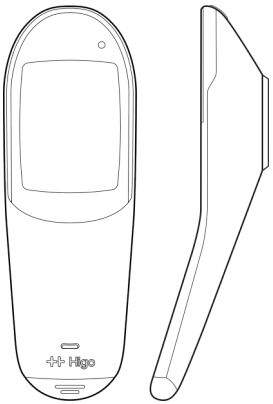
User Manual

EN

Model BSU-003

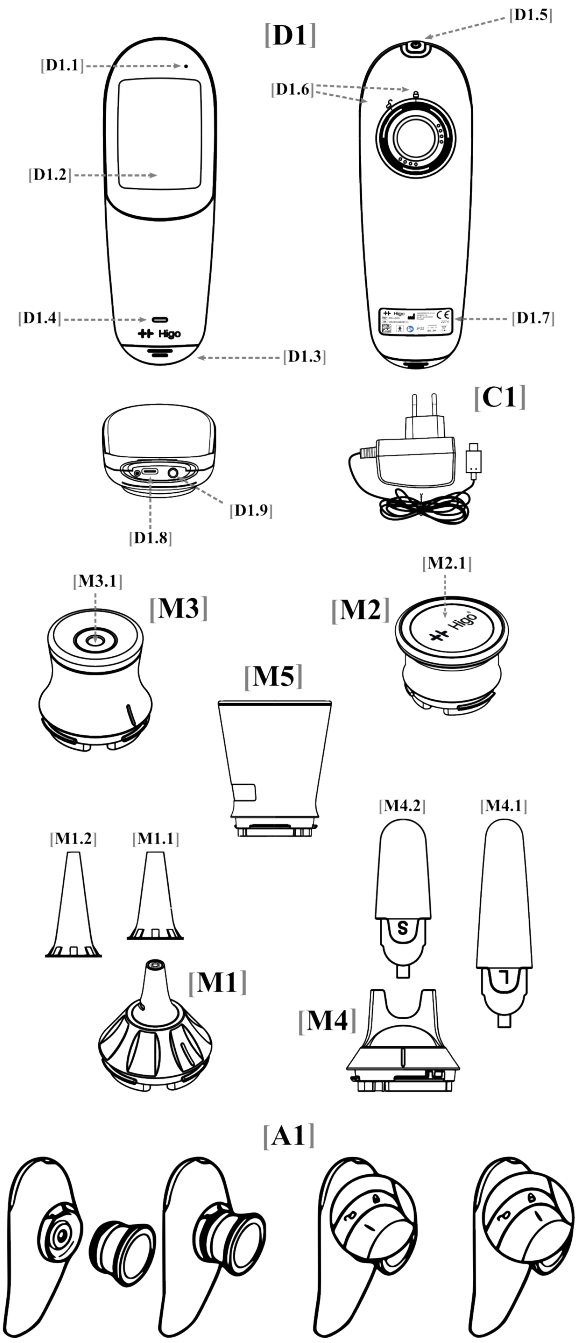


This product is manufactured by:
HigoSense Sp. z o.o.
Zajęcza 15 Street
POLAND
www.higosense.com

CE
2274

v.8.0 edition 2
Issue date: 2024-10

0 Drawings


[D1]
[D1.1]
[D1.2]
[D1.3]
[D1.4]
[D1.5]
[D1.6]
[D1.7]
[D1.8]
[D1.9]
[C1]
[M1]
[M1.1]
[M1.2]
[M2]
[M2.1]
[M3]
[M3.1]
[M4]
[M4.1]
[M4.2]
[M5]
[A1]

Contents

1 Safety information

Warnings (indicates precautions to avoid the possibility of personal injury or death):

Prior to start-up of Higo, carefully read this User Manual. The proper function and safety operation of this device depends on the user complying with the safety recommendations presented below. Keep the User Manual for your safety.

If any symptoms present are severe and/or long-lasting contact a primary care physician or emergency medical service. Higo is not designed for self or automatic diagnosis and to be used in life-threatening situations. Failure to contact appropriate medical authorities may result in serious bodily injury or death.

Do not use the device if the device packaging, the device itself or any of its accessories are damaged or not intact.

Do not disassemble, service or repair this product or any of its parts. Do not remove the covers of the device.

Before each use the outer surface of the device components should be checked. Do not use parts with rough surfaces, sharp edges or protrusions, which may cause harm.

Always use only accessories and disposables delivered by HigoSense. Do not use accessories which are not supplied or recommended by the manufacturer. Connect only authorized accessories to the device.

Do not use the device simultaneously with other electronic equipment, do not use or stack the device near, on or under other electronic equipment to avoid electromagnetic interference with the operation of the device.

Do not use the device during defibrillator use. It is not resistant to electrical shock.

The eyes should not be exposed to the illumination light of the product while using.

The device includes small parts which may be swallowed. Keep away from children.

Use the device only on intact skin.

The device must only be used for the purpose intended by the manufacturer. Arbitrary use of the product which is inconsistent with the User Manual may result in the loss of guaranteed rights and claims in the event of damage.

Any incorrectness related to the device, which could result in health deterioration or loss of life of the user or patient, should be reported to the manufacturer (HigoSense) and the competent authority of your country.

Cautions (indicates a condition that may cause equipment damage or reduce treatment quality):

Do not immerse the device or any of its accessories in water or any other liquid. Do not use a wet device. If Higo is wet, wipe off all moisture and wait at least 48 hours before operating.

Do not drop or insert any objects into any device opening.

Use only the charger which is included in the set by the manufacturer.

Before use, make sure that the device is not broken and works properly.

Make sure that before each use the device is clean. Follow the maintenance instructions specifically described in this User Manual.

Always keep the device and its parts in the storage case. Always store and transport the device in appropriate conditions. Failure to follow these recommendations may cause damage to the device.

Performing any exam is not possible while the device is charging.

During charging no module shall be attached on the base unit.

It is recommended to recharge the battery after each use. Storing the device with a drained battery may shorten the battery life.

Do not expose the device to UV radiation (e.g. from UV lamps used for air disinfection or from the sun). The device is not intended to be sterilized. Do not expose the device and any of its parts to sunlight.

Follow local governing ordinances and recycling instructions regarding disposal or recycling of the device and its components.

Use the device only within the conditions defined in section 2.2.

The device was designed and constructed in accordance with state-of-the-art and applicable standards. Despite the manufacturer's efforts to ensure safety and eliminate hazards when

using the device, some residual risks may appear. They usually result from a method of use that is incompatible with the intended use. Residual risks may arise in exceptional situations, resulting in particular from failure to observe the operating instructions or from failure to pay due attention during operator-device interaction. The greatest danger occurs when performing the prohibited activities described in the Safety information (section 1) and Medical exams (section 3.1) related to using the device in a manner inconsistent with its intended use and its maintenance conditions. Residual risks can be minimized if the following recommendations are respected.

2 Product overview

Higo is a handheld device consisting of a base unit and exchangeable multi-sensor modules, which allows for the exam of the throat, skin, ears, lungs, heart, abdomen, cough and the measurement of body temperature. Higo device can be used by lay persons and healthcare professionals.

2.1 Intended use and indications for use

Higo is a multi-sensor device used for diagnostic support which digitally records the following medical data:

- images of the oral cavity, ear canal and skin,
- audio of the lungs, heart, abdomen, and cough,
- body temperature

Higo is intended for use by lay persons at home and by qualified healthcare professionals in a clinical and ambulatory environment. The product is not intended for self-diagnosis. Higo is a useful tool for collecting medical data on the first symptoms of colds, flu and other viral and bacterial infections of the respiratory tract, middle ear or skin, and gastrointestinal tract and many others. A patient must be diagnosed by a physician.

2.1.1 Contraindications

There are no known contraindications to the use of Higo. However, special attention should be paid when selecting accessories (tongue depressor, ear specula) and performing throat and ear exams on patients under 2 years of age.

2.2 Operating, storage and transport conditions

Operating conditions: 16–40℃ / 10–85% humidity non-condensing / 860–1060 hPa
Storage / transport conditions: -10–45℃ / 10–85% humidity non-condensing / 860–1060 hPa

2.3 Box content

[D1]	Base unit	
[M1]	Otoscope module	(HIGO OTO)
[M2]	Stethoscope module	(HIGO STETHO)
[M3]	Thermometer module	(HIGO THERMO)
[M4]	Throat module	(HIGO THR)
[M5]	Dermhood	(HIGO DERM)
[M2.1]	Stethoscope membrane	
[M3.1]	Infrared sensor	

Accessories:

[M4.1]	2 x large exchangeable tongue depressor
[M4.2]	2 x small exchangeable tongue depressor
[M1.1]	20 x 4.0 mm disposable ear speculum
[M1.2]	10 x 2.5 mm disposable ear speculum
	10 x alcohol wipe
[C1]	Medical grade USB-C wall charger with USB Type-C cable
	Storage case
	User Manual

2.4 Overview of Higo interface

[D1.1]	indication LED
[D1.2]	LED touchable display
[D1.3]	audio speaker
[D1.4]	removable connector cover
[D1.5]	on/off button
[D1.6]	modules locking symbols
[D1.7]	medical device marking plate
[D1.8]	USB-C charging slot
[D1.9]	audio jack 3,5 mm slot


connected; connected to WiFi and connecting to server; not connected


battery level


settings menu


user account management


firmware version


changing the language of user interface


verification of Higo certificates

factory reset

move forward


move backward


skip single auscultation point during a heart, lungs or abdomen exam


redo a measurement or recording

confirmation of the medical quality of registered images - green "tick" mark

This device has an electronic label for regulatory information. Go to **Settings** and **Certificates** tab to see electronic labels.

3 How to use Higo

Prior to the first use unpack the device, check it for completeness against the list in Section 2.3.
and charge the device for at least 1 hour.
The device enables pairing with an external mobile app and wireless transfer of the registered data to the receiving server as a result of which the data can be digitally integrated with a medical health record. The optional first use operation of the Higo device assumes pairing with an external mobile app. Description of the WiFi configuration and mobile app pairing process shall be delivered separately in a step-by-step instructions. If not, contact an authorized HigoSense representative responsible for delivery of the device.
Press the on/off button [D1.5] for at least 1 s to turn on the device. Follow the operation option displayed on the screen to activate Higo. Choose a patient profile and then select a medical exam from the list.

Selection of the correct patient's profile (age, sex) is critical to parameters and setting of the camera, otoscope and stethoscope which selected incorrectly may affect a quality of medical data. Registered data is temporarily stored in the internal SD Card.

3.1 Medical exams

Make sure that before each use every part of the Higo device is cleaned and disinfected according to the instruction in section 3.3.

3.1.1 Temperature

The temperature measurement function of the device is not intended to be used as a contraceptive method.

Note: Before the measurement make sure that the patient and the device remain in the same ambient temperature for at least 10 minutes, skin of the patient's forehead is dry, the measurement is not performed within at least 30 minutes of showering, bathing, exercising or any other physical activity which could influence the forehead surface temperature, the measurement is not taken on scar tissue, open sores or abrasions, hair is removed from the patient's forehead.

Connect the temperature module [M3] to the base unit [D1] according to the instruction [A1] and read instructions on the screen carefully.

Place the device with thermometer module on the center of the forehead above the line of the eyebrows and click START. Move the thermometer over the temporal artery on the temple towards the top edge of the ear dynamically. The measurement takes 5 seconds and stops automatically with a sound. The measurement result is presented on the screen in Celsius degrees. Both sides of the forehead, left and right can be measured. It is recommended to repeat the measurement a couple times on both sides for the best accuracy. Click move forward on the screen to finish the measurement and return to the exams list or redo the measurement.

3.1.2 Heart Rate, Heart exam, Lungs exam, Abdomen exam

The heart rate readout represents an estimation of the physiological heart rate. The readout is based on the same acoustic signal that is delivered to the physician for the diagnostics purposes.
Following the instructions below and executing the exact steps and actions is crucial for the quality of recordings to be interpreted by a physician, especially considering ambient noise, correct stethoscope placement, deep breathing and undisturbed contact between stethoscope membrane [M3.1] and body.

Notes: Before any stethoscope exam ensure conditions with no ambient noise, like music, speaking or other noticeable sounds in the background which could affect the auscultation sounds and the stethoscope membrane is fully applied to the body with its whole surface. Do not place the stethoscope module on the sternum, back plate or any other bones. Do not scratch, tap or scrap the enclosure of the device or module. The patient must be undressed from waist up including bra. Correct recognizing left and right side of the patient is substantial for lungs and heart auscultations quality and accurate diagnosis. The stethoscope module does not provide diagnostic information, but it is a diagnostic aid. It amplifies body sounds, which the physician must interpret to make a diagnosis. The stethoscope does not provide vital signs monitoring and alarms for potential life threatening situations in which medical intervention is necessary.

For all auscultation exams, connect the stethoscope module [M2] to the base unit [D1] according to the instruction [A1] and read instructions on the screen carefully. It is possible to plug headphones into the audio jack slot localized under connector cover for listening life auscultations.
For the lungs exam the patient must breathe deeply in and out through the mouth. For the Heart Rate, Heart and Abdomen exams patients must breathe normally.
Place the device with stethoscope module on the naked skin firmly on the auscultation points presented on the screen starting from the first point according to the displayed order ensuring full contact of the stethoscope membrane [M2.1] with the skin surface. The data registering starts automatically at each auscultation point only when contact between the stethoscope membrane and skin is established and stops automatically after 10 s (lungs or heart exam) or 30 s (abdomen exam). For the Heart Rate data registering stops automatically after 10-60 s with the result or information about inability to calculate the heart rate. A redo of each auscultation point is possible once the registration of the particular point is finished. Once the auscultation points are completed click move forward on the screen to finish the exam and return to the exams list.

3.1.3 Cough registration

Connect the stethoscope module [M2] to the base unit [D1] according to the instruction [A1] and read instructions on the screen carefully.
Place the module next to the patient's mouth (ca. 5cm) and start the registering by clicking START on the screen and instruct the patient to cough loudly 2–3 times directly to the stethoscope during registration. Click STOP to terminate the recording or wait for the automatic registration stop after 15s. Click forward on the screen to finish the exam and return to the exams list.

3.1.4 Left and right ear exam

During the ear exam, choose the correct ear (left or right) before the ear exam. Mixing the data can result in a misleading diagnosis. Do not use a disposable speculum more than once. Discard all the disposables (ear specula, alcohol wipes) after use. Before each use or after a change of viewing modes/settings, check the view observed through the otoscope module. It should be a live image with a correct image orientation. Do not attempt the ear exam without a speculum applied. Do not look directly into the otoscope tip when the light is on. Do not push the otoscope with the speculum too deep into the ear. Be careful not to touch the eardrum. If the ear canal is blocked by earwax, stop the exam and try again after cleaning the ear canal. Do not continue the exam if it causes pain or significant discomfort. In case an ear pain is reported by the patient, start the exam from the other ear.
Pay special attention to earwax, which is the most common reason preventing the effective visualization for the tympanic membrane.

Connect the otoscope module [M1] to the base unit [D1] according to the instruction [A1] and read instructions on the screen carefully. Take clean speculum in correct size according to the patient's age and apply it by inserting it onto the otoscope tip and twisting it until it is locked into place. Use 4.0 mm [M1.1] for patients above 3 years old (>3). 2.5 mm [M1.2] for patients until the age of 3 ($\leq$3).

Before inserting the otoscope into the ear canal, grab the earlobe tightly and pull firmly to the back or diagonally in order to straighten the ear canal.

Start the registering by clicking START on the screen, slowly insert the otoscope tip with the speculum into the ear canal and search for the optimal view of the tympanic membrane by moving the otoscope tip gently forwards and sideways inside the ear canal. Correct image of the ear includes clearly visible umbo, manubrium of malleus, light reflex. Capturing the correct image is confirmed by the green "tick" mark in the top right corner on the screen during the live preview. Once the mark appears the speculum shall be taken out from the ear canal and the exam shall be finished by clicking STOP on the screen. Otherwise, the registering finishes automatically after 30 s. In the case of no diagnostic image is captured, the information appears on the screen. Once the registering is completed click move forward on the screen to finish the exam and return to the exams list.

3.1.5 Throat exam

Do not attempt the throat exam within 15 min after the meal. Always use cleaned and disinfected tongue depressor.

Connect the throat module [M4] to the base unit [D1] according to the instruction [A1] and read instructions on the screen carefully. Selected a correct tongue depressor size with respect to the age of the patient. Large tongue depressor marked with the letter "L" [M4.1] for patients above 5 years old (>5), small tongue depressor marked with the letter "S" [M4.2] for patients until the age of 5 ($\leq$5).

Connect the correct tongue depressor by placing it into the throat module slot until it clicks and is locked into place automatically.

Start the registering by clicking START on the screen and place the depressor on the tongue to ¾ of its length, parallel to the palate and press against the tongue gently and firmly. Ask the patient to say "Ahhh!" without puffing which can cause the camera to fog.

Correct image of the throat includes clearly visible tonsils, back of the throat palatine arches.

Capturing the correct image is confirmed by the green "tick" mark in the top right corner of the screen during the live preview. Once the mark appears the tongue depressor shall be taken out from the mouth and the exam shall be finished by clicking STOP on the screen. Otherwise, the registering stops automatically after 30 s. In the case of no diagnostic image is captured the information appears on the screen. Once the registering is completed click move forward on the screen to finish the exam and return to the exams list.

3.1.6 Skin exam

In case a patient's skin surface is injured, burned, cut, soaking, with abrasions, with open sores or represents any other wounds in a place where the exam expects a physical contact with a device or any accessories, the skin exam should be withdrawn. Do not perform the skin exam during a medical treatment with photoactive substances, due to white light emission by the device's illumination system.

Notes: Disinfect the edges of the dermhood before each use. Make sure that the skin surface is clean, dry, naked. No skin creams, ointments, lotions, emulsions, balsams are allowed to be applied before and during skin exam.

Connect the dermhood [M5] to the base unit [D1] according to the instruction [A1] and read instructions on the screen carefully.

Start the registering by clicking START on the screen and apply the dermhood to the skin in such a way that it touches the skin surface. Do not press it so that you make a bulge in the skin. Click STOP to finish the recording, otherwise the registering stops automatically after 30 s. Once the registering is completed click move forward on the screen to finish the exam and return to the exams list.

3.2 Charging

The device has a rechargeable lithium polymer battery. The status of the battery is presented on the top right corner of the screen. To charge the battery, remove the connector cover [D1.4] situated on the bottom of the device and connect the charger [C1] cable to the charging slot [D1.8]. Charging will not start with any module attached. The LED indicator will light up steady orange.

Possible LED indicator status:

No LED light:	The device is ready to be used or turned off
Blinking ORANGE:	The battery status is below 10%, connect the device to the wall charger
Steady ORANGE:	Charging in progress
Steady GREEN:	The device is fully charged
Blinking GREEN:	The device is in sleep mode, after 60 seconds of idle state
Steady RED:	Safety failure mode, see the Troubleshooting section

After 10 min without any movement of the device it turns off automatically.

3.3 Cleaning and maintenance

Turn off the device before cleaning. Wipe off any visible contaminants from the device's surface with a dry cloth. Clean the entire device housing and camera glass cover thoroughly using 70% isopropyl alcohol wipes for at least 30 seconds. After cleaning, allow the device to air dry for at least 2 minutes in a well-ventilated area before performing any exams. Pay a special attention to the lenses on the front of the otoscope module and thermometer sensor [M3.1] in thermometer module cavity. If necessary, wipe them with a cotton swab moistened with 70% isopropyl alcohol for at least 30 seconds. During cleaning hold module upside down to prevent excess moisture from entering the lenses or sensor area. After the alcohol has dried out (minimum after 2 minutes), you can perform an exam.

Clean the reusable tongue depressor with soap under running water for at least 30 seconds, and dry well. Next, thoroughly clean the surface of the tongue depressor with 70% isopropyl alcohol wipes for at least 30 seconds. Leave to air dry for at least 2 minutes before using the tongue depressor for a throat exam.

For cleaning particularly hard-to-reach places, like the module mechanical interface on the base unit, use a cotton swab dipped in minimum 70% isopropyl alcohol for at least 30 seconds. Make sure you allow the device to dry for at least 2 minutes in a well-ventilated area before performing any exams.

The product has a lifetime of 4 years. Every 2 years the device should be the subject of a technical review during which the overall condition of the device, including temperature measurement accuracy, will be assessed.

The alcohol wipes and ear specula shall be thrown away after use.

3.3.1 Firmware update

The device firmware will be subject to updates to the newest version. Notifications about the new release of firmware updates will be displayed on your Higo device. During the firmware update the device must be connected to the WiFi and to the charger.

4 Troubleshooting

The device does not charge:

Check if you are using the charger provided by the manufacturer. Make sure it is plugged in. Refrain from using any charger other than the one provided and recommended by the manufacturer! If the issue persists, contact your authorized HigoSense representative or HigoSense support.

The device is not turning on:

Make sure the battery is charged by connecting the device to the charger. Current battery level will be displayed on the LCD screen in the upper right corner. If the battery level is below 10%, the device needs to be charged first. If the battery is full, disconnect the charger and try to turn on the device. If the device still does not turn on, make sure you are operating under the acceptable conditions described in section 2.2. If the issue persists, contact your authorized HigoSense representative or HigoSense support.

Although a module is connected, the device still shows the instructions of module connection:

Make sure that the module is correctly chosen. Make sure the base of the module and module mechanical interface on the base unit are clean. Make sure that the module is connected properly so the locking symbol on the device is aligned with lines on the module.

The battery led indicator light is steady red:

Categorically refrain from using the device! Contact your authorized HigoSense representative or HigoSense support via the contact form on the webpage www.higosense.com or by sending an email to support@higosense.com.

The screen is frozen and does not react:

Restart the device. If the problem persists, contact your authorized HigoSense representative or HigoSense support.

The measured temperature is inaccurate or permanently out of range due to small contaminants present on the temperature sensor:

Following the section 3.3, clear the sensor gently and make sure that the surface is the sensor is clean and free from small contaminants.

The temperature measurement result is lower or higher than typical human temperature (34-43^{o}C.):

Redo the exam. If the situation persists, turn the device off and on. If the issue persists, contact your authorized HigoSense representative or HigoSense support.

For more support visit: www.higosense.com -> Help Center

5 Product specification

5.1 Specification of the device

Dimensions	180 mm x 61 mm x 52 mm
Weight	165 g
Display	2.8"
Audio output port	3.5 mm standard headphone connector
Power supply	USB-C plug, wall charger, USB-C cable input: AC 100-240V, 50/60Hz, 0.3A output: DC 5V, 2A
WiFi / Bluetooth frequency range	2.4 GHz and 5 GHz / 2.4 GHz
Max. image sensor resolution	5 Mpx
Effective image resolution	640x480 (VGA)
Stethoscope frequency range	5–5000 Hz
Temperature measurement range	34–43^{o}C
Laboratory accuracy	+/- 0.3^{o}C
Requirements for headphones	3.5 mm audio-jack stereo, cable length of min. 1m, Impedance: 32 Ohm, Frequency response: 20 Hz - 20 kHz

5.2 WiFi network specification

Notes: IEEE 802.11n standard is recommended for optimal performance (IEEE 802.11g is also supported). Bands 2.4 GHz and 5 GHz are supported. The device within the 5150-5250 MHz band is restricted to indoor use only.

The following WiFi network specifications are supported by Higo device:

- Transmitter technical characteristics:
  Frequency band: 2400 MHz – 2483.5 MHz, 5150-5250 MHz, 5250-5350 MHz and 5470-5725 MHz as well as 5725-5875 MHz
  Maximum output power: 20 dBm for 2400 MHz – 2483.5 MHz, 23 dBm for 5150-5250 MHz, 23 dBm for 5250-5350 MHz, 30 dBm for 5470-5725 MHz, 14 dBm for 5725-5875 MHz.
- Antenna information:
  Type: internal, 2.4 GHz and 5 GHz
  Gain: 0.712 dBi for 2.4 GHz and 1.25 dBi for 5 GHz.

Device connectivity (user infrastructure):

2.4 GHz and 5 GHz WiFi band authentication method for WiFi access: WPA2-personal. The length of the access point's authentication password should be less than 32 characters. The SSID of the WiFi access point must be distributed - not hidden WiFi. The length of the access point's SSID (WiFi name) must be less than 32 characters. The DHCP server should be active. WiFi access points have to support the above technologies and work in the same frequencies range. Failure to provide the above network characteristics may lead to an inability to establish a network connection or WiFi connection breaks, thus limiting the possibility of the device to connect and transmit exam data. Higo device should be connected to a WiFi network that is made exclusively for it, to minimize the potential risks of other equipment's influence. This influence may present additional risks of unknown level for the operator, patients or third parties. It is the responsibility of the user to identify, analyse, evaluate and control those risks. Any change introduced in the network configuration may lead to new risks and should be evaluated to determine its safety. Changes that lead to the re-evaluation requirement include:
(1) change of WiFi network configuration; (2) connecting new devices (clients) to the network, including hardware upgrade of existing devices; (3) updating software of the equipment already present on the network. This includes all clients, access points and routers that establish wireless connections.

Device firmware can be run only on Higo hardware, and user has no impact on any of Higo's hardware configuration options. There is no software sold as a standalone product, so requirements concerning host hardware are not applicable.

5.3 Bluetooth Low Energy network specification

- Bluetooth radio technology: Bluetooth Low Energy, LE + 2LE.
- Frequency band: 2400 MHz – 2483.5 MHz. Maximum output power: 10 dBm.
- Antenna information: internal, 2.4 GHz. Gain: 0.712 dBi.

5.4 Declaration of Conformity

The safety, reliability and performance of this device can only be assured under the following conditions: (1) The device has been used for its indicated use and according to the operating instructions in this User Manual; (2) All fittings, extensions, readjustments, changes, or repairs have been carried out by HigoSense.

HigoSense declares that Higo conforms with the essential requirements and other relevant provisions of the Directive 93/42/EEC, Directive 2014/53/UE and the Directive 2011/65/EU. The device conforms to the following standards: IEC/EN 60601-1, IEC/EN 60601-1-6, IEC/EN 60601-1-11, IEC/EN 60601-2-18 and ISO/EN80601-2-56 for general requirements for safety and essential performance of medical electrical equipment as well asnd IEC/EN 62471 for photobiological safety.
Higo has IEC 60601-1-2 Class B compliance which applies to the basic safety and essential performance of medical electrical equipment and ME systems in the presence of electromagnetic disturbances and to electromagnetic disturbances emitted by medical electrical equipment and ME systems.
Declaration – Electromagnetic Emission
Higo is intended for use in the electromagnetic environment as indicated below. The user shall ensure that the device is used in such an environment.

Emission test	Compliance	Electromagnetic environment – guidance
RF emission CISPR 11	Group 1	Higo generates a radio frequency electromagnetic field for the purpose of operating internal functions only. The emission of radio waves is therefore very low and the likelihood of interference with nearby electronic equipment is low.
RF emission CISPR 11	Class B	
Harmonic current emissions IEC 61000-3-2	Class A	Higo device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Voltage changes, voltage fluctuations and flicker emissions IEC 61000-3-3	Complies	

Essential Performances

- The ability to display live view rather than recorded during ear exam (latency lower than 1000 ms)
- The ability to display images in proper orientation during ear exam
- The ability to measure the body temperature with laboratory accuracy (max 0,3 degrees Celsius error)

Warnings:

Use of accessories, transducers and cables other than those provided or specified by the manufacturer could result in increased electromagnetic emission or decrease electromagnetic immunity of this equipment and result in improper operation.

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.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) from any part of Higo, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Declaration of electromagnetic conformity

Immunity test	**IEC 60601 level**	**Compliance level**	**Electromagnetic environment**
Electrostatic discharge (ESD) IEC 61000-4-2	8kV contact 2,4,8,15kV air	8kV contact 2,4,8,15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast tran-sient/burst IEC 61000-4-4	± 2 kV for lines power supply	± 2 kV for lines power supply	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 and 1 kV in differential mode ± 0.5, 1 and 2 kV in common mode	± 0.5 and 1 kV in differential mode ± 0.5, 1 and 2 kV in common mode	Mains power quality should be that of a typical commercial or hospital environment.
Rated power frequency magnetic fields IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity test	IEC 60601 level	Compliance level	Electromagnetic environment
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	0% U_T, 0,5 cycle At 0^0, 45^0, 90^0, 135^0, 180^0, 225^0, 270^0 and 315^0; 0% U_T, 1 cycle; 70% U_T; 25 cycles at 50Hz and 30 cycles at 60Hz Single phase at 0^0 Voltage interruptions; 0% U_T; 250 cycles at 50Hz and 300 cycles at 60Hz	0% U_T, 0,5 cycle At 0^0, 45^0, 90^0, 135^0, 180^0, 225^0, 270^0 and 315^0; 0% U_T, 1 cycle; 70% U_T; 25 cycles at 50Hz and 30 cycles at 60Hz Single phase at 0^0 Voltage interruptions; 0% U_T; 250 cycles at 50Hz and 300 cycles at 60Hz	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply.
Conducted RF IEC 61000-4-6	3V 0,15 MHz-80 MHz 6V in ISM and amateur radio bands between 0,15MHz and 80 MHz 80% AM at 1kHz	3V 0,15 MHz-80 MHz 6V in ISM and amateur radio bands between 0,15MHz and 80 MHz 80% AM at 1kHz	Portable and mobile RF communications equipment should be used no closer to any part of Higo, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d=1.2$\sqrt{P}$ 150 kHz to 80 MHz, d=1.2$\sqrt{P}$ 80 MHz to 800 MHz, d=2.3$\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer and d is the recommended separation distance in metres [m]. Field strengths from fixed RF transmitters, as determined by electromagnetic site survey [a], should be less than the compliance level in each frequency range[b].
Radiated RF EM fields IEC 61000-4-3	10V/m 80MHz -2,7 GHz 80% AM at 1kHz	3V/m 80MHz -2,7 GHz 80% AM at 1kHz 10V/m 80MHz -2,7 GHz 80% AM at 1kHz	
Proximity fields from RF wireless communication equipment IEC 61000-4-3	9V/m 710MHz, 745MHz, 780MHz, 5240 MHz, 5500MHz, 5785 MHz 27V/m 385MHz, 28V/m 450MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845MHz, 1970 MHz, 2450 MHz.	9V/m 710MHz, 745MHz, 780MHz, 5240 MHz, 5500MHz, 5785 MHz 27V/m 385MHz, 28V/m 450MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845MHz, 1970 MHz, 2450 MHz.	a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device. b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
Proximity magnetic fields IEC 61000-4-39	8 A/m – 30 kHz, 65 A/m – 134.2 MHz, 7.5 A/m – 13.56 MHz,	8 A/m – 30 kHz, 65 A/m – 134.2 MHz, 7.5 A/m – 13.56 MHz,	Professional healthcare facility environment and home healthcare environment.

In order to receive declaration of conformity, contact the manufacturer support via the www.higosense.com or by sending an email to support@higosense.com.

Radio frequency and EMC statement
The Higo device is intended for use in an electromagnetic environment with controlled radio frequency interference. The customer or the user of the device may help prevent electromagnetic interference by maintaining the minimum required distance between the mobile device and cellular radio devices (transmitters). This equipment is not subject to protection from harmful interference and may not cause interference with duly authorized systems.

HigoSense is not responsible for any radio or communication interference caused by using an other than recommended charger and battery or by unauthorized modifications of this equipment.

6 Description of label and packaging marking

Symbol	Description
	Manufacturer
 2274	CE marking indicating that the device complies with the Directive 93/42/EEC Conformity assessment performed by notified body no.2274
SN	Serial number identifier (digits from 4 to 7 indicate the date (year and its week) of manufacture, e.g. SN 00D**2221**0056X this product was made on week 21, year 2022
LOT	Lot or batch identifier; where applicable digits from 4 to 7 indicate the date (year and its week) of manufacture of the component e.g. 014**2222**01U this product was made on week 22, year 2022
REF	Model or type reference (for modules and accessories)
IP22	Degrees of protection provided by enclosures (IP Code)
	Direct current
	Type BF applied part
	Read the User Manual before use
	Special precautions must be taken to safely dispose of this device. To protect the environment and human health, discard of the device at appropriate local collection points of electrical and electronic equipment. Do not dispose of it in household waste
	Medical device needs to be protected from moisture
	Temperature limits to which the medical device can be safely exposed
	The range of humidity to which the medical device can be safely exposed
	The limits of atmospheric pressure to which the medical device can be safely exposed
	Single use only

7 Warranty and service

The warranty shall only be valid if accessories approved by HigoSense are used and the device is used as described in the User Manual and according to the intended use. Any actions connected with repairs or replacements may only be performed by personnel of an authorized service of HigoSense. The manufacturer is not liable for any damage caused by non-compliance with the user manual. HigoSense provides a guarantee for the Higo device under the terms and conditions specified in the agreement entered into with HigoSense for the purchase of the Higo device.

8 Serious medical incidents

Any serious incident that occurs in relation to Higo device should be reported to the manufacturer via the contact form on the webpage www.higosense.com or by sending an email to support@higosense.com and to the competent authority of the country in which the user is established.