NEWRONIKA HDCSTIM USER MANUAL

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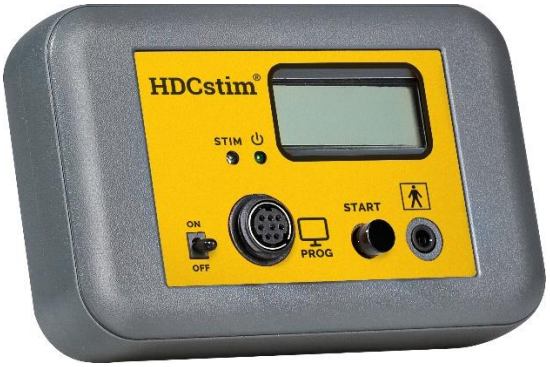
Newronika®

HDCstim®

tDCS - Portable & Programmable Direct Current Stimulator



User's manual

Version V16E – June 2020

HDCstim® is manufactured by

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For every further information it is possible to send an e-mail to

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HDCstim® is a part of HDCkit and it is an active medical device of class IIa (European Notified Body 0068 - MTIC InterCert – Registered Office: Via Leopardi, 14 – 20123 MILANO (MI) ITALY / Operative Lab: Via Moscova, 11 - 20017 RHO (MI) ITALY).

HDCstim is CE marked: CE 0068

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INTENDED USE

HDCstim® is part of the HDCkit system for the delivery of direct current stimulation-controlled treatments. HDCstim® is a battery supplied, programmable system for direct current (DC) stimulation.

HDCstim® can be used only under medical prescription.

Transcranial DC stimulation is a neurophysiological technique able to modulate the excitability of the biological tissue of the central and peripheral nervous system, through the delivery, for a finite time length, of an electrical field. It has been demonstrated in recent years that the technique is safe and beneficial. However, its application must be controlled by specialized medical personnel able to guarantee correct stimulation parameters.

HDCstim® must be always used according to applications already described in the literature. In any other case, the local Ethics Committee or analogous Body must be required.

HDCstim® is specifically designed to be used only under medical prescription. HDCstim® can be used only if programmed by specialized medical personnel through the HDCprog device. Otherwise, HDCstim® cannot and should not be used. The first programming of the device has to be performed by doctor in hospital using HDCprog or ISOcable. HDCstim® can be used at home and the doctor can monitor the treatment at home and eventually renew the cycle of treatment at home using ISOcable system. In this way daily tDCS treatments can be performed at home and programming with ISOcable reduces travel expenses between home and hospital for the treatment renew. Remote control of HDCstim® using PC at home is available starting from HDCstim® firmware version 6.0.

Because the treatment can be performed only following the prescription made by specialized personnel, the DC stimulation delivered by HDCstim® can be considered safe.

It is contraindicated to use the HDCkit system for tDCS treatment in pregnant women, children below 18 years, patients with pacemakers, intracranial electrodes, implanted defibrillators, or any other prosthesis.

Read carefully the User's manual before using HDCstim®.

HDCstim® is intended to be used in home environment, by the patient and/or caregivers (intended as lay operators).

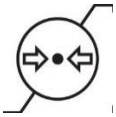
WARNINGS

In the manual, this symbol indicates a warning point.

Not following the instructions by this symbol could cause the HDCstim® to malfunction, cause damage to the unit or create a potential danger in the administration of the treatment.

LEGEND: used symbols according to EN ISO 15223-1:2016

	Caution. It indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Mandatory to follow instructions for use. Refer to instruction manual/booklet
	Type BF applied part.
	Catalogue number. It indicates the manufacturer's catalogue number so that the medical device can be identified.
	Serial number. It indicates the manufacturer's serial number so that a specific medical device can be identified.
	Manufacturer. It indicates the medical device manufacturer.
	Date of manufacture. It indicates the date when the medical device was manufactured.
	Product packaging can be recycled
	Fragile, handle with care. It indicates a medical device that can be broken or damaged if not handled carefully.

	Keep dry. It indicates a medical device that needs to be protected from moisture.
	Temperature limit. It indicates the temperature limits to which the medical device can be safely exposed.
	Humidity limitation. It indicates the range of humidity to which the medical device can be safely exposed.
	Atmospheric pressure limitation. It indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	Recycle: Electronic Equipment. Do not dispose of this product in the unsorted municipal stream. Dispose of this product according to local regulations. For instruction on proper disposal of product contact Newronika.
	Two AA alkaline batteries (not rechargeable LR6)
IP20	Degree of ingress Protection Provided by enclosure. Protected against solid foreign objects of 12.5mm and greater and not protected against the effect of the water.
IP03	Degree of ingress Protection Provided by HDCstim Bag. Not protected against solid foreign objects and protected and against the effect of water sprayed at an angle up to 60° on either side of the vertical.
CE 0068	European Conformity, this symbol is applied in accordance with the relevant provisions of Directive 93/42/EEC on active implantable medical devices. With it, Newronika declares that this medical device is in compliance with the essential requirements and other relevant provisions of this Directive.

APPLIED DIRECTIVES AND STANDARDS

HDCstim® is a class IIa device according to the classification in the Council Directive 93/42/EEC for medical is compliant with to the following Standards and Directives:

Standard	Title
EN 60601-1:2006/A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-11:2010	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN 62304:2006	Medical device software - Software life-cycle processes
IEC 62366:2008	Medical devices - Application of usability engineering to medical devices
EN ISO 13485:2006	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

WHAT YOU WILL FIND IN THE PACKAGING

HDCstim® is given in a packaging containing:

- N.1 HDCstim® stimulator.
- N.1 electrode cable.
- N.1 carrying case for stimulator (HDCstim Bag).
- N.2 batteries 1.5V type AA.
- N.1 user's manual.
- N.1 declaration of conformity.
- N.1 warranty.
- N.1 CE certificate.

SAFETY WARNINGS

- ⚠ **HDCstim® shall be used for applications described in the literature. For any other case, it is mandatory to have the approval of the Ethical Committees.**
- ⚠ There are no studies in the literature describing the effects of direct current treatments on pregnant women, or children below 18 years. Do not use in these patients.
- ⚠ Do not use HDCstim® if pacemakers, intracranial electrodes, defibrillators, or any other prosthesis are implanted in the patient.
- ⚠ HDCstim® must be used AFTER the prescription of a stimulation schedule made by the specialized and qualified medical personnel who owns and operates the HDCprog accessory and a valid PIN for authentication procedures.
- ⚠ The remote control of HDCstim® using ISOcable at home can be performed only AFTER the prescription in hospital of the first cycle of treatment (initialization of HDCstim®) by specialized personnel who owns ISOcable and operates with a valid PIN (personal identification number) for authentication procedures.
- ⚠ During HDCstim® programming, inform the healthcare specialist in case you have pacemakers, intracranial electrodes, defibrillators, or any other prosthesis.
- ⚠ HDCstim® must be used only with HDCel electrodes and strictly following the directions in HDCel manual.
- ⚠ **HDCstim® must never be opened or damaged. Only access to the battery compartment is allowed.**
- ⚠ HDCstim® must not be used with rechargeable batteries.
- ⚠ Before using, please check that the device is undamaged.
- ⚠ In the case of malfunction, immediately contact the manufacturer or the distributor.
- ⚠ HDCstim® is not protected against excessive moisture or immersion in liquid. Keep the device far away from liquids. In the case of HDCstim® becoming wet or damp, do not use the device, remove its batteries and immediately contact the manufacturer or the distributor.
- ⚠ Do not touch HDCel while stimulation is ON.
- ⚠ You must use HDCstim® only with the cable included in the kit. The cable shall not be used for other applications from those described in this manual.
- ⚠ The device shall be used according to the education performed by physician during the delivery of the device. Do not use the device differently.
- ⚠ When HDCstim® is turned on, the device will remain on until the user moves the ON/OFF level in the off position.
- ⚠ At home keep always HDCstim® and its accessories away from children in order to avoid the risk of suffocation and strangulation.
- ⚠ Before connecting HDCstim® to your PC please read carefully the user manual of ISOcable.
- ⚠ While being stimulated, do not use any electronic device such as communication or entertainment devices (i.e. GSM/UMTS cellular phones or cordless phones, MP3 players with headset).

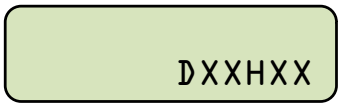
- ⚠ During stimulation, keep all electronic and communication devices (such as GSM/UMTS cellular phones or cordless phones) a minimum distance of 30cm away from the HDCstim® and the person being stimulated
- ⚠ During the use of HDCstim® there might be interference with other instrumentation.
- ⚠ Keep always the stimulator inside the black carrying case: do not use the device without the carrying case.
- ⚠ Do not use HDCstim® and its accessories (including electrodes) if they are damaged, degraded or loosened because the stimulation might be ineffective.

CONDITIONS OF USE

HDCstim must be used in normal temperature and pressure conditions (Temperature range: from +5°C to +40°C; Relative humidity range: from 15% to 90%; Atmospheric pressure range: from 700hPa to 1060hPa).

GLOSSARY

- TRANSCRANIAL DIRECT CURRENT STIMULATION (tDCS): neurophysiological technique consisting in the application of weak direct currents on the skin.
- ANODAL STIMULATION: stimulation in which the active electrode (on the head) is the positive stimulation pole (red connector).
- CATHODAL STIMULATION: stimulation in which the active electrode (on the head) is the negative stimulation pole (black connector).
- MONOCHANNEL STIMULATION: stimulation in which there is one active electrode and one reference.
- BICHANNEL STIMULATION: stimulation in which there are two active electrodes and one reference.
- MINIMUM INTERVAL BETWEEN TWO CONSECUTIVE STIMULATIONS: minimum time that must elapse before the system is allowed to start another stimulation after finishing the current stimulation.
- tDCS TREATMENT: a tDCS treatment consists of a cycle of N stimulations that takes 10-40 minutes and has to be performed daily or 2-3 times a week according to the prescription by the doctor. Time interval between two consecutive stimulation is set during the programmation of the stimulator. If you turn on HDCstim® before this time interval on the display you can see the following code:



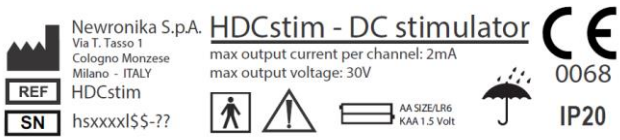
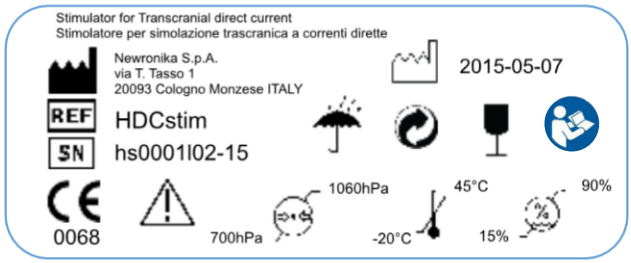
Time to next stimulation

Where DXX is the number of days and HXX is the hours it is necessary to wait before to the next stimulation.

HDCstim® DESCRIPTION

1. LCD screen: indicates the number of programmed stimulations and the time that must elapse (days/hours) before starting a new stimulation. When the stimulation is ON, it indicates the time countdown (minutes/seconds) until the end of the stimulation and the number of failures occurred during the current stimulation.
2. BLUE LED: stimulation ON.
3. GREEN LED: HDCstim® ON.
4. ON switch.
5. Connection to HDCprog or ISOcable.
6. Stimulation ON button.
7. Connection to HDCel.
8. Technical specifications label.
9. Battery compartment.
10. Batteries.
11. Connection cable for electrodes.

LABELING DESCRIPTION

Accessories	Description	Labeling
HDCstim®	Device for providing controlled and programmed treatments for transcranical direct current stimulation	Device Label  External device label 

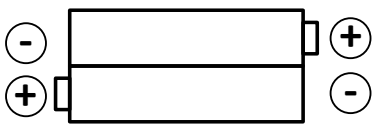
HDCstim® FUNCTIONING

Batteries are supplied with the HDCstim® (2 type AA, 1.5V) and they are already installed in the unit

Inside the device is contained a secondary battery preventing from losing treatment settings during primary battery replacement.

BATTERY INSERTION

Open cover 9 and insert batteries as in the picture.



Close cover 9.

FIRST USE

Put the switch 4 in the ON position. The green led (3) and the LCD (1) are now ON. Because the stimulator is not yet programmed, the LCD (1) will show P00 on the bottom part and the battery charge indicator in the upper part.

Battery charge level indicator

Number of programmed stimulation available

Because no treatments were programmed, **HDCstim® cannot delivery any stimulation.**

HDCstim® PROGRAMMING

Prior to use, HDCstim® **must be programmed by specialized personnel.**

Once programmed, the HDCstim® will be given back to the subject or patient. The first stimulation cannot be started before the interval of time set by the specialized personnel is fully elapsed after the programmation.

Please **follow carefully any instructions given to you by the specialized medical personnel before use.**

HOW TO MAKE A STIMULATION

How to make a stimulation is summarized in the following points.

Read carefully before using HDCstim®.

1. Put the stimulator inside the carrying case and place it in the middle of a table in order to avoid accidental falls of the device during the treatment. The patient must seat down and do not move during the stimulation.
2. Place electrode on the scalp and connect cables according to the tDCS prescription.
3. Connect the red cable to the Ch1 input of cable 11 and the black cable to the central input of cable 11. Insert the jack of cable 11 into the connector 7 of HDCstim®.
4. Switch HDCstim® ON (switch 4).

5. The number of stimulations still available will be displayed on the (which will be different to P00 on the LCD screen)
6. Verify the time interval before next stimulation (button 6, should not be dXXHXX where x is a number different from 0).
7. Press button 6 for 7 seconds (until the line 0000000 appears on the LCD 1).
8. Release button 6 and the blue LED (2) will then flash. 'EL' will appear on the LCD until the current of stimulation reaches 100% of the prescribed intensity and the impedance check finishes.
9. During the stimulation the blue LED (2) is off while the green LED (3) will remain on. The LCD will show a countdown to the end of the stimulation.
10. At the end of the stimulation, the countdown on the LCD screen will display 00:00F00.
11. Switch HDCstim® OFF (switch 4)

THE PROGRAMMED TREATMENT

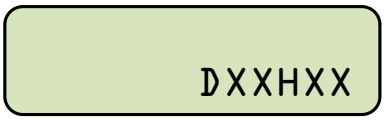
The treatment is prescribed according to a user's needs by specialized personnel. Each treatment consists of a number of programmed stimulations that should be administered, with a minimum time interval elapsing between two consecutive stimulations.

When HDCstim® is switched ON without stimulating, the LCD (1) shows PXX, representing the number of stimulations to be done until the end of the treatment prescribed (for instance, if the prescription was of 5 stimulations, before the first stimulation starts P05 will be shown, whereas, if 2 stimulations have been already done P03 will be shown). In addition, the battery charge level indicator is displayed at the top right corner of the screen.

Battery charge level indicator

Number of programmed stimulation available

By briefly pressing button 6, the time to next stimulation is shown in the form dXXHXX.



Time to next stimulation

For instance, if one stimulation every 2 days was prescribed, and the last stimulation ended on Monday at 12am, the display will show d01H02 if the time is currently 10am on the following Tuesday. Therefore, before the next stimulation, the user should wait 1 day and 2 hours (until Wednesday at 12am).

Stimulation cannot be administered before the time indicated is fully elapsed.

Only in case of use in presence of specialized personnel (inside hospital), the stimulator HDCstim® can be programmed in “Free” mode (*only available in firmware version 5 and later) that allows infinite number of stimulations (N) and without time constraints (interval). In this case the LCD shows:

Where:

x.x is the current intensity (mA); yy is the stimulation duration (minutes)

n is the number of channel (1= monochannel, 2 = bichannel).

CONNECTION TO ELECTRODES HDCel

Use HDCel to administer the treatment.

Read carefully the instructions on HDCel user’s manual before making the connection.

When HDCstim® is OFF, place the electrodes as described in HDCel user’s manual and connect cable 11 to connector 7. Then, connect the electrodes: the cathode must be connected to the black socket and the anodes to the red sockets.

If the stimulation prescribed is monopolar, connect only one anode to one red socket. If the stimulation is bipolar, connect both red cables.

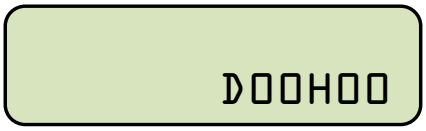
After the connection, switch HDCstim® ON (switch 4). The green LED (3) and the LCD (1) will be ON. The LCD (1) will show the number of stimulations still available.

USE FOR A PROGRAMMED STIMULATION

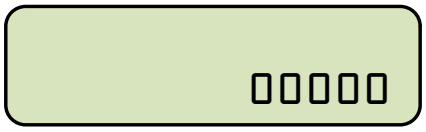
After electrode connection, if the time interval between two consecutive stimulations is fully elapsed, the simulator can be used.

HDCstim® can deliver the stimulation if and only if the minimum time interval between two consecutive stimulations is fully elapsed.

To verify the residual time, press button 6 and verify that DXXHXX is written, where X is a number. Time is described as dXX = days and HXX = hours. The system does not consider minutes and rounds down the time to the last hour. Hence, if the last stimulation was delivered at 2:50pm, and there is set a 2-hours minimum interval, it will be possible to deliver the next stimulation at 4:01 pm. When the minimum interval is fully elapsed, the display will show d00:H00.

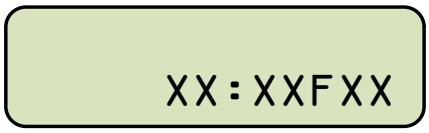


If the time interval is elapsed, press down button 6, without touching HDCel. While pressing down the button, the LCD (1) screen will show a sequence of '0's.



When the sequence of 0 reaches the end of the screen (7 zeros), **release button 6**.

The LCD will then display a countdown of the time remaining before stimulation ends, followed by the letter F and two numbers.



The Letter FXX (failure) is the number of failures occurred during the current stimulation (see next section).

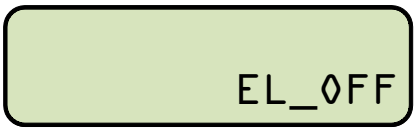
During stimulation, the blue LED (2) will flash each second.

At the end of the stimulation, the blue LED (2) will go OFF. The LCD will display PXX, representing the number of stimulations still available. Turn the HDCstim® OFF by using switch 4, and disconnect the cable from the HDCel (11). Disconnect the HDCel as described in HDCel user's manual.

STIMULATION FAILURE

In case of accidental electrode disconnection, or of dry electrodes (see HDCel user's manual), it is possible that the stimulation will be automatically stopped, because the treatment is no longer compliant with the prescription.

In this case, the blue LED (2) will remain on and the following code will appear on the LCD.



By pressing button 6, the LCD will display an error message and error code. For example, if code 2929 appears, the cause of the stimulation's failure is the excessive impedance detected.

The user should then switch the HDCstim® OFF and verify that:

1. The Electrode's contact with the skin is adequate;
2. The connector (7) is connected correctly;
3. Electrodes are sufficiently wet.

If the problem is one of the above, apply the HDCel again after having wet the electrodes with the physiological solution (as described in the HDCel user's manual). Then, connect to the HDCel to the HDCstim® once more, following the instructions above.

Now it is possible to restart the treatment:

- Switch HDCstim® ON.
- Press down button 6.
- A countdown to the end of the stimulation will be displayed on the LCD (1) followed by the letter F and the number of failure occurred (if it is the first one, it will be F01; if, during the same stimulation, another failure has previously occurred, it will be F02).
- End the stimulation.

It is recommended to restart a failed stimulation as soon as possible, to guarantee an optimal administration of the treatment.

The number of failures per stimulation is stored on the HDCstim® archive, where it can be checked at the end of the treatment by the specialized personnel who made the prescription.

HOW TO ABORT A PROGRAMMED STIMULATION

In the case of stimulation failure seconds from the end of the stimulation, or if for any other reason, you want to end the stimulation session, it is possible to do so by:

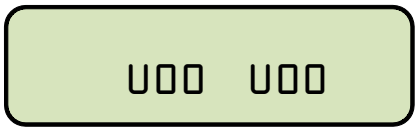
- Switching the HDCstim® to OFF
- And then holding down button 6 and switching the HDCstim® to ON (switch 4).

The LCD (1) will display an updated number of stimulations still available as well as the current stimulation was done. The number of aborted stimulation is stored in the HDCstim® archive and it will be checked at the end of the treatment by the specialized personnel who made the prescription.

STIMULATION IMPEDANCE MONITORING

To check the electric impedance between electrodes, hold down for 1 second the stimulation button (6) during treatment.

The stimulation impedance is indicated in Kohm and it is updated every second.



The first value (on the left) is the impedance measured on channel 1's stimulation and the second (on the right) is the impedance measured on channel 2's.

BATTERY REPLACEMENT

The LCD (1) shows the charge level of the batteries.

Battery charge level indicator

Number of programmed stimulation available

The batteries are fully charged when all the squares are full. When the indicator shows a low level (one to two squares), it is recommended to replace the batteries.

The device cannot be used when the battery level is low (no full squares). The internal test circuit will automatically interrupt the stimulation in the case of a discrepancy between the administered and set treatment, due to discharged batteries.

Two type AA batteries (1.5V) must be used. Do not use rechargeable batteries.

To change the battery follows these steps:

- Switch OFF the stimulator;
- Open the battery case (9) on the back of HDCstim®
- Change the batteries
- Close the battery case (9)

WARNING: If batteries are changed when the HDCstim® is ON then all the treatment memory will be lost.

After 2 minutes of no interaction with the device, the HDCstim® automatically switches OFF. If this occurs, manually switch OFF the HDCstim®, wait for 2 seconds, and switch the HDCstim® on again. The device will then be ready.

HDCstim® MAINTENANCE

The HDCstim® must be kept far away from liquids and heat sources. It must not be used if the unit appears damaged.

To clean the HDCstim®, use a damp cloth. For the display, use one of the cleaners available on market.

At the end of each stimulation, before to put the device into its packaging, please clean and dry the stimulator, the cable and the carrying case.

WARNING: never spray liquid cleaners directly on the HDCstim®. This will invalidate your warranty

HDCstim® does not need to be disinfected or sterilized.

HDCstim® packaging guarantees a safe, reliable transport.

HDCstim® is an electronic device so it does not have an expiration date if the environmental conditions for transport, storage and use are respected.

HDCstim® can be used for a maximum of twenty (20) years, if stored according to the instructions for use and if cleaned as described in the instructions of use. At the end of the service life, it is required to return the device to the manufacturer for performance control and safety verification.

WARNING: do not expose the HDCstim® to low or high temperatures or to thermic shocks. This will invalidate your warranty

ENVIRONMENTAL CONDITIONS OF TRANSPORT, STORAGE AND USE OF HDCstim®

The environmental conditions of transport and storage of HDCstim® depend on its components. The permissible temperature range during storage and transport is between -20°C and +45°C, humidity range between 15% to 90%, and pressure range between 700 and 1060hPa. During the transport and storage, the device must be always kept inside its packaging.

HDCstim® must be used in the following environmental conditions: temperature range is +5°C - +40° C, humidity range is 15%-90% RH and pressure range is 700-1060hPa.

Keep always the stimulator inside the carrying case.

After each use the device has to be keep inside its packaging.

The HDCstim® must be always kept far away from heat sources (radiators, gas, light, heater…), liquids source (tap, sink, tank) or vapour source (electric iron, kettle or nebulizer) and from lint, dust and light (including sunlight) because there might be a damage of the device resulting in loss of stimulation.

CUSTOMER SERVICE/WARRANTIES

For any question and clarifications or in case of malfunction or defect of the product or to report unexpected operation or events please contact immediately the distributor or the manufacturer:

Informative support: info@newronika.com

Technical support: support@newronika.com

All the products are guarantee for 2 years by the manufacturer. Inside the packaging you can find the guarantee form where you can find contacts and address of the manufacturer.

DISPOSAL

In order to receive disposal instructions please contact the manufacturer at

support@newronika.com

Do not throw HDCstim® in generic waste.

Discharged batteries must be disposed appropriately.

HDCstim® Electromagnetic Compliance

HDCstim® shall be able to stimulate the target area based on the stimulation parameters set by HDCprog.

HDCstim devices manufactured by Newronika conform to IEC60601-1-2:2014 Standard for both immunity and emissions. HDCstim is intended to be used in home healthcare environment and in hospital environment by patients under a specific medical prescription.

Nevertheless, special precautions need to be observed:

- The use of accessories and cables other than those specified by Newronika, with the exception of cables sold by Newronika as replacement parts for internal components, may result in increased emission or decreased immunity of the device.
- The medical devices should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the medical device should be observed to verify normal operation in the configuration in which it will be used.
- Refer to further guidance below regarding the EMC environment in which the device should be used.

TABLE 1. Manufacturer Declaration – Electromagnetic emissions HDCstim

Test for emissions	Compliance	Guidelines for electromagnetic environment
CISPR 11: RF emission	Group 1	HDCstim does not use RF energy for its internal functions and for managing system interfaces. RF emissions are extremely reduced and are not likely to cause any interference in nearby electronic equipment.
CISPR 11: RF emission	Class B	HDCstim 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 test and voltage fluctuations / flicker emissions test are not applicable because the HDCstim is classified as an internally powered me equipment.
IEC 61000-3-2: Harmonic emissions	Not Applicable	
IEC 61000-3-3: Voltage fluctuations/ flicker emissions	Not Applicable	

TABLE 2. Manufacturer Declaration – Electromagnetic immunity

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

Test for immunity	Test level IEC 60601-1-2	Compliance level	Guidelines for electromagnetic environment
IEC61000-4-2 (ESD) – Electrostatic Discharges	±2kV, ±4kV, ±8kV, ±15kV on air ±8kV in contact	IEC 60601-1-2 Test Level	The floor should be wood, cement or ceramic tiles. If floors are covered with synthetic material, the relative humidity should be at least 30%.
IEC61000-4-3 – Radiated Electromagnetic Field	10 V/m 80Mhz to 2.7 GHz	IEC 60601-1-2 Test Level	Portable and mobile RF communications equipment should be used no closer to any part of HDCstim, including cables. Minimum distance 30 cm.
IEC61000-4-4 - Fast electric transient/burst	Not Applicable	IEC 60601-1-2 Test Level	Not Applicable because HDCstim is classified as an internally powered me equipment
IEC61000-4-5 – Surges	Not Applicable	IEC 60601-1-2 Test Level	Not Applicable because HDCstim is classified as an internally powered me equipment
IEC61000-4-6 – Conducted disturbances inducted by RF filed	Not Applicable	IEC 60601-1-2 Test Level	Not Applicable because HDCstim is classified as an internally powered me equipment.
IEC61000-4-11 – Voltage dips, short interruptions and voltage variations on power supply input lines	Not Applicable	IEC 60601-1-2 Test Level	Not Applicable because HDCstim is classified as an internally powered me equipment
IEC61000-4-8 – power frequency (50-60Hz) magnetic field	30 A/m	IEC 60601-1-2 Test Level	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. Magnetic fields from common appliances are not expected to affect the device.

TECHNICAL SPECIFICATIONS
HDCstim®

Manufacturer	Newronika S.p.A.
Address	Via Dante 4 20121 Milano - Italia
Operative Lab	Via T. Tasso 1 20093 Cologno Monzese (MI) - Italia
Description	Portable and programmable direct current (DC) simulator.
Intended Use	HDCstim® is part of the HDCkit system for the delivery of direct current stimulation-controlled treatments. HDCstim® is a battery supplied, programmable system for direct current (DC) stimulation.
Sterilization	Not sterile
Latex-Free Product	Yes
Phthalate-free Product	Yes
Disposable or reusable	Reusable
Packaging	Single packaging
Net charge exchange	0
Applied parts	BF type (IEC-EN 60601-1)
Power source	• Internal supply battery: 2 batteries AA/LR6 – 1.5V – KAA. Commercially available battery. Typical operation time: 24 hours, typical service life: 5 years; using different batteries manufacturer might result different values for typical operation time and service life. • Secondary Battery: Renata batteries CR2032. Nominal capacity: 190mAh – current intensity in standard conditions: 0.3 mA – maximum intensity: 3mA.
Stimulator size	11.5cm x 7cm x 2cm
Maximum output voltage	28 VDC per channel
Maximum output current	2.0 mA per channel (2000 uA)
Minimum output current	0.2 mA per channel (200 uA)
Current generator accuracy	< 0.1mA*
Mean impedance check resolution	30 VDC*

Stimulation type	Monochannel stimulation (1 anode and 1 cathode) Bichannel anodal stimulation (2 anodes, 1 cathode)
Stimulation Characteristics	• Current ramp OFF_ON and OFF-ON stimulation: from 0% to 100% linear ramp of 5 -30 seconds. • Maximum number of stimulations: 99. • Treatment duration: 1 to 40 minutes with 1 minute resolution. • Ramp duration: 5 to 30 seconds with 1 second resolution. • Sham duration: 0 to 100% of stimulation duration.
Transport and storage conditions	Temperature range: from -20°C to +45°C Relative humidity range: from 15% to 90% Atmospheric pressure range: from 700hPa to 1060hPa
Device operating conditions	Temperature range: from +5°C to +40°C Relative humidity range: from 15% to 90% Atmospheric pressure range: from 700hPa to 1060hPa

*measured during standard test with 100% battery charge.

** the method for mean impedance estimation is described in the HDCprog manual.

Newronika S.p.A.

Via Dante 4

20121 Milano - Italy

(operative labs: Via T. Tasso 1 - 20093 Cologno Monzese (MI) – Italy)

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www.newronika.com

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