User Manual

Neurosens

IMU Sensor

Revision 1.0.0
US-edition

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5, Voronin str., Ivanovo, 153032, Russia
Phone: +7 (4932) 95-99-99, +7 (4932) 24-04-34 Fax: +7 (4932) 24-04-35
E-mail: info@neurosoft.com Internet: www.neurosoft.com

Contents

Introduction

This user manual (hereinafter referred to as “manual”) is the combined document describing operation and servicing of the Neurosens set (hereinafter referred to as “set”).

The document certifies technical parameters of the set which are guaranteed by the manufacturer.

Read the manual carefully prior to use!

You can send your responses and recommendations by e-mail:

help@neurosoft.com

You can find additional information on **Neurosoft** products in the Internet:

www.neurosoft.com

or contact us by phone:

+7 (4932) 59-21-12 (Service Centre)

+7 (4932) 95-99-99

+7 (4932) 24-04-34

You can also contact TeleEMG LLC Authorized USA Representative of **Neurosoft Ltd.** by the following contacts:

Phone: 1-877-835-3364.

E-mail: sales@mycloudtms.com

Abbreviations

EMC — electromagnetic compatibility

EMG — electromyography/electromyogram

LAN — local area network

PC — personal computer

IMU – inertial measurement unit

Indications for Use

The Neurosens set is intended for use together with medical devices that require recording of accelerometer, gyroscope, magnetometer and EMG data.

General Information

The main component of the set is the Neurosens IMU sensor (hereinafter referred to as “sensor”).

The Neurosens set features:

- data recording from each sensor:
  - 3-axis acceleration;
  - 3-axis angular velocity;
  - 3-axis magnetic field;
  - 2 EMG channels;
- transfer of recorded data using wireless Wi-Fi protocol;
- storage of recorded data on the sensor memory card;
- transfer of data from the sensor memory card to PC using USB interface;
- possibility of attaching the sensor to the subject;
- charging sensor battery.

Please note that this manual describes all functions and technical specifications of Neurosens IMU sensors. However, the described functions can be limited by the registration certificate issued in the particular region for the medical device the sensors are used with. Refer to the user manual for the respective medical device.

Contraindications

There are no contraindications for use of the set.

Safety Precautions

To ensure safety of medical personnel or a patient and prevent the user from electrical injury medical staff is PROHIBITED from:

- **connecting devices that are not included in the list of components to the electrode sockets;**
- **eliminating faults that requires opening enclosures of the sensor or sensor charging station;**
- **using the set if the enclosure of the sensor or sensor charging station is open;**
- **connecting electrodes placed on the patient to protective earthing or other conductive surfaces;**
- **immersing components of the set (hereinafter referred to as "set components") in water or other liquids;**
- **allowing children to use the set;**

- **dropping or damaging the set components.**

If the set components were damaged, return them to the manufacturer for repair and/or calibration according to section 8 "Warranty" and section 9 "Reclamations" of this manual. Do not use the set if you suspect any damage.

***To ensure safety of medical personnel or a patient and prevent the user from electrical injury medical staff is REQUIRED to*:**

- **check set components for signs of damage of the enclosure, cable isolation, contacts, etc. regularly and carefully;**
- **clean and disinfect the reusable components of the set after each use according to the established rules;**
- **switch off and unplug all the set components prior to cleaning and disinfection.**

The manufacturer is not responsible for any health or material damage caused by fault of the user, servicing or medical personnel.

The set shall not be placed near active HF surgical equipment or MRI imaging equipment.

Possible Side Effects

Inform patient about possible side effects prior to using the set.

1. In rare cases the skin irritation and local allergic reactions to patient skin preparation agents and adhesive and working surfaces of disposable electrodes may occur.

2. During the long-term fixation of the IMU sensors with tapes the transient skin redness under the tapes can occur. The medical treatment is not needed.

1. Description

1.1. Principle of Operation

The block diagram of the sensor is shown in Fig. 1.

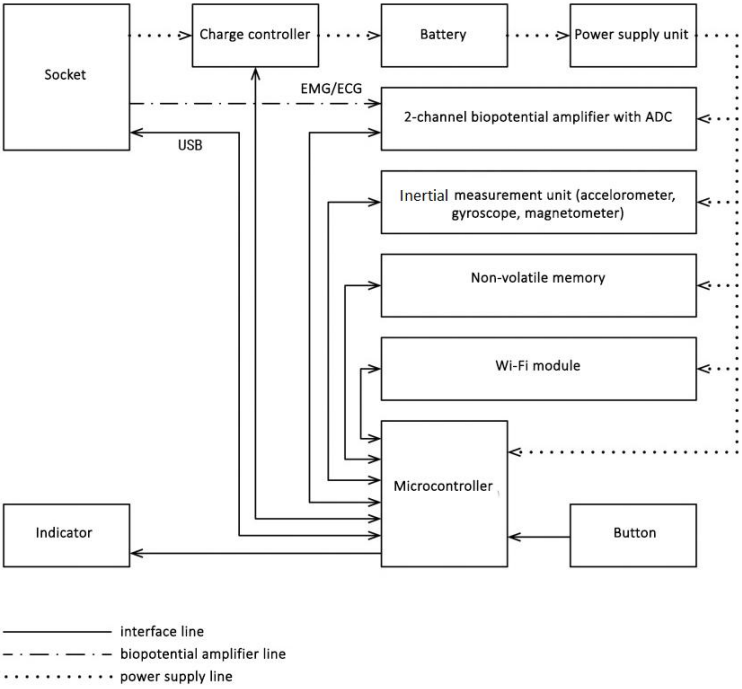


Fig. 1. The block diagram of the sensor

Designation of sensor components:

1. Button: on/off power switch.

2. Wi-Fi module: data transfer using wireless interface.

3. Indicator: informs about battery status and sensor operation mode.

4. Non-volatile memory: storage of recorded data (accelerometer, gyroscope, magnetometer, 2 EMG channels).

5. 2-channel amplifier with ADC: biopotential (EMG signal) amplification and its conversion to digital signal.

6. Inertial measurement unit sensor: recoding of 3-axis acceleration, rotation speed and magnetic field data.

7. Socket: connection to charging station or connection of charging USB cable, connection of EMG cable.

8. Charge controller: control of sensor battery charge level.

9. Microcontroller: sensor operation control.

The set has three operation modes that are enabled depending on the medical device it used with:

- Transfer of data to PC using Wi-Fi.
- Saving of data to memory card.
- Transfer of data to PC using Wi-Fi and data saving to memory card.

The operation principle of the first mode (transfer of data to PC through Wi-Fi) is shown in Fig. 2.

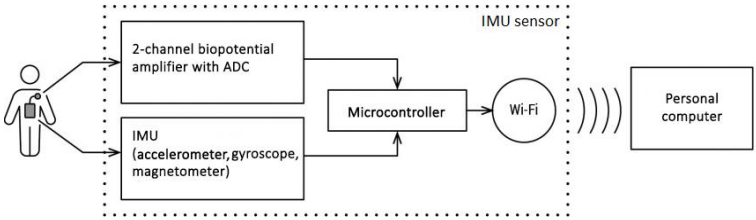


Fig. 2. The principle of sensor operation in data transfer mode

Each sensor simultaneously records two types of data: biopotentials (EMG signals) and navigation data (accelerometer, gyroscope and magnetic field data). Biopotentials (first through electrodes and then through EMG cable) are delivered to amplifier input and after that to ADC for their conversion to digital signal. Navigation data is recorded by IMU that is also responsible for data conversion to digital signal. The obtained digital data (biopotentials and navigation) is transferred to microcontroller which generates data packet for its further transfer through Wi-Fi. The information is received by PC where it is processed depending on the used software.

This mode is mostly needed in medical devices requiring immediate response to patient motion (for example, in upper/lower limb trainers with biofeedback (BFB), in functional electrical stimulation systems where it is important to deliver pulse at a particular motion phase and in other devices).

The operation principle of the second mode (data saving to memory card) is shown in Fig. 3.

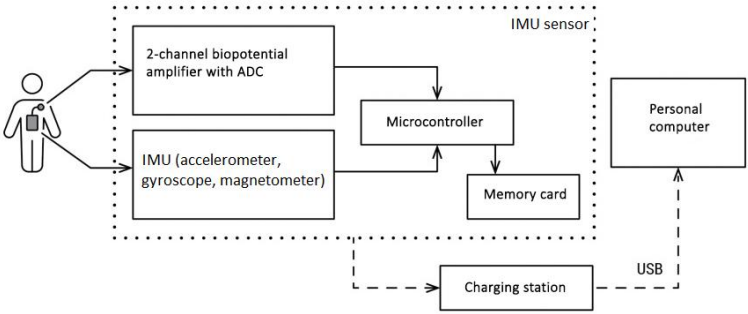


Fig. 3. The principle of sensor operation in data saving mode

The main difference of that mode from the previous one is that the digital data is saved to a memory card instead of being transferred to Wi-Fi module after it is received by microcontroller. Later when the sensor is placed into the charging station the data can be loaded from the memory card to PC for further processing.

This operation mode is usually needed in diagnostic systems that do not require online motion data processing.

The operation principle of the third mode (transfer of data using Wi-Fi and data saving to memory card) is shown in Fig. 4.

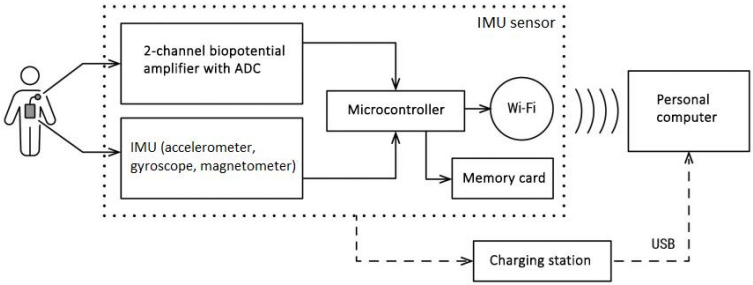


Fig. 4. The principle of sensor operation in the mode of data transfer using Wi-Fi and data saving to memory card

This operation mode combines the two described above modes which means that the recorded data is transferred to PC using

Wi-Fi protocol and is saved to the memory card at the same time.

1.2. Control Buttons, Sockets and Indicators

The front and bottom edge panels of the sensor are shown in Fig. 5.

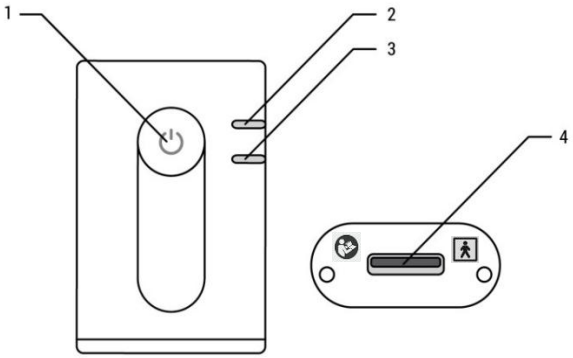


Fig. 5. The front and bottom edge panels of the sensor

1. Power button.

2. Battery status indicator.

3. Operation mode indicator.

4. Socket for charging station, charging USB cable or connection of EMG cable.

Battery status indicator provides information about the current battery charge level of the sensor (Table 1). The indicator is active when the sensor is switched on and/or is placed into charging station.

Table 1. Battery status indication

Indication	Battery charge level
Green (lights)	Battery charge level is higher than 70% of the maximum value.
Green (flashes, 1Hz)	Battery charge level — 20–70% of the maximum value.
Green (flashes, 2Hz)	Battery charge level — 10–20% of the maximum value.
Green (flashes, 5Hz)	Battery charge level — lower than 10% of the maximum value.
No indication	Sensor is powered off. Charging is not started.

It is not recommended to use the sensor if the battery charge level is less than 20% of the maximum value. Otherwise data recording can be terminated before it is planned.

Operation mode indicator informs about the current operation mode of the sensor (Table 2). This indicator is active only if the sensor is switched on.

Table 2. Operation mode indication

Indication	Sensor operation mode
White[1]	Sensor battery charging is going on
Blue (flashes)	Data is being transferred using Wi-Fi.
White (flashes)	Data is being saved to memory card.
White-blue (flashing alternately)	Data is being both transferred using Wi-Fi and saved to memory card.
Blue (lights)	Sensor is connected to Wi-Fi and is waiting for command.
No indication	Sensor is switched off or is not connected to Wi-Fi.

Red and blue alternating flashlight of the sensor that is placed into the charging station means that the sensor cannot be removed out of it because reading of data from memory card or updating of the installed sensor software is performed.

The front and side panels of the sensor charging station are shown in Fig. 6.

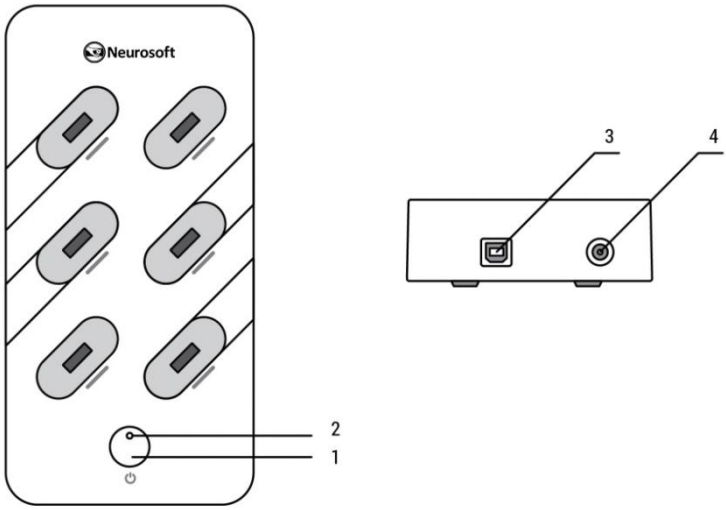


Fig. 6. The front and side panels of the sensor charging station

1. Power button.
2. Power ON/OFF indicator.
3. USB connector for connection to PC.
4. Power supply unit connector.

Power ON/OFF indicator shows if the sensor charging station is switched on or off at the moment (Table 3).

Table 3. Sensor charging station indication

Indication	Status
Blue (lights)	Charging station is switched on.
No indication	Charging station is switched off.

1.3. Labeling

The example of the label for the IMU sensor is shown in Fig. 7. The example of the label for the sensor charging station is shown in Fig. 8.

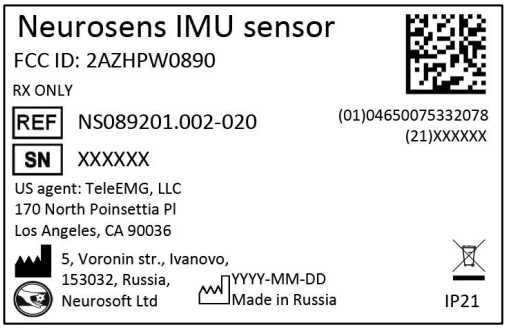


Fig. 7. The example of the label for the IMU sensor

Fig. 8. The example of the label for the sensor charging station

Interpretation of label symbols:

	– type BF applied parts according to ANSI AAMI ES60601-1. ***The sign is on the bottom panel of Neurosens IMU sensor.***
	– mark of conformance to 2012/19/EC directive “On waste electrical and electronic equipment (WEEE)”.
	– consult operational documentation.
	– attention: consult user and user manuals. ***The sign is on the bottom panel of Neurosens IMU sensor.***
REF	– catalogue number according to ISO 15223-1.
SN	– serial number according to ISO 15223-1.
	– manufacture date according to ISO 15223-1.
	– manufacturer’s name and address according to ISO 15223-1.
RX ONLY	– federal law restricts this device to sale by or on the order of a physician
FCC ID: 2AZHPW0890	– this exterior label referring to the enclosed module according to part 15.212 vi(A) of CFR

The device is identified with GS1-128 barcode that includes GTIN code and serial number (Fig. 9).

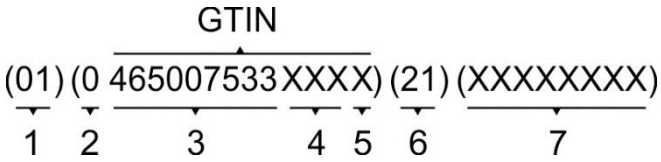


Fig. 9. GS1-128 barcode

1 – device identifier GTIN.

2 – indicator digit.

3 – company prefix.

4 – item reference number.

5 – check digit.

6 – serial number identifier.

7 – serial number.

GTIN – global trade item number (product or service) used for its identification. It is assigned to any trade item (product or service) that is priced, ordered or invoiced at any point in the supply chain.

To ensure automatic reading of barcode GS1-128 it is represented as DataMatrix code on the label (Fig. 10).

Fig. 10. DataMatrix code

DataMatrix – two-dimensional matrix barcode made up of black and white or light and dark square modules of different shade arranged in a square or rectangular pattern. Information on DataMatrix code is provided in ISO/IEC 16022:2006.

For decoding item information DataMatrix code can be read using scanner or smartphone camera.

2. Preparing the Product for Use

2.1. Personnel Requirements

The set is prepared for use by a person enabled by the manufacture or a technical specialist of a medical facility for which it is intended. Please mind that correct assembly determines safe use and efficient operation of the set. Particular requirements that determine safe use of the set are given below in ***bold italics.***

2.2. Room Selection and Placement

Prior to assembly choose the site for the set considering power wiring and protective grounding in the room intended for equipment placement and read the following requirements and recommendations.

Requirements and recommendations for equipment placement:

- Use the set at the maximum possible distance from power cables, switchboards, and different powerful electrical devices that can emit electromagnetic fields of mains frequency.

- Do not use the set in the immediate vicinity (less than 5 meters) of short-wave or microwave therapeutic equipment. It may lead to its unstable operation.

- ***The sensor charging station and PC shall be placed at the minimum distance of 1.5 meters from the patient environment, otherwise PC shall comply with safety requirements of ANSI AAMI ES60601-1 for medical devices and systems or PC shall be connected to the mains and LAN only using isolators that comply with the above mentioned requirements.***

Requirements to the mains:

- ***The use of electric mains where neutral and ground conductors are combined is strongly prohibited.***

- ***To avoid electrical injury, the sensor charging station and PC must be only plugged in an appropriate mains outlet that has protective earthing conductor.***

- ***Use of multi-socket extension cables without additional precautions is prohibited for the reason that the probable break of the circuit of protective ground of the multi-socket extension cable might lead to leakage current summation up to dangerous values.***

- ***Check of three-pole sockets and protective ground carried out by an electrician is strictly required prior to use the set.***

2.3. Unpacking the Set

If the box with the set was kept under the conditions of high humidity and low temperature that differ greatly from operating values keep the box for 24 hours in the room with normal ambient conditions.

Open the box and take out the set components from package. Check whether the delivery conforms to the packing report.

Examine the set and make sure there is no visual damage.

2.4. Assembly and Connection to PC

Follow the steps below:

1. Connect the charging station to the mains using power supply unit included in the list of components for the set.

2. Connect the sensor charging station to PC using USB cable included in the list of components for the set.

Sensor charging does not require charging station to be connected to PC using USB cable. However, if this type of connection is not ensured the following options shall not be available:

– transfer of data from sensor memory card to PC;

– setup of Wi-Fi parameters of the sensors;

– update of the sensor firmware.

3. If the charging station was connected to PC with the help of USB cable, make sure that the station is placed at more than 1.5 meter distance from the patient environment.

2.5. Applying Number Sticker to the Sensor

It is recommended to number the sensors using particular stickers with numbers 1 to 12 prior to use the set. This makes the use of the set easier.

Apply the sticker with a desired number to the sensor as shown in Fig. 11.

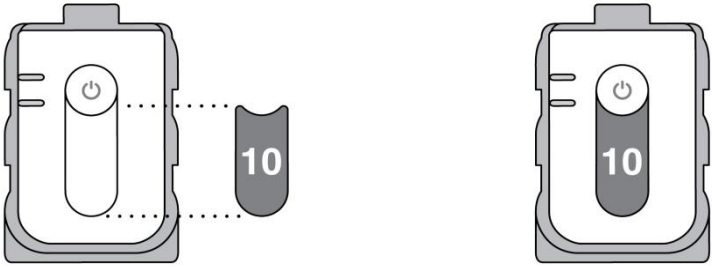


Fig. 11. Application of number sticker to the sensor

Make sure that numbers do not repeat to avoid further confusion.

2.6. Elastic Strap

Pass elastic strap of a particular size through the bars on the back side of the sensor mount as shown in Fig. 12.

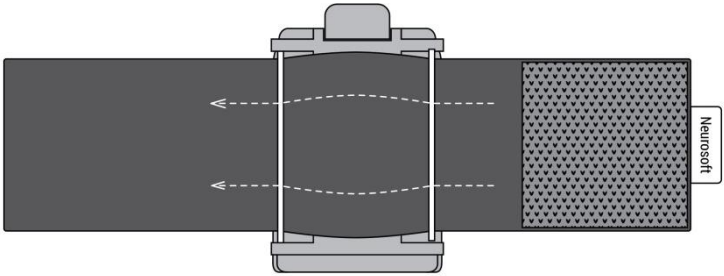


Fig. 12. Arrangement of the sensor elastic strap

3. Proper Use

3.1. Getting Started

Operational limitations are specified in Table 5 (see climatic conditions at operation).

Before power supply is switched on make sure that the sensors, the sensor charging station and the cables have no apparent mechanical failures that might cause danger.

The range of setting up procedures depends on the medical device the set is used with.

Usually it includes the following steps:

1. Charging of sensors.
2. Application of sensors to a subject.
3. Connection of EMG cables and application of electrodes.
4. Sensor switch on.

3.1.1. Charging of Sensors

The sensor can be charged in two ways:

1. Using special USB cable included into the list of components.
2. Using the sensor charging station.

It is recommended to use the sensor charging station.

To charge the sensors with the help of the charging station, perform the following steps:

1. Plug the sensor charging station into mains outlet.

2. Power the charging station on by pressing power button located on the station (Fig. 6).

3. Place the sensor into the charging station (Fig. 13).

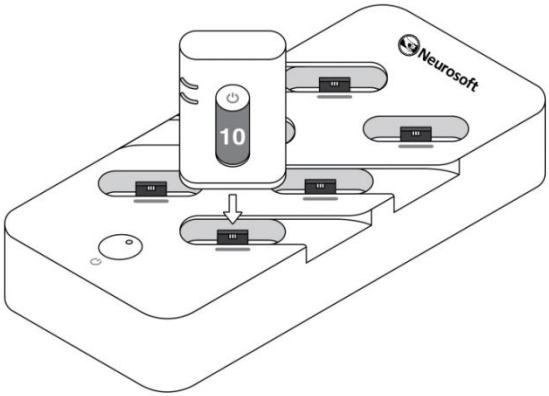


Fig. 13. Sensor battery charging

4. Make sure that the battery charge indicator of the sensor lights (shows current charge level). This means that the sensor battery charging started.

5. Remove the sensor from the charging station when the desired charge level is reached (Table 1).

To charge the sensors with the help of the USB cable, perform the following steps:

Connect one end of the USB cable to the sensor (pos. 4 in Fig. 5) and another end of the cable – to the USB port of the computer (Fig. 14).

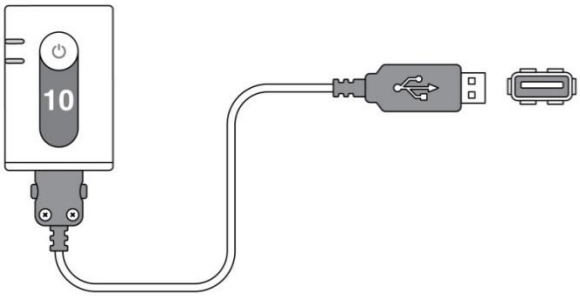


Fig. 14. Charging the sensor using USB cable

1. Make sure that the battery charge indicator of the sensor lights (shows current charge level). This means that the sensor battery charging started.

2. Disconnect USB cable from the sensor and PC when the desired charge level is reached (Table 1).

3.1.2. Attaching the Sensor to a Subject

The sensor is attached to a subject using elastic straps and sensor mounts included into the list of components.

To fix the sensor on a subject, do the following:

1. Pass elastic strap through the sensor mount bars (see section 2.6 “Elastic Strap”), if it was not done earlier.

2. Attach elastic strap with the mount to a subject (Fig. 15).

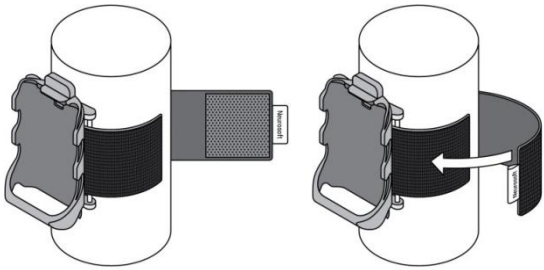
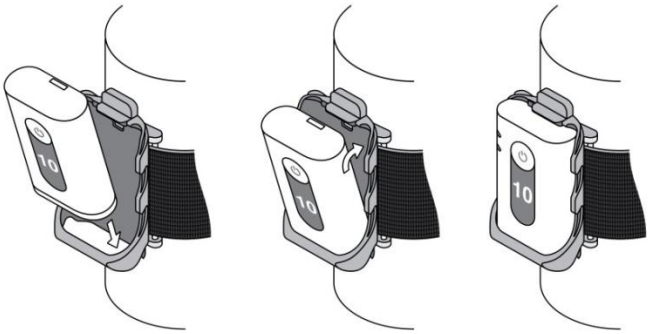


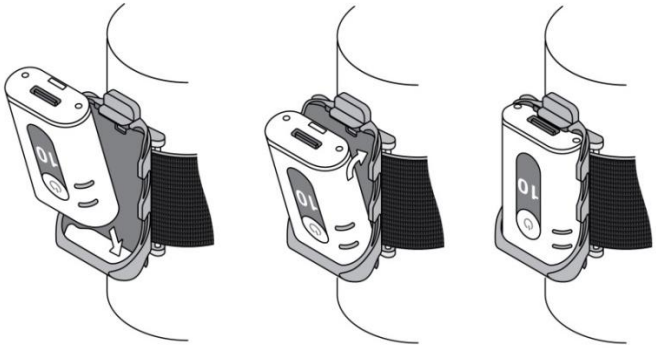
Fig. 15. Attaching elastic strap with a mount to a subject

Make sure that the strap is securely fixed (tightened) to prevent mount shift during data recording because it may lead to measurement error of navigation data values.

3. Place the sensor into the mount right on a subject (Fig. 16).



(a)



(b)

Fig. 16. Variants of sensor placement into the mount: (a) with socket facing down, (b) with socket facing up

3.1.3. Connection of EMG Cables and Electrode Placement

Electrode placement is determined by the medical device the set is used with.

Apply the electrodes to a patient as follows:

1. Apply the electrodes to patient's skin.
2. Connect EMG cables to the sensors (Fig. 17).

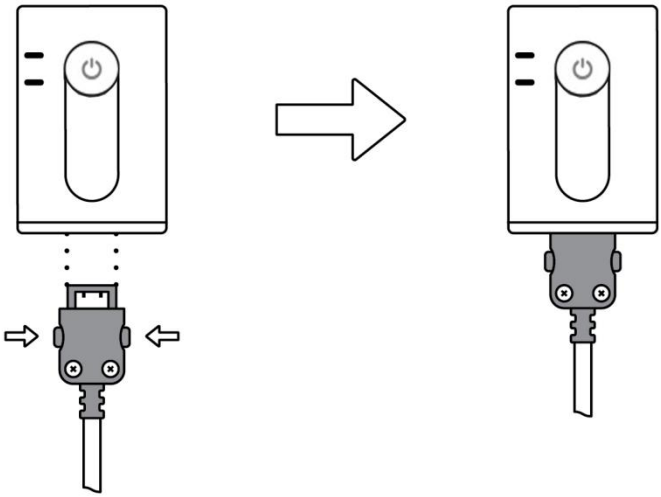


Fig. 17. Connection of EMG cable to the sensor

3. Connect EMG cables to the electrodes.

Taking into consideration that "red/black" pair is "+/–" of the 1st EMG channel, "yellow/purple" pair is "+/–" of the 2nd EMG channel and green one is grounding electrode.

3.1.4. Power ON/OFF

To switch the sensor on, press and hold power button (pos. 1 in Fig. 5) for 2 seconds. If the battery status indicator lights, it means that the sensor is switched on.

The sensor is switched off in the same way (by pressing and holding power button for 2 seconds).

If the battery status indicator doesn't light, it means that the sensor is switched off.

3.2. Workflow

The workflow depends on the medical device the set is used with. Please follow the instructions of the user manual for the particular medical device.

3.3. After Use Procedure

Upon test completion perform the following steps:

1. Disconnect EMG cables from the electrodes applied to a patient.
2. Disconnect EMG cables from the sensors.
3. Take elastic strap together with sensor that is still in the mount off a patient.
4. Take the electrodes off a patient. Discard disposable electrodes according to section 6 "Disposal".
5. Switch the sensor off. To do this press and hold sensor power button (pos.1 in Fig. 5) for 2 seconds. If the battery status indicator doesn't light, it means that the sensor is switched off.

6. Take the sensors out of the mount and insert them into the charging station.

7. Perform disinfection of the used EMG cables and sensor mounts according to section 4.3 “Disinfection”.

8. If a long interruption in use of the set is supposed, unplug the charging station and place it for storage under the appropriate conditions (see Table 5, climatic conditions).

If long interruption in use of the set (one month and more) is supposed it is necessary to perform full charge of sensor battery regularly (not less than once a month). This prevents the battery from full discharge which may affect battery capacity.

3.4. Troubleshooting

The list of possible troubles that can be eliminated by the user on its own are given in Table 4. If troubles other than those specified in the table below occur, the user shall contact the service center of Neurosoft.

Table 4. Possible troubles and the way of their removal

Trouble symptom	Cause	Solution
The sensor fails to switch on.	The sensor battery is discharged.	Charge the sensor battery.
The sensor battery discharges fast (holds the charge for less than 4 hours at the full charge).	The service life of the sensor battery is expired.	Contact service center of Neurosoft.

Table 4 (continued)

Trouble symptom	Cause	Solution
The sensor is connected to the computer using USB cable, but it fails to charge (battery status indicator doesn't light).	USB port of the computer is faulty.	Connect the sensor to another USB port of the computer.
	USB cable is damaged.	Replace the USB cable.
	The computer is switched off.	Switch the computer on.
The sensor is placed into the charging station but fails to charge (battery status indicator doesn't light).	The charging station is switched off.	Switch the charging station on.
	The charging station is not plugged to the mains.	Check connection of the charging station to the mains.
	The sensor is placed into the charging station incorrectly.	Check if the sensor is placed into the charging station correctly (see Fig. 13).
The sensor is switched on, but the operation mode indicator doesn't light.	The router is switched off.	Switch the router on.
	The sensor didn't receive the IP-address of the access point.	Enable DHCP in router settings.
	The access point specified in the sensor settings is not found.	Make sure that the channel number in the router settings is within the range 1…13 and standard 802.11b/g/n is selected. Check if Wi-Fi network name is correct in the sensor settings using the software of the medical device the set is used with.

Table 4 (continued)

Trouble symptom	Cause	Solution
	The password specified in the sensor settings is incorrect.	Check if Wi-Fi network password is correct in the sensor settings using the software of the medical device the set is used with.
No EMG signal or strong interference of EMG signal is detected.	EMG cable is damaged.	Replace the EMG cable.

4. Maintenance

4.1. General Requirements

Safety precautions when carrying out maintenance comply with those described in section “Safety Precautions”.

The requirements to the service personnel qualification are specified in section 2.1 “Personnel Requirements”.

When detecting a trouble, please refer to the information given in section 3.4 “Troubleshooting”. If the trouble cannot be eliminated, please contact the service center of Neurosoft (5, Voronin str., Ivanovo, 153032, Russia).

The set is subject to user maintenance. The volume of the user maintenance is specified in section 4.2 “User Maintenance”.

4.2. User Maintenance

User maintenance of the set includes visual inspection, check of connectors and cables, decontamination of enclosure surface and disinfection according to the recommendations specified in section 4.3 “Disinfection”.

4.3. Disinfection

Clean the enclosure of the set components using cloth slightly dampened with mild soap solution.

Dry the surfaces with a clean dry cloth or air dry naturally.

Do not use silicon-based solvents, abrasive cleaners, scrubbing pads, or other abrasive applicators.

For disinfection use one of the following disinfectants:

- phenols (Bacillotex®),
- 70 % ethyl or isopropyl alcohol solution,
- 0,5 % chlorohexidine solution.

If hepatitis or any other dangerous virus contamination is suspected use:

- aldehydes (Cidex®, Korsolin®) or
- chlorinates (Diversol BX®).

Prepare and use disinfectant as stated by the manufacturer.

Be careful not to drip water or disinfectant directly into the input and output plugs and other openings of the sensors and the charging station. Keep all cleaning fluids away from electrical connectors.

Remove excess disinfectant with a dry cloth.

4.4. Lifetime

The set lifetime is 3 years from the shipment date to the user.

The manufacturer is obliged to provide technical support of the product throughout its lifetime.

5. Current Repair

5.1. General Requirements

The repair of the set components requires special training of the technical staff, special equipment and service software that are available from the manufacturer or the company representative. On-site repair that requires opening sensor enclosure and charging station enclosure is prohibited.

The set components must be switched off and disconnected form mains during the repair.

6. Disposal

The set shall not be disposed of in the general waste. The set disposal is performed according to your local regulations.

The used rechargeable batteries should be disposed as a hazardous waste as they contain hydride of heavy metals.

7. Acceptance and Package Data

The set of Neurosens IMU sensors is collected, packed and ready for operation in compliance with the requirements of design documentation.

Packed by _____

signature

The detailed information about the list of components is provided in the packing report which is an integral part of the present document and should be kept with it.

8. Warranty

8.1. The manufacturer guarantees the set quality conformance to the design documentation requirements if the rules of operation, storage, transportation, installation and maintenance established in the technical documentation are observed.

8.2. Warranty period for the sensors and charging station is 24 months from the date of shipment to the customer. The shipment date is the date of invoice or any other document the items were delivered with.

Warranty period for components subject to wear and tear (EMG cables, sensors mounts, fixing and elastic straps) is 30 days.

The warranty does not cover consumables (surgical tapes, pastes and disposable electrodes).

The warranty period can be prolonged for the period from reclamation submission up to repair completion (see section 9 “Reclamations”).

Warranty storage period is not less than 6 months.

8.3. Warranty is voided in the following cases:

- if the rules of operation, storage, transportation, installation and maintenance established in the technical documentation are not observed;

- when the warranty period is expired;

- if a user breaks the seal without permission of the manufacturer.

8.4. The manufacturer is obliged to repair the set components in case of their failure within the warranty period free of charge. The repair is carried out in the service center of Neurosoft (5, Voronin str., Ivanovo, 153032, Russia) according to the procedure described in section 9 “Reclamations”.

9. Reclamations

9.1. In case of the set components failure or detection of their fault within the warranty period or during primary acceptance the consumer shall send written notification to Neurosoft, to the authorized European representative or to the nearest distributor. The actual list of Neurosoft distributors is available at the website: **www.neurosoft.com/en/pages/dealers**. This notification shall include the following information:

- consumer’s name and address;

- serial number of the sensor or sensor charging station (specified in package report and on the label);

- number and date of the invoice or other document confirming the set purchase;

- detailed description of faults. If possible state the reasons and circumstances preceding fault detection (in addition it is recommended to attach test report, exam data, photos and other materials that allow solving the problem as soon as possible).

9.2. If the set components are returned to the service center for repair the following rules should be observed:

- they should be disinfected before sending to the service center. Please refer to cleaning and disinfection rules specified in section 4.3 “Disinfection”;

- they should be packed in such a way to prevent the possibility of their damage during transportation;

- the notification (see p. 9.1) must be included into the shipment with the set components being returned.

Annex 1. Main Specifications

Main specifications of the set are given in Table 5.

Table 5. Main specifications

Parameter	Value
Neurosens IMU Sensor	
Battery type	Li-pol
Battery capacity	not less than 850 mAh
Battery voltage	3.7 V
Maximum battery charge time using USB cable	not more than 3 h
Channel type	accelerometric gyroscopic magnetometric electromyographic
Channel type	accelerometric gyroscopic magnetometric electromyographic
Wireless connection with PC	yes
Continuous operation at a fully charged battery	not less than 4 h
Wireless IMU connection	
Interface	Wi-Fi, standard IEEE 802.11n
Transmission range	not less than 10 m, in the line of sight
Maximum number of sensors simultaneously connected to PC	12 pcs.
Mal-synchronization of the sensors	not more than 0.005 s
EMG Acquisition	
Number of differential channels	2
Sampling rate	2 kHz
A/D converter	24 bits
Common mode rejection ratio at 50 Hz	not less than 100 dB
Bandwidth in EMG measurement mode	5 to 500 Hz @ (– 3 ± 0.5) dB

	cut-off frequency with possibility to choose low limit value from the range 5, 10, 20 Hz
Noise level in EMG measurement mode within the range 5 to 500 Hz	not more than 2 μV RMS
Input impedance (differential mode)	not less than 100 MΩ
Input range of EMG signal	0.07 μV to 20 mV
EMG signal measurement error within the range 0.07 μV to 20 mV and bandwidth 5 to 500 Hz	not more than ± (7 μV + 5% of the measured value)
DC offset rejection	– 330 mV to + 330 mV
Patient leakage current	not more than 0.1 μA
Suppression of power line interference by on/off notch filter	not less than 40 dB
Electrode impedance	5 – 100 kΩ
Electrode impedance error	not more than ± (3 kΩ + 10% of the measured value)
Accelerometer and Gyroscope Channels	
Sampling rate	200 Hz
Input range of measured accelerations (for each axis)	– 16 g to + 16 g
Permissible acceleration measurement error (for each axis)	not more than ±(0.04 g + 5% of the measured value)
Angular velocity input range (for each axis)	– 2000 deg/s to +2000 deg/s
Permissible angular velocity measurement error (for each axis)	not more than ±(0.5 deg/s + 2% of the measured value)
Magnetometer Channel	
Sampling rate	20 Hz
Input range of measured magnetic field (for each axis)	– 1000 μT to + 1000 μT
Permissible magnetic field measurement error (for each axis)	not more than ± (3 μT + 5% of the measured value)
Charging Station	
AC frequency	50/60 Hz
AC voltage	(220 ± 22) V
DC voltage	5 V

Power consumption including power supply unit	not more than 100 W
Maximum number of simultaneously charged sensors	6
Battery status indicator of each sensor	yes
Maximum battery charge time of each sensor (fully discharged up to fully charged state)	not more than 3 h
Power Supply Unit of the Charging Station	
Input voltage	100–240 V, 50/60 Hz, 0.7–1.4 A
Output voltage	5 V DC, 6.0 A
Rated output power	not less than 30 W
Climatic Conditions	
• Operation: o ambient temperature o relative humidity o atmospheric pressure • Transportation: o ambient temperature o relative humidity o atmospheric pressure • Storage: o ambient temperature o relative humidity o atmospheric pressure	 + 15 to + 35°C 30 to 75%, non-condensing 70 kPa to 106 kPa –25 to +60°C 20 to 95%, non-condensing from 70 kPa +5 to +45°C 30 to 75%, non-condensing 70 kPa to 106 kPa
General Specifications	
Ingress protection provided by sensor enclosure and charging station enclosure	code IP21 according to EN60529
Cable length: • EMG cable: • for NS089103.001-015 • for NS089103.001-020 • for NS089103.001-030 • for NS089103.001-040 • for NS089103.001-050 • for NS089103.001-060 • for NS089103.001-070 • for NS089103.001-080 • Charging cable • USB cable A-B	 0.15 ± 0.01 m 0.20 ± 0.02 m 0.30 ± 0.03 m 0.40 ± 0.04 m 0.50 ± 0.05 m 0.60 ± 0.06 m 0.70 ± 0.07 m 0.80 ± 0.08 m 1.50 ± 0.10 m 1.80 ± 0.10 m
Dimensions: • Neurosens IMU sensor • IMU Sensor mount • Charging station	 (60×40×17) ± 2 mm (70×70×20) ± 2 mm (205×120×40) ± 5 mm

• Elastic strap:
  • width
  • length:
  • for NS089221.002-020
  • for NS089221.002-030
  • for NS089221.002-040
  • for NS089221.002-050
  • for NS089221.002-060
  • for NS089221.002-070
  • for NS089221.002-100
  • for NS089221.002-140
• Fixing elastic strap:
  • width
  • max. length
• Bottom box insert
• Upper box insert
• Transportation bag
	
	50 ± 2 mm
	
	200 ± 10 mm
	300 ± 10 mm
	400 ± 10 mm
	500 ± 10 mm
	600 ± 10 mm
	700 ± 10 mm
	1000 ± 10 mm
	1400 ± 10 mm
	
	25 ± 2 mm
	1000 ± 10 mm
	(403×307×60) ± 10 mm
	(403×307×43) ± 10 mm
	(430×345×165) ± 10 mm

Weight:
• Neurosens IMU sensor
• IMU Sensor mount
• Charging station
• Elastic strap:
  • for NS089221.002-020
  • for NS089221.002-030
  • for NS089221.002-040
  • for NS089221.002-050
  • for NS089221.002-060
  • for NS089221.002-070
  • for NS089221.002-100
  • for NS089221.002-140
• Fixing elastic strap
• EMG cable:
  • 0.15 m length
  • 0.2 m length
  • 0.3 m length
  • 0.4 m length
  • 0.5 m length
  • 0.6 m length
  • 0.7 m length
  • 0.8 m length
• Charging cable
• USB cable A-B
• Bottom box insert
• Upper box insert
• Transportation bag
	
	40 ± 4 g
	18 ± 2 g
	300 ± 30 g
	
	10 ± 2 g
	14 ± 2 g
	19 ± 2 g
	23 ± 2 g
	28 ± 3 g
	32 ± 3 g
	46 ± 5 g
	65 ± 7 g
	18 ± 2 g
	
	15 ± 2 g
	16 ± 2 g
	20 ± 2 g
	25 ± 3 g
	27 ± 3 g
	30 ± 3 g
	35 ± 4 g
	40 ± 4 g
	37 ± 4 g
	95 ± 5 g
	94 ± 5 g
	53 ± 5 g
	1.2 ± 0.1 kg

Total weight with accessories in package	not more than 5 kg
Applied parts (sensors)	BF type

Safety and electromagnetic compatibility

Electromagnetic compatibility (EMC) of the set is ensured by compliance with the requirements of IEC 60601-1-2-2020.

The set is intended for operation in electromagnetic environment described in Annex 3.

Portable and mobile RF communication equipment may affect operation of the set.

Use of accessories not specified in Annex 2 of this manual may increase electromagnetic emission or reduce interference immunity of the set.

Regarding safety the set complies with the requirements of ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] and EN 60601-2-40:2019. EMC of sensors and sensor charging station is ensured by compliance with the requirements of IEC 60601-2-40(2016). The sensors fall under the class of equipment with a built-in power supply unit according to ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021].

Annex 2. List of Components

The list of components (the number of sensors, fixation and elastic straps, EMG cables, etc.) depends on the medical device IMU sensors are delivered with. The complete list of components for the Neurosens IMU sensors is given in Table 6.

Table 6. List of components

Name	Order code or main specification	Qty, pcs.
Neurosens IMU sensor	NS089201.002-020	2 to 12
Charging station	NS089201.003-02	Up to 2
Power supply unit	• input voltage: 100–240 V, 50/60 Hz, 0.7–1.4 A; • output voltage: 5 V DC, 6.0 A, • maximum power consumption: 30 W	Up to 2
Main supply cable	• connectors: NEMA 5-15P, IEC 320-C13 • 15A/125VAC • length: 2 m	Up to 2
Charging cable	NS089103.002-15	Up to 12
USB cable A-B	NS007103.005-01	Up to 2
IMU sensor mount	NS089221.010	Up to 24
IMU sensor stickers	NS089210.002	1
Fixing elastic strap	NS089221.003	Up to 2

Table 6 (continued)

Name	Order code or main specification	Qty, pcs.
Elastic strap	NS089221.002-020	Up to 12
	NS089221.002-030	Up to 12
	NS089221.002-040	Up to 12
	NS089221.002-050	Up to 12
	NS089221.002-060	Up to 12
	NS089221.002-070	Up to 12
	NS089221.002-100	Up to 12
	NS089221.002-140	Up to 12
EMG cable	NS089103.001-15	Up to 12
	NS089103.001-20	Up to 12
	NS089103.001-30	Up to 12
	NS089103.001-40	Up to 12
	NS089103.001-50	Up to 12
	NS089103.001-60	Up to 12
	NS089103.001-70	Up to 12
	NS089103.001-80	Up to 12
Operational documentation		
User manual	W089201.002.D100.03.000	1
Package		
Package set	NS002901.001	Up to 2
Bottom box insert	NS089212.002	Up to 2
Upper box insert	NS089212.004	Up to 2

Annex 3. Emissions and Immunity

Guidance and manufacturer's declaration – electromagnetic emissions

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

Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The set uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The set 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.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity

The set is intended for use in electromagnetic environment described below. The customer or the user of the set should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact	±6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
	±8 kV air	±8 kV air	
Electrical fast transient/burst IEC 61000-4-4	± 2 kV − for power supply lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
	± 1 kV − for input/output lines	Not applicable	
Surge IEC 61000-4-5	± 1 kV differential mode	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
	± 2 kV common mode	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the set requires continued operation during power mains interruptions, it is recommended that the set is powered from an uninterruptible power source.
	40% U_T (60% dip in U_T) for 5 cycles	Not applicable	
	70% U_T (30% dip in U_T) for 25 cycles	Not applicable	
	<5% U_T (>95 % dip in U_T) for 5 s	Not applicable	
Power frequency magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Note: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The set is intended for use in electromagnetic environment described below. The customer or the user of the set should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Radiated RF IEC 61000-4-6	3 V/m 80 MHz to 2.5 Hz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the set, including cables, than the recommended separation distance calculated from the equation below applicable to the frequency of the transmitter: $d = 1.17\sqrt{P}$ (80 MHz to 800 MHz) $d = 2.33\sqrt{P}$ (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 meters (m).

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[1)] should be less than the compliance level in each frequency range[2)] Interference may occur in the vicinity of equipment marked with the following symbol: 

[1)] 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 set is used exceeds the applicable RF compliance level above, the set should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the set.
[2)] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Notes:
1) At 80 MHz and 800 MHz, the higher frequency range applies.
2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended separation distances between portable and mobile RF communications equipment and the set

The set is intended for use in an environment in which radiated RF disturbances are controlled. The customer or the user of the set can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the set as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	$d = 1.17\sqrt{P}$ 150 kHz to 80 MHz	$d = 1.17\sqrt{P}$ 80 MHZ to 800 MHz	$d = 2.33\sqrt{P}$ 800 MHz to 2.5 GHZ
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.689	3.689	7.379
100	11.667	11.667	23.333

Notes:
1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
3. For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Annex 4. FCC Statement

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. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause 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 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.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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.

RF Exposure Information:
FCC RF Exposure requirements: The highest SAR value reported under this standard during product certification for use next to the Body/ Limb with the minimum separation distance of 0mm. This transmitter must not be collocated or operating in conjunction with any other antenna or transmitter.

This product is compliance to FCC RF Exposure requirements and refers to FCC website https://apps.fcc.gov/oetcf/eas/reports/GenericSearch.cfm search for FCC ID: 2AZHPW0890

All transmission frequencies of U-NII-2A and U-NII-2C comply with 47 CFR FCC Part15.407(g) and the manufacturer declares that their transmission is maintained within the U-NII-2A and U-NII-2C bands.