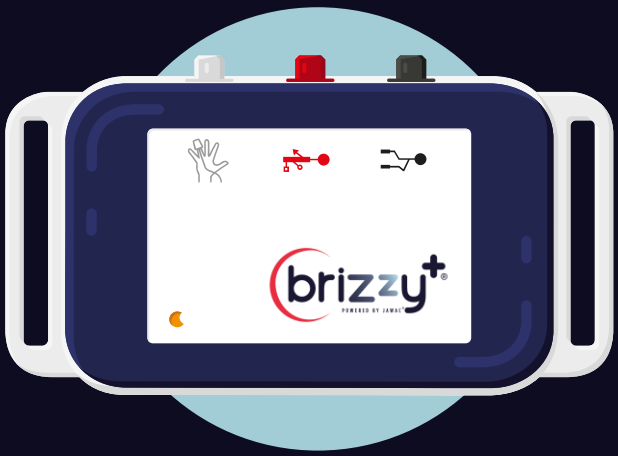

User Guide

Nomics®

Liège Science Park 4, Rue des chasseurs Ardennais 4031 Angleur (Belgium)

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GENERAL INFORMATION

INDICATIONS OF USE

BRIZZY+ is indicated for use in the screening and diagnostic evaluation of sleep breathing disorders in paediatric and adult patients.

BRIZZY+ produces a report for the HCP that may aid in the diagnosis of sleep breathing disorders or for further clinical investigation.

INTENDED USE

BRIZZY+ is a portable device made for detecting and assisting in diagnosis of sleep apnea syndrome and for monitoring its treatment.

It is intended for use by health professionals having basic knowledge of sleep disorders, in particular of sleep breathing disorders.

The system is simple to use. After having received a short training from a qualified member of staff, the patient can go back home and install the device himself with the help of the patient leaflet. Thanks to the automatic wake/sleep discrimination feature, there is no need to set the time at which the recording should begin.

Furthermore, the software that accompanies the device delivers a high-performance automatic analysis of the recorded data.

Brizzy+ (NS26 model) records the following parameters:

- Jawac: mouth activity presents characteristics which permit the detection of respiratory events during sleep,
- Jawac Effort: derived from the Jawac signal, band-pass filtered signal to display the oscillatory component of the signal,
- Airflow: respiration through a cannula connected to an auxiliary flow sensor,
- Snoring (inspiratory and expiratory): vibratory signal from the nasal cannula,
- Respiratory movements: an accelerometer that measures a respiratory movement comparable to that of a chest or abdominal belt,
- Oxygen saturation (SpO2): given by the oximeter.
- Pulse frequency: given by the oximeter.
- Plethysmography waveform: given by the oximeter,
- Body position: indication of the patient's sleeping position.

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As an option, Brizzy+ allows the connection of an auxiliary sensor other than the flow sensor, such as a pneumotachograph for therapeutic monitoring by CPAP (Continuous Positive Pressure).

CERES – the software – allows the patient's data to be sent to a secure and anonymized site. The analysed data is in the form of an analysis report and can be retrieved on the same site. This report then helps the operator determine:

- Wether the patient suffers from sleep disordered breathing,
- Wether the treatment delivered to such a patient needs to be adjusted.

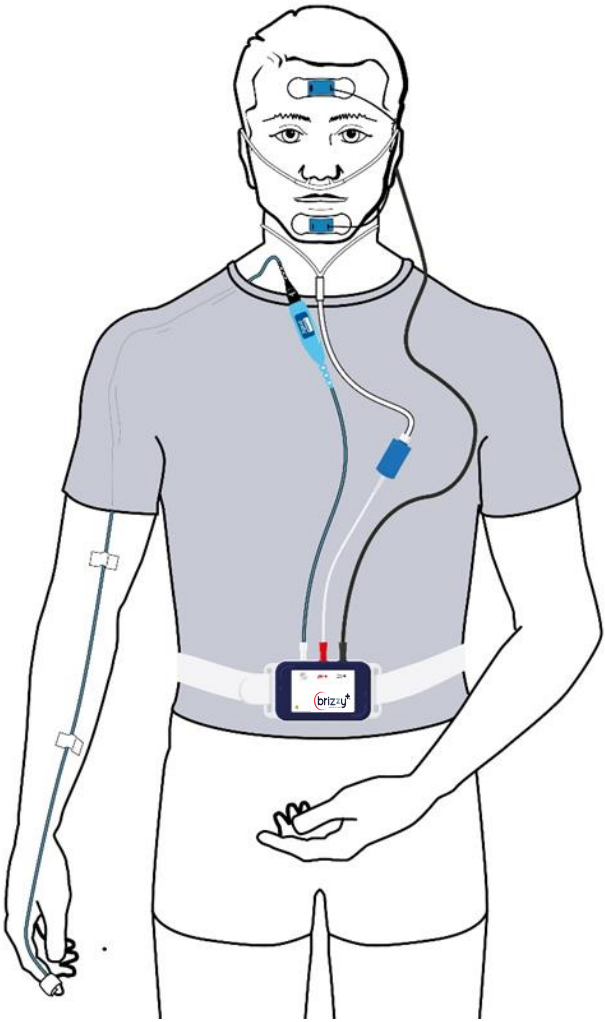
CERTIFICATION

Brizzy+ is manufactured by Nomics. The product is certified according to European Medical Device Directive (MDD) 93/42/EEC.

Description of symbols:

	Warning / Caution
	Port for the Jawac sensor
	Port for oximetry sensor
	Port for auxiliary sensor
REF	Catalogue number
SN	Serial number
LOT	Batch number
	Do not reuse
	Manufacturer
	Refer to operating instructions
IP22	Protected against solid foreign objects of 12.5mm Ø and greater. Protected against water droplets up to 15° of the vertical
CE 2797	Indication of conformity to the requirements of the European Medical Device Directive 93/42/EEC

	Waste electrical and electronic equipment must not be disposed of with the remainder of un-separated waste
Storage: 	Admissible storage temperature range



Installation of BRIZZY+ NS26

BRIZZY+ consists of a recording device, of sensors as illustrated above. A Nomics-designed special USB cable to transfer the recordings onto a computer, as well as several accessories complete the set.

The table hereafter lists the different items composing the system as well as accessories and replacement parts which are available:

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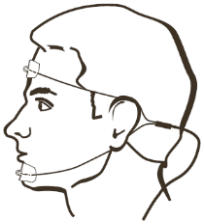
Nomics Ref	Items	NS26
NS26-MUP	Patient leaflet (available on the Apios website)	√
NS26-MU	User guide (available on the Apios website)	√
NS126	Brizzy+ device	√
NS405	Sensor for measurement of Jawac Distance Sensor calibration Tool	√
NS921	Special USB cable for data transfer	√
NS920	Nonin Xpod® oximeter module for BRIZZY+	√
8000SM	Soft Sensor reusable pulse oximetry sensor - Nonin Model 8000SM	√
NS962	Flow sensor module for nasal cannula connexion	√
15805-2	Adult Nasal Pressure Monitoring Cannula	√
NS900	Device fastening belt	√
NS924	Carrying case/pouch	√
NS896	USB charger 5W	√
NS819	Box BRIZZY+ package	√
NS910	JawaGrips – Jawac Adhesive Supports (pack of 20)	√

✓ : indicates that the item is provided with the system. The other items (oximeter module, oximetry sensor, flow sensor, canula, JawaGrips and pneumotachograph module) are proposed according to the user's request.

JAWAC SENSOR



The Jawac sensor is a distance sensor which permits observation of mandibular movements. The signal given by this sensor is known as Jawac, short for "Jaw Activity".

Observing and analysing Jawacs during sleep allows not only to identify the different sleep disturbances such as mouth breathing, snoring, apnoeas (central, obstructive, and mixed) and hypopneas, but also to detect conditions of upper airway resistance (UARS).

It is recommended to become acquainted with the characteristics of the Jawac signal before using the device. If need be, contact your distributor or the manufacturer who will tell you where to find the necessary documentation.

BODY POSITION SENSOR

The device is equipped with an integrated position sensor. This sensor measures the patient's position via a 3-axis accelerometer.

FUNCTION OF THE DEVICE

The device processes and stores the acquired signals in memory. It is powered by a Lithium Polymer battery. The battery is rechargeable through USB. If necessary, it stores patient information before recording.

NASAL CANNULA

Nasal cannulas are used to assess airflow from nasal pressure measurement. They must be directly connected to the corresponding protruding endpiece on the flow sensor module, connected on the auxiliary input of Brizzy+.

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RESPIRATORY MOTION SENSOR

Brizzy+ incorporates an accelerometer to measure a respiratory motion signal comparable to that of a chest or abdominal belt.

PULSE OXYMETER

The Xpod module from Nonin measures the blood oxygen saturation level (SpO2), the pulse frequency, and the plethysmography waveform. Only oximetry sensors from Nonin should be connected to the module.

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WARNINGS AND SAFETY NOTICES

For your safety and patient safety, please adhere to the following recommandations :

- Please read this user guide and the corresponding patient leaflet carefully. They are part of the system and must be available at all times. Please pay particular attention to the sections marked with a triangle bearing an exclamation mark. Also observe the directions for use of all the accessories used in conjunction with the device.
- BRIZZY+ is an internally powered equipment. The device is a class IIa equipment according to the European Medical Device Directive 93/42/EEC.
- The device is intended strictly for assisting in the diagnosis of sleep apnoea syndrome and for monitoring its treatment. It is not intended for life support neither for real-time apnoea monitoring.
- The device is not intended for use on children under three years.
- Do not operate the device in an environment with explosion hazard like in an oxygen-rich environment or in presence of other flammable agents.
- Do not use the device in an MRI environment.
- The device is not defibrillator proof.
- Do not immerse the device in water or other liquids, or splash it.
- Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC). Information relative to EMC are given at chapter “Technical Specifications”.
- Portable and mobile RF communications equipment can affect medical electrical equipment.
- The equipment should not be used adjacent to or stacked with other equipment and, if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.
- Avoid using the device close to another device emitting strong electromagnetic interferences.
- It is recommended that you do not use the device on people with pacemakers or similar medical equipment.
- Only accessories provided by Nomics may be used. In particular, the Jawac sensor (NS405), the ECG module (NS965), the Nonin branded oximetry sensor (NS920) and the special USB cable (NS921) delivered by Nomics can be connected to the port of the device. Using accessories or equipment other than those specified may

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cause malfunction, increased emissions or reduced immunity to electromagnetic interference and/or damage and will void the warranty. Please note that Nomics is not responsible for any loss or damage arising from the use of accessories or equipment that has not been approved.

- Only Nonin branded oximetry sensors must be connected to the Nonin branded Xpod module (NS920).
- Do not use any defective equipment. Replace the items that are damaged, worn or contaminated.
- The device may only be opened by specialized personnel authorized by the manufacturer, otherwise all warranty rights will be voided.
- The device contains a rechargeable Lithium Polymer battery. Like any other type of battery, the battery can leak, overheat or cause a fire if its internal components are damaged. If the device is handled properly, there is no probability of an incident. Therefore, please, observe the following rules:
  - ✓ The battery may not be replaced, except by the manufacturer himself.
  - ✓ Do not expose the device to fire or high temperatures over 60°C (140°F). Do not leave the device inside a vehicle or in direct sunlight.
  - ✓ Do not expose the device to water, or to moisture, or operate it with wet hands. Do not use if liquid has entered the device.
  - ✓ Do not subject the device to strong impacts.
  - ✓ Do not attempt to use or charge a damaged device; the protective packaging of the battery could be ruptured or pierced and cause the battery to overheat, ignite, rupture, or leak.
  - ✓ Do not use the device if the battery has leaked. If fluid from the battery makes contact with your eyes or skin, immediately rinse with plenty of water (at least during 15 minutes) and contact a doctor. Wash your clothes if they have been contaminated.
  - ✓ Only use the special USB cable provided by Nomics in order to recharge the battery. Only plug this cable into the USB port of a computer or of a USB charger.
- Sale of the equipment is subject to each country's laws and regulations.
- Nomics declines all responsibility for any loss or damage and all guarantee rights will be void if the equipment is used in any manner that does not conform to the instructions given in this user guide.

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OPERATING THE DEVICE

PREPARING A RECORDING

BRIZZY+ is a simple device that the patient can easily install himself/herself. A certain number of operations are nevertheless required in order to prepare the device before handing it to the patient. Please read carefully the following instructions and apply them before each recording.

BATTERY

The device is powered by a Lithium Polymer battery, rechargeable via USB. To recharge the battery, follow the instructions given at the section "Recharging the Battery".

If the battery is completely charged its autonomy is sufficient to ensure a full night recording. It has to be recharged after every recording.

CALIBRATION

Calibration of the device should be performed if:

- the device is used for the first time,
- the Jawac sensor associated with the device is getting replaced.

The calibration automatically adjusts the device parameters so that they best fit the Jawac sensor in use. The calibration procedure is described at the "Calibrating the Device" section of this guide. Recalibration of the device can also help if a problem in acquisition of the Jawac signal arises (see the "Troubleshooting" chapter).

EQUIPMENT CHECK-UP

You should perform the following checks before each use:

- Check all cables and connectors. If a sensor or an accessory is damaged, replace it.
- Make sure that each item has been cleaned/disinfected according to the instructions given in the corresponding directions for use. Each item must be clean and dry.
- Make sure that the device works by making a starting test.

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CARRYING BAG

The carrying case allows the patient to carry the equipment home. It should contain everything the patient needs to perform a recording.

Check that the special USB cable which serves to connect the device to a computer is NOT included in the carrying case when it is handed to the patient!

The case should contain the following items (Brizzy+ NS26):

- the patient leaflet,
- the device (battery charged),
- the Jawac sensor,
- Jawagrips to fix the sensors of the Jawac on the chin and forehead,
- the auxiliary flow sensor and a new, unopened, nasal cannula,
- the Xpod oximetry module, and an oximetry sensor from Nonin,
- the device fastening belt.

Additional adhesive tape (of hypoallergenic type) can be added to hold the cables in place.

In addition to the diagnosis assistance of sleep apnoea syndrome, Brizzy+ authorizes a study under Continuous Positive Pressure (CPAP) to measure the efficiency of a treatment.

In this case, to record the pressure of the mask, the nasal cannula is replaced by a pressure tube from the Luer-Lock connector of the flow sensor to the CPAP mask.

Flow sensor module (Nomics reference NS962) can be added if needed and proposed according to the user's request.

A more detailed study under CPAP with Brizzy+ is possible by replacing the flow sensor (Nomics reference NS962) by a pneumotachograph module (Nomics reference NS960). For more information, refer to the instruction manual of the pneumotachograph sensor.

RECOMMANDATIONS TO BE GIVEN TO THE PATIENT

To ensure that the recording takes place in the best possible conditions and to avoid damage or misuse, it is advised to explain to the patient how to operate the device and how to position the sensors.

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If the device is to be used on a child, make sure that a responsible adult is clearly shown how to install the cables. Good installation of cables is important particularly in children to avoid any risk of strangulation. Cables should not be left loose around the patient's neck. It is recommended to tape the cables with adhesive strips or to slip a shirt on over the device and the sensor cables.

Before the patient carries the device home, give him/her the corresponding patient leaflet and bring his/her attention to the warnings and notices indicated in the leaflet.

INSTALLING THE DEVICE

The illustration shown at the beginning of this guide gives a general picture of the installation of the device and the sensors in the case of a diagnosis assistance of sleep apnoea syndrome.

In order to record the correct position, the device must be well maintained and positioned at the front, at waist level. The front panel of the device must be visible with connectors on the top.

INSTALLATION OF THE JAWAC SENSOR

Placement of the sensor on the patient's face is illustrated in the patient's leaflet. One is simply reminded here that it is important that the probes be parallel and on the same vertical axis.

Please only use the Jawagrips delivered by Nomics to prevent any risk of allergy. For more details, refer to the patient's leaflet.

The sensor for measurement of Jawac is reusable but must be properly cleaned between each use (see "CLEANING" section hereunder).

INSTALLATION OF THE OXYMETRY SENSOR

Installation of the sensor is illustrated in the documents accompanying the sensor. It is recommended to run the sensor cable along the arm under the pyjama top. The finger on which the oximetry sensor is placed must be free of coloured nail varnish.

The 8000SS, 8000SM and 8000SL SpO2 sensors from Nonin are reusable. Consult their directions for use.

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INSTALLATION OF THE NASAL CANNULA

Insert the prongs into the nostrils. Loop the tubing around the ears, then under the chin. Move the cinch tube up under the chin to tighten. The cannula can also be secured using adhesive tape strips (of hypoallergenic type).

It is strictly recommended to use nasal cannulas only during sleeping hours. They can cause respiratory problems if used for long periods. Nasal cannulas should be disposed of after each use in order to prevent the accumulation of bacteria that could result in microbial infection.

CONNECTIONS

Connections	
	Mandibular lowering sensor plug into the black input symbolized by the opposite pictogram.
	The oximeter module plug into the white input symbolized by the opposite pictogram.
	The auxiliary flow sensor is connected to the red input symbolized by the pictogram opposite.
	Install (screw) the nasal cannula on the tip of the flow sensor intended for pressure measurement.

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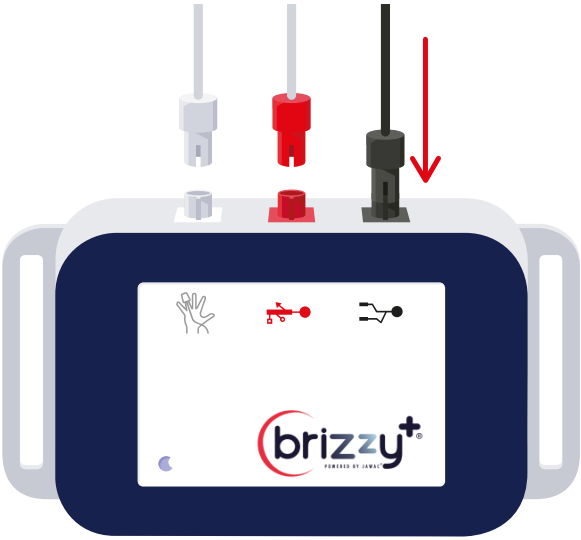
Each connector, excepted the one connecting the nasal cannula on the flow sensor, has a notch, which matches a bump on the corresponding socket on the device. Once notch and bump are aligned, push the connector in until locked in place.



Always handle accessories with care, by firmly holding the connector between your fingers, **never pull on the wires.**

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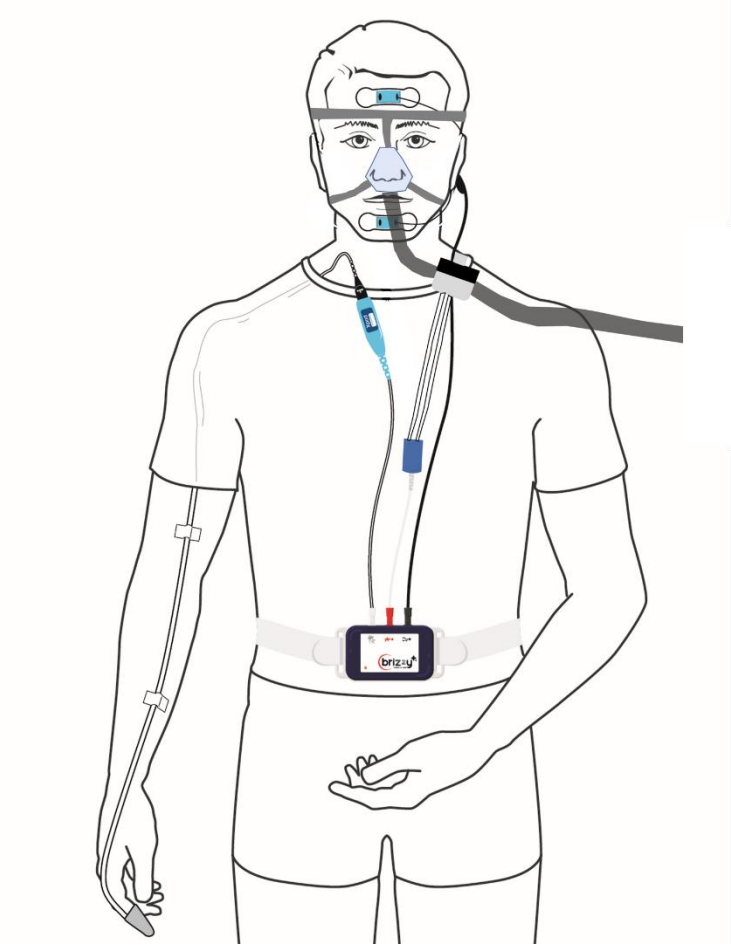
FOLLOW-UP OF A CPAP TREATMENT

For following-up the treatment under CPAP, the nasal cannula should be replaced with a tube of pressure from the Luer-Lock connector of the flow sensor (Nomics reference NS962) to the CPAP mask, as shown in the figure below:



When connecting the pneumotachograph auxiliary sensor, refer to the sensor's operating manual.

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MAKING A RECORD

To start recording, simply connect the mandibular lowering sensor (Jawac) to the unit. When the indicator lamp lights up, the unit is ready for use. Recording starts as soon as the indicator light begins to flash. Depending on the device version, flashing starts immediately or after about 2 minutes, and continues for the duration of the recording.

To stop recording, simply disconnect the mandibular lowering sensor (Jawac). The indicator light stops flashing, and the recorder returns to standby mode. Data can then be downloaded to a computer via the special USB cable.

Notes:

Recording stops automatically when the battery charge level becomes insufficient to ensure proper operation. Always ensure that the battery is sufficiently charged when you start recording.

The memory can hold several recordings.

The device saves data in internal memory and retains it until it is connected to Ceres. As soon as a connection to Ceres is made, the memory becomes erasable, i.e. when the next recording is started, the entire memory will be erased beforehand to free up memory space for new data to be recorded.

To avoid any risk of data loss, we recommend that you always download a recording as soon as it has been made.

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INDICATOR LIGHT

Device		Indicator light
Reset		Green and orange light up briefly
Standby		Green and orange are off.
Start recording	Normal conditions, at ECG connection	Green lights up and flashes 16 times to signal first acquisition.
	Normal conditions for Jawac sensor connection	Green lights up if the Jawac sensor probes are within the permissible distance range [7.5 cm - 23.5cm]. (*) Orange lights up if the Jawac sensor probes are not within the permissible distance range [7.5 cm - 23.5cm]. (*)
	Verification mode (auxiliary sensor acceptance time) - Duration 2 minutes	Green lights up if the Jawac sensor probes are within the permissible distance range [7.5 cm - 23.5cm]. (*) Orange lights up if the Jawac sensor probes are not within the permitted distance range [7.5 cm - 23.5cm]. (*)
	Insufficient battery	Green and orange remain off. Recording does not start.
	Memory full	Orange flashes four times. Recording does not start.
	Memory error	Orange lights up briefly. Recording does not start.
During recording	Normal conditions with only the ECG sensor connected	Green flashes briefly once every 3 seconds, and 16 times rapidly with each acquisition.

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	Normal conditions with Jawac sensor connected	Green flashes once per second if the Jawac sensor probes are within the permissible distance range [7.5 cm - 23.5cm]. (*) Orange flashes once per second if the Jawac sensor probes are not within the permissible distance range [7.5 cm - 23.5cm]. (*)
Stop recording	Normal conditions	Green and orange go out.
	Shutdown due to low battery	Green goes out. Orange flashes 10 times rapidly, then goes out.
USB connected	Normal conditions	Orange is permanently lit.
	Battery charging in progress	Orange flashes regularly.
	Calibration in progress	Green flashes rapidly.

(*): Depending on the device version, the indicator light stays on for 2 seconds or 2 minutes before flashing to indicate that recording has started.

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RECHARGING THE BATTERY

The device contains an internal battery. The battery is a rechargeable Lithium Polymer type battery. The battery is recharged via the same USB cable used for importing recordings. For a full recharge, connect the device to a **USB charger.**

In order to ensure optimal safety, please observe the rules given for battery in the section "Warnings and Safety Notices"

It is recommended to recharge the battery completely in between each recording. When charging, the orange indicator light on the front face of the selected device will start flashing and will keep flashing until its battery is fully recharged. A full charge takes between 3 and 4 hours. When fully charged, the light stays ON permanently. It is advisable not to unplug the unit while charging is in progress.

SETTING TIME OF THE DEVICE

As soon as the CERES program recognizes your BRIZZY+ (displaying its serial number), the device automatically adapts to your computer's time.

CALIBRATING THE DEVICE

Before first use, the parameters of the device must be adjusted so that they best fit the Jawac sensor in use. It is not necessary to calibrate the device at each use provided a particular device is always used with the same Jawac sensor. However, the device must be recalibrated in case a different Jawac sensor is associated with it. Recalibration of the device can also help if a problem in acquisition of the Jawac signal arises (see the “Troubleshooting” chapter).

Each time a new Jawac sensor is associated with the device, the device must be recalibrated.

To calibrate the device, follow these instructions:

- Gather the device, the Jawac sensor which is associated with the device, and the calibration tool provided with the sensor,
- Connect the device to the computer,
- Open the software and follow the instructions displayed.

Once it has been launched, the calibration process runs automatically. It takes about 20 seconds to complete. The green indicator light on the device flashes rapidly during calibration.

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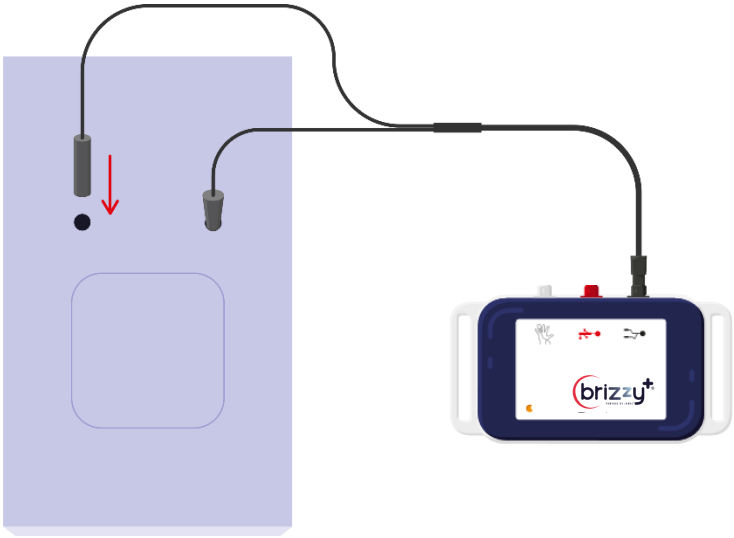
The probes must be held deep down into the holes of the calibration tool during the whole calibration process. If a calibration is started when the probes are not in the proper position, this will result in incorrect Jawac measurement. Recalibrate the device in this case.



During calibration, the calibration tool should stand at a distance of at least 20cm (8") from any metallic object and from any other electronic device (ex: computer). If you put the calibration tool down on a table, pay particular attention to the material (possibly metallic) from which is made the structure supporting the table.

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USING THE SOFTWARE

Some operations execute through the USB cable specially designed by Nomics to connect the device to a PC. For safety reasons, it is strictly forbidden to connect the device to a computer while the patient wears the device. The patient must be kept at more than 1.50m (5') from the device while the device is connected to the PC. Do not hand the USB cable to the patient with the device.

REQUIRED CONFIGURATION

The minimum system requirements for Windows computers are:

√ Windows® 10, or later

√ An active internet connection

√ Recommended graphics resolution min 1920 x 1080

√ 1 USB- Type A port

The minimum system requirements for MACOS computers are:

√ MACOS 12 (Monterey), or later

√ An active Internet connection

√ Recommended graphics resolution min 1920 x 1080

√ 1 USB-Type A port

INSTALLATION OF CERES

√ In order to install the CERES software, please check that your computer meets the minimum requirements given above.

√ Double-click on the 'CERES' file provided or download it from the Apios dashboard.

√ You will then be informed of all the steps by the installation utility. Depending on computer configuration, installation may take several minutes.

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ACCOUNT ACTIVATION ON THE APIOS DASHBOARD

Brizzy+ data is sent for analysis via CERES software to a secure server belonging to nomics.

Before using this service, users must activate their account on the Apios dashboard.

ACTIVATION PROCEDURE

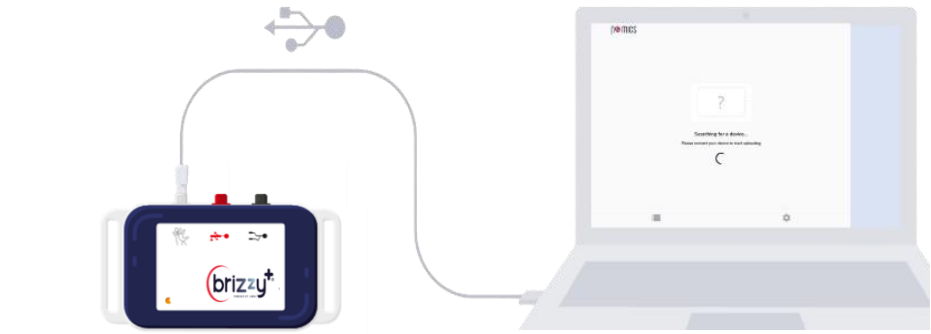
- ✓ You will receive an invitation e-mail from noreply@nomicscare.com to configure your password.
- ✓ Click on the 'Accept invitation' button in the e-mail.
- ✓ You'll be redirected to the Apios dashboard, where you'll need to set your password.
- ✓ Once you've set your password, you'll have access to the dashboard.

UPLOAD OF A RECORD

To transfer data from the recorder to Nomics' secure site, make sure you have an active Internet connection, launch the CERES software, and connect Brizzy+ to your computer via the special USB cable.

Once this has been done, the last registration will appear in the CERES window.

Select the record and then click the "upload selection" button.



Please do not hesitate to contact our technical support:

support@nomicscare.com

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MAINTENANCE

SERVICE

The device does not need any special kind of servicing. The operator must nevertheless check the device and its accessories regularly in order to detect any damage (see section “Preparing a recording“).

If the device is damaged, do not use it. Indeed, the internal battery itself could be damaged and cause leak, overheating, or fire. If you notice damage to the device, contact your local distributor or Nomics technical services (see the “Troubleshooting” chapter).

See also the section "Calibrating the Device”.

CLEANING

If necessary, the surface of the device may be cleaned with a dry or slightly damp cloth. You may use slightly soapy water or an alcohol-based disinfectant. Ensure that no moisture penetrates inside. Do not submerge the device in water or any other liquid. Immersion is likely to damage the product and will invalidate the guarantee. Do not autoclave.

The reusable sensors which come in contact with the patient must be cleaned/disinfected in between each use. Please follow the cleaning instructions given in the corresponding directions for use.

Consumables (JAWAGRIPS) should be disposed of after a single use.

Nasal cannulas are for single use. For hygiene reasons, do not use cannulas which have already been used. Dispose of them immediately after use.

In sleep centers and hospitals, the hygiene and waste management rules in force must be observed.

ENVIRONMENT

Admissible environmental conditions of operation, storage, and transport are given in the section "Technical Specifications". Do not use the device if the environment presents a high level of humidity; condensation could form on the inside of the device and could damage its components. The device must be handled with care. It is recommended to use a carrying case or bag which protects the device from shocks during transport.

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DISPOSAL

When you are disposing of the device or of electrical or electronic accessories, please use the collection and processing services for this type of equipment in your area.

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TROUBLESHOOTING

Please consult the following table in the event of a problem. Contact your local distributor or Nomics technical services if the problem does not appear in the list below or if the proposed solutions do not solve the problem.

In case of technical problems, the technical service may ask you a remote access to your computer. The technician will guide you to provide him with the identification code and password.

If the device needs to be sent to technical services for repair, enclose all the sensors and accessories in the package in order to allow for the best possible diagnosis.

Contact details of technical services:

Technical Services

Nomics s.a.

Liege Science Park

4, rue des Chasseurs Ardennais

4031 Angleur (BELGIUM)

Tel: +32 (0)4 372 93 42

support@nomicscare.com

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Problem	Possible cause	Solution
The recording does not start.	The Jawac sensor is not properly connected to the device or is damaged.	Check that the Jawac sensor is properly connected to the device or check, if possible, with another sensor. If the sensor is damaged, contact Nomics or your local distributor.
	The battery is empty.	Recharge the battery.
	The memory is full.	Connect the device to the computer and import the data stored in memory.
	The USB cable is connected to the device.	Disconnect the USB cable.
The recording stops prematurely.	The battery has not been sufficiently charged.	Recharge the battery completely after each recording.
	The battery has worn out. Even if it is completely recharged, the battery is not able to provide enough power for a full night recording.	Battery life depends on usage and several factors such as operating, charging, and storage temperatures. If the battery has worn out, contact Nomics or your local distributor.
	There is no more space in memory for new data.	It is recommended to import the recording stored in memory before starting the next one. This will free up memory space for new data.
On the reporting, the Jawac signal appears completely flat or does not appear to be physiological	The probes of the sensor were not properly positioned or they moved during the recording.	Ensure that the probes are properly positioned and held in place. One must attach to the forehead and the other one to the chin. They must be parallel and on the same vertical axis. The probes must not be positioned head-to-tail!
	The Jawac sensor used for the recording is not the one with which the device was calibrated.	Recalibrate the device with the sensor associated with it.

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Problem	Possible cause	Solution
	The recorder was calibrated when the Jawac sensor probes were not inserted in the calibration tool, or when the probes were close to a metal object or other electronic device.	Follow the instructions given in this guide to recalibrate the device.
	The sensor is damaged or faulty.	Replace the sensor if it is damaged or faulty, then recalibrate the device with the new sensor.
	Unknown cause.	Recalibrate the device with the Jawac sensor associated with it.
The orange indicator light is shining while the device is connected to a computer.	The shining of the orange indicator light is normal in these conditions. It indicates that the device has detected the presence of a USB connection.	
The computer does not detect the device.	If the orange indicator light on the front of the device does not light up, it is likely that a plug is not correctly inserted into its socket.	Reinsert the plug of the special USB cable in the white socket of the device. Reinsert the USB plug of the cable into a USB port on the computer.
	The computer has not detected the device correctly.	If necessary, unplug the device from the computer and replug it. If it still does not work, restart the computer and try again.
The date of start of the recording doesn't match what was expected	The latest recording hasn't started and the memory of the device still contains the previous recording(s).	Check that recording starts as soon as you plug in the sensor Start the recording again.
	The device must be set to the right time.	Set the time of the device. The following recordings should have the correct date.
Calibration – an error message is displayed.	The Jawac sensor was not correctly connected to the device during the calibration process.	Make sure the Jawac sensor is correctly connected to the device during calibration.

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Problem	Possible cause	Solution
	The probes of the Jawac sensor were not inserted into the holes of the calibration tool during the calibration process.	Insert the probes all the way down the holes of the calibration tool. Start a new calibration.
	The Jawac sensor got disconnected from the device during calibration.	Replug the sensor and start a new calibration.
	The Jawac sensor is damaged or faulty.	Replace the sensor. Recalibrate the device with the new sensor.
On the recording, the respiratory flow signal, respiratory movement or oximetry has a completely flat profile or non-physiological.	The sensor or cannula was not connected to the device.	Connect the sensor or cannula to the device
	The sensor plug is not fully inserted into the connector.	Push the plug into the socket.
	The sensor or cannula was not correctly placed or has moved**.**	Position the sensor or cannula with reference to the corresponding instructions. If necessary, maintain the sensor or the cannula in place with additional pieces of tape. The tape used should be of hypoallergenic type.
	The sensor is dirty, damp or damaged.	Clean the sensor as indicated in the corresponding user manual. Replace sensor if it is damaged. Replace the nasal cannula if dirty, clogged or if it has already been used.
	The plugged oximetry sensor on the Nonin XPOD is not a Nonin branded.	To ensure compatibility with the Xpod module use only brand Nonin sensors.

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GUARANTEE

Nomics guarantees that this product is free from defects in material and workmanship that may result in failure during normal usage and will, for a period of two years from the date of delivery, provide free warranty service.

For sensors or equipment used in conjunction with the product, the guarantee period is the one indicated on their packaging or in their directions for use. As for the Xpod oximeter module from Nonin, it is guaranteed for one year.

In the event of product failure or failure of one of its accessories, the faulty part will be either repaired or replaced free of charge. At the end of the guarantee period, Nomics will no longer be explicitly or implicitly liable.

This guarantee will be declared null and void and Nomics will not in any way be held liable if the product or its accessories have been misused, have been the object of abusive use or handling errors, have been opened by an unlicensed staff member, have been modified or taken apart. Any damage inflicted on the product caused by force majeure (e.g. fire, etc.) or by inappropriate packaging when returning it to the sender, normal wear and tear of the product and its accessories, and disposables are not covered by the guarantee. You cannot claim under this guarantee for damage caused by leaking batteries or by the use of inappropriate chargers.

IMPORTANT: The use of sensors, equipment or spare parts other than those provided or authorized by Nomics will render this guarantee invalid.

Nomics declines all responsibility for any direct, indirect or subsequent loss or damage, including all damage or injuries caused by the use or inability to use this product.

This guarantee replaces all other guarantees expressed or implied and only covers the original purchaser.

In case of problem, please consult the "Troubleshooting" chapter. In the event of an emergency, contact directly your local distributor or Nomics technical.

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TECHNICAL SPECIFICATIONS

WARNING: Do not modify this equipment without authorization of the manufacturer.

Permissible environmental conditions (applicable to all items of the system unless otherwise stipulated)	
Operating temperature	5°C (41°F) to 40°C (104°F)
Charging temperature	5°C (41°F) to 40°C (104°F)
Storage temperature	**Accessories:** -10°C (14°F) to 60°C (140°F) **Device:** -10°C (14°F) to 60°C (140°F) / 1 month -10°C (14°F) to 40°C (104°F) / 3 months -10°C (14°F) to 30°C (77°F) / 6 months **Note: in order to preserve battery performance, long-term storage of the device should be done at low temperature.**
Transport temperature	-10°C (14°F) to 60°C (140°F)
Humidity	15% to 90%

Device (without auxiliary sensor)	
Dimensions	85 mm (3.35") x 55 mm (2.16") x 16 mm (0.63")
Weight	80g (2.8oz)
Power	Lithium Polymer rechargeable battery
Charging duration	Between 3 and 4 hours for a complete recharge
Autonomy (full charge)	In recording mode WITH oximeter & Flow Sensor: minimum 16h
Average consumption	In recording mode, with oximeter & Flow Sensor (from battery): 130mW When charging (from USB): 3.5W
Memory	32MB, i.e. up to 40h of recording
Data transfer	Via USB to PC

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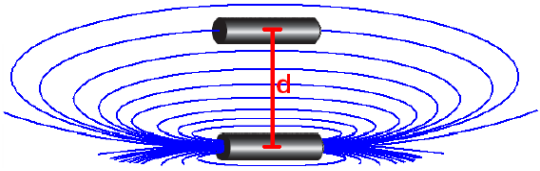
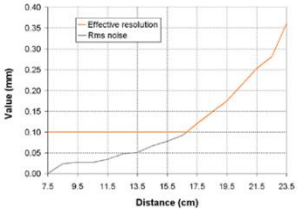
Position sensor	
Technology	3D accelerometer
Sampling frequency	lying supine / lying on the right side / lying on the left side / lying prone / upright
Conditioning	1Hz

Jawac sensor	
Technology	Resonant magnetic field transducer. Short (< 2.5ms) magnetic pulses of 8kHz frequency and of very low energy are generated by the emitter probe of the sensor. The signal received by the other probe is analysed in order to infer the distance (d) between them. 
Measurement range	70mm (2.75") to 235mm (9.25")
Resolution	The numerical resolution on display is 0.1mm. The resolution achieved in practical usage is linked to the distribution of noise in measurements. The effective resolution is defined as the maximum of numerical resolution and rms noise value. It depends on the distance between the two sensor probes: 
Sampling frequency	10Hz
Conditioning	Low-pass filtering with 1Hz cutoff frequency

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Oxymeter (Nonin Xpod)	
SpO2	Measurement range: 0 to 100% Accuracy (for adults using the 8000AA Finger Clip Sensor, in 70 to 100% range, with ±1SD): ±2% Sampling frequency: 3Hz Conditioning: 4-beat Average
Pulse rate	Measurement range: 18 to 300bpm Accuracy (for adults using the 8000AA Finger Clip Sensor, no motion): ±3bpm Sampling frequency: 3Hz Conditioning: 4-beat Average
Plethysmographic wave	Sampling frequency: 75Hz

Respiratory movement sensor	
Technology	3D accelerometer
Sampling frequency	10Hz
Conditioning	Band-Pass filter 0,02Hz-2Hz

Flow sensor	
Technology	Pressure sensor
Range	Differential pressure sensor from ambient : -2.5 to +20 mbar
Resolution	In the order of 0,006mbar
Sampling frequency	10Hz
Conditioning	Band-Pass filter 0,02Hz-4Hz (snoring excluded…)

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INSTRUCTIONS AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

BRIZZY+ is intended for use in the electromagnetic environment specified below. The customer or the user of BRIZZY+ should assure that it is used in such an environment.

ENVIRONMENT SUITABLE FOR USE

BRIZZY+ is suitable for use in all premises, including domestic premises and those directly connected to the public low-voltage power supply network supplying buildings for domestic use.

ESSENTIAL PERFORMANCE

The recording of physiological parameters during sleep to allow the detection, by visual or automatic analysis of recorded signals, of events related to sleep disorders must not be adversely affected.

RECOMMENDATIONS

See the chapter "Warnings and Safety Instructions".

TEST COMPLIANCE

BRIZZY+ has been declared compliant with the emission and immunity tests required by the standard "EN 60601-1-2:2015" with the essential performance criterion listed above.

The table below shows all the tests and compliance levels:

Emissions test	Conformity
Emissions RF CISPR 11	Class B
Harmonic Emissions CEI 61000-3-2	Not applicable
Voltage fluctuations / Flicker emissions CEI 61000-3-3	Not applicable

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Immunity test	Conformity
Electrostatic discharge (ESD) CEI 61000-4-2	+/- 8kV contact +/- 2kV, +/- 4kV, +/- 8kV, +/- 15kV air
Radiated RF CEI 61000-4-3	10 V/m 80 MHz - 2,7 GHz Modulation according to Table 9 of EN60601-1-2:2015
Electrical fast transient / burst CEI 61000-4-4	Not applicable
Surge CEI 61000-4-5	Not applicable
Conducted RF CEI 61000-4-6	6 V/m 0.15 MHz – 80 MHz
Magnetic field (50/60 Hz) CEI 61000-4-8	30 A/m 50Hz
Voltage dips, short interruptions and voltage variations on power supply input lines CEI 61000-4-11	Not applicable

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NOMICS' Jawac sensor technology is covered by an international patent.

For further information, please contact:
Nomics (sales@nomicscare.com) or your local distributor.

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