Neteera 130H/131H
Instructions for use

Reviewers				
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Revision History		
Version	**Author**	**Changes**
0.7	Hanna Riezk	First Issue
1.0	Hanna Riezk	Initial Release
1.1	Idan Yona	Added Part 15 of the FCC Rules claims.

Neteera 130H/131H Instructions for use

For any question or help during installation/operation of the system, contact your FAE representative or support@neteera.com

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Table of Contents

1. INTRODUCTION

1.1 Acronyms and Terminology

Term	Description
Neteera130/131H	Neteera's System (Micro-Radar Based system)
VS	Vital Signs
HW	Hardware
SW	Software
HR	Heart rate
RR	Respiratory rate
BCG	Ballistocardiograph

	Caution		Manufactured by
	Warning		Date of manufacture
	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
	Indoor operation only	*Rx Only*	US Federal Law restricts this device to sale by or on the order of a physician
IP22	Solid object protected and splash-proof accessory		This side up

Image 1: Explanation of system labels

FCC ID: 2AYVO-NETEERA1301

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.

1.2 About this product

Neteera device is a contact-free vital-signs monitor based on a high frequency (122.25-123 GHz) micro-radar on-chip and algorithm, capable of detecting a variety of parameters: Respiration Rate (RR), Heart Rate (HR), during rest or subject's mild body movement.

More information about these parameters is provided in chapter 5.3 - parameters displayed.

The Neteera device is intended for contactless monitoring of HR and RR, for spot and continuous monitoring by healthcare professionals (in healthcare facilities and home monitoring).

The indications provided are to be used by health care practitioners and are intended to be reviewed and interpreted by clinicians to assess patient's medical situation.

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).

Neteera novel micro radar-based solution enables to measure remotely, in real-time, in a non-invasive, non-contact manner, only the micro-motions 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 – as detailed below.

The presented product is divided into two different configurations:

- **130H**: contains a Wi-Fi component that enables communication and data transfer over an internet network.
- **131H**: enables P2P communication only through a USB connection between the device and an external Windows device.

1.3 Hardware requirements

The Neteera 130/131H has a hardware component (the case housing the radar itself) and the software that operates it and runs over the device. To collect the data from the device and to display it, an external device is needed that will communicate with the device.
The requirements for such a device as below:

- PC/tablet with:
- Windows 10
- USB 2.0 port
- Core i3
- 8 GB RAM
- display resolution HD
- SSD 64GB
- Wi-Fi 2.4GHz 802.11b/g

2. HW INSTALLATION

Neteera 130/131H consists of:

		
Neteera 130/131H main unit	**USB 2.0 cable**	**Power supply (130H)**

Image 2: system parts

When the installation is complete (according to the instructions found below), it should look like this:

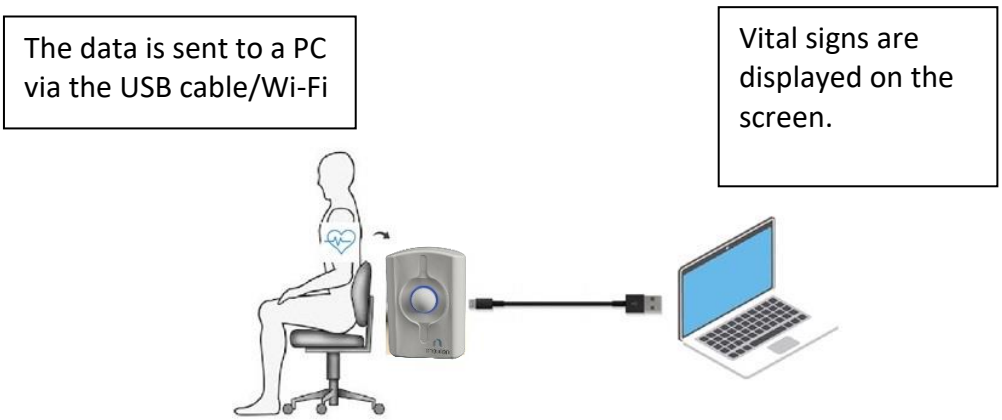


Image 3: Neteera 130/131H system operation

2.1 HW Technical description

Component	Description
Neteera130/131H Main unit	Full p2p radar-based system with PLL working at 116-123 GHz
USB cable	Standard 2.0 USB cable

2.2 Neteera 130/131H characteristics

2.2.1 Vital signs

Parameter	Value
HR – Heart Rate Range	40 to 160 BPM (Beats Per Minute)
HR output rate	Every 1 second
Maximal HR change speed	4 BPM/sec
RR – Respiration Rate Range	5 to 40 BrPM (Breaths Per Minute)
RR output rate	Every 2 second
Maximal RR change speed	2 BrPM/sec
HR accuracy	Up to 10% deviation
RR accuracy	Up to 10% deviation, or up to 2 BrPM
RA scale	1 (low) to 5 (high)

2.2.2 Operation Specifications

Parameter	Value
Measuring Range to the Subject	0.16–0.65 ft./5-20cm: Mounted in back. 0.65-4.92 ft./20-150cm: Mounted in front.
Mounting Options	Mounted in the back/front of a chair

2.2.3 Sensor Characteristics

Parameter	Value
Maximum Radiated Power (E.I.R.P)	Up to 20 dBm
Field of View (-6dB Beam Width)	13 deg
Polarization	Linear

2.2.4 Electrical Characteristics

Parameter	Value
Operating Voltage	5V +/-5%
Power/Data Connector	USB 2.0
Power Consumption, typical (130H)	4.5W
Power Consumption, typical (131H)	3 W
Power Supply Options	Charger 5V/1A or Type A USB 2.0 port of a host device

2.2.5 Physical Characteristics

Parameter	Value
Dimensions (L x W x H)	3.22*1.22*2.36 in. /82*31*60mm
Weight	0.661 lb./300 gr.

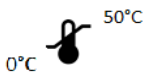
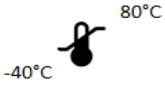
2.2.6 Occupancy detection characteristics

Parameter	Value
Accuracy	96%
Response time	Up to 5 sec

2.2.7 Data Connectivity

Parameter	Value
Wired	USB 2.0
Wired data protocol	CDC transfer protocol
Wireless (optional)	Wi-Fi 801.22 b/g
Wireless data Protocol	Neteera MQTT

2.2.8 Environmental Characteristics

Parameter	Value	symbol
Operation Temperature	32 to +122 °F/ 0 to +50 °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	

2.3 The main unit – the Neteera130/131H radar

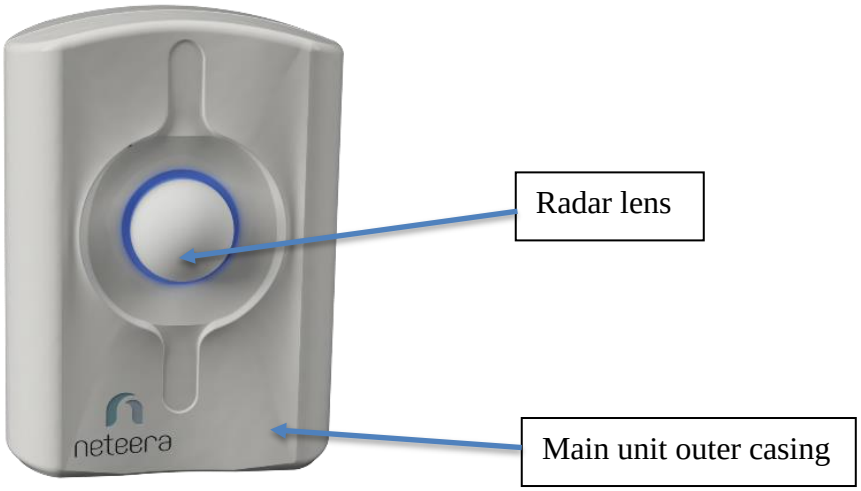


Image 4: Neteera 130/131H main unit

The main unit has a lens, outer casing, and a mounting accessory. The unit will be mounted on a chair seat (as will be detailed below). In case there is a need to install it on a bed, kindly contact the support team.

PLEASE NOTE: ONLY mount and use this unit assembled as originally received. DO NOT try to disassemble the black casing – may compromise device safety and proper functionality.

3. GENERAL SAFETY GUIDELINES

3.1 General Hazards

- Do not use a damaged sensor.
- The use of damaged components might result in the malfunctioning of the system.
- Handle the sensing unit with care.
- Do not drop, knock, or shake the sensing 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 sensor should not be disposed of as unsorted municipal waste. Contact your local distributor for unit disposal.
- Changes or modifications not expressly approved by Neteera technologies could affect the safety or effectiveness of the Neteera 130/131H performance and void the warranty.
- The Neteera 130/131H standard 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 disrupt the performance of this device.

3.2 Contraindications for Use

Neteera 130/131H is contraindicated for use in:

- Patients in whom proper positioning cannot be achieved or maintained.
- An explosive atmosphere 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 the Neteera Technologies Company

3.3 Warnings and Cautions

- If a sensor does not operate properly, contact Customer Support.
- Use only the supplied accessories and parts. In case a part or accessory should be replaced, contact Neteera support. Do not attempt to replace parts or accessories without prior consultation by Neteera support.
- Do not share the chair with another person or pet during Neteera 130/131H recording session. Sharing the chair could affect the effectiveness of the system and the accuracy of the measurements.

- Avoid using heating blankets, or any other metal-containing heating item located between the chair and the patient. The use of heating blankets could affect the effectiveness of the Neteera 130/131H and void the system's warranty.
- The patient should not have direct contact with the Sensing Unit.
- The Neteera 130/131H is not intended for monitoring high-risk situations where ECG monitoring is required. The most reliable method of patient monitoring combines close personal surveillance with the correct operation of the monitoring equipment.
- The Neteera 130/131H technology and parameters have not been studied on any specific patient group, neither has it been studied as a diagnostic tool of any specific disease or medical condition. It is meant as an adjunctive tool only for measuring respiratory rate, heart rate.
- As with all medical equipment, carefully route sensor cables and connections to reduce the possibility of entanglement or strangulation.
- The Neteera 130/131H monitoring system is not intended to be used as an alarms system for potentially life-threatening situations in which medical intervention is necessary.
- Interconnection of this equipment to other equipment not described in the instructions for use is prohibited.

RF EXPOSURE STATEMENTS

Exposure to radio frequency 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 (5cm).

4.DEVICE INSTALLATION

4.1 Mounting accessories

There are three mount devices supplied by Neteera to perform installations. The mount devices are supplied to the customer as a kit according to request.

1. Tripod – part number: 130-00-903-00

   The tripod is not part of the product, meaning it can be supplied in small quantities to test the technology or for demonstrations. The tripod is supplied with a ball-joint for easy adjustment.

Image 5: Tripod mount

2. Table / Pole mount – part number: 130-00-901-00

The table/pole mount is part of the product, meaning this can be supplied in large quantities. This device is supplied with a ball-joint (and hinge for assembly) for easy adjustment.

Image 6: Table/Pole mount

3. Wall mount - part number: 130-00-902-00

The wall-mount is part of the product, meaning this can be supplied in large quantities.

Image 7: Wall mount

4.2 Installation types

130/131H product can be installed in front of the measured subject. The mounting devices mentioned above can be installed while the subject is sitting on a chair or lying on a bed.

Chair installation: the product will be installed on a table using a tripod or table mount as presented below.

Image 8: tripod installed on a table

Image 9: table mount installed on a table

Bed installation: the product will be installed above the subject using a wall mount or pole mount as presented below:

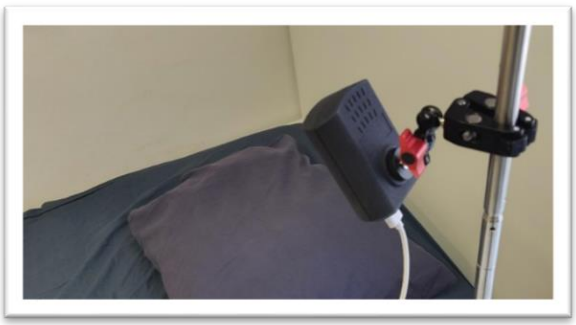


Image 10: pole mount installed above bed

Image 11: wall mount installed

4.3 Installation instructions

Please read the instructions carefully before beginning installation

The first step is to install the HW. Before you begin, please make sure you have:

- All the required HW parts - main unit (130/131H) and the USB 2.0 cable.
- An external device - PC/Tablet with the needed requirements.
- "Neteera" SW (supplied by Neteera) on the external device.

Installation steps:

- Front installations can be done within a minimum distance of 20 cm and up to 150 cm from the subject's body (0.65-4.92 ft.).
- Back installations can be done within a minimum distance of 5 cm and up to 20 cm from the subject's body (0.16–0.65 ft.).
- The lens located at the center of the product main unit should point to the center of mass of the subject's body. Meaning that it towards the subject's torso.
- The main unit should be parallel as possible to the subject's body.
- The device should be installed on a stable surface/location to avoid performance disruptions.

NOTE: Back installation are possible and are defined as integration projects. The minimum distance of a back installation is 5 cm (0.16 ft.) from the subject.

The path of the Radar to the subject's body should be clear from metal parts

5. SOFTWARE INSTRUCTIONS

5.1 Connect to an external device – PC/Laptop/Tablet

Use the supplied USB 2.0 cable to connect the Neteera 130/131H main unit to the external device. Make sure that the blue LED illuminates steadily after 10 seconds of connecting the system. This is an indication that the system is receiving voltage and can operate properly.

5.2 Starting a monitoring session

- Run the Neteera software (supplied with the system) by double-clicking the "Neteera_run.bat" file. The Neteera UI will appear.

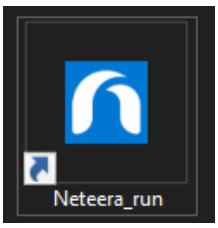


Image 12: the icon of Neteera software

- Click once on the "start" button.

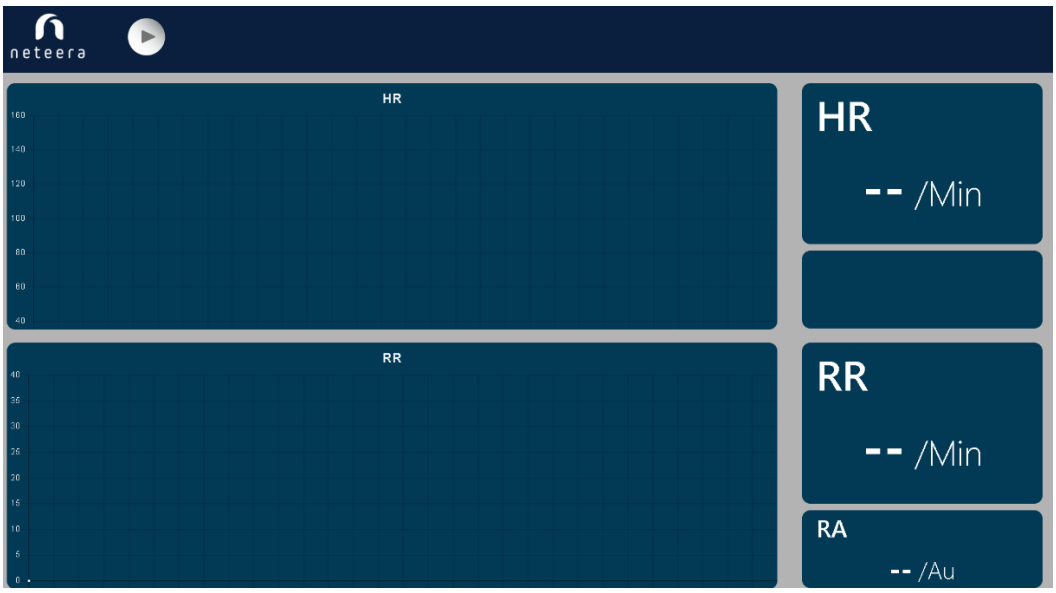


Image 13: the system is ready to start the monitoring session

If there is a USB image flashing on the screen, or if there is no "play" symbol – the main unit is not connected properly, check the USB cable connection.

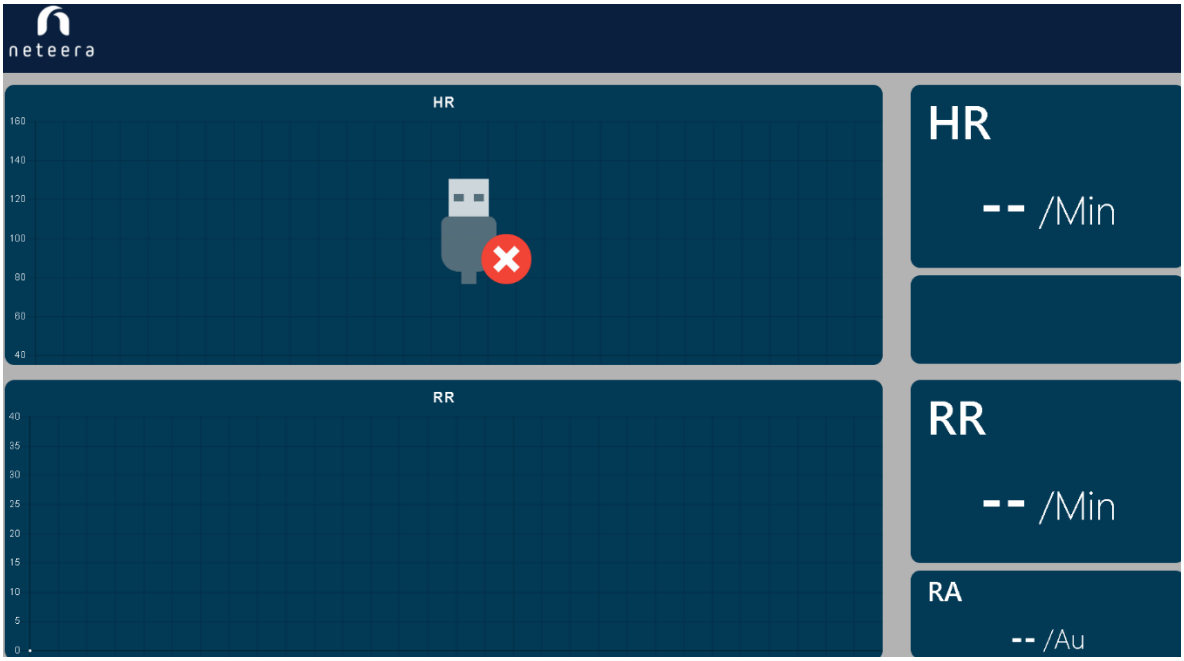


Image 14: – main unit is not connected properly, check the USB cable

- A menu will appear – "insert patient info"

  - Patient's ID - kindly use an up to a 22 digit number (only). **This number should be anonymous, as for now, the cloud is not GDPR/HIPAA certified** (pending for future version).
  - Patient's weight (Kg)
  - Patient's body temperature (Celsius)
  - Patient's age
  - Patient's blood pressure (systolic and diastolic)

  When finished inserting the required info - click "start session".

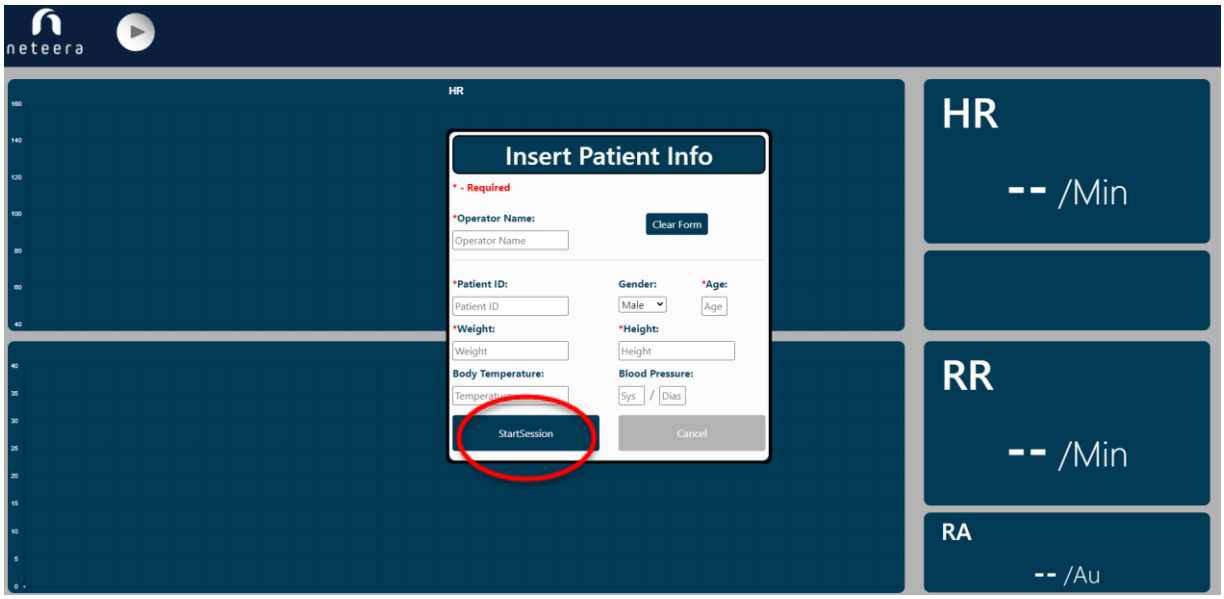


Image 15: Enter patient's information

- About 30 seconds after clicking "start session", the vital signs will start streaming. As presented in the image below.

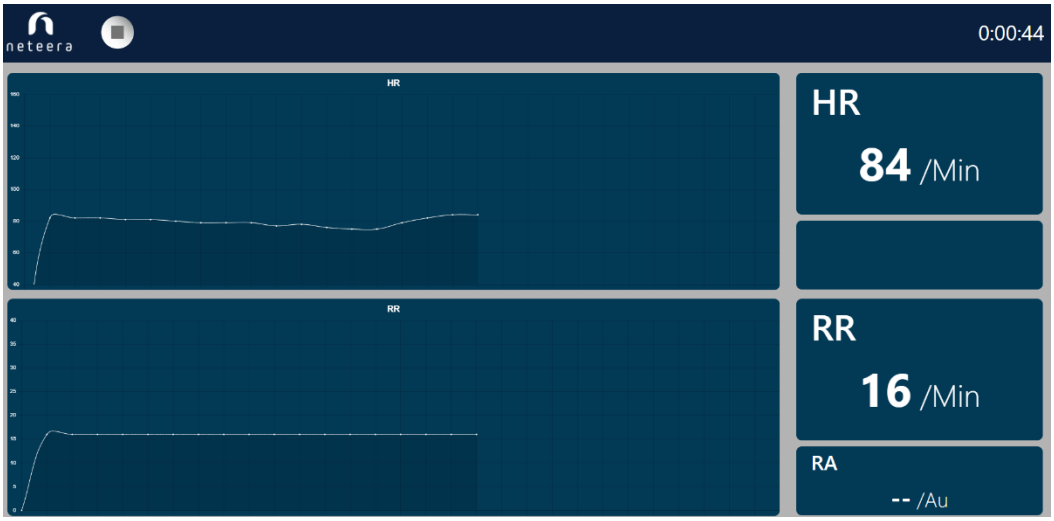


Image 16: Neteera's streaming vital signs

- If Neteera 131H signal is compromised due to excessive movement of the subject, the message will change to **"Low signal reliability"** – which means that the received vital signs should be discarded.

Image 17: message on the screen

- In case the subject is leaving the device's field of view, the UI will indicate it by display **"Empty-seat"**

Image 18: message on the screen

5.3 Parameters displayed

- The left part of the screen displays HR and RR trends:

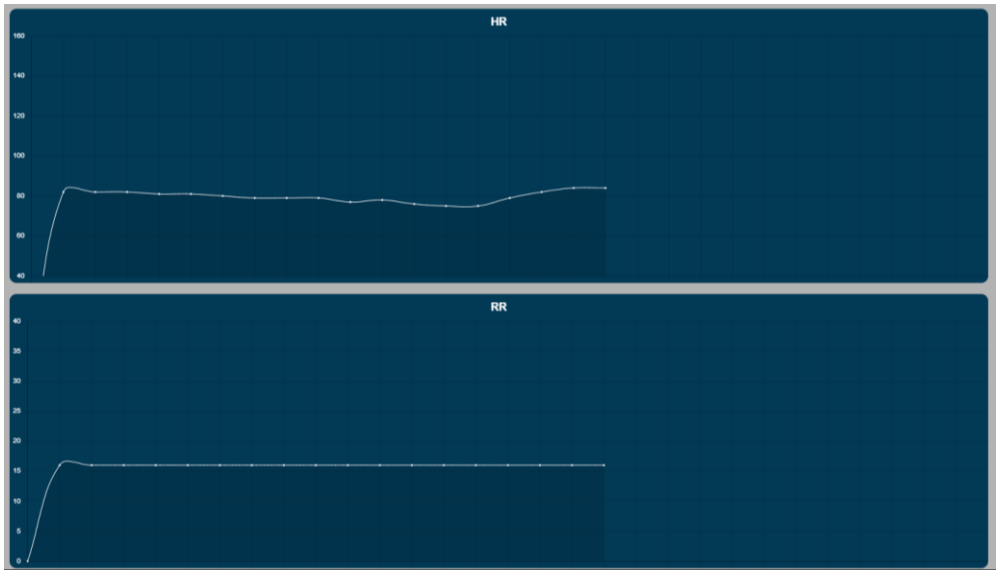


Image 19 – Left part of the screen: a streaming wave of HR and RR trends

- The right part of the screen shows the real-time results for HR, RR, and RA and the timer as well:

Image 20 – right part of the screen

5.4 Finishing the monitoring session

- To terminate the session, click the “Stop” button:

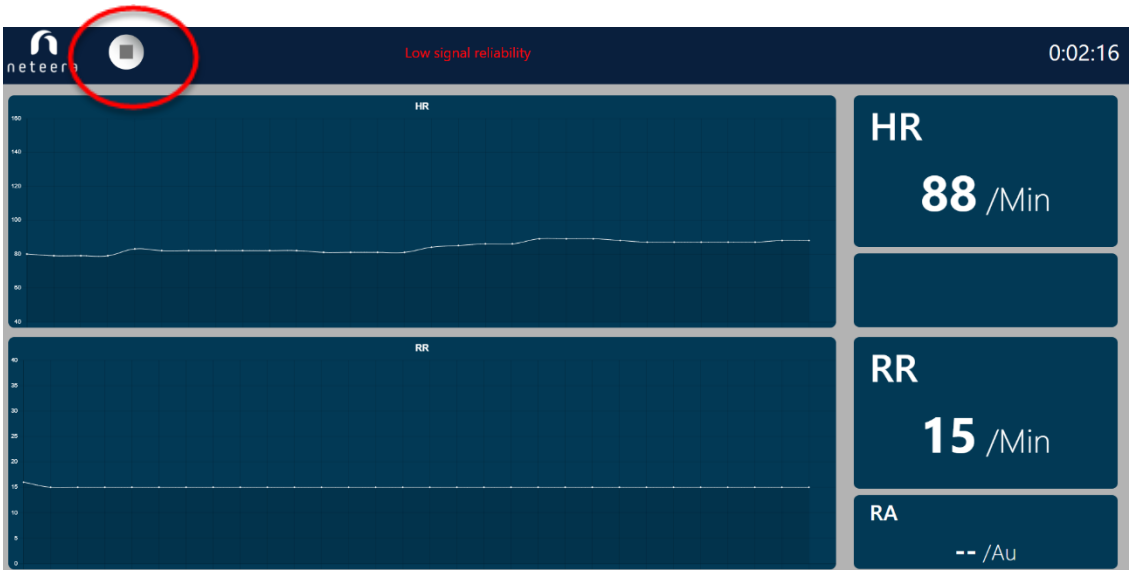


Image 21 – terminating monitoring session

- Session results will appear on the screen, together with a “reference info” menu.

Image 22 – session results and reference info

- In case the session quality was low – a suitable message will be displayed. No data will be saved from this session for later review.

Image 23 – Low Session Quality message

- If a reference device for heart rate, respiratory rate, and saturation levels was used during the session, please enter the recorded values in the appropriate places (this is an optional step – if no reference was used, click "cancel"):

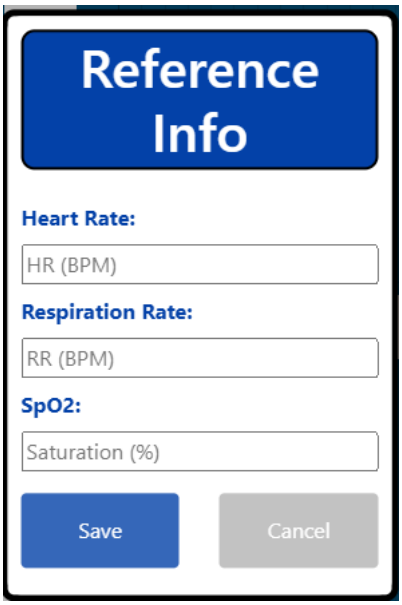


Image 24 – session results and reference info

- The session should last at least 30 seconds. In case it was terminated before 30 seconds had passed, the RR and HR will have a negative value:

Image 25 – session too short

6. VIEW RESULTS ON LOCAL DB

- Recorded sessions are automatically uploaded to the local DB on the customer's side (once an hour). To access this information double-click on the "Neteera_local_DB" icon.

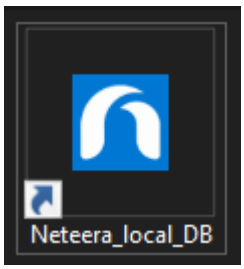


Image 26: the icon of local DB

- After pressing it the following web window will appear with all the sessions that were recorded by the customer.

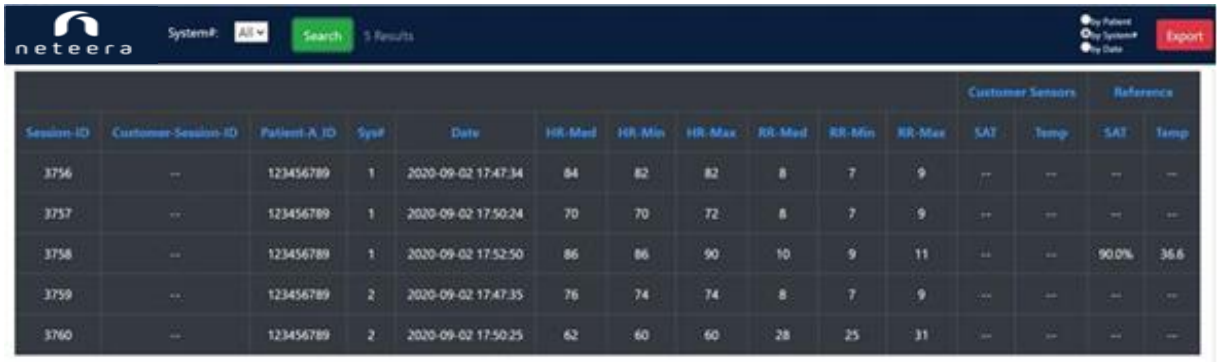


Image 27 – Recorded sessions summary

- On the top right side, the customer can filter by different parameters

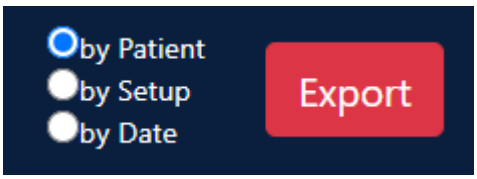


Image 28 – search parameters

- Parameters on the top menu:

  - **Session ID** – session numbering (automatically numbered by Neteera – this number can be used as a reference in case a specific session requires support or investigation by the Neteera team)
  - **Customer session ID** – future feature
  - **Patient -A_ID** - the anonymous ID that was entered at the beginning of the session
  - **System #** - the device identifier
  - **Date** – session recording date
  - **HR/RR med, min, max** – Heart rate and respiratory rate median, minimal and maximal values.
  - **Customer sensors/reference** – customer's reference results (manually entered by the customer)

- Single session view

To see more information about a particular session, click the relevant session line. The next screen will follow:

Image 29– Single recorded sessions detailed information

7. PATIENT/USER PREPARATION

Before beginning the monitoring session, make sure that:

- The patient/user is sitting comfortably in the chair, facing forward.
- The patient/user sits upright (not slouching), and his back is leaning against the chair's back
- There is no interfering object between the patient's/user's torso and the sensor's field of view.
- The patient/user is at rest, and not moving or speaking
- Neteera 130/131H is properly mounted to the chair

8. MAINTENANCE AND CLEANING

The Neteera 130/131H is designed to provide a 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 radar 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 sensor is dry before re-use.

9. TROUBLESHOOTING

Issue	Possible reason	How to fix
The screens of the UI are greyed out and no vital sign is demonstrated	Software launch issue	Re-activate the Neteera software – follow the instructions on part 3.2 “operating the software” in this manual
After clicking the start button, Neteera’s UI is not displaying any vital signs	The main unit connection issue	Check the cable connection to the Neteera 130/131H and the PC/laptop, and then re-activate the Neteera software – follow the instructions on part 3.2 “operating the software” in this manual
Heart rate or respiratory rate (or both) are not streaming on the right part of the screen, and some numeric parameters related to them are not displayed	The signal is not stable or reliable	The Signal was not reliable
“Session failed – Error description: Low session quality, please restart the session” message displayed instead of session results (after the session was stopped)	Low signal quality	Usually due to excessive patient motion)
“Session failed – Error description: Session was too short, please restart the session” message displayed instead of session results (after the session was stopped)	Session too short	Session running time was shorter than 30 seconds
USB symbol is flashing on the screen	USB cable connection issue	Check the USB connection and inspect the cable for damage. In case the USB cable needs to be replaced, kindly contact the Support team, as a new configuration should apply.

For any question or help during the installation/operation of the system, contact our FAE representative or support@neteera.com