

## RESPIRO™ NOTES AND WARNINGS

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.



**CAUTION:** Use only the included charger 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.



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

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**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.

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**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.

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**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.

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**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.

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

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

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

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## NOTE

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

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# Bittium

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- NOTE** Do not use excessive force when connecting the nasal cannula
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- NOTE** Keep the devices, medical device components and other system parts out of reach for children and pets.
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- NOTE** Body and hand creams as well as sunscreens can damage the device
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- NOTE** Skin must be intact, clean, and dry in the area where the ECG electrode is attached (applicable only in ECG use case).
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- NOTE** Body-worn components (eg. medical tape) may irritate skin, but there are no other known ad-verse 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).
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- 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.
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- 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.
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- NOTE** The screenshots shown in the document may not represent the latest software User Interface views.
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## Intended use

The device is intended to be used as an ambulatory recording device for 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 bio signals. The device does not actively monitor the patient's status, diagnose, or treat the patient and it cannot be used as a life-sustaining device. The device is not designed to be used with children. The device is operated by healthcare professionals at hospital, the patient, or another person at the patient's home. A healthcare professional always gives instructions to the patient or the device operator on using the device and starting the recording before use at home. The patient is provided with an illustrated quick guide for home use.

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

Signal	Sensor
Airflow	Nasal cannula+ 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











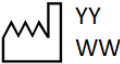




## Indications

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

## 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 recording at home

Device	Storage temperature range	Operating temperature range	Humidity
Respiro	- 25... + 70 °C	+5... + 40 °C	Operating 15...90 % (non-condensing) Storage 10...90 % (non-condensing)
Pulse oximeter			
Other medical device components and system parts	+10...+30 °C		
Pressure: 700 hPa-1060 hPa, operating.			
Always transport the equipment in the carry case. Protect the carry case from snow and rain.			

Symbol	Description	Symbol	Description
	The device is CE-marked for the conformity to Council Regulation 2017/745 regarding medical devices.		Do not re-use.
	Swiss authorized representative.		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).		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).
	Consult instructions for use.		Use-by date.
	Wireless transmission symbol.		Medical device.
IP31	Ingress protection rating. Device is protected against small objects ( $\geq 2,5$ mm) and condensation.	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.
	Date of manufacture.		Manufacturer
	Multiuse single patient		Serial number
	Type BF applied part (electrically isolated).		

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## Bittium Respiro HSAT™

Assembled and distributed for



### Bittium Biosignals Ltd

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## WEBSITE

You can find up-to-date product information, documents, and updates by visiting the Bittium website at [www.bittium.com](http://www.bittium.com)

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## SALES

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

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