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BITTIUM 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 be-tween 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: 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.

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⚠	**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:** 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 (eg. medical tape) may irritate skin. 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.

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.

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

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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	Operating temperature range	Humidity
Respiro	+5… + 40 °C	Operating 15…90 % (non-condensing)
Pulse oximeter		
Other medical device components and system parts		
Pressure: 700 hPa-1060 hPa, operating.		

Symbol	Description
CE 0537	The device is CE-marked for the conformity to Council Regulation 2017/745 regarding medical devices.
CH REP	Swiss authorized representative.
EC REP	Authorized representative in the European Community/European Union.
⬚ (person symbol)	Type BF applied part (electrically isolated).
⊘ (do not reuse symbol)	Do not re-use.

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📖ℹ	Consult instructions for use.
LOT	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).
MD	Medical device.
⧗	Use-by date.
(((•)))	Wireless transmission symbol.
%	A relative humidity range of 10 % to 90 %, non-condensing.
☂	During transportation: keep package dry, protect from rain.
⋀YYYY-MM-DD	Date of manufacture.
🏭	Manufacturer
(1↑)	Multiuse single patient
SN	Serial number
IP31	Ingress protection rating. Device is protected against small objects (≥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.
▦	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).

Bittium Respiro HSAT™

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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