NerveCheck Master

Quick User's Guide

Phi Med
EUROPE

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This is a Quick User's Guide. The information in this user's guide is subject to change without prior notice.

For the full operating User's Manual refer to website below.

For more information, contact:

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Dear Customer,

Thank you for choosing one of our products.

Please read this Quick User's Guide for use carefully and keep it for later use.

For more information concerning this product, please visit our website or contact us.

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1. Disclaimer

Phi Med Europe is not liable for the use of this document if any unauthorized change has been made to either its content or format.

This document has been drafted to closely ensure that the information it contains is correct. However, Phi Med Europe assumes no responsibility for errors, inaccuracies or omissions contained herein. Phi Med Europe reserves the right to change the contents of this manual without prior notice for improving both reliability, functionality, security, efficiency, aesthetics and design. Phi Med Europe reserves the right to make changes to any part or all NerveCheck software without obligation to notify changes to any person or entity.

This manual is provided without warranty of any kind, either express or implied, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.

Before to attempt to work with the equipment strictly read and observe all warning, contraindications and notes of this equipment.

2. Unpacking and Installation of NerveCheck Master

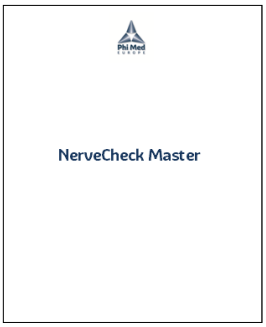
2.1. Unpacking

After receiving the device check that the following accessories are present.

NerveCheck Master Equipment

(Main unit + Remote-control)

Quick User's Guide for NerveCheck Master



Charger

Standard USB-mini USB charging cable

Memory stick NerveCheck Master

Feeder pins

3. Contraindications. Warning. Notes.

Before to attempt to work with the equipment strictly read and observe all contraindications, warning, notes of this equipment.

CONTRAINDICATIONS

- Do not use the device on open wounds or mucous membranes.
- Do not use the device in patient under psychiatric medical treatment or pathological cognitive status.
- Do not use the device on children under the age of 15 years old.
- Not indicated for pregnant and nursing women.
- Do not use in people with pacemakers due to electromagnetic disturbances. Likewise, any medical implantation instrument that contains an RF system, if implanted, makes the application of this study not possible and in the case of being external (i.e. insulin pump), the development of the test must be done without the operation of this instrument.

WARNING

- Side-effect: Possible local erythema of the skin may occur.

WARNINGS REGARDING EMC

The equipment is in conformity with the standards regarding Electromagnetic Compatibility, not causing electromagnetic disturbances, and complying with immunity standards.

To prevent adverse events to the patient and Operator due to electromagnetic disturbances, the device requires the following special precautions regarding EMC:

- The equipment should not be located close to other devices or stacked with other devices.

- The use of accessories, transducers or cables not specified or provided by Phi Med Europe S.L. may negatively affect EMC performance.

- "Portable RF communications equipment including antennas should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result"

Recommended distances to portable or mobile RF communications devices			
The equipment is intended for using in an electromagnetic environment in which RF radiations are controlled. User can help prevent electromagnetic interference by maintaining a minimum distance between portable or mobile RF communications devices (transmitters) and the equipment as recommended below, according to the maximum output power of the communications devices.			
Maximum power output of the transmitter (W)	**Distance according to the frequency of the transmitter** (m)		
	150 kHz to 80 MHz $d=1.17\sqrt{P}$	**80 MHz to 800 MHz** $d=1.17\sqrt{P}$	**800 MHz to 2.5 GHz** $d=2.33\sqrt{P}$

0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.74
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters with a maximum output power not listed above, the recommended distance d in meters (m) can be determined using the equation applicable to the transmitter frequency, where P is the maximum power output in watts (W) according to the manufacturer of the transmitter. NOTE 1: At the frequencies of 80 MHz and 800 MHz, the distance is applied for the highest frequency range. NOTE 2: These guidelines cannot be applied in all situations. Electromagnetic propagation is affected by absorption and reflection			

- All the mentioned warnings and instructions must be followed for maintaining basic safety with regard to electromagnetic disturbances for the expected service life.

NOTE: "The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment"

NOTES

- NerveCheck Master is intended for use by healthcare professionals.
- In the events that the charge indicators do not turn on, the power connection indicator does not turn on, the screen does not turn on and / or the thermal protector indicator lights up. In all these cases, it is a must to turn off the equipment and consult with your supplier. Likewise, in the event of an anomaly in the product, stop using it and contact the distributor
- This equipment may cause radio interference or may disturb the operation of equipment in your surroundings. Mitigation measures may need to be taken, such as reorienting or relocating the NerveCheck Master or shielding the site.
- The use of NerveCheck Master may be affected due to other equipment that communicate by RF. For commissioning, we recommend that you consult the Electromagnetic Compatibility (EMC) section supplied in the user manual.
- NerveCheck can be used in Healthcare environments as Hospitals, private offices, institutions of healthcare, places for which the equipment is suitable.
- During the tests the user can be exposed to non-ionising radiation.
- As a consequence of Thermode and/or Vibrameter test, Cytotoxicity, sensitization, irritation or intracutaneous reactivity may occur in the event that the patient has allergy to the material.
- Do not modify the device. In no event should you open, tamper with or modify the device. This could cause damage to it.
- NerveCheck Master is intended for indoor use.

- The NerveCheck Master is not resistant to water or the ingress of other substances.
- In case of breakage of the thermal disposable grid (thermode), turn off the equipment. Do not use the equipment until it is repaired.
- Both disposables have unique serial port designs to prevent incorrect attachment to the main unit. Pay special attention and make sure that both consumables are properly connected in its Stimulator connector. Refer to the manual on "Replacement of disposables."
- Make sure you have both units with a charged battery before starting the test.
- It is recommended to write down the RF channel for each equipment NerveCheck Master.
- Both Thermode and Vibrameter provided by the manufacturer of NerveCheck Master are properly calibrated.
- Follow the instructions on the remote-control screen.
- In the case of not responding to stimulus, the test will be aborted.
- Before carrying out the tests, we recommend sanitizing the skin area of the patient, to be studied.
- Do not use gel, paste or other material between the contact surface of the stimulator, Thermode or Vibrameter, and the skin of the patient.
- Use of the equipment is limited only to those stipulated here. Both the manufacturer and the distributor are not responsible for damage from misuse.
- Make sure the technology will be used within the specified conditions of work.
- Always consult a physician for evaluation of results.
- Disinfect the equipment and the stimulators after each use.
- A gauze containing a small amount of Chlorhexidine can be used to disinfect the surface of as well as Unit A -B and both stimulators, Thermode and Vibrameter, in contact with the patient's skin.
- The equipment may be damaged if not used carefully.
- For its disposal and to avoid possible damage to the environment, the device must be separated from other waste and recycled correctly for subsequent reuse of the materials. Likewise, the product labelling symbol  indicates that it must be disposed of according to the regulations of the country.
- The batteries in Unit A and B must be recharged every 5 months, starting from the date indicated on the NerveCheck Master box by the symbol  .
- The NerveCheck Master should not be used on the patient while charging.
- Before downloading Data of the Remote-Control be sure Unit A is charged as it could lead to an error in the data transfer to the PC, losing in this way the data.
- Do not use the NerveCheck on the patient while the device is charging.

- Technical specifications subject to change without prior notice.

4. Installation

NerveCheck Master does not need installation. Both the main and remote-control units are equipped with batteries so that the use of a mains power supply is unnecessary.

In the event that either the main and / or remote-control unit indicate low battery power, use the power supply adapter provided to re-charge either unit's battery (as instructed in the "**Charging the battery**" section see User's Manual).

You are still able to use NerveCheck Master while charging the battery of either unit.

5. Terms of use

NerveCheck Master's vibration stimulator (Unit B) has been developed on a weight-calibrated basis. It is necessary to ensure that the NerveCheck Master stimulator (Unit B) is placed on an even (horizontal) surface so that its weight is distributed uniformly and the patient senses the stimulus correctly. Ideally, we recommend that stimulator is placed on level ground for normal and optimal operating use. Any tilt can cause incorrect stimuli.

The patient must place the test-foot in front of and opposite the operator.

To use NerveCheck Master, both units A (remote control) and B (stimulator) must be operating.

Each unit has an On/Off button indicated by the symbol ⏻. If the unit is turned off, then pressing the button for at least a second will start the unit, whereas, if it is already operating pressing the button for at least 3 seconds will turn it off.

When unit A is on, information on the screen will indicate this, while a green LED with the symbol ⏻ indicates that unit B is operating. For the correct operation of

NerveCheck Master it is necessary to start unit B first, and then unit A. Shutting down NerveCheck Master can be done in any sequence.

To perform the test, see paragraph "**Test Execution**" (or as instructed in the User's Manual "**Enter Menu"**).

6. Safety Guidelines

6.1. Safety requirements

Do not replace or modify any component of NerveCheck Master. They may only be connected and replaced with those accessories exclusively designed for NerveCheck Master. Use of other accessories not provided by the manufacturer of NerveCheck Master will not guarantee compliance with standard medical device regulations and subsequently we cannot guarantee the validity of the diagnosis.

The device is equipped with a secondary safety system that prevents injury to the patients when the Thermode is in use.

6.2. Safety and Regulatory Summary

NerveCheck Master and its disposables comply with the requirements of the European Medical Device Directive 93/42 / EEC and its transposition into Spanish law.

For more detailed information please refer to User's Manual of NerveCheck Master.

7. Technical Data

The following table describes the technical specifications and features of NerveCheck Master.

Instrument	
Medical Equipment	Class IIA
	Non-invasive
Stimulation Methods	Levels Limits
Compatible Operating Systems	Windows Vista Windows 7 Windows 8 Windows 8.1 Windows 10
Screen	LCD Alphanumeric 2x16 characters
Interface between NerveCheck Master and PC	USB
Batteries Unit A / Unit B	Lithium-polymer 392mAh / Lithium-polymer 5000mAh
Stimulator	
Vibration Stimulator: Operating frequency	248 Hz ± 1%
Vibration Stimulator Active area	50 mm^2
Thermal Stimulator: Temperature Range	Cold Test: 15 °C - 25°C ± 0.5ºC Warm Test: 40 °C - 46 °C ± 0.5ºC Heat Pain Test: 32 °C - 49.5°C ± 0.5ºC
Thermal Stimulator active area	50x25mm
Environmental conditions	
Operating conditions: Temperature	18 °C (64 °F) -30 °C (86 °F)
Operating conditions: Humidity	20 - 80 %
Operating conditions: Pressure	20 – 300 KPa
Storage conditions: Temperature	-20 °C (-4 °F) - 60 °C (140 °F)
Storage conditions: Humidity	20 - 80 %
Charger	
Voltage	100 – 240V AC
Frequency	50 - 60 Hz
Power adapter output	18W
Dimension / Weight	
Height / Width / Depth	113 x 267 x 66 mm
Weight (Battery included)	1.130 gr.
Certifications	
CE marked	CE 1639

Company Certified with ISO13485:2016	

*Technical specifications subject to change without prior notice.

7.1. Replacement Units reference (thermode and vibrameter)

The model of the replacement units indicates the number of tests that the disposable pack (thermode and vibrameter) can perform.

FAMILY	MODEL	REFERENCE
Replacement Units (thermode & vibrameter)	20 tests	0110
Replacement Units (thermode & vibrameter)	110 tests	0112
Replacement Units (thermode & vibrameter)	180 tests	0111

8. Maintenance and calibration

8.1. Cleaning method

- A gauze containing a small amount of Chlorhexidine 2% can be used to disinfect, moving the gauze over the surface of the Thermode and Vibrameter that is in contact with the patient's skin.
- A gauze containing a small amount of Chlorhexidine 2% can be used to disinfect Unit A and Unit B, moving the gauze all over the surface.

8.2. Calibration

NerveCheck Master does not require calibration and nor requires installation.

During the manufacturing process of the NerveCheck Master, the disposable elements Thermode and Vibrameter are calibrated and is not necessary to calibrate the equipment.

This process ensures that throughout the useful life of the Thermode and the Vibrameter, they remain correctly calibrated. This period is defined by the number of tests that the disposables pack allows to perform.

9. NerveCheck Master Description

NerveCheck Master is a Quantitative Sensory Testing (QST) medical device used for detecting and characterizing sensory thresholds of small and large nerve fibres through the performance of 4 different tests: Vibration, Cold, Warm and Heat Pain test which can be performed independently or serially.

NerveCheck Master provides quantitative results increasing the ability of better and early diagnoses as well as used for monitoring the treatment of the patient.

At the end of every test, the software will quantify the patient's sensory threshold, analyse the responses given and the test results will be stored with the patient's data. Immediately after completion, the test result will be shown on the screen.
The use of the NerveCheck Master medical device is as stipulated by Phi Med Europe S.L. and specified in the user manual.

10. NerveCheck Master Users

This device is recommended to be operated by physicians, general practitioners of Health or by personnel under the direction of a physician.

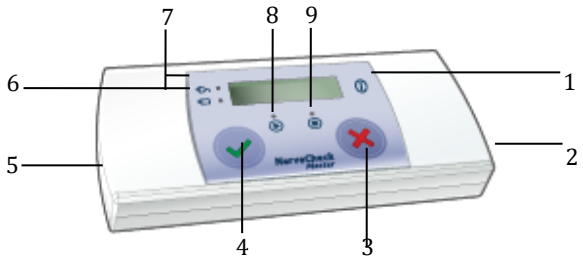
11. Pathologies for which this device is intended

- Patients who require a neurological diagnosis for the condition of the large and small sensory nerve fibres.

- Patients with Sensory Neuropathy and Polyneuropathy.
- Patients with Diabetes.

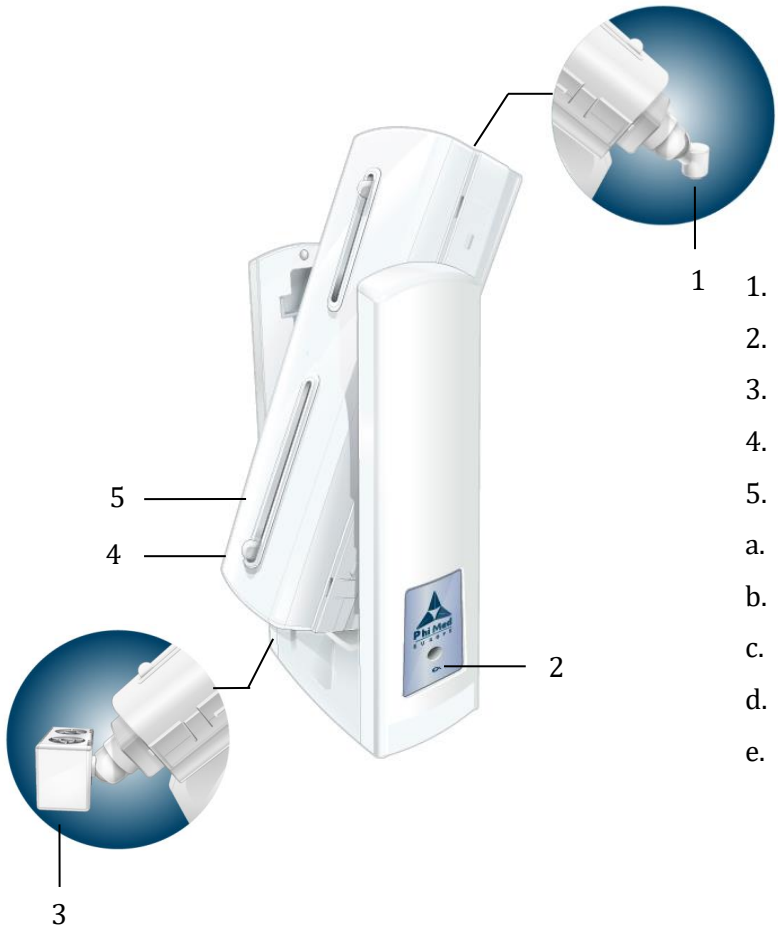
12. NerveCheck Master Overview

Unit A: Remote control



1. On/Off
2. Mini-USB socket for downloading
3. " No" button
4. " Yes" button
5. "Battery Charge" socket
6. Battery indicator.
7. "Connector connected" indicator.
8. "Device operating" indicator.
9. "Stimuli in course" indicator.

Unit B: Stimulator (comprising Thermode and Vibrameter)



1. Vibration test arm.
2. "Battery Charge" socket.
3. Thermode test arm.
4. On/Off switch
5. Indicator lights associated to:

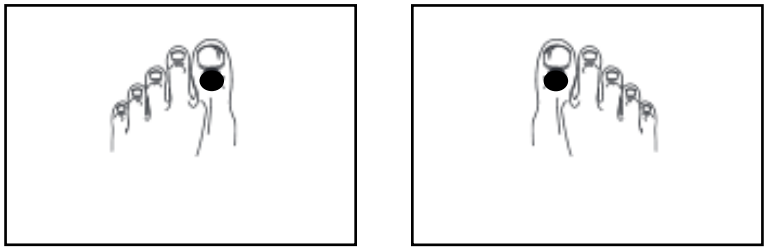
a. Power Connector "connected".
b. Thermal Protector "activated".
c. Charge indicator.
d. Power indicator.
e. Operating indicator.

13. Sites to be tested on the patient

For evaluation of neuropathy, favourable skin sites are the following. Other sites may be chosen depending on the purpose of the study.

Vibration Testing:

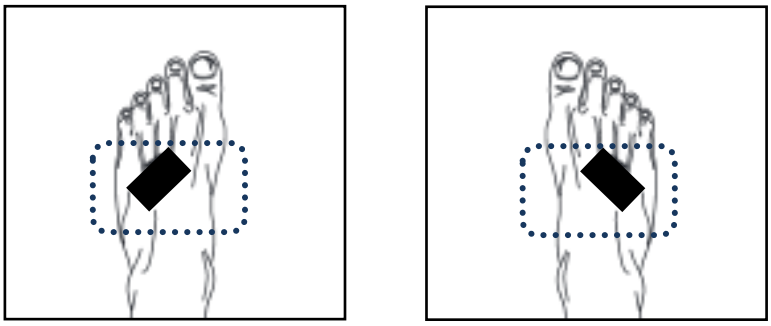
1. Foot: toes of both feet can be tested. Starting with non-dominant foot.



● Vibration stimulator surface.

Thermal Testing:

1. Foot: both feet area can be tested. Starting with non-dominant foot.



▬ Thermal stimulator surface

..... Area to test.

14. Test Options

Two possible programs:

1. **Serial Test**: encompasses all 4 tests which are made one after the other. This program is fixed and no possible modifications can be made.

    1. Vibration Test

2. Cold Test
3. Warm Test
4. Heat Pain Test

2. **Single Test**: this program allows customization, and the user can choose which tests are going to be made.

1. Vibration Test
2. Cold Test
3. Warm Test
4. Heat Pain Test

Please note that both programs contain the same option of tests.

15. Utilities menu

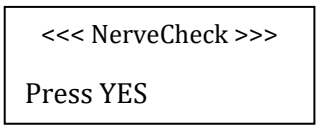
"**Utilities Menu**" contains an assortment of features listed below:

- **Download to PC:** Press "**Yes**" to download the Data to your PC.
- **Change Temperature Range:** Press "**Yes**" when the cursor is on your selected Range. Use **"No"** to move between Ranges.
    - Range 1: 18°C - 28°C. (Range recommended).
    - Range 2: 18°C - 30°C.
- **Change Date and Hour:** Press "**Yes**" to modify each unit of time. Use **"No"** to move between units of time. To save press **"No"** after setting the minute value (hh : mm).

- **Change RF Channel:** In cases where two or more NerveCheck Masters are being operated simultaneously and in close proximity, we recommend that you use a different radio frequency (RF) for each set of equipment. (To avoid confusion we recommend that you note down the RF channel number and the Serial Number of the equipment).

16. Test Execution

1. Switch "**On**" remote-control
2. Switch "**On**" Stimulating device
3. The screen will display**:**



16.1. Administering Vibration test

The **Vibration Test** can be performed either as a part of the serial program or as a single test.

The screen on the control remote will show the steps to perform the test. Pull the arm with the vibrator and place it on the part of the body that is going to be tested.

Make sure that the whole of the surface of the vibrator is in full contact with the area of skin that is going to be tested.

The full test is comprised of stimuli of different levels of intensity of which some are void. Stimuli can be of 3 kinds:

- Weak
- Normal
- Strong

A beep from the Unit B before the beginning of a test announces the first vibration stimulus. After each stimulus, the beeping will stop and the user will be required to answer, "**Yes**" or "**No**" as to whether or not he or she has felt it.

If the user answers "**Yes**" to 2 void stimuli in a row, the test will be interrupted and the screen will show the message **"Try again"**, to which the user may want to answer "**Yes**", and start over again, or "**No**".

Result of the tests:

Once the test has been completed, the result "**Normal"** or **"Abnormal"** will appear on the screen.

16.2. Administering Temperature test

Prior to undertaking the 3 **Temperature Tests**, pull out and extend the Thermode arm which will be used to produce the stimuli and let NerveCheck measure:

"**Room temperature**" (must be between the range option chosen in Utilities Menu).

"**Body Skin Temperature**" (must be between 34**°**C and 36**°**C).

Instructions:

Pull out the stimulating device (unit "B") to proceed to the Room and Body Skin Temperature tests.

1. If the Room Temperature is in the acceptance range, the next step is the Body Skin Temperature Test.

2. If the Room Temperature is not in the acceptance range, the error messages "**Ambient Temperature too High**" or "**Ambient Temperature too Low**" will appear, depending on whether the temperature is too high or too low, and the test will start again.

Place the thermal stimulating surface on the skin. Make sure that the whole of the surface of the vibrator is in full contact with the area of skin that is going to be tested.

The Body Skin Temperature test will be made automatically.

1. If the Body Skin Temperature is in the acceptance range, the Cold Stimuli Test will begin.
2. If the Body Skin Temperature is not in the acceptance range, the error messages "**Body Skin Temperature too High**" or "**Body Skin Temperature too Low**".

Before the beginning of each test, the stimulating arm (Unit "B") will beep.

16.3. Administering Cold test

Cold Test will start after the Room and Body Skin Temperature Tests or if in the serial program, without the need of these.

This test consists of:

- Weak stimuli
- Normal stimuli
- Strong stimuli
- Void stimuli.

After each thermal stimulus, the user is required to answer "**Yes**" or "**No**" as to whether or not they have felt the stimulus.

Result of the tests:

Once the test has been completed, the words **"Normal"** or **"Abnormal"** will appear on the screen and the user will be asked to press **"Yes"** to continue.

16.4. Administering Warm test

Warm Test will begin after the Room and Body Temperature tests, or if in the serial program, without need of these.

This test consists of:

- Weak stimuli
- Normal stimuli
- Strong stimuli
- Void stimuli.

After each thermal stimulus, the user is required to answer "**Yes**" or "**No**" as to whether or not they have felt the stimulus.

Result of the tests:

Once the test has been completed, the words **"Normal"** or **"Abnormal"** will appear on the screen and the user will be asked to press "**Yes**" to continue.

16.5. Administering Heat Pain test

Heat Pain Test will begin after the Room and Body Skin Temperature tests, or if in the serial program, without need of these.

During the test, the user must press "**Yes**" on the remote (Unit "A") to stop the test when they feel uncomfortable perception.

If the user does not press "**Yes**" the stimulus will stop when the thermal stimulator (Unit "B") reaches 49.5**°**C and will go back to 32**°**C.

Result of the tests:

Once the test has been completed, the words **"Normal"** or **"Abnormal"** will appear on the screen and the user will be asked to press "**Yes**" to continue.

17. Installation Software for Downloading Data

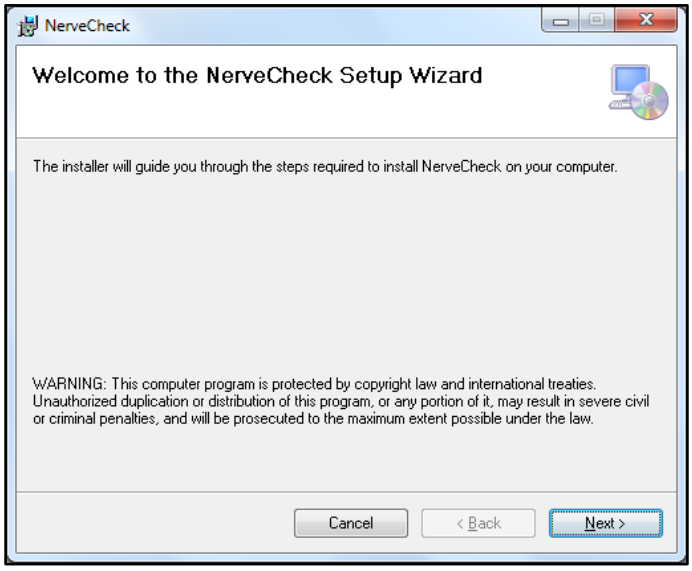
Installing the software, we provide on your PC, will allow you to download the data stored for the completed tests.

Before starting, make sure your computer meets the system requirements specified on the table called "**Features of NerveCheck Master**".

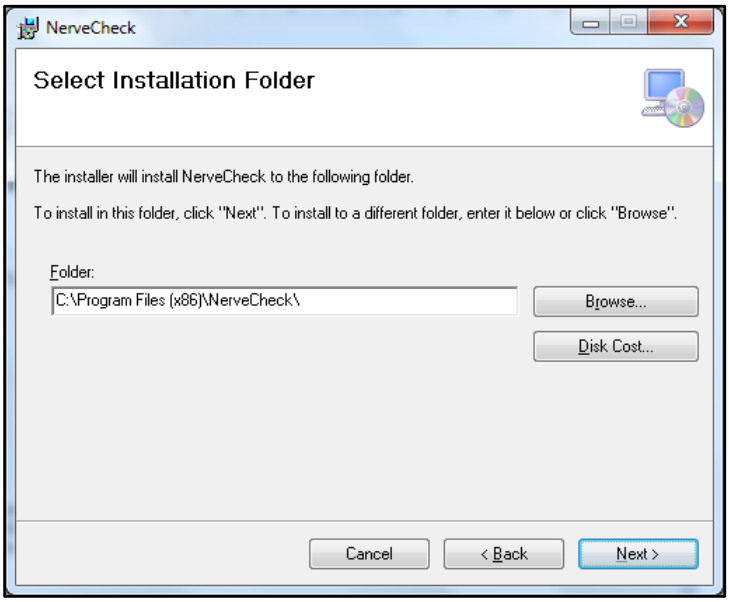
Insert the pen-drive into your PC.

1. Within the "My Computer" window, find the pen-drive and open it: Click on **Setup.exe**

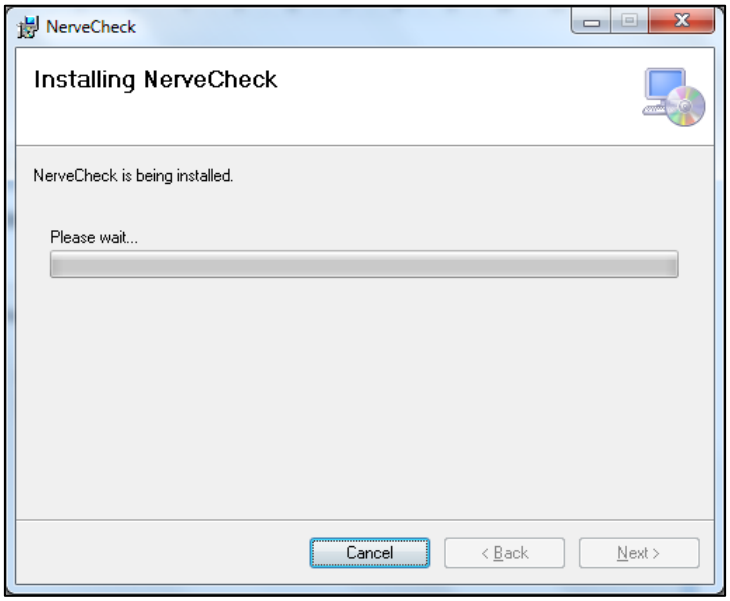
2. Press **Next** in the window below that will show up in your screen.



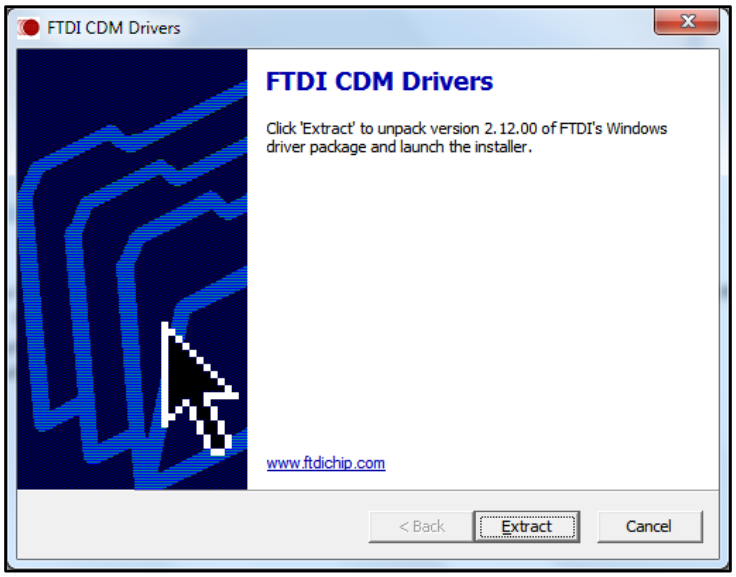
3. Press **Next** in the "Select Installation Folder" screen:



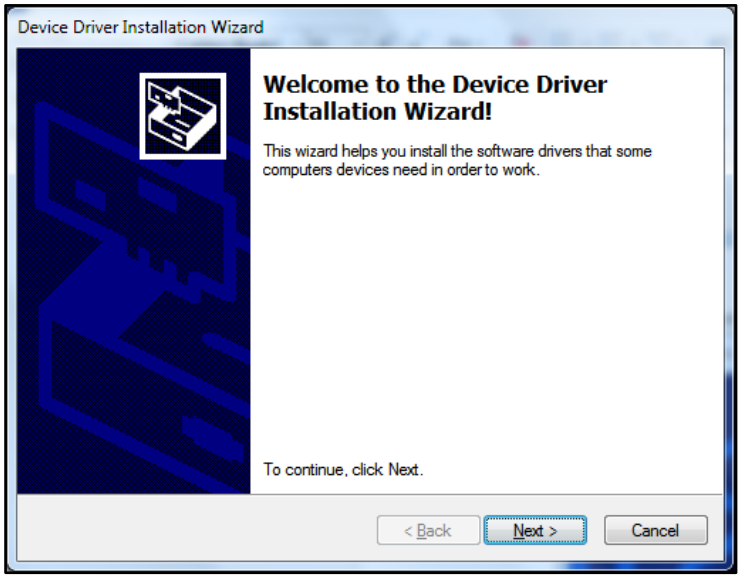
4. Press **Next** after NerveCheck has been installed.



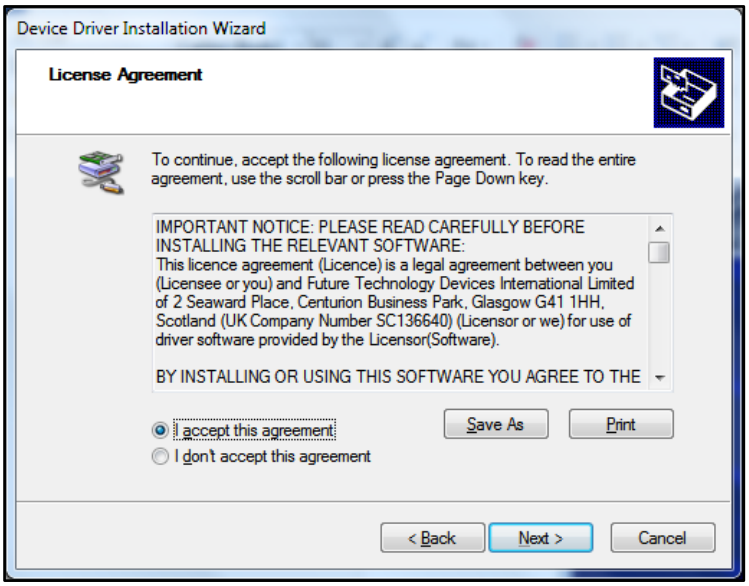
5. Press **Extract** on the window below.



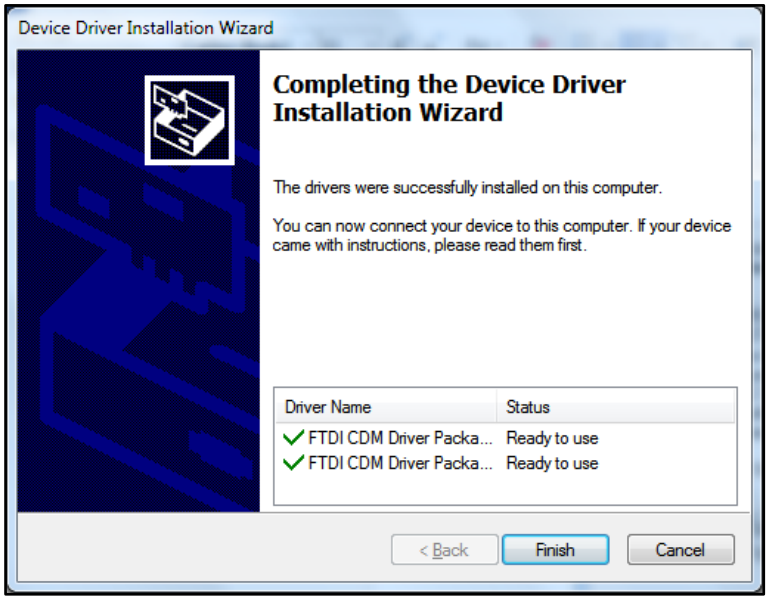
6. Press **Next** on the window below:



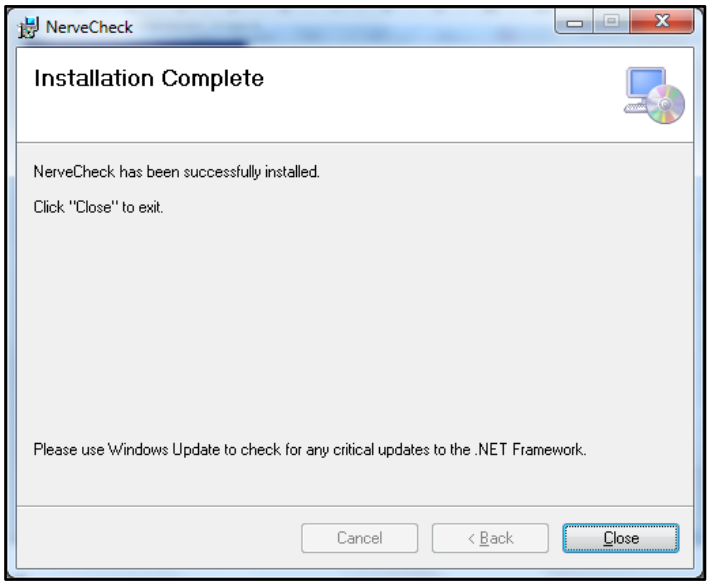
7. **Accept** the license of agreement and press **Next**:



8. Click on **Finish** once the window below is show on your screen.



9. The installation has been successfully completed.



Once the installation has been successfully completed you will find the NerveCheck file on your Desktop or main menu.

18. Instructions to Download the Data to your PC

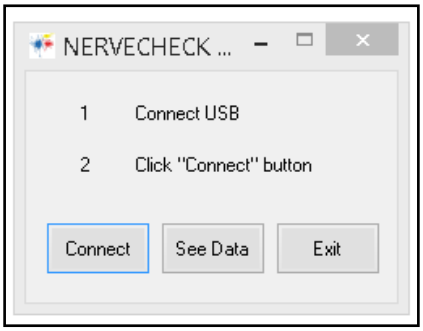
The data from every test is saved in the remote control. If the device unexpectedly turns off, either by accident or because it ran out of battery, data from incomplete tests will be lost.

1. Switch **On** Unit A. On the option **Utilities Menu** press "**Yes**". Select **Download to PC**.

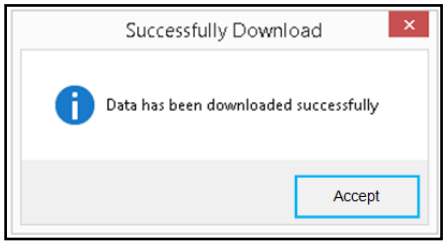
2. Connect the USB-mini USB cable to the Unit A and your PC. Now press **"Yes"** on the remote control.

3. On your PC desktop double click on NerveCheck file:

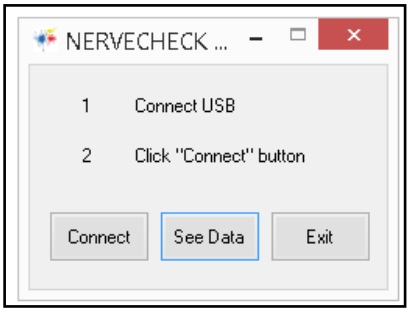
4. Click on "**Connect**" to download the Data saved:



5. Click "**Accept**"

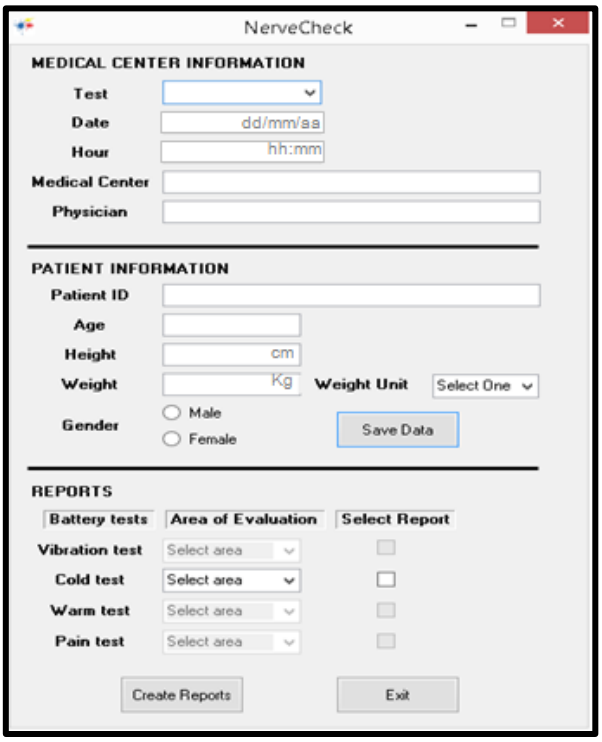


6. To edit the data saved, click "**See Data**".



7. In "**Test**" dropdown window you can find all completed tests.

   Fill all fields with the patient's information. Once complete, click on "**Create Reports**"

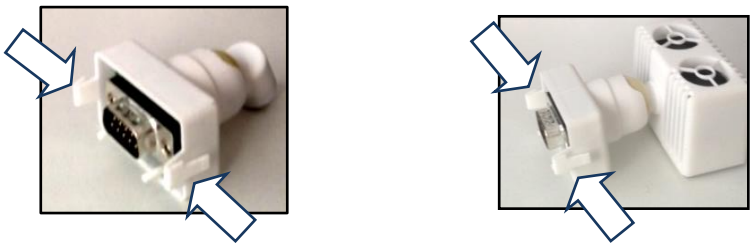


19. Replacement of Disposables

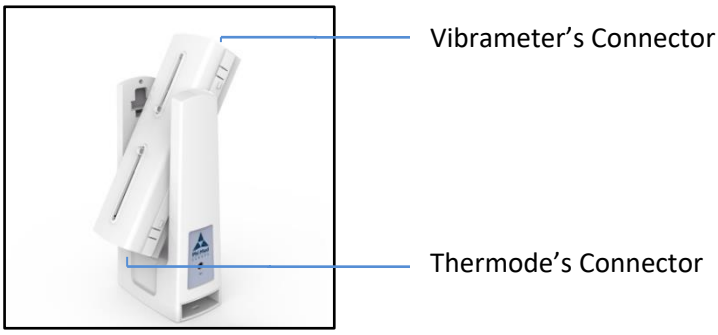
The life time of each Thermode and Vibrameter disposable is limited by the number of administered tests. It is necessary to replace the pack of disposables once this limit has been reached.

To replace the pack of disposables (Thermode and Vibrameter):

1. Switch "**Off**" the remote-control and the Stimulator device.
2. Press the flaps as the image shows and remove the disposables from the Stimulator.

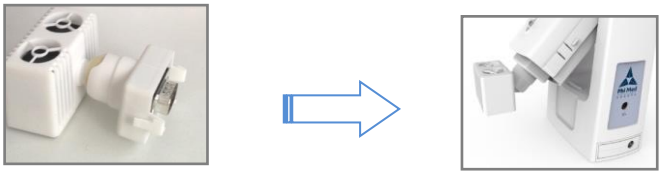


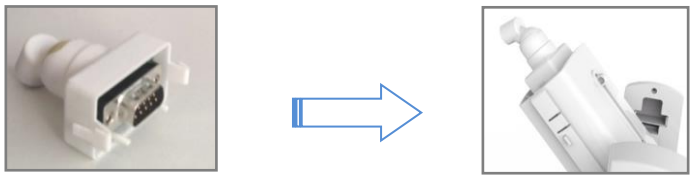
3. Place NerveCheck Master in the upright position.



4. Connection of the new pack of Thermode and Vibrameter.

Check that both flaps of each disposable, Thermode and Vibrameter, are locked to the Stimulator unit.





5. Switch "**On**" the remote-control and Stimulator device. Wait until it completes the installation procedure.
6. If the procedure has been successful the screen will show **"Enter Menu".**

20. Spare parts

Find below the list of spare parts that can be provided for your distributor.

Contact your distributor or www.phimedeurope.com to order replacement disposables.

Spare parts	Code	Picture
Remote Control NerveCheck Master	2001-0101	
Standard USB-mini USB charging cable	2002-0101	
Memory stick NerveCheck Master	2003-0101	
Quick User's Guide	2004-0101	
Charger	2005-0101	
Feeder pins	2006-0101	

21. Transporting NerveCheck Master

Please refer to User's Manual.

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