Neteera 130H-Plus/131H-Plus Instructions for Use

Reviewers				
	Name	**Position**	**Date**	**Signature**
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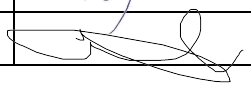
Approver	Shahar Yaron	VP Product	22-Dec-22	

* Release date is same as last signature date

Revision History		
Version	**Author**	**Changes**
1.0	Amatzia Mass	First Issue (based on IFU 130H US Rev 3.0)

*** This page should not be included in the printed version.**

User Manual – 130H-Plus/131H-Plus

Registered Manufacturer:
Neteera Technologies Ltd at:
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US Importer:
Hudson Scientific
103 W Main Street
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Product name/model:
Neteera 130H-Plus/131H-Plus

Device Description:
The Neteera device is a contactless vital signs monitor for measurement, data collection, and display of Heart Rate and Respiratory Rate.

Neteera's device is based on a high frequency (122.25-123 GHz) micro-radar on-chip and algorithm, capable of detecting physiological parameters (Respiration Rate (RR), Heart Rate (HR)) during rest or while monitoring a person's mild body movement.

Neteera's novel micro- radar-based solution enables remote measurement, in real-time, in a non-invasive and contact-free manner. The system works by measuring only the micro-movements of the skin (BCG) through non-conductive materials such as furniture and clothing at a high resolution, and it has several different mounting options and measuring ranges.

The presented product, the Neteera 130H-Plus/131H-Plus, contains a Wi-Fi component that enables communication and data transfer over the internet to the Neteera cloud, "HealthGate".

Intended Use:
The Neteera System, Neteera 130H-Plus/131H-Plus device, is intended for spot and continuous measurement of heart rate and respiration rate in adult patients in healthcare facilities.

The indications provided are to be used by health care professionals and are intended to be reviewed by clinicians to inform patient care.

The Neteera monitoring system is not intended to be used as an alarm system for potentially life-threatening situations in which medical intervention is necessary (e.g., ICU).

Contra-Indications:

Neteera 130H-Plus/131H-Plus is contraindicated for use in:

- People for whom proper positioning cannot be achieved or maintained.
- A combustible environment or in the presence of flammable anesthetics or gases.
- Situations where a dry environment cannot be ensured.
- A Magnetic Resonance Imaging (MRI) environment.
- Any other system or environment which was not authorized by Neteera Technologies LTD. Company.

General Hazards:

- Do not use a damaged Neteera 130H-Plus/131H-Plus device – cracked/broken plastic case, cracked/broken lens, defective USB connection, or any other indication of physical damage to the Neteera 130H-Plus/131H-Plus device. The use of a damaged Neteera 130H-Plus/131H-Plus device might result in the malfunction of the system.
- Handle the Neteera 130H-Plus/131H-Plus device with care.
- Do not drop, knock, or shake the unit.
- Rough handling can damage the internal circuit boards.
- The sensor is intended for indoor operation only. Avoid any contact with water or any other chemical. Cleaning is only allowed using a damp clean cloth, without harsh detergents, or per healthcare facility procedures.
- A damaged Neteera 130H-Plus/131H-Plus device should not be disposed of as unsorted municipal waste. Contact your local distributor for unit disposal.
- Changes or modifications not expressly approved (in writing) by Neteera technologies could affect the safety or effectiveness of the Neteera 130H-Plus/131H-Plus device performance and void the warranty.
- The Neteera 130H-Plus/131H-Plus device is designed with reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to proximity or strength of a source might impact the performance of the Neteera 130H-Plus/131H-Plus device. Additionally, interference from emitters such as diathermy or electrocautery devices or wireless power transfer devices (e.g., wireless phone chargers) may impact performance of the Neteera 130H-Plus/131H-Plus device.

Warnings and Cautions:

- If the device does not operate properly, contact Neteera Support.
- Use only the supplied accessories and parts. In case a part or accessory should need to be replaced, please contact Neteera support. Do not attempt to replace parts or accessories without prior consultation by Neteera support.
- When using the Neteera system, do not share the chair/bed being monitored with another person or pet during Neteera 130H-Plus/131H-Plus device recording session.
    - Sharing the chair or bed could affect the effectiveness of the system and the accuracy of the measurements.
- Avoid using heated blankets, or any other metal-containing heating item located between the Neteera 130H-Plus/131H-Plus device and the monitored person. The use of heating blankets could affect the effectiveness of the Neteera 130H-Plus/131H-Plus and void the system's warranty.
- The monitored person should not have direct contact with the Unit – a minimum distance of 5cm should be maintained.
- Neteera 130H-Plus/131H-Plus device is not intended to be a replacement for monitoring high-risk situations where ECG monitoring is required. The most reliable method of monitored person monitoring combines the close personal surveillance with the correct operation of the monitoring equipment.
- The Neteera 130H-Plus/131H-Plus technology and parameters have not been studied on any specific monitored person or group, nor has it been studied as a diagnostic tool for any specific disease or medical condition. It is meant to be an adjunctive tool only for measuring respiratory rate, heart rate.
  The device has not been validated in a pediatric population or in individuals with arrhythmia.
  The device is not intended for ambulatory conditions.
- As with all medical equipment, carefully route and secure Neteera 130H-Plus/131H-Plus device cables and connections to reduce the possibility of entanglement or strangulation.
- Interconnection of this equipment to other equipment not described in the instructions for use is prohibited.
- The Neteera 130H-Plus/131H-Plus monitoring system is not intended to be used as an alarm system for potentially life-threatening situations in which medical intervention is necessary.
- The device is not intended to be used as a real-time monitor or apnea monitor. Do not rely on the respiration monitoring for detection of cessation of breathing and always follow hospital guidelines and best clinical practices, including monitoring additional parameters that indicate the patient's oxygenation status.
- Prior to delivering medical treatment based on a high heart rate reading (120 to 160 bpm), the subject should be asked to remain still for several minutes to allow the reading to be verified under no motion conditions.

EMC Warnings:

- WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- WARNING: The use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- WARNING: 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 Neteera 130H-Plus/131H-Plus, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- WARNING: Neteera 130H-Plus/131H-Plus needs special precautions regarding EMC and needs to be installed and put into service according to the specific instructions for maintaining basic safety and essential performance with regard to electromagnetic disturbances for the expected service life. Refer to System Compliance Appendix for further details on EMC safety conditions.

RF EXPOSURE STATEMENTS

Exposure to radiofrequency during wireless operation: based on the FCC RF exposure compliance requirements, the separation distance between a wireless antenna and any person's body must be at least 2 inches / 5 cm.

Maintenance and Cleaning

The Neteera 130H-Plus/131H-Plus is designed to provide trouble-free and maintenance-free operation. The only maintenance required is to keep the system clean and dry and to verify that there is no physical damage to the Sensor.

Gently wipe the Neteera 130H-Plus/131H-Plus device lens using a soft, damp cloth/wipes containing anti-septic substances. Wipes containing alcohol, Chlorhexidine, and bleach material can be used. Please ensure that the Neteera 130H-Plus/131H-Plus device is dry before re-use.

Specifications

Indications

Rx Use	The device is intended to perform measurements in healthcare settings. The data provided by the device is intended to be reviewed and interpreted by healthcare practitioners to assess a person's medical condition.
Sterile	The device is contact-free and does not need to undergo sterilization.
Multiple Use	The device is intended for multiple uses, spot, and continuous monitoring.

Measured Parameters

HR – Heart Rate Range	40 to 160 BPM (Beats Per Minute)
Maximal HR change speed	4 BPM/ sec
HR output rate	Every 1 sec
RR – Respiration Rate Range	5 to 40 BrPM (Breaths Per Minute)
Maximal RR change speed	1 BrPM/ 3 sec
RR output rate	Every 1 sec
Respiratory Amplitude scale	1 (low) to 5 (high) arbitrary units
Respiratory Amplitude output rate	Every 1 sec
IE ratio scale	Positive numbers
Low RR (respiration rate)	Less than 5 BrPM No respiratory numeric values and trends are displayed while detected
Occupancy	No numeric values and trends are displayed while not occupied

Operation Specifications

Mounting Options	Mounted in the front of a chair, or above a bed. Range: 8–60 in. / 20-150 cm
Integration mounting options	Mounted in the back of a chair, or below a bed. Range: 2–8 in. / 5-20 cm
Applicable patient positioning	Sitting, laying (according to installation guidelines)

Electrical Characteristics

Operating Voltage	5V +/-5%
Power/Data Connector	USB 2.0 type A + power supply
Power Consumption, typical	2.9W
Power Supply Options	Charger 5V/1A **or** Type A USB 2.0 port of a host device

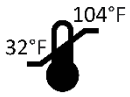
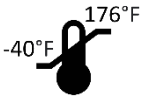
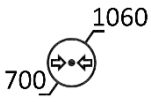
Physical Characteristics

Dimensions (L x W x H)	3.22 x 1.22 x 2.36 in. / 8.2 x 3.1 x 6 cm
Weight	2.7 Oz / 76 gr.

Data Connectivity

Wired	USB 2.0
Wireless	Wi-Fi 2.4GHz 802.11 b/g
Data Protocol	Neteera MQTT for wireless communication, CDC transfer protocol for wired communication

Handling and Storage

Operation Temperature	**32 to +104 °F/ 0 to +40 °C**	
Storage Temperature	**-40 to +176 °F/ -40 to +80 °C**	
Operating and Storage Humidity	**Up to 75% (non-condensing)**	
MR Compliance	**Not MR compliant**	
Atmospheric Pressure	**700-1060 hPa**	

Service Life

The device service life is 5 years.

Symbols

	Caution		Manufactured by
	Warning		Date of manufacturing
	Consult accompanying documents		MR Unsafe - keep away from magnetic resonance imaging (MRI) equipment
	Sorted disposal		Temperature limitation
	Fragile, handle with care		Humidity limitation
	Keep dry		Atmospheric pressure limitation
IP21	Solid object protected and splash-proof accesory		This side up
	Indoor operation only	Rx Only	Prescription use only

FCC ID: 2AYVONETEERA130PLUS

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, and
(2) This device must accept any interference received, including interference that may cause undesired operation.
Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the 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.

The maximum output power of our Wi-Fi module ESP-WROOM-32DC (FCC ID:2AC7Z - ESPWROOM32DC), is limited, to 19 dBm.