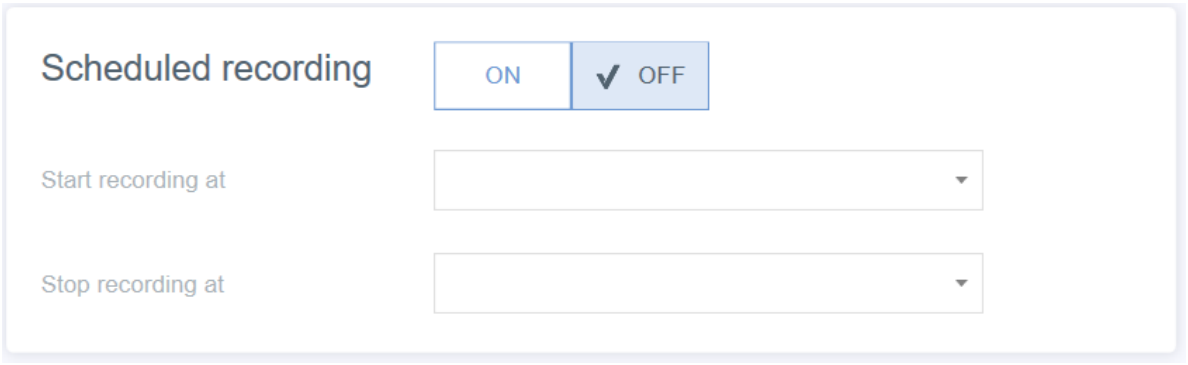


Figure 22 Set the scheduled recording ON

1. Set the Scheduled recording On.
2. Select the starting time from the drop-down list.
3. Select the ending time from the drop-down list.
4. Click “Save”.

TIP	Recording duration must be between 4 and 20 hours.

TIP	In scheduled recording mode when the preset registration start time is reached, the Respiro device wakes up and the system level initialization phase is started. Nonin pulse oximeter's start-up time (wake-up) may vary, but in any case, after a short delay (max 1 minute) Nonin pulse oximeter is started and the polygraphy registration is ongoing.

TIP	It is recommended to synchronize the device time with the PC time. This can be done in the Respiro Device Manager home view on the lower left-hand side of the view. Remember to always detach Respiro safely from the computer using the Windows Safely remove hardware function or via Respiro Device Manager's Eject function.

4.8.2 Starting a recording manually

When Bittium HSAT recording is performed with manual start and stop, the patient starts a recording manually by pressing the Respiro power button first shortly, **approx.. 3 seconds**, to wake up the device and then about **8 seconds** press to start a recording. Starting a recording is indicated by a short vibration.

Figure 23 Respiro recorder button

Before starting a recording, Respiro, pulse oximeter and sensors are attached onto a patient according to the instructions related to the recording configuration used. The recording equipment can be attached either already at the clinic or by the patient at home. When all sensors are attached, the devices are switched on and the device connectivity and sensor functionality is checked using Respiro LED indicators. See the recording configuration specific **Quick Guide** for more detailed information on attaching recording equipment.

4.9 During recording

When Bittium HSAT recording is ongoing, the recording data is automatically stored on Respiro. While awake during a recording, the patient may make patient event markings on the recorded data by pressing the Respiro button shortly (less than 3 seconds) to indicate going to bathroom, drinking or eating, lying on bed, reading a book or other reason. This is indicated by blinking blue LED.

4.10 Stopping recording

Bittium HSAT recording can be set to stop automatically with scheduling time or with manual stop. The used operating mode is selected using **Bittium Respiro Device Manager** when setting up Respiro for a recording.

4.10.1 Scheduled recording stop

A scheduled recording stops automatically at the predefined time. Respiro stops recording and turns off automatically at the scheduled ending time, whereas a pulse oximeter stops recording and turns off automatically. Stopping of Bittium Respiro recording is indicated by vibration of three times and with blue LED lights (lit in blue one by one from left to right). Note that the blue (and stabile) Respiro LEDs are lit for 5 minutes after stopping, but the device can be detached from the body and packed to the carry case.

4.10.2 Manual recording stop

When Bittium HSAT recording is performed with manual start and stop, the patient stops the recording manually by pressing the Respiro button continuously about **3 seconds** when waking up. Stopping the recording is indicated by vibration of three times and with blue LED lights (lit in blue one by one from left to right. Note that the blue LEDs of Respiro are lit continuously for 5 minutes after stopping, but the device can be detached from the body and packed to the carry case. A pulse oximeter turns off automatically.

4.11 After the recording

4.11.1 Uploading the recording data after HSAT recording

Respiro Device Manager application works in Windows 10 operating system. If a recording state is accidentally on in Respiro device, it is ended automatically when the Respiro device is set in the charging dock.

Follow these instructions to upload the recording data from the Respiro device:

1. Connect the charging dock to a computer with the USB cable.
2. Set the Respiro device in the charging dock. Ensure that the device rests properly in the charging dock.

TIP Do not remove Respiro from the charging dock while uploading recording data. Respiro device memory's read function may malfunction and cause an error state that can only be repaired in a service facility.

3. Start Respiro Device Manager application. Wait for the application to detect Respiro. Respiro Device Manager home view opens. See chapter 4.7.1 for information on how to start the Respiro Device Manager application.
4. Select “Tools” from the top of the view.
5. Click “Save recording files”.

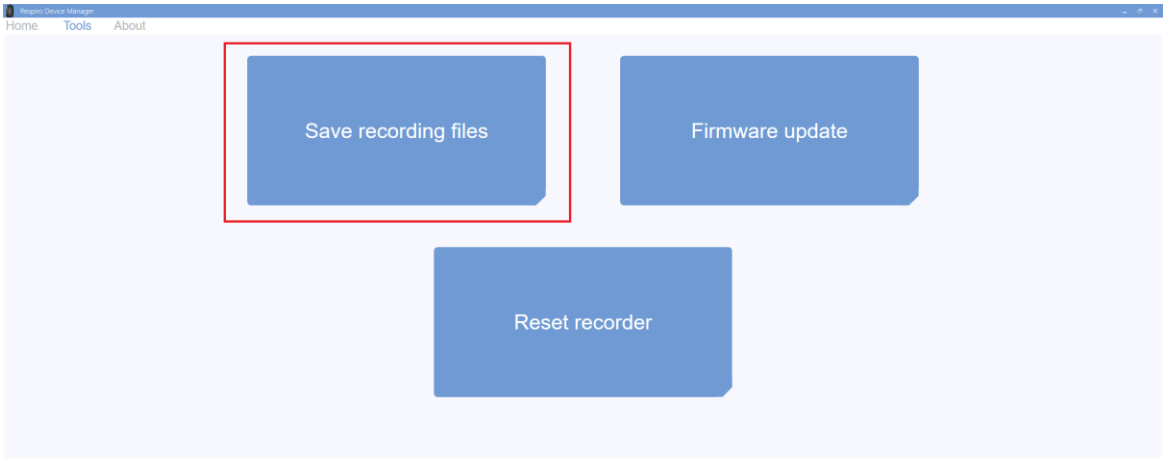


Figure 24 Save recording files

6. Select the uploaded file(s) and click “Browse”.

TIP You can select several files at the same time by pressing the Ctrl-button during selection.

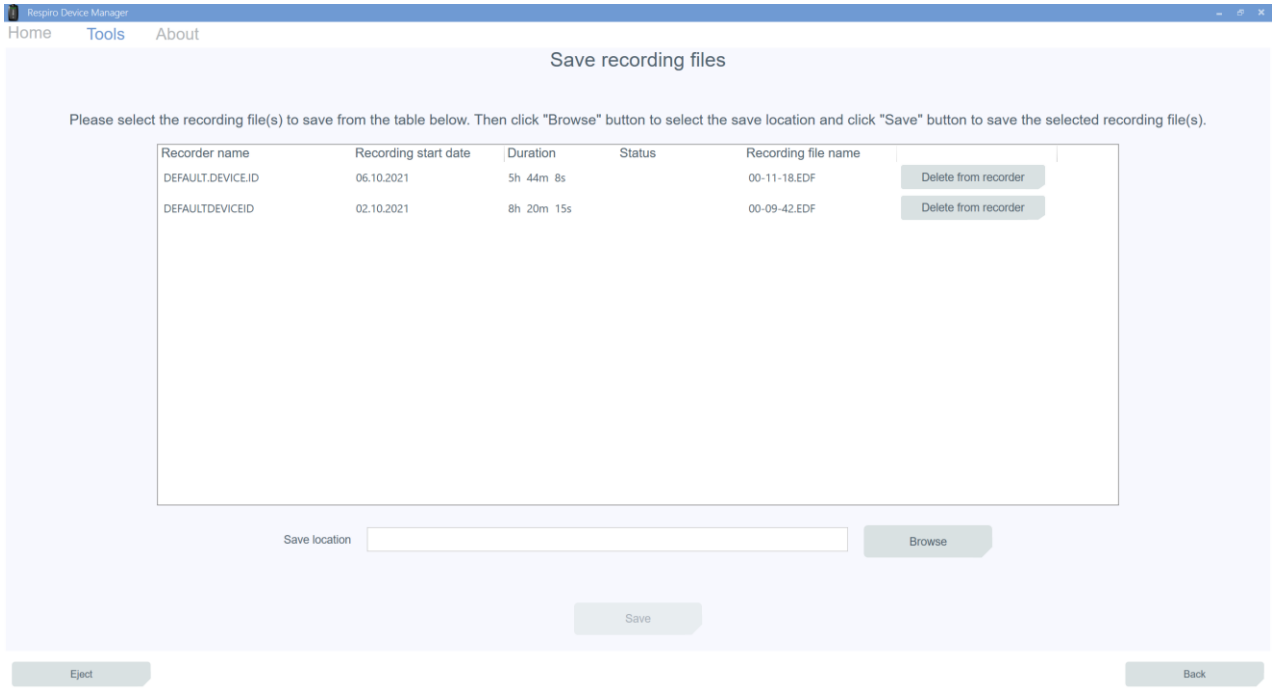


Figure 25 File selecting

7. Select a save location for the file(s) and click “Save”.

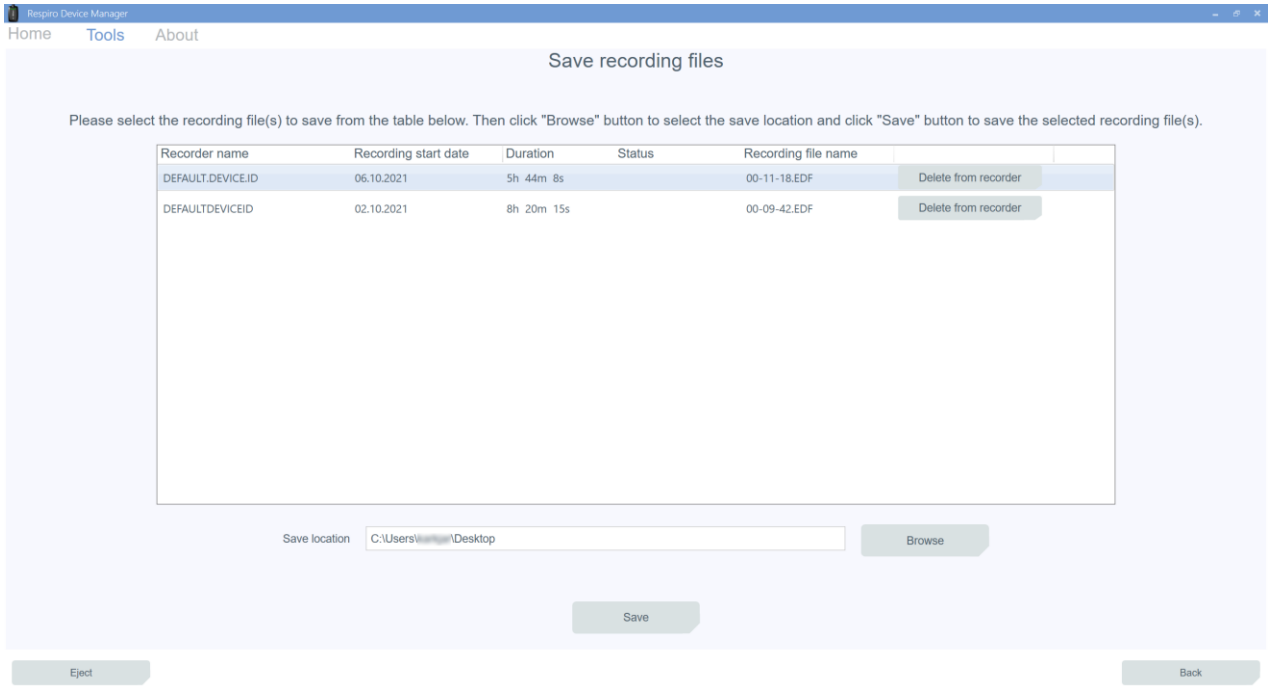


Figure 26 Save location selection

After the files are saved erase the recording data from the recorder by clicking “OK” in the Information view.

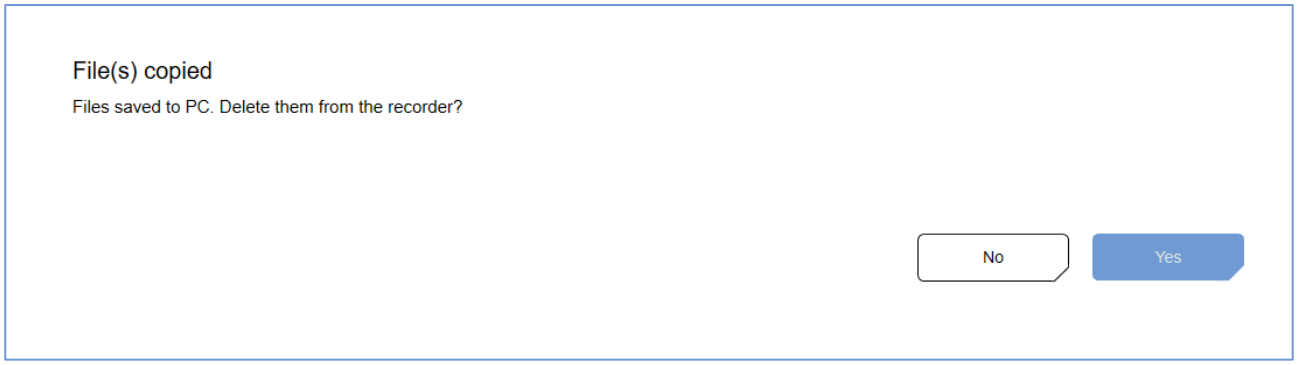


Figure 27 Files copied to PC confirmation window

Those files that were not removed will then remain visible in the Save recording files view.

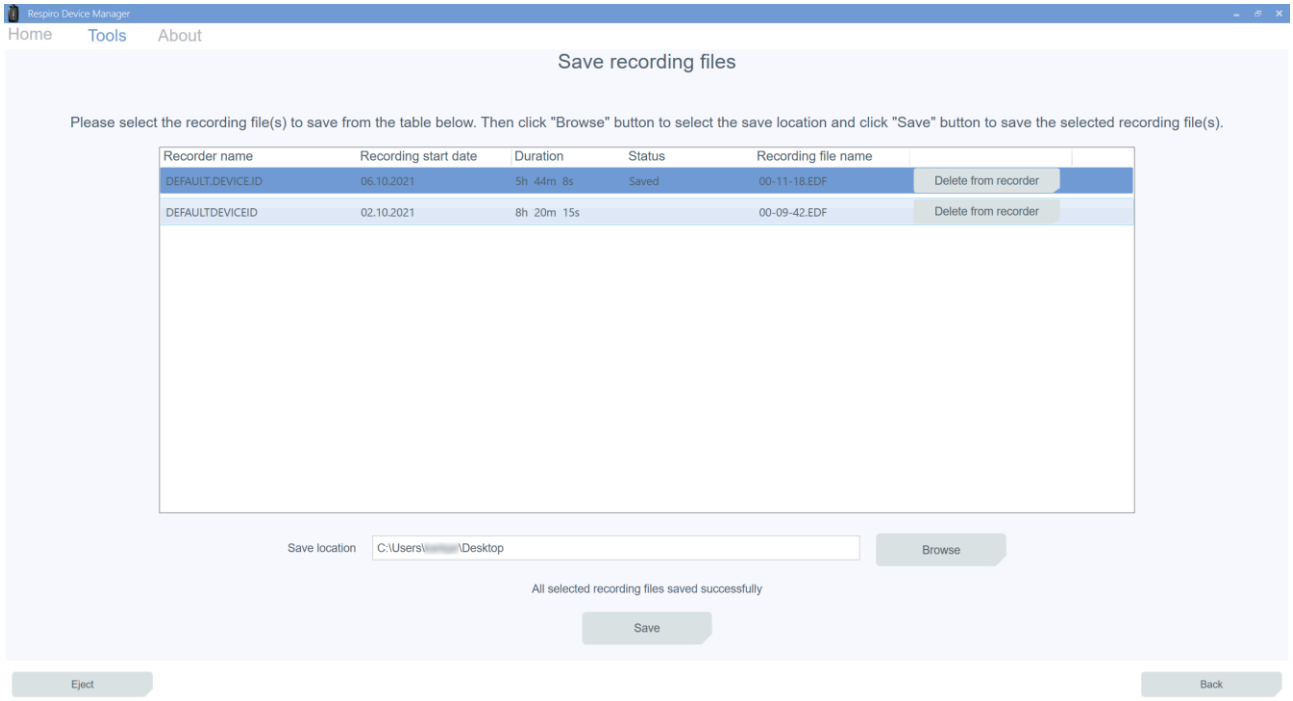


Figure 28 Unremoved files

8. Click “Eject”. You can remove Respiro from the charging dock when the application instructs you to do so.

NOTE	Before starting a new HSAT recording, the data of the previous recording needs to be deleted for privacy reasons from Respiro device by using Bittium Respiro Device Manager. See chapter 4.11.1.

TIP	If the device contains corrupt files, they will appear with a yellow notification triangle. These unusable files can be deleted from the device in the same way as other files by clicking Delete from device.

4.11.2 Other actions

Remember to erase prior recording data from the Respiro device before preparing it for a new patient. See chapter 4.11.1.

Charge the Respiro and replace the pulse oximeter batteries as required. **Replace batteries to a pulse oximeter when it reaches less than three segments on the screen.** Different types of batteries (alkaline, lithium, rechargeable) can have an effect on the pulse oximeter's operating time.

When registration is on OR when Respiro is set in the Charger dock, the communication between Respiro and the pulse oximeter is active which also drains the pulse oximeter’s batteries. This is why we recommend changing the pulse oximeter batteries only after Respiro has been prepared for the next patient.

Pack the carry case for the next patient, see Chapter 4.2.

4.11.2.1 Factory reset

It is possible to perform a factory reset which removes the log files, EDF files, name of the device (if set) and sets the configuration of the device as default. Resetting the device does not remove the pulse oximeter that has been paired with the Respiro.

Follow these instructions to reset the Respiro device:

1. Connect the charging dock to a computer with the USB cable.
2. Set the Respiro device in the charging dock. Ensure that the device rests properly in the charging dock.
3. Start Respiro Device Manager application. Wait for the application to detect Respiro. Respiro Device Manager home view opens. See chapter 4.7.1 for information on how to start the Respiro Device Manager application.
4. Select Tools from the top of the view.

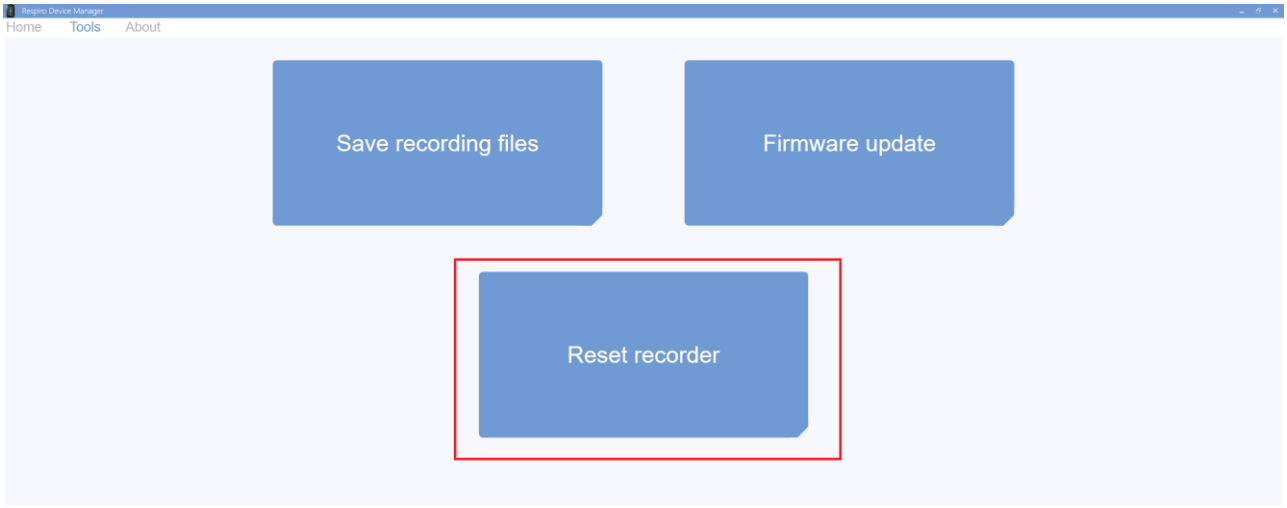


Figure 29 Reset recorder selection on Tools tab

5. Click on “Reset recorder”. A confirmation window opens.

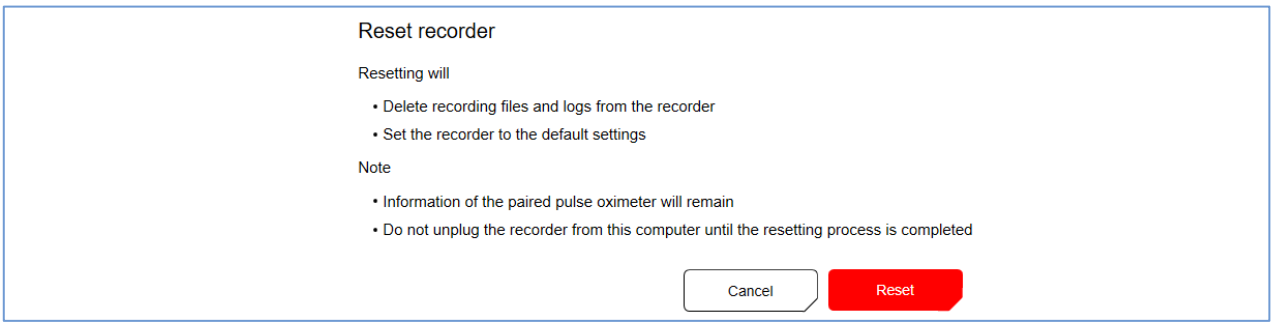


Figure 30 Reset recorder confirmation window

6. Click on Reset and let the reset operation go through.

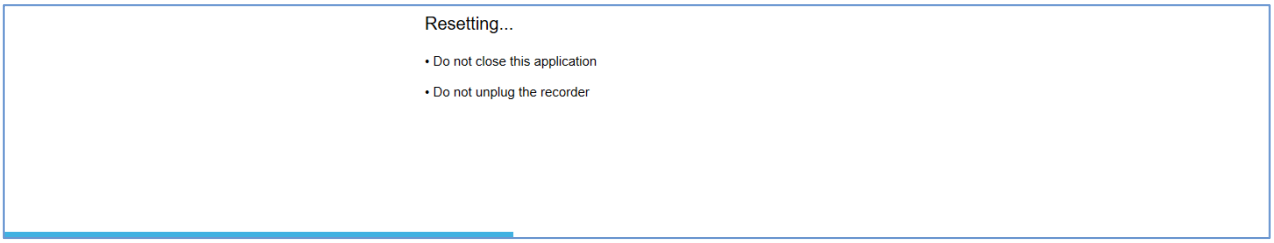


Figure 31 Reset ongoing

TIP Do not remove Respiro from the charging dock while resetting the device. Respiro device functionality may malfunction and cause an error state that can only be repaired in a service facility.

7. When the resetting is complete, a window informing that the recorder was reset successfully. If there are unexpected errors, an error dialog is shown (see chapter 6.2.2).

Figure 32 Reset was successful

NOTE If you have set a password for the device, the "Reset Recorder" function will also erase the set password.

5 MAINTENANCE

You must ensure that the operating system in the computer you are using is up-to-date and secure.

5.1 Cleaning and disinfection

Respiro, pulse oximeter, wristband, Respiro patches, charger dock as well as the carry case, laminated Quick Guide and laminated Notes and Warnings must all be cleaned and disinfected before first use and also after every recording. Cannulas, RIP belts, ECG adapter as well as ECG electrodes are disposable. RIP belts can be used more than once with same patient.

Table 6 Cleaning and disinfection method

Item	Cleaning method	Disinfection method
	Non-fluffing cloth dampened with water and mild detergent.	**Non-fluffing cloth dampened with allowed disinfectant**
Respiro	X, Avoid wiping the nasal cannula interface with a too wet cloth.	X
Pulse oximeter*	X	
Respiro patch for 1 RIP belt, patch for 2 RIP belts	X	X, Check that the patch is intact. The patch can be used in approx. 20 recordings.
Charger dock	X	X
Power supply**		
Carry case	X	X
Quick Guides and Notes and Warnings	X	X
The pulse oximeter's wristband is handwashed using a mild detergent in 30 °C water.		

For cleaning, wipe the devices with a non-fluffing cloth dampened with water and mild detergent.

For disinfecting the Respiro device and other medical device components and system parts, the following disinfectants may be used:

- Medical alcohol
  - 70% ethyl alcohol
  - 70% isopropyl alcohol

Wipe the devices with a non-fluffing cloth dampened with e.g. isopropyl alcohol or with disinfection wipes.

*Check the detailed cleaning and disinfection instructions for the pulse oximeter from pulse oximeter's operator's manual: **Operator's Manual Model 3150 WristOx$_2$® Pulse Oximeter BLE and USB**: https://www.nonin.com/support/3150-ble/.

**Wipe with a dry cloth only, do not use fluids or chemical cleaning agents for cleaning. Power supply must be disconnected before cleaning.

NOTE The power supply is maintenance-free. In case of a faulty power supply or malfunctions that cannot be solved, please contact Bittium.

WARNING: Risk of lethal electric shock if fluid leaks into the power supply. Do not use fluids or chemical cleaning agents for cleaning. Disconnect power supply before cleaning.

Ensure that the devices and the wristband can dry properly after the cleaning. Use air-drying and do not tumble dry the wristband, for example. Dispose of used nasal cannulas, ECG adapters and ECG electrodes as energy waste.

5.2 Changing the Respiro Device Manager language

Respiro Device Manager language can be changed by choosing "About" in the home view. Language options are available via Change language menu.

5.3 Updating Respiro firmware and Respiro Device Manager software

Respiro device firmware and Respiro Device Manager can be updated via internet by fetching update package from Bittium server. If new updates are available, the Respiro Device Manager will inform about those in the Home -page when the software is opened. Available updates can be also checked and installed via Tools page:

1. Connect the charging dock to a computer with the USB cable.
2. Set the Respiro device in the charging dock. Ensure that the device rests properly in the charging dock.
3. Start Respiro Device Manager application (see Chapter 4.7.1). Wait for the application to detect the Respiro device. Respiro Device Manager home view opens.
4. Select "Tools" from the top of the view.
5. Select Update firmware. Updates are checked from Bittium's server.

TIP Checking for updates can be cancelled by pressing "Cancel".

6. If there are no new updates, a window showing current versions is shown:

Figure 33 Firmware and software versions are up to date

7. If new updates are available, a confirmation window is shown:

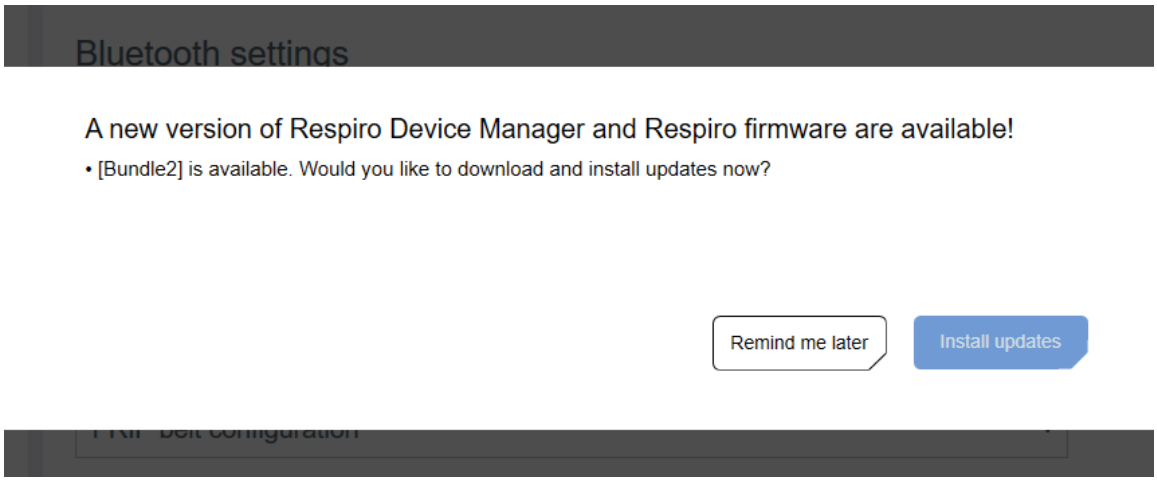


Figure 34 Update available

TIP Updates can be installed later by pressing “Remind me later”. The Respiro Device Manager informs about available update next time it is opened again.

8. Press “Install updates”. A window with a progress bar is shown to indicate the progress of the update process. Wait until the installation process is finished:

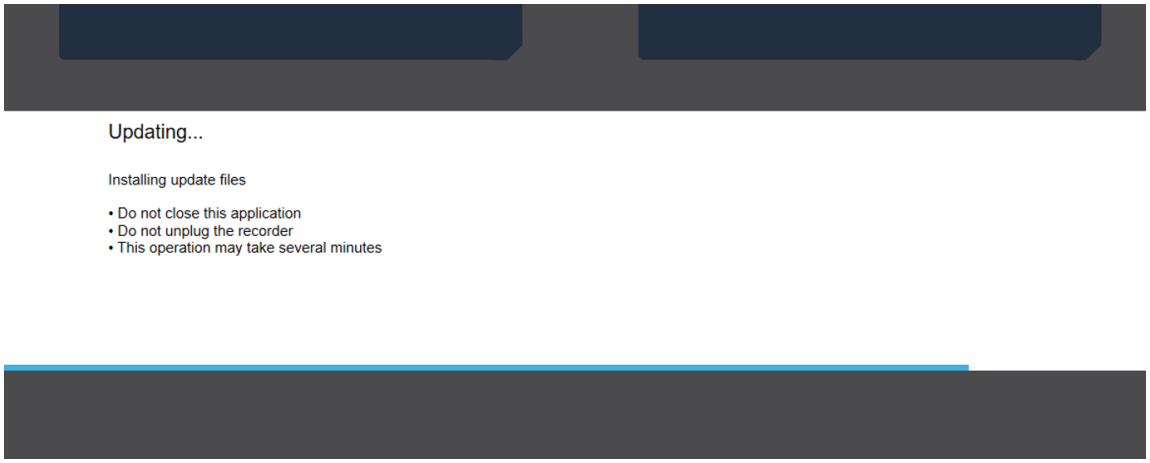


Figure 35 Updates installing

TIP	Do not remove Respiro from the charging dock while the firmware update is ongoing

NOTE	If error occurs during installation, an error window is show with additional information about the error. Updating can be tried again, but if the problem persists, please contact Bittium.

9. After installation, the new versions are shown briefly and then the Respiro Device Manager restarts automatically:

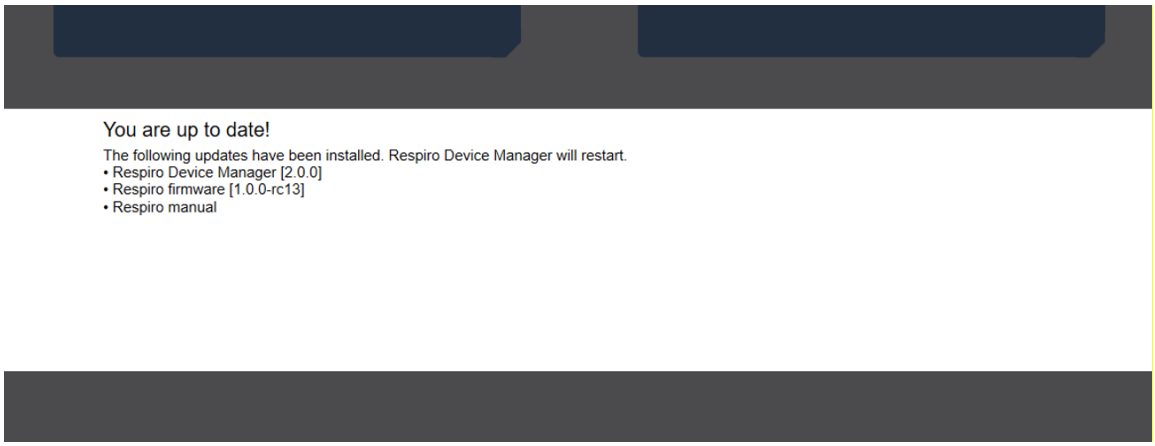


Figure 36 Latest updates have been installed

10. After the restart, the Respiro Device Manager confirms that the update installation was successful. If something went wrong, an error window is shown in the Home -page (see also chapter 6.2.1):

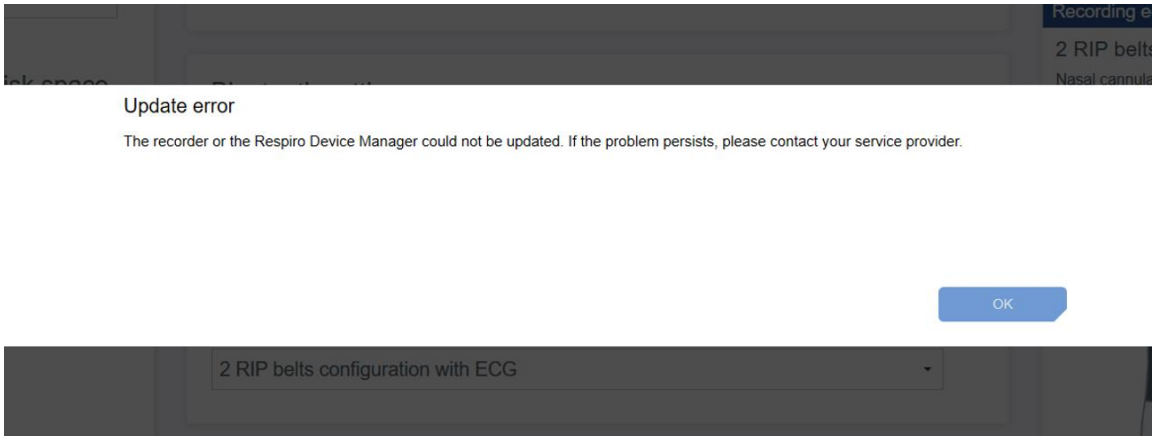


Figure 37 Update error view after restart

The Respiro device firmware and Respiro Device Manager software can also be updated manually in cases where the online update process is not working or there are other unexpected problems. For further instructions, please contact Bittium.

5.4 IT network

- End-user is responsible that device is used according to their organization's IT procedures.
- IT infrastructure shall be designed in a controlled manner with Bittium Biosignals Ltd. Changes to the IT-network could introduce interruption in the data analysis.
- Connection of the system to an IT-network that includes other equipment could result in previously unidentified risks to patients, operators or third parties. The responsible organization should identify, analyze, evaluate and control these risks.
    - Subsequent changes to the IT-network could introduce new risks and require additional analysis.
    - Changes to the IT-network include changes in the IT network configuration, connection of additional items to the IT-network, disconnecting items from the IT-network, update of equipment connected to the IT-network, upgrade of equipment connected to the IT-network.

5.5 Battery replacement

Respiro device battery is an in-built part of the device and can be changed only by Bittium Biosignals Ltd. Battery lifetime depends on device usage modes and recharging cycles. It is recommended to replace the battery after max. 2 years. Scheduled maintenance of the device is performed every 2 years. The battery is replaced during scheduled maintenance.

When battery replacement is needed, please contact your local distributor or Bittium Biosignals Ltd for battery replacement.

6 TROUBLESHOOTING

6.1 Potential issues with the Respiro device

- Respiro does not start recording: Press the power button first <3 seconds until the blue indicator lights are lit blue and then approx. 8 seconds until the device vibrates once to start recording. Make sure that the device is charged.
- Respiro has red light(s) on:
    - If some of the Respiro device's indicator LEDs is red see Table 7, Table 8 and Table 9 below.

Table 7 Respiro common LED indications in error states

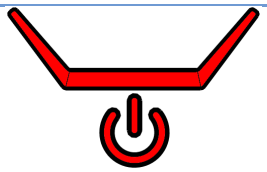
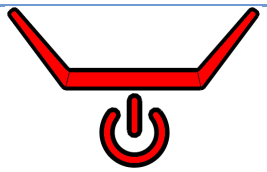
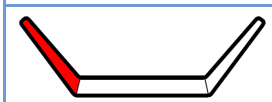
Color	Meaning
	All LEDs flash red once: Failed recording start. Not enough battery charge or device internal memory full. Charge device or free device memory.
	All LEDs and power button LED red: Device internal error. Press power button for 12 seconds and try starting the recording again.
	All LEDs and power button LED red after power button is first pressed for 12 seconds to switch device off and then pressed again twice to start recording: Device requires maintenance.

Table 8 Respiro 3 sensor configuration LED indications in error states

3 sensor configuration (1 or 2 RIP belts), 1 LED on for 1 second cycling from left to right	
	Left LED yellow: Pulse oximeter is connected but finger is not inserted in the sensor. Check connection.
	Left LED red: Pulse oximeter error. Check connection.

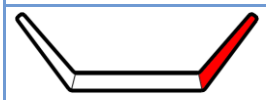
	Center LED red: Nasal cannula error. Check connection.
	Right LED red: RIP belt(s) error. Check RIP belt(s) as well as the connection between Respiro and the patch (press studs).
It is possible to have errors in several sensors simultaneously. Error states are indicated when the equipment is worn on body. If some of the LEDs are green, the sensor in question is ok.	

Table 9 Respiro 4 sensor configuration LED indications in error states

4 sensor configuration (2 RIP belts with ECG), 2 LEDs on for 1 second cycling from left to right	
	Left LED yellow, center green: Pulse oximeter is connected but finger is not inserted in the sensor. Check connection.
	Left LED green, center LED red: Nasal cannula error. Check connection.
	Left LED red, center LED green: Pulse oximeter error. Check connections.
	Left and center LED red: Pulse oximeter and nasal cannula error. Check connections.
	Center LED green, right LED red: RIP belts error. Check RIP belts.
	Center LED red, right LED green: ECG error. Check electrode.

	Center and right LED red: ECG and RIP belts error. Check RIP belts and electrode.
Error states are indicated when the equipment is worn on body and recording is ongoing. If some of the LEDs are green, the sensor in question is ok.	

- Pulse oximeter does not start: Press the pulse oximeter's power button with e.g. your fingernail to start it if it does not start automatically. If pulse oximeter still does not start, replace batteries.
- Computer does not detect Respiro when Respiro is in the charging dock and the charging dock is connected to the computer: Check the charging dock connection to the computer and that Respiro is properly set in the charging dock.
- How to connect devices for example after a device failure: See Chapter 4.7.2.
- Respiro LED indicators are dark during charging: Ensure that the power supply and the USB connector are properly connected.
- You get the following notification when Respiro is connected to a computer:

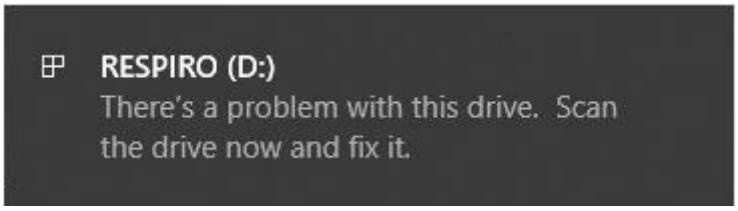


Figure 38 Respiro notification

Click the notification and follow the on-screen instructions. Remember to always detach Respiro safely from the computer using the Windows Safely remove hardware function or via Respiro Device Manager's Eject function. In Windows the icon can be seen by clicking the ^-icon (Show hidden icons) at the bottom of the display on the right.

6.2 Potential issues with Respiro Device Manager

6.2.1 Update error

During updating, there are few possible error situations. Below is a list of possible errors and instructions on how to try solving them. If the problems persist, please contact Bittium for further help.

Network error – An error occurred while installing the updates because the internet connection was interrupted: make sure your PC has an internet connection.

Recorder unplugged – An error occurred while installing the updates because the device was unplugged: Make sure that the device stays plugged in the charging dock through the whole updating process. If problems persist, check that the dock's and Respiro's contact sensors are clean. Check that the USB-cable is properly inserted.

General error – An error occurred while installing updates: close the program and try to install the updates again.

Update error – The recorder of the Respiro Device Manager could not be updated. If the problem persists, please contact your service provider.

Firmware update failed – The device's firmware could not be updated because the selected package is damaged: Please contact Bittium medical support (medical.support@bittium.com)

6.2.2 Reset Error

If the recorder is unplugged or if there are unexpected error while resetting, an error message is shown.

Unplugging error – An error occurred while resetting the device because the device was unplugged: Make sure that the device stays plugged in the charging dock through the whole updating process. If problems persist, check that the dock's and Respiro's contact sensors are clean. Check that the USB-cable is properly inserted.

Error – An error occurred while resetting the device: close the program and try again. If the problem persists, please contact your service provider.

7 PRODUCT SAFETY AND REGULATORY INFORMATION

7.1 EU Declaration of Conformity

Certificate of Conformity and Declaration of Conformity in accordance with the applicable directives and standards can be requested from bbs@bittium.com

7.2 EMC

This product meets the requirements of the electromagnetic compatibility (EMC) standard EN 60601-1-2.

8 TECHNICAL INFORMATION

8.1 Respiro dimensions and weight

Height: approx. 81 mm.

Width: approx. 46 mm.

Depth: approx. 19 mm.

Weight: approx. 48 g.

8.2 Device IP classifications

Respiro: IP67

Charging dock: IP31

Pulse oximeter: IP33

8.3 Operating and storage conditions

Table 10 Operating and storage conditions

<table>
<tr><th>Device</th><th>Storage temperature range</th><th>Operating temperature range</th><th>Humidity</th></tr>
<tr><td>Respiro</td><td rowspan="2">- 25… + 70 °C</td><td rowspan="3">+5… + 40 °C</td><td rowspan="3">Operating 15…90 % (non-condensing)

Storage 10…90 % (non-condensing)</td></tr>
<tr><td>Pulse oximeter</td></tr>
<tr><td>Other medical device components and system parts</td><td>+10…+ 30 °C</td></tr>
<tr><td colspan="4">Pressure: 700 hPa-1060 hPa, operating.</td></tr>
<tr><td colspan="4">Battery charging: Battery manufacturers restrict charging the battery above the defined battery temperature limit to avoid overheating the battery and to ensure safe user experience in all conditions. As the device manufacturer, Bittium recommends ensuring that Respiro charging environment temperature is max.+30°C to enable smooth and uninterrupted battery charging.</td></tr>
</table>

Always transport the equipment in the carry case. Protect the carry case from snow and rain. Remove the batteries from the pulse oximeter when storing it.

8.4 Respiro specifications

Table 11 Respiro specifications

Respiro		
Nasal pressure	Pressure range	± 7 kPa
	Sampling and storage rate	100 Hz
	ADC conversion	12 bits
Blood oxygen saturation (SpO_2) and pulse rate	SpO_2 range	70 to 100 %
	Pulse rate range	40 to 250 bpm
	Sampling and storage rate (SpO_2)*	1 Hz
	Sampling and storage rate (pulse rate)	1 Hz
Body position and movement	Acceleration range	± 2 g
	Sampling and storage rate	10 Hz
	ADC conversion	12 bits
Respiration effort	Movement range	± 1,5 mm
	Sampling and storage rate	100 Hz
	ADC conversion	10 bits
Mode of operation	Continuous	
Wireless transmission and reception	Bluetooth Low Energy (BLE)	
* Pulse oximeter's PPG sampling rate is 75 Hz. SpO2 value is calculated based on PPG signal once per second (1Hz). This is a reasonable sampling rate due to the nature of the particular biosignal (slowly variable parameter)		

8.5 Magnet specification

Bittium Respiro device incorporated the Allegro O09.0021 magnet in the bottom side of the housing.

Magnet used in this device is within International Commission on Non-Ionizing Radiation Protection (ICNIRP) guidelines for general public use. The static magnetic field strength is less than 400 mT at component surface and less than 0.5 mT at (7,1 mm) distance.

CAUTION: Respiro device contains a magnet. Do not place it directly next to a medical device (e.g. pacemaker) during use.

8.6 Electromagnetic emissions

Table 12 Electromagnetic emissions

Manufacturer's declaration - Electromagnetic emissions		
Respiro is suitable for use in an electromagnetic environment as described below. The users should ensure that the device is used in such an environment.		
Emission test	Compliance	Electromagnetic environment
RF emissions CISPR11	Group 1	Respiro uses RF energy exclusively for its internal function. Thus, the RF emission is very low and it is unlikely that nearby electronic devices would be disturbed.
RF emissions CISPR11	Class B	

8.7 Immunity test levels

Table 13 Immunity test levels

Phenomenon	**Basic EMC standard or test method**	**Immunity test level** **Home healthcare environment**
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF EM fields	IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM, 1 kHz

Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See Table on next page.
RATED power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz
Conducted disturbances induced by RF fields	EC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Voltage dips	IEC 61000-4-11	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0 % U_T; 250/300 cycle
Surges, Line-to-line	IEC 61000-4-5	± 0,5kV, ±1kV
Surges, Line-to-ground	IEC 61000-4-5	± 0,5kV, ±1kV, 2kV
Electrical fast transients / bursts	IEC 61000-4-4	± 2kV 100kHz repetition frequency

Table 14 Immunity test levels, continued

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27
450	430-470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0,3	28

710 745 780	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0,3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3,4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9

APPENDIX 1: SETTING THE DEVICE PASSWORD

Follow these instructions to set a device password for Respiro. It is not mandatory to set this password, so use this function only if it is absolutely required.

Note that the password is device-specific, so keep track of these passwords!

Before you start: Copy the Respiro Device Manager folder e.g. to your desktop. After the password is set Respiro Device Manager can only be started from this folder.

1. Put Respiro in the Charging Dock and connect the Charging Dock to your computer.
2. Open Windows File Explorer and select the RESPIRO device drive.
3. Double-click SYS folder.
4. Open DEVICE.CFG file with e.g. Notepad++
5. Add line"disk_password":"password_here", after e.g. line "spo2_serial":
6. Enter a password in the password_here -part between the “-characters:"disk_password":"password_here",
   You can use any of these characters for a password max. 16 characters in length:
   ! " # $ % & ' ( ) * + , - . / 0 1 2 3 4 5 6 7 8 9 : ; < = > ? @ A B C D E F G H I J K L M N O P Q R S T U V W X Y Z [\ ] ^ _ ` a b c d e f g h i j k l m n o p q r s t u v w x y z { | } ~
   Example string below with password set as 123456:

```
{

"sys_config":{

    "configuration":2,

    "device_id":"DEFAULT_DEVICE_ID",

    "spo2_serial":"123456789",

    "disk_password":"123456",

    "vbat_recorded":1

    }

}
```

7. Save the changes by pressing Ctrl+S.
8. Close the DEVICE.CFG file.
9. Eject Respiro by using the Safely Remove Hardware and Eject Media-function.
   Note that after the password is set Respiro must be powered off and restarted to make the change effective (12 second press to power off device).
   a) Remove Respiro from the charging dock.
   b) Power off Respiro by pressing the button for minimum 12 seconds.
   c) Put Respiro back in the charging dock to verify that password is active. Note that Respiro is no longer visible via File Explorer after the password is set. Start Respiro Device Manager from eg. the desktop where the Respiro Device Manager folder was copied before the password was set.

TIP If you forget the password the device must be sent to maintenance to unlock it!

MANUFACTURER INFORMATION

Bittium Respiro HSAT™

Assembled and distributed for

Bittium Biosignals Ltd
Pioneerinkatu 6
70800 Kuopio
Finland

CH REP

evismo AG
Schweighofstrasse 409
8055 Zürich
Switzerland

Manufacturers of the system components

Bittium Respiro™

Bittium Biosignals Ltd
Pioneerinkatu 6
70800 Kuopio
Finland

CE 0537

CH REP

evismo AG
Schweighofstrasse 409
8055 Zürich
Switzerland

OmegaSnap™

Bittium Biosignals Ltd
Pioneerinkatu 6
70800 Kuopio
Finland

CE

CH REP

evismo AG
Schweighofstrasse 409
8055 Zürich
Switzerland

Nonin WristOx2® Pulse Oximeter

Nonin Medical, Inc
13700 1st Avenue North
Plymouth, MN 55441, USA

CE 0123

MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, GERMANY

MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug
Switzerland

EU Importer for

Bittium Biosignals Ltd
Pioneerinkatu 6
70800 Kuopio
Finland

CNSAC Nasal Pressure monitoring cannula

CNSAC MedShop GmbH
Am Sonnenstuhl 63
97236 Randersacker
Germany

CE

Somnovum
Industriestrasse 14
CH-5036 Oberentfelden

WEBSITE

You can find up-to-date product information, documents, and updates by visiting the Bittium website at www.bittium.com

SALES

Please contact your sales representative for any questions that you may have about Bittium products.

Bittium Biosignals Ltd.
Pioneerinkatu 6
70800 Kuopio
Finland

Tel.: +358 40 344 2000
Email: bbs@bittium.com
Web: https://www.bittium.com

SERVICE DESK

If you encounter any issues with Bittium medical products, please contact our technical support at

medical.support@bittium.com