NOTES AND WARNINGS - BITTIUM RESPIRO™

- Do not use a broken device or electrodes/cannulas whose packing is opened.
- Use only the included charger and the charging dock when charging Respiro™.
- The connector for the pulse oximeter is a push-pull connector. Do not twist or bend the connector when connecting the pulse oximeter sensor.
- 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 parts may lead to contamination.
- Do not use excessive force when connecting the nasal cannula.
- RIP belts must not be worn against skin.
- Respiro device's internal pressure sensor is very sensitive. Do not produce excessive pressure to nasal cannula's pressure hose.
- Use only mild detergents when cleaning the devices. Immersing the devices in liquids is prohibited.
- Contact nursing staff if the devices and sensors are damaged.
- Damaged or detached parts lead to incorrect recording results. Return the equipment to nursing staff.
- Nail polish and artificial nails must be removed before recording as they interfere with the pulse oximeter.
- Do not open and/or modify the equipment.
- Keep the devices and accessories out of reach for children and pets.
- Do not use the devices in shower or sauna.
- EMC disturbances may cause interference and/or noise to recording data.
- Use the device only with accessories provided by Bittium Biosignals Ltd. Other accessories may negatively affect the device performance or cause non-recognized issues and non-conformities or break the device.
- 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.
- Respiro is not suitable for use in MRI environment.
- Respiro is not intended to be used at the same time with high frequency (HF) surgical equipment or with a defibrillator.
- 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.
- Body and hand creams as well as sunscreens can damage the device.
- Skin must be intact, clean, and dry in the area where the ECG electrode is attached (applicable only in ECG use case).
- Body-worn parts (eg. 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).
- 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 a nurse (hospital), the patient or another person at the patient's home. The nurse gives instructions to the patient or the device operator on attaching the sensors and starting the recording before using it at home. The patient is provided with an illustrated quick guide for home use.

Indications

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

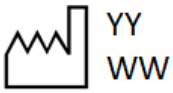
Table below lists the biosignals and sensors used in Bittium Respiro:

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
ECG monitoring	1-channel ECG electrode
Body position	Integrated accelerometer
Snoring	Integrated microphone for audio volume

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

Symbol	Description	Symbol	Description
CE 0537	The device is CE-marked for the conformity to Council Regulation 2017/745 regarding medical devices.		Do not re-use.
	Type BF applied part (electrically isolated).	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).		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.
	Manufacturer.	IP67	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.	IP31	Device is protected against small objects (≥2,5 mm) and condensation.

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

MANUFACTURER

Bittium Biosignals Ltd
Pioneerinkatu 6
70800 Kuopio
Finland

bbs@bittium.com

www.bittium.com
medical.support@bittium.com

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