Mediracer NCS User's Manual

South Korea Edition

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GLOSSARY

Averaging

A method where the measured signals are converted to digital format and data from several signals are added together and averaged to improve signal/noise ratio.

Bluetooth

A standardized radio frequency wireless link for data transfer using radio waves.

CTS

Carpal Tunnel Syndrome

CE

The CE marking certifies that a product has met EU consumer safety, health or environmental requirements.

DPN

Diabetic Peripheral Neuropathy

Electrode

Here: A non-invasive disposable surface electrode, type SE-02 or DPN-01 to be used to measure sensory nerve action potentials. The low impedance skin contact is made with conductive adhesive developed for medical use.

EAC (Electrode Activation Code)

Electrode Activation Code ensures that proper Electrode is used during test.

EMC (Electromagnetic Compatibility)

Electromagnetic Compatibility studies the unintentional generation, propagation and reception of electromagnetic energy with reference to the unwanted effects.

EU (European Union)

European Union.

IEC (International Electrotechnical Commission)

International Standards and conformity assessment for government, business and society for all electrical, electronic and related technologies.

Lifetime of Mediracer NCS

The time which Mediracer NCS is designed to operate in normal use. The lifetime for Mediracer NCS is defined to 5 years by the Manufacturer.

Mediracer®

Internationally registered trade mark owned by Mediracer Ltd. Used to identify products belonging to the Mediracer® product family.

MAC (Mediracer Analysis Center)

A software application, which is a part of the products belonging to the Mediracer® product family. Provides support for patient management and real-time graphical visualization of signals etc.

Mediracer Ltd

The manufacturer of the Mediracer® product family.

Mediracer® NCS

A product designed for NCS, belonging to the Mediracer® product family.

Test Device

Handheld test unit (product code ENG-CC-02), part of the Mediracer® NCS product.

NCS (Nerve Conduction Study)

A nerve conduction study (NCS) is a test commonly used to evaluate the function, especially the ability of electrical conduction of the motor and sensory nerves of the human body.

Nerve response

The electric response peak measured with surface Electrodes from the nerve through the skin.

PC

Here: Portable Computer. The acronym "PC" is commonly known as "Personal Computer".

Recording amplifier

An amplifier to amplify the measured signal recorded at the wrist or arm and passed to the Test Device through the interconnecting cable.

Stimulation

Electric stimulation of the nerve with adjustable voltage to activate a Nerve response.

UNE

Ulnar Nerve Entrapment

User's Manual

This document.

1 PRODUCT INFORMATION

1.1 SAFETY INSTRUCTIONS

1.1.1 General

The Mediracer® NCS has been designed and tested according to the IEC-standard 60601-1 (EN 60601/BS 5724). This User's Manual consists of instructions and precautions, which the user must follow to ensure the safe use of the product and to maintain the product in good operating condition.

The Mediracer® NCS can be used by physician, licensed practitioner or personnel trained in basic health care practice according to the order of a physician or a licensed practitioner (See Chapter 1, Product Information and Chapter 3, Operating Instructions).

1.1.2 Test Device

The Test Device has been designed to be used at normal room temperature (+10 C° - +32 C°) and in normal room humidity and atmospheric pressure at the range of normal conditions. The Test Device is not waterproof. Therefore, care should be taken not to let any liquid enter the Test Device. Cleaning according to cleaning instructions is allowed (See Chapter 4, Service and Maintenance). The charger included in the product case is medically approved and can be connected to the mains voltage with or without protective grounding. This can be either medically or non-medically classified.

When the Test Device is not being used it should be stored in the product case.

The Test Device fulfils the demands of EMC-standard IEC 60601-1-2 (See EMC Information). Nevertheless, it is recommended to keep all sources producing strong electromagnetic disturbances far away from the Test Device and the cables when operating the device.

CAUTION

Device or its parts temperature may rise above the temperature limit described in IEC 60601-1 if the ambient temperature is exceeding the normal use temperature. Measuring such high temperatures should be avoided.

CAUTION

During the measurement if patient feels hot or burning sensation on the skin area of electrodes measuring must stopped immediately.

1.1.3 Cyber security

It is always recommended to have proper antimalware and firewall installed on the user operating system. Do not leave MAC software unattended or logged in when you're not using the device. Do not share the personal login credentials to any other persons. For preventing thefts don't store your credentials and leave them visible to other people.

1.2 SYMBOL DEFINITIONS

Symbol	Definition
	BF-type connection. An accurate explanation can be found from the standard IEC 60601-1, paragraph 6.8.1-2.
CE	Item containing this symbol meets all the essential requirements of all applicable EU directives and the applicable conformity assessment procedures have been applied to it. The Mediracer NCS product is CE marked and has been designed according to the directive for medical devices 93/42/EEC.
	Attention, consult accompanying documents.
	Electromagnetic interference may occur in the vicinity of equipment marked with this symbol.
	JQA-symbol. Japan Radio Law Certificate for Radio Frequency devices
	Prescription only - device restricted to use by or on the order of a physician
	Class II medical equipment
	Refer to instruction manual

1.3 INTENDED USE AND OPERATING PRINCIPLE

The Mediracer NCS is intended to measure sensory and motor nerve conduction from peripheral nerves. The measured data can be utilized in evaluating patients suspected of having focal neuropathies. The measured data must be used in the context of other patient information and must be reviewed and interpreted by a physician.

Testing is conducted using disposable, non-invasive single patient use Electrodes designed for the product. The nerve is stimulated with electric pulses and the Nerve responses are recorded. The measured data is automatically transferred to a PC via Bluetooth. The Nerve response data is displayed on the PC screen with

Mediracer Analysis Center (MAC) software and from that data can be found information on the condition of the nerve between the stimulus and recording points.

1.4 CONTRAINDICATIONS

Patient with an implanted electronic device should not be subjected to electrical stimulation unless specialist medical opinion has first been obtained.

Patient with an acute lesion in the hand, e.g. skin laceration, abscessed skin infection or swelling should have the examination done only after the lesions have healed.

Connection of a patient to an h.f. surgical equipment and an electromyograph or evoked response equipment may result in burns at the site of the electrical stimulator of biopotential input part electrodes and possible damage to the electrical stimulator or biological amplifiers.

Operation in proximity of short wave or microwave therapy equipment may produce instability in the electrical stimulator output.

CAUTION

Do not modify or alter the device or its parts. Modifying or altering voids warranty and Mediracer Ltd. will not take any responsibility damages incur.

CAUTION

Use only for nerve conduction studies (e.g. CTS) from the limbs. The Electrodes must not be placed on any other part of the body!

CAUTION

Avoid accidental contact between connected but unused applied parts and other conductive parts including those connected to protective earth!

1.5 CONTENTS OF THE PRODUCT

1.5.1 Basic examination set

Mediracer NCS device and its parts are delivered in intended box.

Figure 1 Examination set

1.5.2 Test Device

The Test Device (ENG-CC-02) is a hand-held unit, which is used for acquiring nerve response data from patients.

The front side of the Test Device contains the operation buttons, which are arrow up, arrow down and OK button. The OK button is used for switching the Test Device on and for proceeding when a dialogue is presented on the display. The arrow buttons are used for adjusting the Stimulation level and for navigation in the system menu.

Above the operation buttons is an LCD display, where the user is able to follow the dialogue and proceed with using the Test Device.

The white light above the display starts blinking, when the Test Device is connected to a charger. When the battery is fully charged, the light is constantly on. When the device is not connected to a charger, the light is off.

Figure 2 The CTS Test Device from the front side

The top side of the Test Device contains the terminals for the Stimulation and recording cables, and a terminal for the Charger.

1.5.3 Stimulation and Recording Cables

The Stimulation cable (SC-01) is used for connecting the Stimulation Electrode to the Test Device through the Stimulation cable terminal.

Figure 3 SC-01 Stimulation Cable

The stimulation cable (SC-02) has a reusable metal stimulation head attached to it.

Figure 4 SC-02 Stimulation cable

The recording cable (CC-01) is used for connecting the recording Electrode to the Test Device through the recording cable terminal, respectively. It is used for measuring **Sensory** Nerve responses.

Figure 5 CC-01 Recording Cable – Sensory

The recording cable (CC-02) is used for connecting the recording Electrode to the Test Device through the recording cable terminal, respectively. It is used for measuring **Motor** Nerve responses

Figure 6 CC-02 Recording Cable - Motor

> CAUTION
>
> Never wrap the cables around the Test Device or twist them with a small radius.

1.5.4 Charger

The Charger (FW8002M/XX) is used for charging the Test Device. The Charger is connected directly to the Test Device through the Charger terminal.

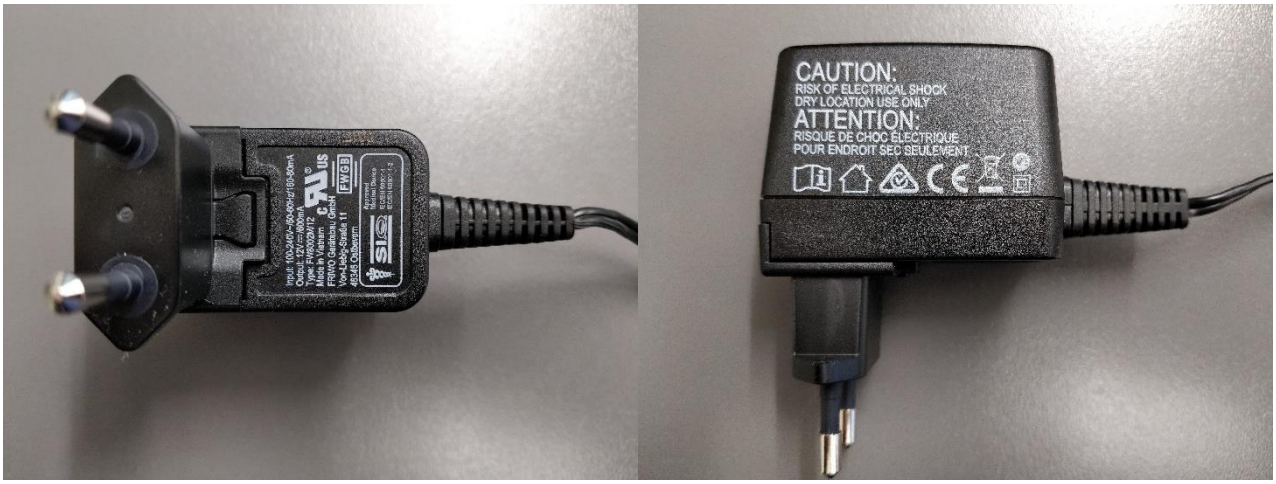


Figure 7 Charger

CAUTION

The device cannot be used while it is charging. Device will automatically shut down when it detects input current via charging connector.

1.5.5 Electrodes

The Electrodes are used for stimulating the nerves and/or for recording Nerve response signals through the skin.

Figure 8 CTS Electrode

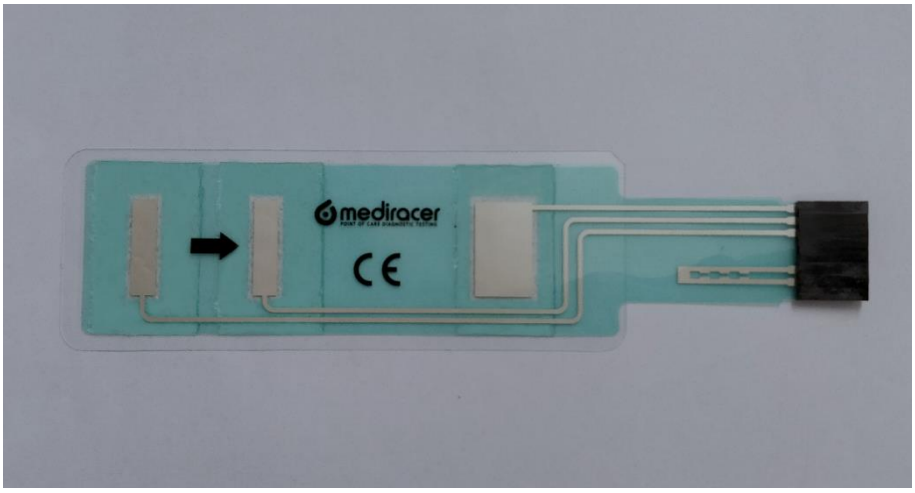


Figure 9 DPN Electrode

The disposable Electrodes are sold separately as sets. There are two types of disposable electrodes available, CTS and DPN for different purposes. Electrode is packed in a sealed pouch to prevent the drying of the conductive adhesive on the Electrodes. When the Electrodes are stored in sealed pouches at room temperature, protected from direct sunlight, they are usable up to the expiration date stated on the pouch label (See Storage and Transportation Conditions).

The Electrode pouch has a label with an Electrode Activation Code (EAC) on it. The EAC is used to ensure the quality of the Electrode and to check that the Electrodes being used are specifically designed for the Test Device. When a new examination file is prepared for tests (See Preparing for an Examination), the MAC software asks for the EAC, which must be read into the file with a bar code reader, or by typing in the 20-character code. The software allows up to 20 tests to be performed on the same patient within 24 hours period, inside the same examination file, with one EAC.

Reusable, a fixed stimulation bar electrode can alternatively be used together with a recording part of the disposable electrode for ulnar nerve entrapment ad CTS motor tests. With the fixed electrode, the metal studs need to be moistened with water or gel for better conduction to locate and stimulate the nerve.

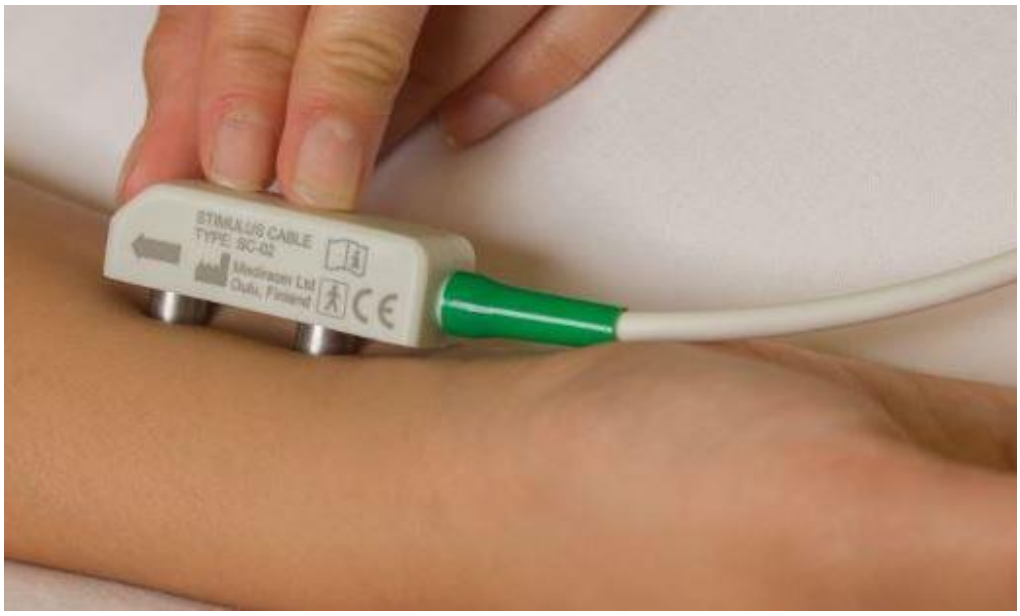


Figure 10 SC-02 Bar electrode

1.5.6 Patient Simulator

The patient simulator (PS-01) is used as the patient to test the device functionality. See more: 4.1 Testing the device.

Figure 11 PS-01 Patient Simulator

1.5.7 Bluetooth Connection

When operating with a PC with an internal Bluetooth device the dongle is not needed. Otherwise a Bluetooth Dongle is supplied with the product for connecting the Test Device to the PC. The wireless connection is automatically created for the devices by the software after first set up.

The device uses Bluetooth 2.1 version Class 2, capable of transmitting at 2.5 mW with a **range** of 10 meters or 33 feet. Bluetooth is backward and forward compatible and can be used with any current Bluetooth versions. Pairing requires authentication and security of wireless Bluetooth transfer is very good level. In case of connection problems check '**Troubleshooting**'

1.5.8 PC

The PC connects with the other parts of the product, i.e. Test Device, Bar Code Reader, and Bluetooth Dongle (in case of non-built-in BT in PC).

1.5.9 Symptoms Questionnaire (Optional)

Special questionnaire templates are provided, which are used to map examination specific symptoms. The mapped symptoms are used together with the results of the NCS for accurate diagnosis.

2 GETTING STARTED

Before the Mediracer® NCS can be used properly, the following steps must be taken.

2.1 SETTING UP THE TEST DEVICE

Charge the battery of the Test Device, as instructed in Charging the Test Device.

2.2 SETTING UP THE PC

Refer to the instructions supplied with the PC on how to set up the PC the first time. For the Mediracer® NCS, perform the following steps:

Make sure the PC is turned on

If laptop is used, make sure it has enough battery or connected to charger

Start 'Mediracer Analysis Center' -software from desktop shortcut

(OPTIONAL) Connect the Bar Code Reader in one of the USB terminals of the PC.

(OPTIONAL)Connect the Bluetooth Dongle in one of the USB terminals of the PC if the PC does not have a built-in Bluetooth device.

CAUTION

The PC is not a medical approved device; therefore, it must not be used inside the patient treatment area. The patient treatment area is approximately 1.5 m of free space around the patient (See the standard IEC 60601-1-1 for a more detailed explanation).

2.3 PREPARING THE ENVIRONMENT

Eliminate the electrical interference coming from surroundings. Keep away from all devices which can cause electromagnetic disturbances during examination. For example, a refrigerator, a heater panel, or a mains cables.

CAUTION

For accurate results, the mains voltage cable of the examination table (if within treatment area) should be disconnected before the examination.

The software of the Test Device eliminates the effects of random external disturbances by discarding the samples with excess noise from the averaged Nerve response. High electrical disturbance in the environment can cause too few samples to be averaged and the low sample count can be seen on the data display.

Every test situation is different and every examination room has different electrical disturbances. Therefore, attention should be paid on eliminating any sources of electrical interference to achieve the best quality of signals with the Test Device. Due to unpredictable nature of electromagnetic interference, sometimes you may need to change the location in the room to get the noise level down. When the potential sources of electromagnetic interference are eliminated, you can move to the next step, and start preparing the patient for the examination.

3 OPERATING INSTRUCTIONS

3.1 PREPARING FOR AN EXAMINATION

3.1.1 Preparing the Patient

Prepare the patient's measuring area for nerve conduction study in order to get the best possible contact for the Electrodes. The electrode placement area must be cleaned properly with pure alcohol or preparation gel. If preparation gel is used it must be removed and area cleaned well. For CTS testing, normal hand washing is usually enough but if hand lotion or disinfectant has been used, the hand washing must be done more thoroughly. If the noise level is too high due to poor skin contact, clean the electrode placement area by wiping the skin with alcohol or other medical grade cleaning agent, and dry out to get a better contact for the Electrodes.

If the patient has damaged or blistered skin where the Electrodes should be placed, consult the doctor before starting the preparations.

3.1.2 Preparing a Patient File

If this is the patient's first NCS examination at the current location, you need to create a new patient file into MAC. Otherwise, you may open the existing patient file.

3.1.3 Preparing an Examination File

Before any tests can be done, a new examination file needs to be created.

To start the test, activation code is required. At this point, you can either use the bar code reader (See Bar Code Reader) or manually type the code to field. The EAC is found on the Electrode pouch label.

You may use the same Electrode for the same patient during 24 hours for the same examination. After that, the EAC will expire and you need to use a new Electrode. The used EAC works only for the patient for whom it was initially activated.

A good Electrode adhesive is moist and has a good adherence on the skin. A fresh Electrode and proper preparation of the skin are the key elements for a high-quality test.

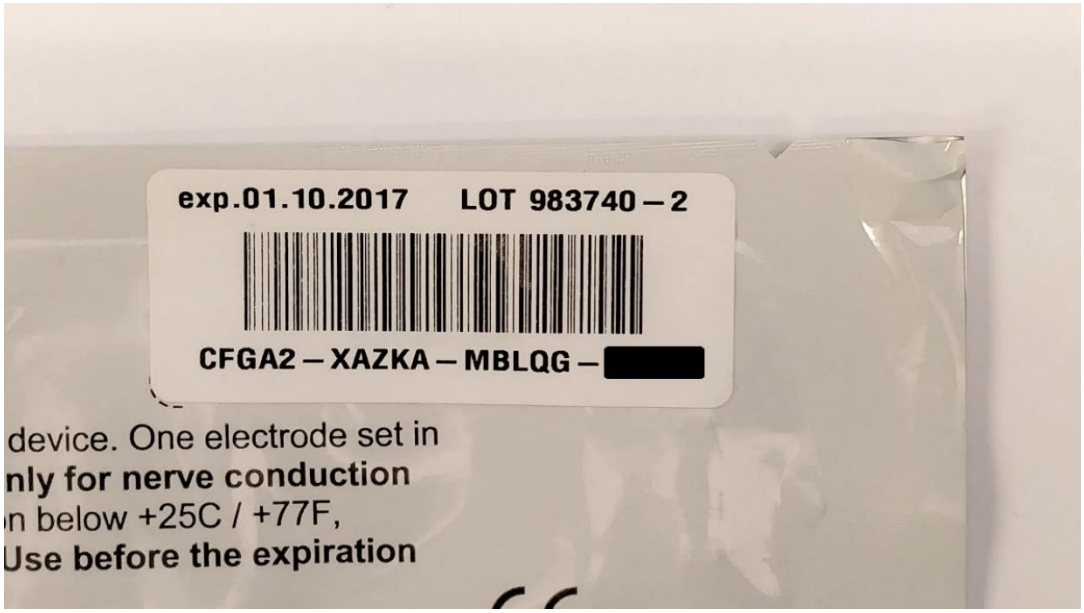


Figure 12 Activation code

CAUTION

Check that the expiration date has not passed and that the pouch is undamaged before opening it and using the Electrodes. A damaged pouch will most likely contain a dried Electrode.

3.2 PERFORMING THE EXAMINATION

Perform the following steps for each nerve conduction study.

3.2.1 Preparing a Test File

See the instructions for creating a new test file.

3.2.2 Attaching the Electrodes

Depending on the type of examination being done, see the electrode positioning instructions.

CAUTION

The disposable Electrodes are for single patient use. Do not reuse the disposable Electrodes. To prevent cross infection or contamination do not move the Electrode from one patient to another. Once used dispose of the Electrode according to your local procedure for waste disposal.

CAUTION

Take care of the Test Device before connecting the Electrodes to the cable terminals to prevent the Test Device dropping on the floor. The connecting operation occupies both hands of the operator.

3.2.3 Performing the Test

Please refer to the step by step instructions

3.2.4 Device display explanation

Text on display	Explanation
Start test?	Displayed when the device is ready for a test
Low battery	The battery level is too low for a test. For continuing, recharge the battery.
Check cable	The recording cable is of wrong type or not connected properly. Check the cable connection to continue.
Set level	The device is sending stimulation pulses with the displayed level (0-100). Level can be adjusted with the arrow keys.
Completed!	The device has completed a test.

CAUTION

Establishing the Bluetooth connection takes some time and the test signal should be visible on the PC screen in 10 to 30 seconds, if not increase stimulation level by one and check back screen.

To minimize the noise, the patient must be away from sources of electrical interference such as lifts and mains voltage cables. The Electrode contacts must also be checked, since poor contact increases noise.

It is essential to get the patient fully relaxed during the nerve conduction study to minimize muscle tension related disturbances, which are the most common source of noise.

Continuous muscle tension effects the test results more than small random movements, because the Test Device eliminates the Nerve responses with excessive noise level from the Averaging.

If nothing helps to get the noise level down, test the whole system with the test module as described in Testing the System. A broken cable or broken Electrode contact can cause similar type problems.

3.2.5 Checking the Test Result

Take a look at the results to confirm the quality of the test. First observe the overall form of the curve, if it matches a typical result from the corresponding target. Furthermore, check the "Samples" value (20 out of 64 is adequate in most cases, but the cursor placing is proposed by the software only when 32 or more samples are averaged). If the quality of the test is not good enough, perform a new test on the same target (return to Preparing a Test File). Otherwise, continue with the examination. Typical result from ring finger

Figure 13 Test View

3.3 AFTER THE EXAMINATION

When needed tests have been done to the patient:

Disconnect the Electrodes from the Electrode terminals.

Remove the Electrodes from patient. Adhesive, which may sometimes remain on the skin, is water soluble and therefore easy to remove.

Dispose of the used Electrodes according to local regulations and instructions.

Connect the Test Device into the charger for next tests.

4 APPLICATIONS

Mediracer NCS -test device allows user to perform different types of nerve conduction tests. Possible examination sets are listed in the software and classified as their type.

Sensory nerve conduction studies:

CTS-S

UNE-S

Median Plantar-S

Radial-S

Sural-S

Median-S

Ulnar-S

Superficial Peroneal-S

Motor nerve conduction studies:

CTS-M

Median-M

Ulnar-M

Tibial-M

Deep Peroneal-M

CTS-S and UNE-S are Mediracer NCS specific methods and easy to perform. Some of the applications may require long term training or expert level of knowledge in the area of neurology, therefore no specific guidance is provided for those.

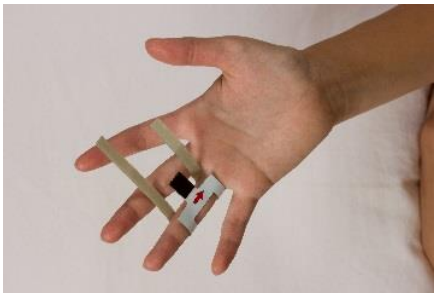
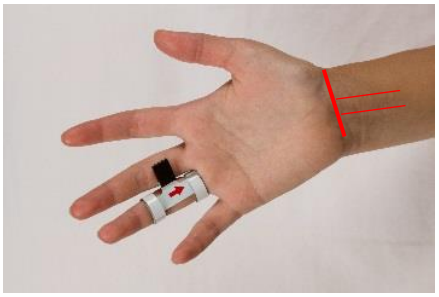
4.1 TEST PROCEDURES

4.1.1 CTS-S

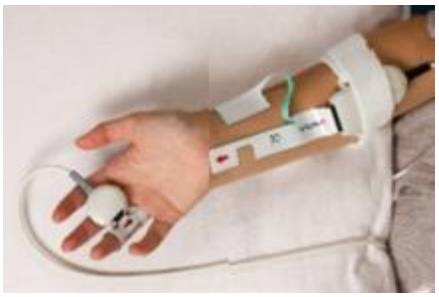
Sensory nerve peak latency comparison method

Both median and ulnar sensory nerves are studied to examine the difference in peak latencies. The test result is considered abnormal if the time difference is more than 0,7 ms. The method is effective in early detection of the carpal tunnel syndrome.

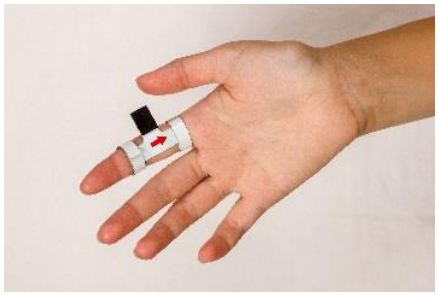
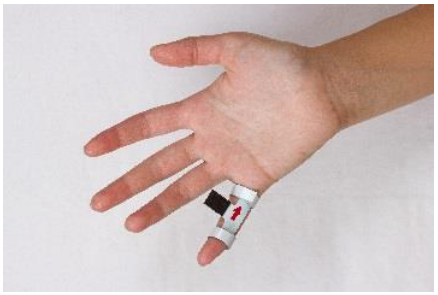
Attach the stimulation electrode in the ring finger, and locate the distal fold at the wrist.

Attach the recording electrode on the wrist, and attach the cables with electrodes and the device.

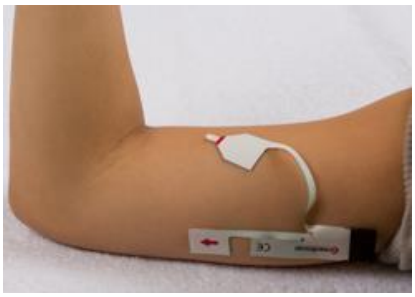
Find the optimal stimulation level (supramaximal stimulus is usually the best) and start the test. Repeat the test from index and little finger.

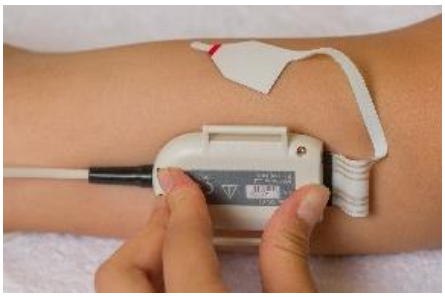
4.1.2 UNE-S

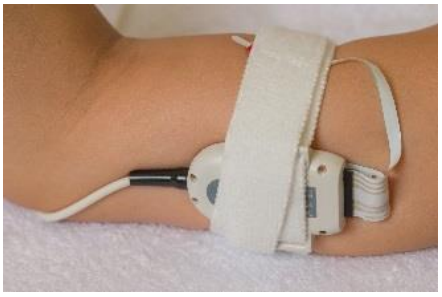
Ulnar nerve entrapment at the elbow (mixed nerve conduction study). Median-ulnar peak latency comparison method.

Measure 10 cm from the medial epicondyle of the humerus to the area between the biceps and the triceps. Then attach the recording electrode onto that position, with the arrow pointing towards the elbow. Attach the grounding part of the electrode to the muscle.



Connect the cable with the electrode and turn it over on the electrode. Wrap the stretch band tightly over the electrode and around the arm.



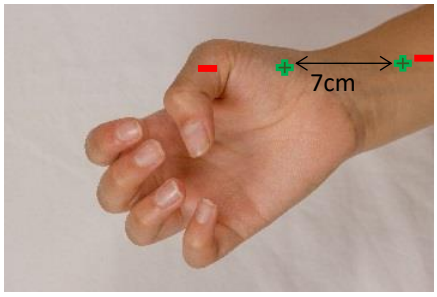


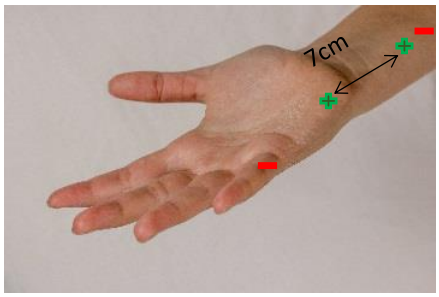
Moisten the metal studs of the stimulation electrode, raise the stimulation level and locate the median nerve. Increase the stimulus and once the thumb shows motor movement check the screen for clear peak. Stimulus can be raised for the supramaximal and start the testing. Moving on to ulnar nerve, check that the distance is same as with the median nerve. Moisten the metal studs and locate the ulnar nerve. Increase the stimulus and once the motor movement shows up check the screen for a clear peak. Again, raise the stimulus towards to supramaximal and start the test.

4.1.3 CTS-M

Median-Ulnar Distal Motor Latency Comparison for Carpal Tunnel Syndrome (CTS-M)

Locate the measuring points for the median and ulnar nerve

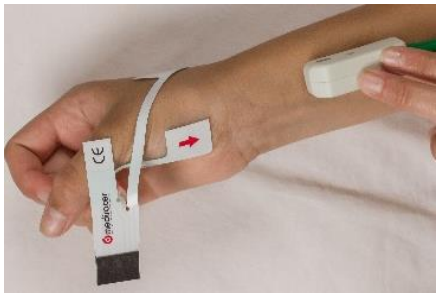


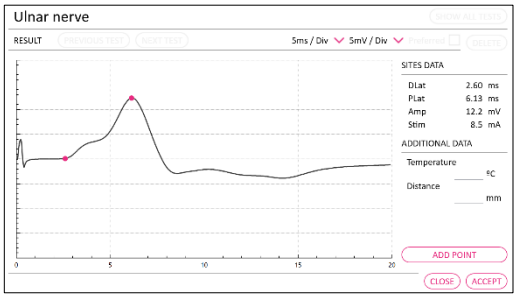


Place the recording electrode on the thickest part on the thumb muscle towards the wrist, with the short part (reference) to the outer side of the thumb, between the second and third joint. Then place the grounding part of electrode on the back side of the hand.

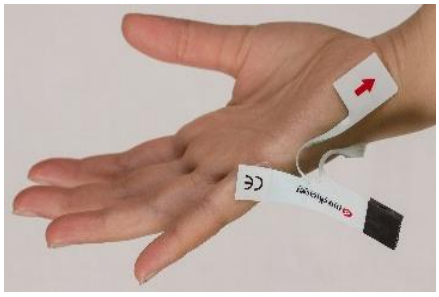
Attach the cables (SC-02 and CC-02) and then moisten the metal studs of the stimulation electrode with water or conductive gel.

Raise the stimulation level to 10-15 and start locating the median nerve. When found increase the stimulus until clear motoric movement of the thumb (dig I, II, III) is present. That response should be also visible on the software. When supramaximal stimulus is reached and clear peak formed to graph, the test can be started, and aborted after about 1 sec into the test. 1-2 samples are fine because motor testing does not require averaging.

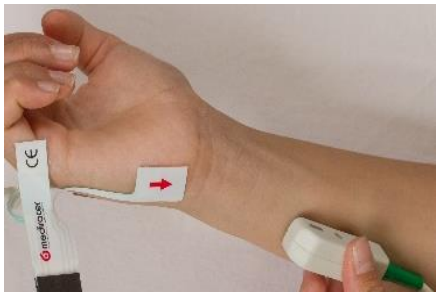


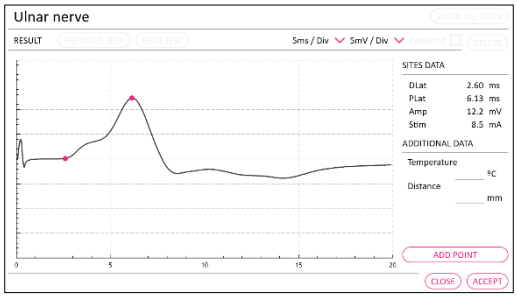


Then move to ulnar nerve. Place the recording electrode on the thickest part of the little finger side muscle towards the wrist with the short part (reference) to the outer side of the little finger, between the first and second joint. Place the grounding part of the electrode on the back side of the hand.



Again, moisten the metal parts of the stimulation electrode with water or conductive gel and start locating the ulnar nerve with the stimulus range of 10-15. As ulnar nerve is found, stimulus increased, the digits V, IV (whole hand) will show motoric movement, The test can be performed similarly as for the median nerve by stopping the recording after 1 sec once clear peak is formed.

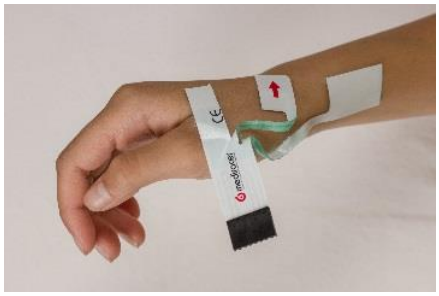




4.1.4 Radial-S

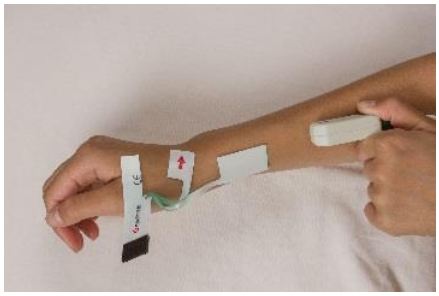
Radial sensory nerve conduction study

Locate the anatomical snuffbox between the tendons of the thumb. Place the red arrow of the recording electrode on the location and the reference part on top of the hand. Grounding part can be along the wrist.

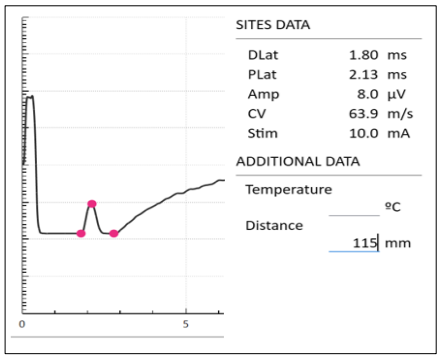
Position the hand so that the radial nerve is upwards. Measure 10-12cm from the recording electrode along the radial nerve and mark the place.


Moisten the metal studs of the stimulation electrode with water or conductive gel. Increase the stimulus and place the electrode on the marked spot. Locate the best measuring point by moving the electrode. Check the screen for a clear peak.

Fill in the measured distance between stimulation and recording point to calculate the conduction velocity. The test is antidromic, by recording from the wrist and stimulating 10 – 12 cm along the radial nerve. The conduction velocity calculation is done as follows:

Distance (mm) ÷ Latency (ms) = Conduction velocity (m/s)

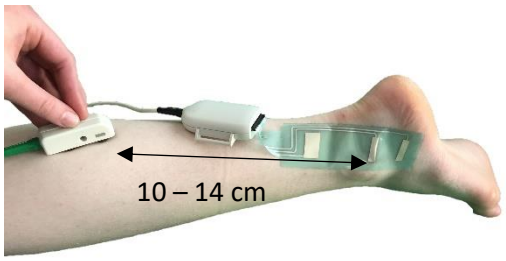


4.1.5 Sural-S

Sensory nerve peak latency method

Sural sensory nerve is studied to examine the peak latency and conduction velocity for Sural Nerve. The method is effective in early detection of the diabetic peripheral neuropathy, with trend monitoring over time.

Attach the registering electrode under lateral malleolus and connect the cable. Attach the cables with electrodes and device. Measure 10 – 14 cm from registering to stimulating point.



Use SC-02 stimulation electrode for stimulation. Moisten the metal studs of the stimulation electrode with water or conductive gel. Increase the stimulus, place the electrode on the calf and locate the sural nerve.

Fill in the measured distance between stimulation and recording point to calculate the conduction velocity. The test is antidromic, by recording from the ankle and stimulating 10 – 14 cm along the sural nerve. The conduction velocity calculation is done as follows:

Distance (mm) ÷ Latency (ms) = Conduction velocity (m/s)

5 SERVICE AND MAINTENANCE

5.1 CLEANING THE PRODUCT

When needed, clean the Test Device and the cables as described below:

Turn off the power from the Test Device and disconnect the charger if connected.

Use clean tissue or cotton, slightly moistened with isopropanol or alcohol. You can also use the cleaning tissues used to clean your PC display and keyboard. The adhesive from Electrodes may attach to the Test Device but is easily removed with water moistened tissue.

Take care no water or other liquids enter inside the Test Device or connectors. Do not use a wet tissue.

Clean the cables with water or mild dish washing detergent. Do not use solvents because those may damage the cables.

Dry the surfaces with dry tissue when needed.

CAUTION

Do not use any solvent, silicone based nor abrasive cleaning agent. Be sure no liquid enters inside the Test Device through the openings nor connectors during the cleaning process.

5.2 TESTING THE SYSTEM

To check the functionality of the whole test system, connect the test module (PS-01) to the Test Device, between the Electrode terminals (SC-01 and CC-01). Perform a test normally, as with patient. To avoid using new EAC code you can perform the test adding a new test to a valid examination file of a patient and delete the test afterwards. This test should be repeated half-yearly to ensure proper operation of the system.

Figure 14 PS-01 Patient Simulator

Figure 15 PS-01 Attached to cables

Use Stimulation level 50. The Test Device should give two peaks at 2.4 ms and 3.8 ms. The peak values should be 2.4 ms +/- 0.2 ms and 3.8 ms +/- 0.2 ms and the difference between the peaks should be 1.4 ms +/- 0.2 ms.

Figure 16 Test result of functionality testing

5.3 CHARGING THE TEST DEVICE

Charge the Test Device on regular basis, once a month when not used. In daily use, keep the Test Device connected to charger when not in use (if possible) to ensure the maximum capacity of the batteries for carrying out examinations.

CAUTION

Use only the medical approved charger delivered with Mediracer® NCS for charging. Use of another type of charger may cause hazard.

The Test Device has automatic battery test. If Low battery is displayed, connect the charger at least for 2 hours before starting a test. When the device is being charged, the white LED flashes. It is suggested to keep the Test Device connected to charger whenever not used. The automatic charging control cuts off the power when the battery is fully loaded. The Charger connector is located between the cable connectors.

Figure 17 Charging device

CAUTION

The device cannot be used while it is charging. Device will automatically shut down when it detects input current via charging connector.

CAUTION

In clinical use, it is recommended to keep the battery fully charged during the day.

5.4 REPLACING THE BATTERY

When it is time to change the battery (normally after 2 to 3 years), follow these steps:

1. Open the two screws and remove the battery cover
2. Lift the battery slightly
3. Pull out the wire terminal from the connector on the circuit board
4. Connect a new battery wire terminal to the connector on the circuit board. The terminal fits to the connector only one way - don't use force
5. Place the battery on its place
6. Place the wire like it is in the picture below and ensure it doesn't get pinched below the battery cover
7. Reassemble the battery cover
8. Charge the battery at least 10 hours at the first time.

Figure 18 Remove only two screws from battery casing

CAUTION

Do not loosen or dismount other screws than the two middle screws holding the battery cover! Always use a proper tool (Phillips 01).

CAUTION

Change of battery is recommended to be performed only by a professional or expert in technology. Non-trained personnel are required to state hazards that may occur during repairs i.e. excessive temperatures, fires and explosion.

Figure 19 Battery casing

> CAUTION
>
> Use only the battery designed for the Test Device, Mediracer® Battery 2350006.

5.5 REPLACING THE STIMULATION AND RECORDING CABLES

The cable connectors make it possible to replace the cables with new ones when needed. Both cables have a shielded metallic connector which only fits into its dedicated terminal at the Test Device, though they have the same outlook and size. Recording cable has a 5-pin connector, and the stimulating cable has a 2-pin connector.

Figure 20 Detaching/attaching cable

CAUTION

Do not turn the outer shield of connector to avoid taking the connector to pieces. Never pull from the cables nor twist them too tight. Though no damage may be apparent for the first time, the fatigue stress will damage the cable in the long-term.

CAUTION

Always check before connecting the cables that you are connecting the right connector pair together. The black cable collar on the Electrode cable and black ring at the Test Device socket determines the correct pair. The connection position is indicated with a red dot and a red stripe at the back side of the connectors. The marks must be aligned before the Electrode cable connector is joined to the connector at the Test Device.

5.6 DISCARDING THE PRODUCT AND THE COMPONENTS

Following components demand special treatment while discarding:

Battery

The printed circuit board of Test Device

Follow local regulations and instructions for discarding the Mediracer® NCS. You may also send the product as whole to a licensed reseller or to the manufacturer for discarding.

5.7 OTHER SERVICES

Any other service operations may not be done by the user. If there are any problems with the product, contact your reseller.

6 SPECIFICATIONS

6.1 TECHNICAL DATA

Table 1 General Data

Item	Explanation
Battery	IEC Battery 2350006. (5 x 1.2V) Use of any other battery is not allowed.
Device class	Class IIa: Active device for diagnostics. (Rule 10), Type BF applied part.
Service	See Chapter 4, Service and Maintenance
Protection against electric shocks	Never connect the Test Device directly to heart through a pacemaker and direct contact to the wires of pacemaker or other type of implants should be carefully avoided.
Protection against water	IP20: Closed device without any shields to prevent water entering inside the device. Use in dry room only.
Protection for flammable gases	The Test Device is not rated for use in the presence of flammable gases or mixtures.
Operating principle	Continuous operation (automatic power turn off 5 minutes after the last push of buttons).
Electrode cable connector types	Lemo, 2- and 5- pins, customized.
Test signal for the test circuit.	Generated with the test module PS-01 delivered in the product case with Mediracer® NCS.
Resolution and sampling frequency	10 bit / 14.6 kHz
Display ranges	Voltage range +/- 20µV, latency acquisition range 0-10 ms
Averaging	max 64 Nerve responses
Data transfer	Bluetooth version 2.0 low power, class 2
Rating	220 V~, 60 Hz, 5 VA

Table 2 Recording Amplifier

Item	Explanation
Input impedance	Balanced: >100 MΩ, Common mode: > 50 MΩ / 25 pF
Typical noise level (RMS)	1.0 µV (2 Hz - 10 kHz) input shorted
Common Mode Rejection Ratio	CMRR typically 95…100dB at 1 kHz
Filters	High pass 20 Hz, low pass 3 kHz
DC components in patient connection	Recording amplifier does not contain any DC component

Table 3 Stimulator

Item	Explanation
Stimulator max voltage	163 V

Stimulator max current / 1kΩ	50 mA, adjustment in 0.5 mA steps
Stimulator max energy / 1kΩ	10µC
Stimulation pulse dual phase, rectangular	0.2 ms DC with negative start
Stimulator frequency	2 Hz

Table 4 Stimulus pulse voltage and energy with 1kΩ load according to product test limits

Level %	Min V	Mid V	Max V	Min mJ	Mid mJ	Max mJ
0	0	**0**	<1	0	**0**	0
10	5	**6**	7	0.005	**0.0072**	0.0098
20	9.5	**11**	12.5	0.018	**0.024**	0.03125
30	14.5	**16.5**	18.5	0.042	**0.054**	0.06845
40	19.5	**22**	24.5	0.076	**0.097**	0.12005
50	25	**27.5**	30	0.13	**0.15**	0.18
60	31	**33.5**	36	0.19	**0.22**	0.2592
70	36.5	**39**	41.5	0.27	**0.30**	0.34445
80	42.5	**45**	47.5	0.36	**0.41**	0.45125
90	48	**50.5**	53	0.46	**0.51**	0.56
100	52	**55**	58	0.54	**0.61**	0.67

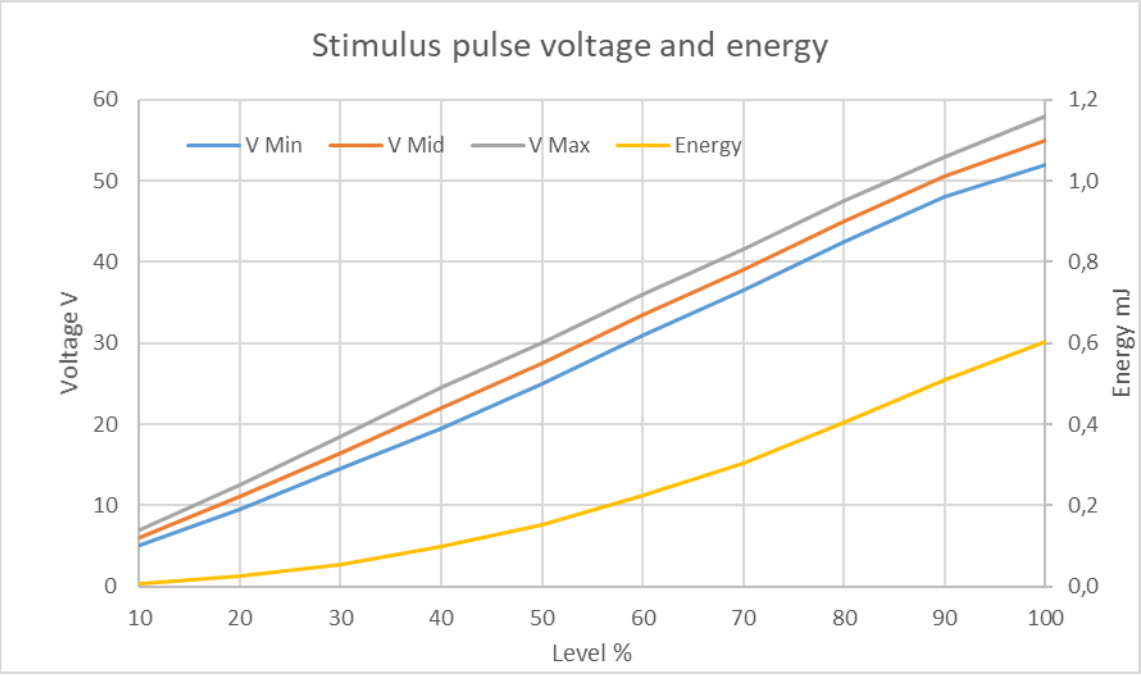


Figure 21 Stimulus voltage and energy graph

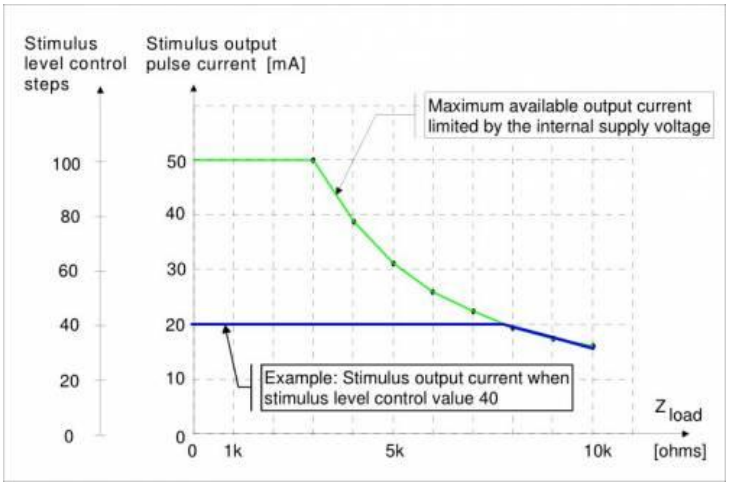
Table 5 Electrode

Item	Explanation
Electrode type	Disposable, single patient use, non-invasive surface Electrode with conductive adhesive
Base material	Polyester film 3 mils (0.075 mm)
Leads and contact areas on Electrodes	Silver paste, printed on film
Conductive adhesive	Conductive hydrogel for medical use ISO 10993-1 approved

The patient connection in the Stimulus Cable contains a DC component in normal use due to the nature of the stimulus signal, which is unipolar.

The level of the DC component depends on the stimulus level and varies from the value below 10 uA to a value 30 uA when the stimulus level control varies from value 0 to 100 and a resistive 1 kΩ load impedance is used.

This DC component is not expected to provoke skin reactions or burns in normal use



6.2 EMC INFORMATION

The Test Device meets the requirements of the EMC-standard IEC 60601-1-2 for Medical electrical equipment. Medical electrical equipment need special precautions regarding EMC and need to be installed and put into service according to the EMC information provided here.

Portable and mobile RF communications equipment can affect the Test Device. The tables presented in this section are a guide to minimize or prevent such interferences.

The use of Electrodes or cables other than those specified by Mediracer Ltd, with the exception of Electrodes and cables sold by Mediracer Ltd as replacement parts, may result in increased emissions or decreased immunity of the Test Device.

6.2.1 Guidance and manufacturer's declaration – electromagnetic emissions

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

Table 6 Emissions

Emission test	**Compliance level**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Test Device 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 Test 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
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

6.2.2 Guidance and manufacturer's declaration – electromagnetic immunity

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

Table 7 Immunity

Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/-6 kV contact +/-8 kV air	+/-6 kV contact +/-8 kV 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 transient/burst IEC 61000-4-4		Not applicable	
Surge IEC 61000-4-5		Not applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11		Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	180 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

6.2.3 Guidance and manufacturer's declaration - electromagnetic immunity in RF-field

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

Table 8 Immunity in RF Field

Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Test Device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = 1.2√P from 80 MHz to 800 MHz, and d = 2.3√P from 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

CAUTION

At 80 MHz and 800 MHz, the higher frequency range applies.

CAUTION

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

CAUTION

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 Test Device is used exceeds the applicable RF compliance level above, the Test Device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Test Device.

6.2.4 Recommended separation distances between portable and mobile RF communications equipment and the Test Device

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

Table 9 Separation Distances

Rated maximum output power of transmitter W			
	150 kI-Iz to 80 MHz	**80 MHz to 800 MHz d = 1.2√P**	**800 MHz to 2.5 GHz d = 2.3√P**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

CAUTION

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated 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.

CAUTION

At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

CAUTION

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

7 MANUFACTURER IN RESPONSE

The manufacturer of Mediracer® NCS is:

Mediracer Ltd
Kasarmintie 13 D
FI-90130
Oulu
Finland
info@mediracer.com

For accurate contact information, see the manufacturer's website at www.mediracer.com.

8 STORAGE AND TRANSPORTATION CONDITIONS

The Test Device with accessories is packed in a product case which is closed in a plastic bag. The product case is packed in a carton.

During transportation, the cartons should be kept dry and it is not allowed to place loads on them. The humidity should be less than 95% and the temperature from 0°F to 100°F (-18°C to 38°C).

A long-term storage should be done in warm and dry place without exposing to direct sun light. Temperature should be 50°F to 80°F (10°C to 26°C) and humidity below 80% and atmospheric pressure at the range of normal conditions. The product must be kept in the original package during storage.

9 USER INTERFACE STRUCTURE

The following flow charts represent the structure of the user interface implemented in the Test Device.

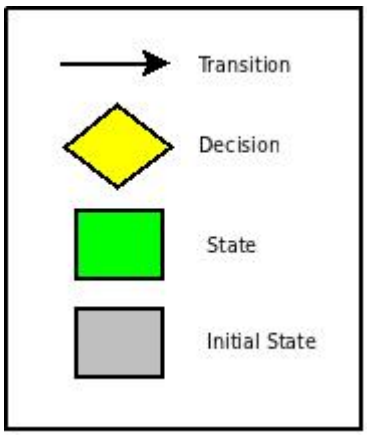


Figure 22 Key to symbols

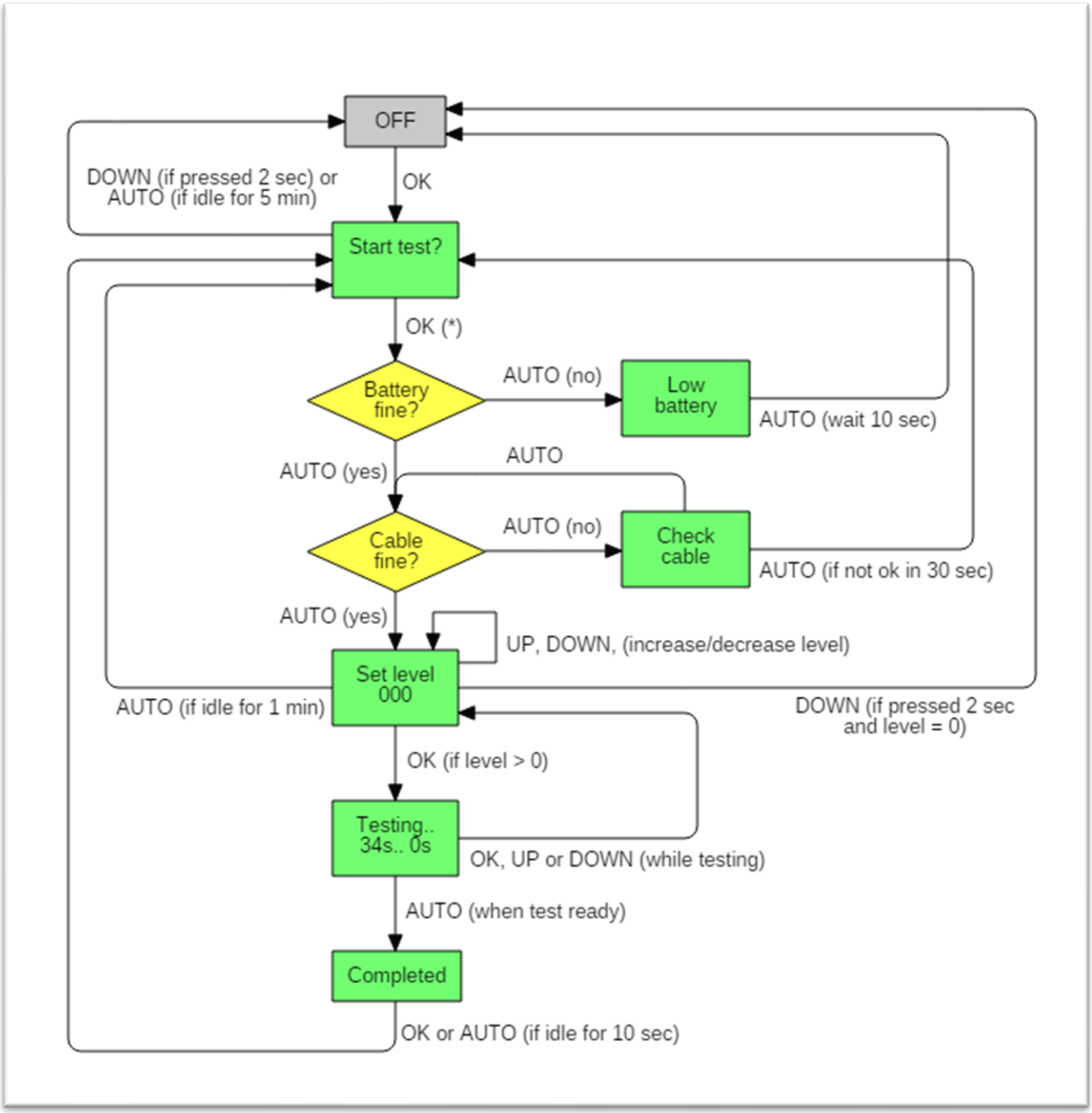


Figure 23 Main functions

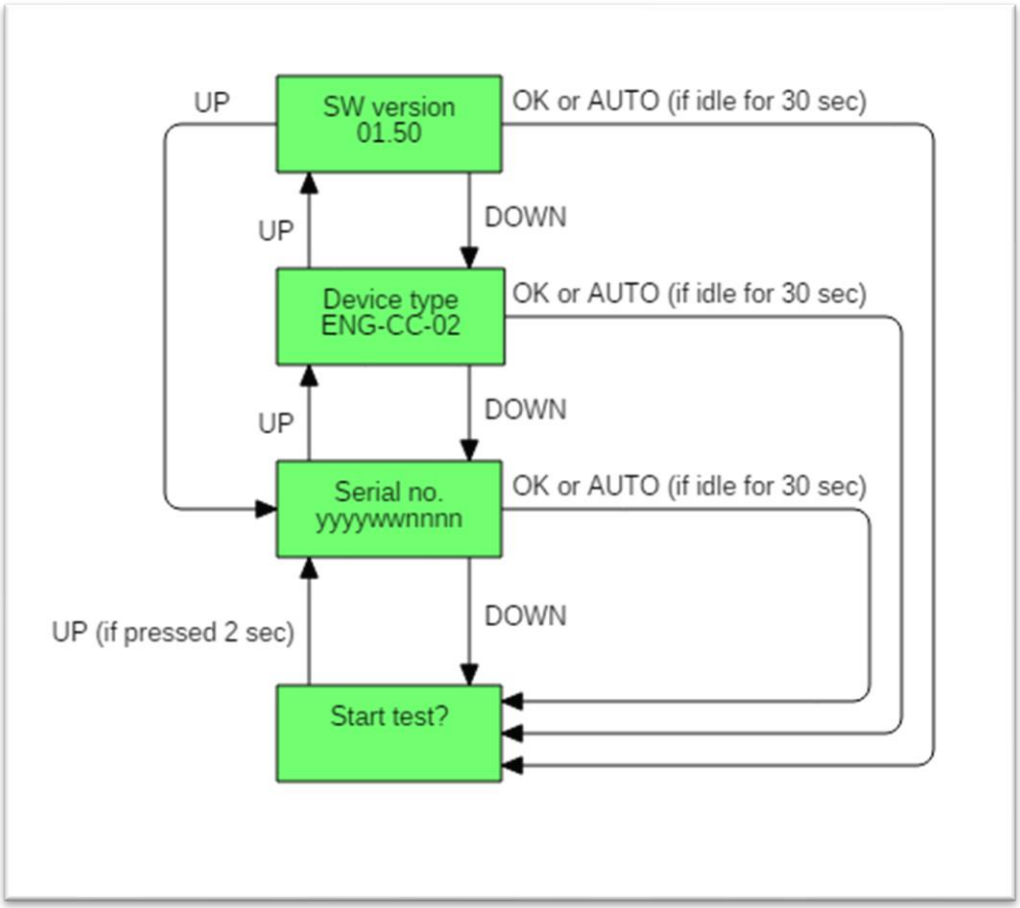


Figure 24 System functions

10 TROUBLESHOOTING

1. **Unable connect the device from Mediracer Analysis Center**

   Make sure device is turned ON when trying to connect the device first time. Check that your pc is equipped with Bluetooth chip or external dongle.

2. **Device won't power on**

   Fully charge the device until the indicator led light stays on.

3. **Noise during the measurement**

   Try moving the device away from other electrical devices and big metal objects. Sometimes noise also occur when patient is not relaxed enough and this will add muscle generated noise, in this case try adjusting the patient to more relaxed position.

4. **Unable to log in Mediracer Analysis Center**

   Make sure you are using correct credentials to login. If you can login with general support user:
   ID: support
   Password: support123
   Please contact manufacturer in case for resetting your password.

   If your problem still persists or you're having different problem, contact your IT personnel or local supplier or directly to manufacturer.

11 CHANGE HISTORY

Date	Revision	Page(s)	CR	Changes
2020-11-03	1	-	-	Document created from the basis of original User's Manual. Added 'Applications'