

The User Recording Unit (URU) is designed to be used as part of the Patch system. The URU is a wearable sensor intended to record biological signals from the user during sleep.

Cautions and Warnings for URU

- Read the entire manual before using the URU.
- When using consumables and accessories, please read the manufacturer's information supplied with the products.
- It is important to inspect the condition of the URU. If there are any visible defects, the URU should not be used.
- It is recommended to initiate recording on the URU immediately before going to sleep.
- Do not submerge the URU in liquid.
- Do not modify the URU.
- Excessive noise may affect the quality of the recording. When using the URU, the patient should sleep in a quiet environment to minimize the impact of the ambient noise.
- Wireless communication devices might have an impact on the system. Do not place too close to the patch.
- Small parts may be a choking hazard to children.
- The healthcare professional is responsible for explaining to the patient the functions of the URU and how to operate it safely with the help of the patient User Guide.

URU LED Light Indicators



URU LED Light Indicator

Light	Description
Solid Green	URU will start recording
Flashing Green	URU recording in progress
Solid Red	URU in error state

Charging URU

1. Plug the data collection unit (DCU) into a wall outlet.

2. Insert the URU to the charging dock in DCU.
3. The URU should be charged for approximately 2 hours.
4. The URU should be charged the day you wish to conduct the home sleep test.

Directions for Use

Note: The URU must be fully charged prior to usage. See charging instruction for URU.

1. Attach the URU on the neck.
2. Turn on the URU by pressing the button. The green LED light will turn on solid.
3. Once all components are connected, LED light on URU will flash green and eventually turn off within a minute.
4. Go to sleep.

Cleaning and maintenance

1. Wipe all outer surfaces of URU using antiseptic isopropyl alcohol wipe.
2. Leave the components to dry.

FCC Regulatory Statements

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference.
- (2) This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the Federal Communication Commission (FCC) rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment causes harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by doing one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

NOTE: THE GRANTEE IS NOT RESPONSIBLE FOR ANY CHANGES OR MODIFICATIONS NOT EXPRESSLY APPROVED BY THE PARTY RESPONSIBLE FOR COMPLIANCE. SUCH MODIFICATIONS COULD VOID THE USER'S AUTHORITY TO OPERATE THE EQUIPMENT.

RF Exposure Warning

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. In order to avoid the possibility of exceeding the FCC radio frequency exposure limits, human proximity to the antenna must not be co-located or operating in conjunction with any other antenna or transmitter.

ISED Regulatory Statements

This device complies with ISED Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage; (2) l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

CAN ICES-3 (B)/NMB-3(B)

RF Exposure Information

This equipment complies with ISED RSS-102 radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other Ω .

Storage/Environmental/ transport conditions

Environmental operating conditions	Temperature	+5°C to +40°C
	Relative Humidity	15% - 93%, non-condensing
	Atmospheric Pressure	700 - 1060 hPa
	Altitude	Up to 4000 meters
	Temperature	-40°C to +70°C

Environmental conditions of transportation and storage before first use	Relative Humidity	10% - 100%, including condensation
	Atmospheric Pressure	50 - 106 kPa
Environmental conditions of transportation and storage between uses	Temperature	-25°C without relative humidity control; and +70°C at a relative humidity up to 93%, non-condensing

Safety and EMC Compliance

1. IEC 60601-1:2005+AMD1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-2:2014: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
3. IEC 60601-1-6:2010+AMD1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
4. IEC 60601-1-11:2015: Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
5. IEC 62366-1:2015: Medical devices -- Part 1: Application of usability engineering to medical devices
6. IEC 62133-2:2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes -Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
7. ISO 10993-1:2018 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
8. ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
9. ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

Symbols

	Medical Prescription required
	Operating instructions Consult operating instructions
	Caution, Consult accompanying documents
	Follow instructions for use
	General warning sign
	Type BF applied part
	Manufacturer information
	WEEE
	Catalogue number
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	Fragile, handle with care

IPN₁N₂	Degree of protection against harmful ingress of water or particulate matter, where N1 defines the degree of protection against harmful ingress of particulate matter and N2 the degree of protection against harmful ingress of water
MD	Medical device
	Non-ionizing electromagnetic radiation. Equipment includes RF transmitters. Interference may occur in the vicinity of equipment marked with this symbol.

Manufacturer's info

Manufacturer name: Bresotec Inc.

Manufacturer address: Unit 407, 555 Richmond Street West, Toronto, Ontario M5V 3B1, Canada.

Manufacturer website: www.bresotec.com

Contact information:

info@bresotec.com

+1.844.276.3239

Technical Specification

Function and Features		
URU	Recording time per session	8 hours maximum
	Sample Resolution (Sound/snoring)	8000 Hz, 24 bits
	Sample Resolution (Neck/Chest Movement)	100 Hz, 12 bits x 3 axis
Power Requirements		
Power Source	URU	Lithium-ion rechargeable battery, 3.7V, 170mAh, 0.6Wh IEC62133-2:2017 Certified
Battery Life	URU (continuous and repeated uses)	17 hours (new and fully charged battery)
	URU (idle, not in use)	> 6 months (new and fully charged battery)
Physical Specification		
URU	Dimension	17.4mm x 38.7mm x 35.5mm (H x W x D)
	Weight	17 grams
Transmitter		
URU	WLAN compliance	802.11 b/g/n
	Antenna Type	Internal, 2.4GHz Chip Antenna
	Operating Frequency	2.4 GHz
	Band Width	20 MHz
	Operation	WLAN Station
	Modulation	1 DSSS, 6 OFDM, 54 OFDM
	FCC ID	2AYNV-BTSM1URU
	IC	26577-BTSM1URU
Expected Service Life		
URU		50 Recordings (8 hours per recording)