SHUNTCHECK

III

# Operating Manual

**For**

## ShuntCheck Natural Flow Test

NEURODX DEVELOPMENT

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## Table of Contents


*Warnings & Cautions…….....3*

*Indications for Use……..……..…...4*

*Contraindication……..……..……...4*

*IEC 60601 Classification & Device Descriptions……..……..…...4*

*ShuntCheck DAQ Description & Specifications..……...….....5*

*ShuntCheck Thermosensor Pack Description & Specifications…….6*

*ShuntCheck Computer Description & Specifications……..……..7*

*Environmental Conditions That Affect Use……..…...…7*

*Setup Instructions & Check Out……..…...….....8*

*Introduction……...…..…...9*

*Conducting a ShuntCheck Test……...…..…...10*

*Repeating a ShuntCheck Test……..……...…..…...29*

*Viewing Graphical Data……..……30*

*Printing & Saving Test Data……..……..……..…33*

*Viewing Graphical Data of Previous Patients …..……..……..…34*

*Troubleshooting, Error Checks, Restarting a ShuntCheck Test.....36*

*Error Message Types……...……...…...38*

*Administration……..…...…..…41*

*EMC Guidance…….....43*

*Isolation Diagram……..……....47*

*Maintenance & Symbol Chart…..……..……..…...48*

## Warnings

- Inspect DAQ before each use to check for cracked enclosures or broken exposed wires. Discontinue use of device and contact NeuroDx Development for replacement device.
- Do not connect components to equipment which is not part of system.
- Avoid operating device around sources of high voltage as results may be affected.
- EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE.
- Equipment not for use with Oxygen or Oxygen enriched atmospheres.
- Do not install ShuntCheck software on non-IEC 60601/60950 certified computers to be operated on outlet power
- Do not charge battery-powered, non-60601/60950 certified computers while conducting the test.
- Do not open the DAQ. It contains no user serviceable parts .
- Do not pour isopropyl alcohol into the device.
- Do not place the Thermosensor on or near open wounds, and only place on hirsute skin after shaving.

## Cautions

- Federal law restricts this device to sale by or on the order of a physician.
- Before operating the ShuntCheck III device, carefully read all instructions and the warnings provided on this page.
- Clean surfaces with 70% isopropyl alcohol only.
- The patient must remain still throughout the testing period.
- The Patient ID entered at the beginning of the test procedure becomes the file name of the test. Do not include protected patient information in this ID.
- Turn up sound on computer used in the ShuntCheck test—the on-screen instructions include audible prompts.
- Unplug DAQ from computer before charging computer.

## Indications for Use

ShuntCheck® is an aid to the detection of flow in implanted cerebrospinal fluid (CSF) shunts. ShuntCheck cannot alone diagnose CSF shunt function or malfunction. The clinical diagnosis of CSF shunt function or malfunction, incorporating the flow information from ShuntCheck, should be made only by a qualified neurosurgeon.

## IEC 60601 Classification

- DAQ is USB Powered Equipment
- DAQ intended for Continuous Operation of 10 minutes or less per test cycle
- Type BF Applied Part
- Computers with IEC 60601-1 or 60950 certification have been designed to meet a series of electrical and radiation emissions standards to ensure patient safety when used in the healthcare setting

## Description of the Device

ShuntCheck III System contains the following:

- Data Acquisition Unit (DAQ)
- ShuntCheck Pack (which includes a thermosensor, an instant ice pack and a skin marker

And uses an IEC 60601/60950 certified computer or battery-powered laptop or tablet computer running ShuntCheck III software

See descriptions of ShuntCheck components on pages 5 - 9

All ShuntCheck III system components are supplied non-sterile.

All ShuntCheck III system components plus the laptop or tablet computer running ShuntCheck software can be used within the patient environment.

## ShuntCheck DAQ Description & Diagrams

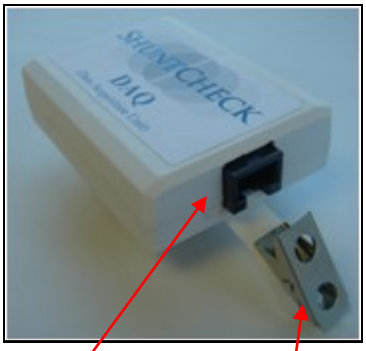
The DAQ amplifies and converts the thermosensor signal into digital form

| Data Acquisition Unit (DAQ) | Specification |
|---|---|
| Model | DAQ 1 |
| Size | Length 3.0” x Width 2.3” X Height 1.0” |
| Weight | 50 grams |
| Material | ABS |

The ShuntCheck Data Acquisition Unit (DAQ) has a top, front, and back panel. Each panel’s various functions are described below.

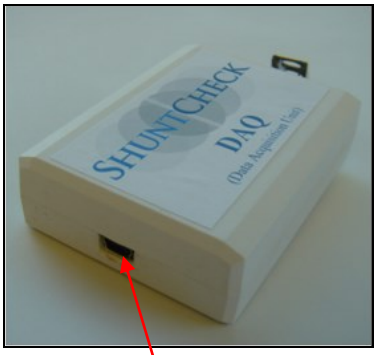
**Top Panel**
The top panel contains the receptacle for the Thermosensor jack and a clip to hold the DAQ on the patient’s clothing;

**Bottom Panel**
The bottom panel contains the receptacle for the USB cable which attaches to the laptop or tablet computer;




*Thermosensor Jack*

*Clothing Clip*




*USB Jack*

**Front Panel**
The front panel contains the DAQ label;

*Warning: Do not open the DAQ. It contains no user serviceable parts*

*Caution: Clean surfaces with isopropyl alcohol only.*

## ShuntCheck Test Pack Description & Diagrams

The Thermosensor detects changes in skin temperature due to the flow of cooled CSF through the shunt.
The Instant Cold Pack cools the shunt transcutaneously
The skin marker marks the path of the catheter at the clavicle to guide the placement of the Thermosensor

| ShuntCheck Test Pack | Specification |
|---|---|
| Model | TP 1 |
| **Thermosensor** | |
| Size & Weight | Length 24” x Width 2.5” X Height 1.5”, 20 grams |
| Material | EVA patch with medical grade adhesive |
| **Accessories** | |
| Instant Cold Pack | Rapid Relief, Instant Cold Pack, #31346<br>or Dynarex, Instant Cold Pack, #4511 |
| Skin Marker | Viscot, Surgical Marker, #1451 |

Used Thermosensors, instant ice packs and a skin markers can be disposed of in regular waste per institutional policies.

## ShuntCheck Computer Description &Specifications

A computer running ShuntCheck software provides step-by-step instructions, analyzes the temperature readings and displays test results

| ShuntCheck Computer | Specification |
|---|---|
| Power—IEC 60601/60950 | Outlet ≤ 240v or battery |
| Power—non 60601/60950 | Battery operated, less than 20 volts |
| Operating System | Windows 7 |
| Conditions | Ethernet Port Plugged |
| | USB Port for Power |
| | Meets Environmental Conditions Below |
| Software | Installed with ShuntCheck |
| | Installed with Crystal Reports |
| Power Cord | For Charging only |
| Operating Manual | Included |
| Standard | Includes UL marking for Information Technology Equipment |

## Environmental Conditions Which Affect Use

***Environments***

- Temperature Range: 5˚ to 50˚C (41˚ to 122˚F)
- Relative Humidity (maximum): 10% to 90% non-condensing

***Charging the laptop or tablet used in ShuntCheck testing***

A non-60601/60950 laptop/tablet should be turned off and charged whenever it is not in use. Do not begin conducting a test if the battery is low. Do not charge in operating theater. Disconnect the DAQ from the computer before charging

**Conditions during ShuntCheck Test**

- Avoid operating device around sources of high voltage as results may be affected.
- The patient must remain still throughout the testing period.
- Do not place the Thermosensor on or near open wounds, and only place on hirsute skin after shaving.
- Known Issue: Instructional text may not appear with IE 9.

## Set Up Instructions

Please check for the following list of items. If you find any items missing please contact NeuroDx Development.

ShuntCheck III System contains the following:

- Data Acquisition Unit (DAQ)
- ShuntCheck Pack (which includes a thermosensor, an instant ice pack and a skin marker

And uses a computer running ShuntCheck III software

The ShuntCheck III device software provides step-by-step on-screen instructions to guide the operator while conducting a ShuntCheck test.

## Set Up Notes

## Check-Out

Inspect DAQ before each use to check for cracked enclosures or broken exposed wires, Discontinue use of device and contact NeuroDx Development for replacement device.

## Introduction

The ShuntCheck III device software provides step-by-step on-screen instructions to guide the operator while conducting a ShuntCheck test. At the completion of each step, tap the 'Next' button on the bottom menu bar to progress to the next step. Select the 'Previous' button on the bottom menu bar to return to a previous step.

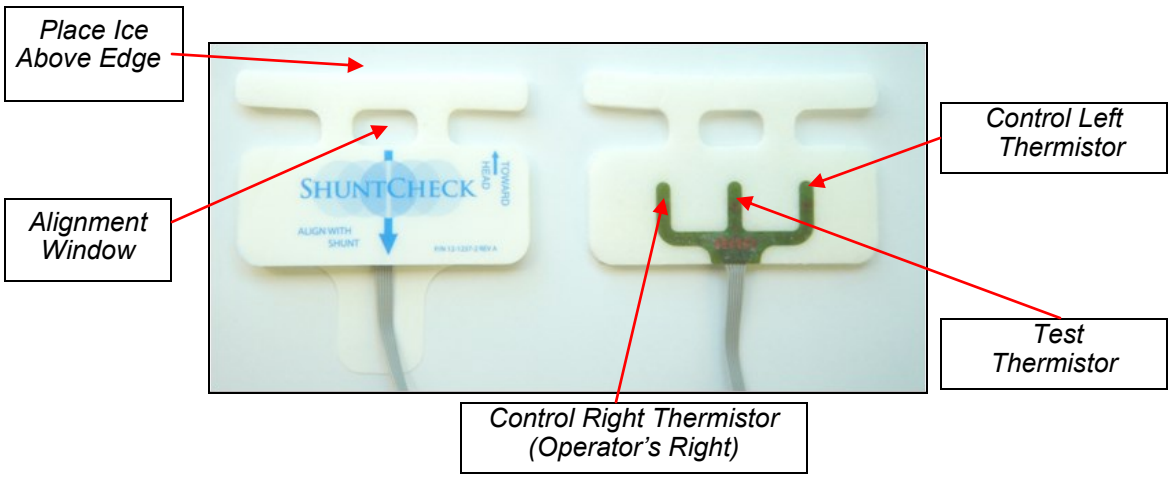
Prior to conducting the test, ensure the patient is sitting up comfortably with back support. The patient position may be changed during the test as directed by a physician.

***Ice***

In a ShuntCheck test, CSF in the shunt is cooled transcutaneously by an instant ice pack. The ice pack is placed above the upper edge of the ShuntCheck Thermosensor:

**Thermosensor**

The thermosensor front (left) and back (right—with liner paper removed to show thermistor circuit):




**The Thermosensor contains a hypoallergenic acrylate adhesive designed for medical/surgical use.**

**The ShuntCheck Thermosensors contain no latex.**

## Conducting a ShuntCheck Test

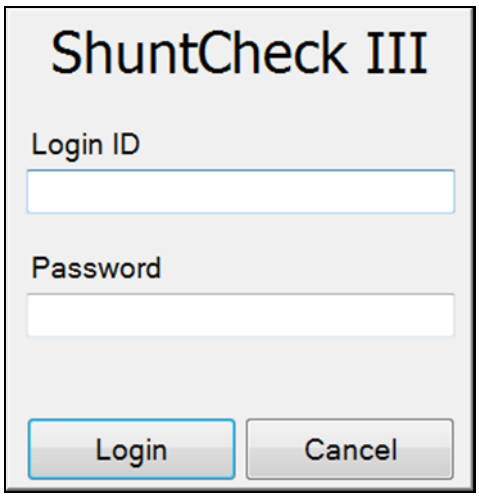
Turn on the laptop or tablet computer and activate the ShuntCheck III software program.

Screen navigation is done with a mouse, stylus or finger depending on the computer.

An on-screen keyboard can be activated at any time by tapping the icon located at the left side of the screen.

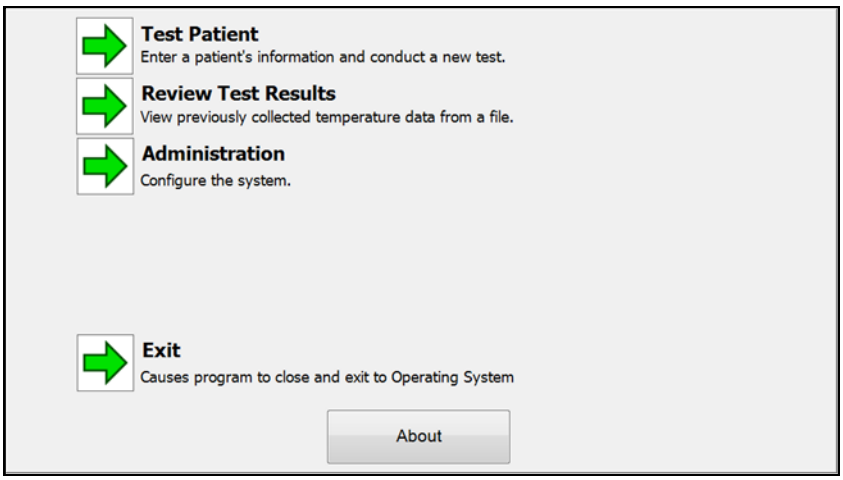
Follow the instructions for conducting a ShuntCheck test as they appear on the screen of the computer.

Click OK



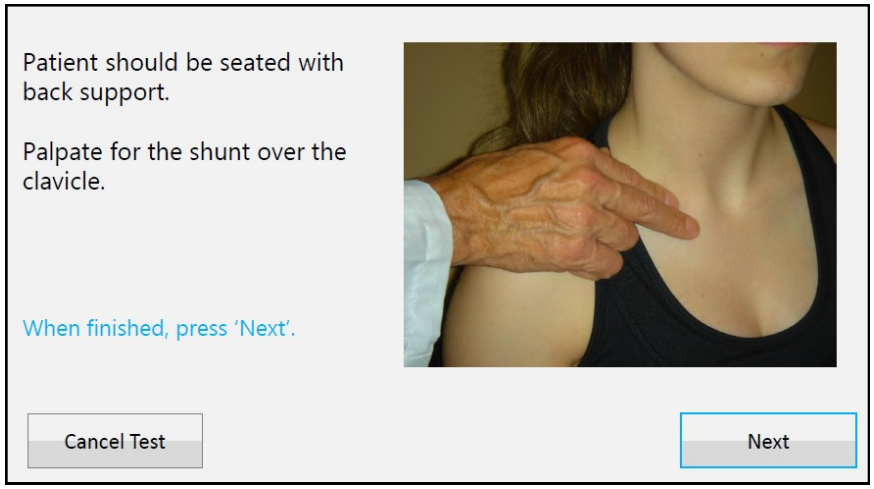

Enter user name (admin) and password (shuntcheck)
and click Login for initial access to Administrative mode.
To create an individual user see
ADMINISTRATION section in Manual.

*Warning: Do not conduct the test while a non-60601/60950 device is charging.*

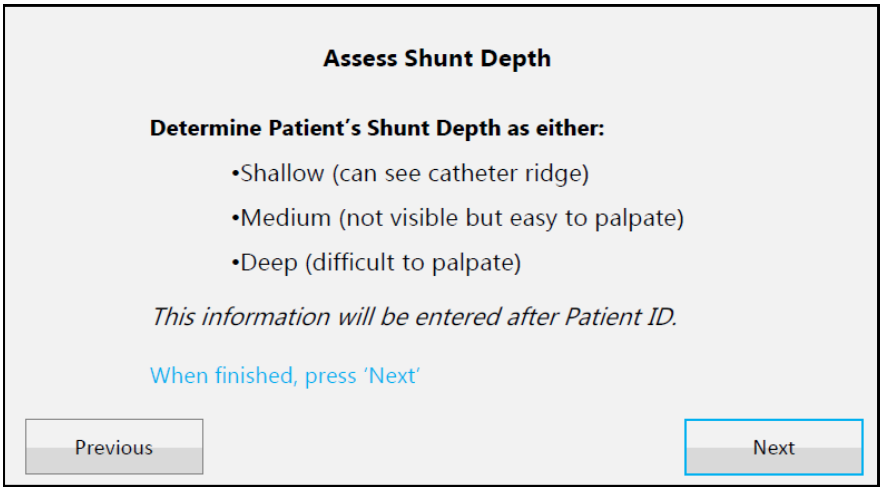



Click Test Patient

The test provides step-by-step instructions as follows:




(ShuntCheck tests of NPH patients have shown flow in the sitting and 45° positions but low or no flow when supine)



Indicate the shunt location using a skin marker.

When finished, press 'Next'.

Previous Next

Peel the backing from the Thermosensor.

When finished, press 'Next'.

Previous Next

Place the Thermosensor over the shunt, aligning the arrow on the sensor with the skin mark.

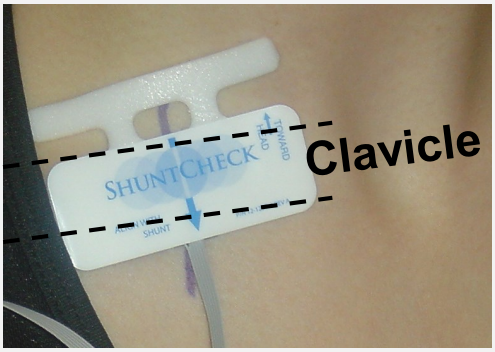
When finished, press 'Next'.

Previous | Next

*Caution: <u>Do not</u> place the Thermosensor on or near open wounds, and only place on hirsute skin after shaving.*

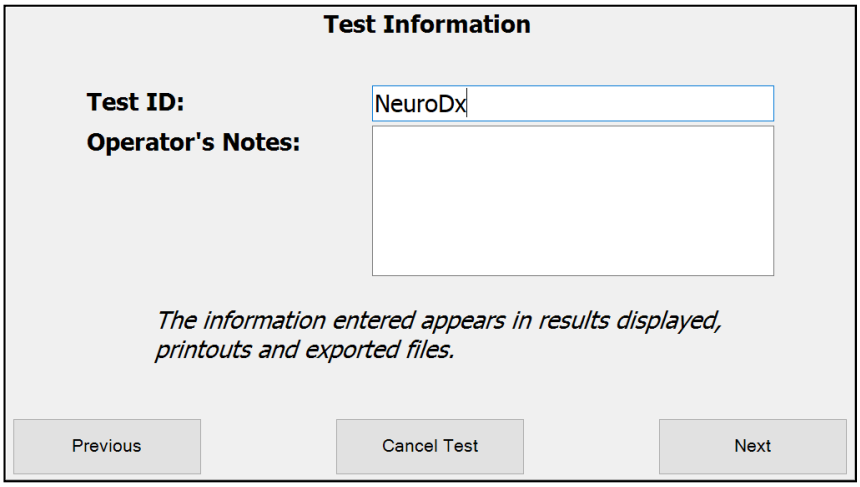
The lower section of the Thermosensor should be placed on the clavicle.

The arrow on the sensor should align with the catheter line. So the sensor will be slightly angled over the clavicle.

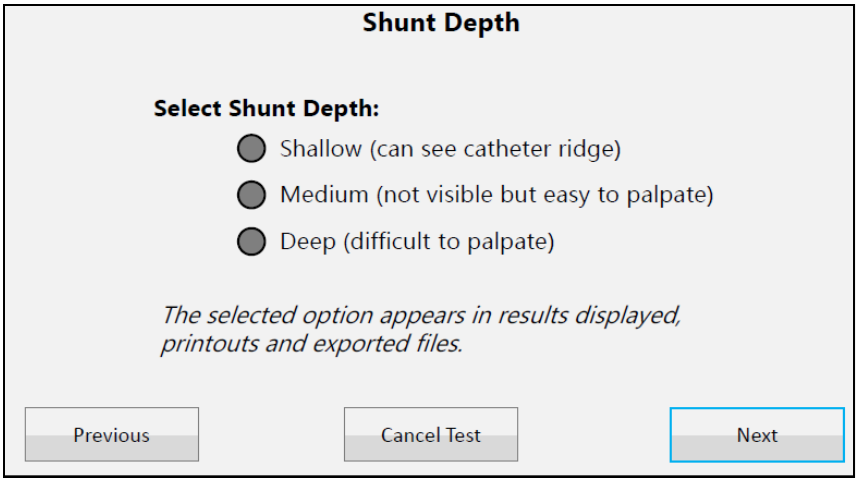



1

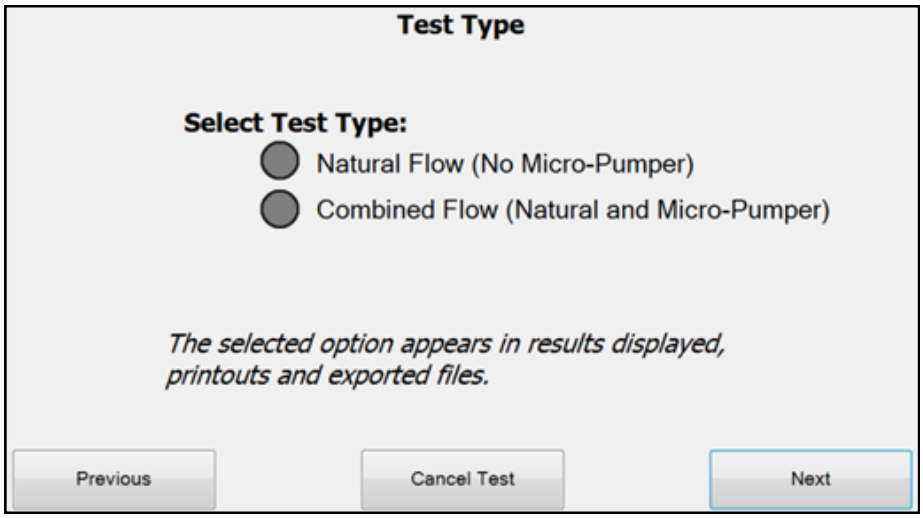
The device will then ask the user to confirm that the Thermosensor is correctly placed on the patient.



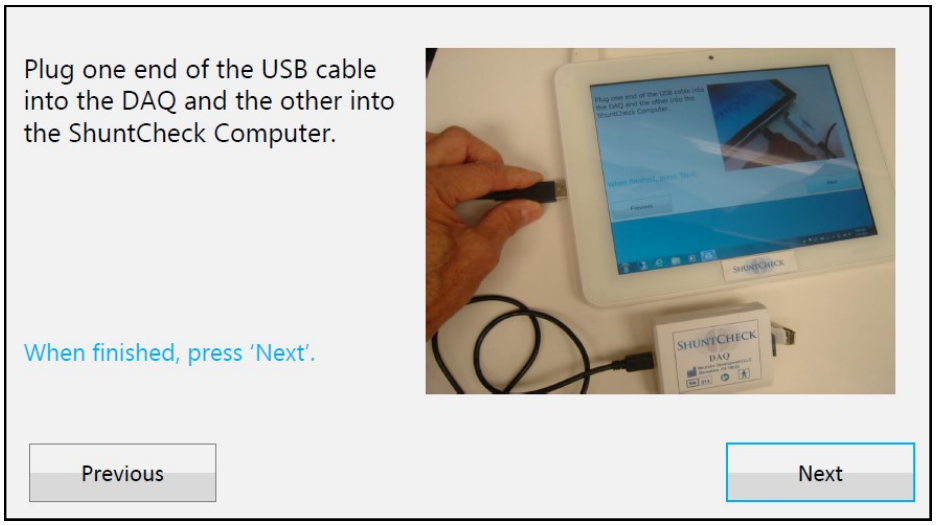

Enter the Test ID and any operator notes.
This information will appear in results displays, printouts & exported files

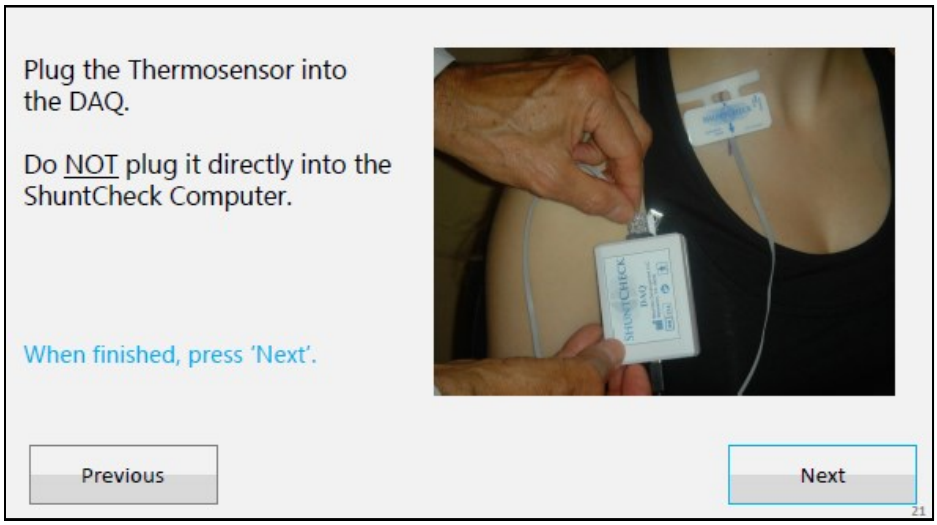



Enter shunt depth information by clicking radio button

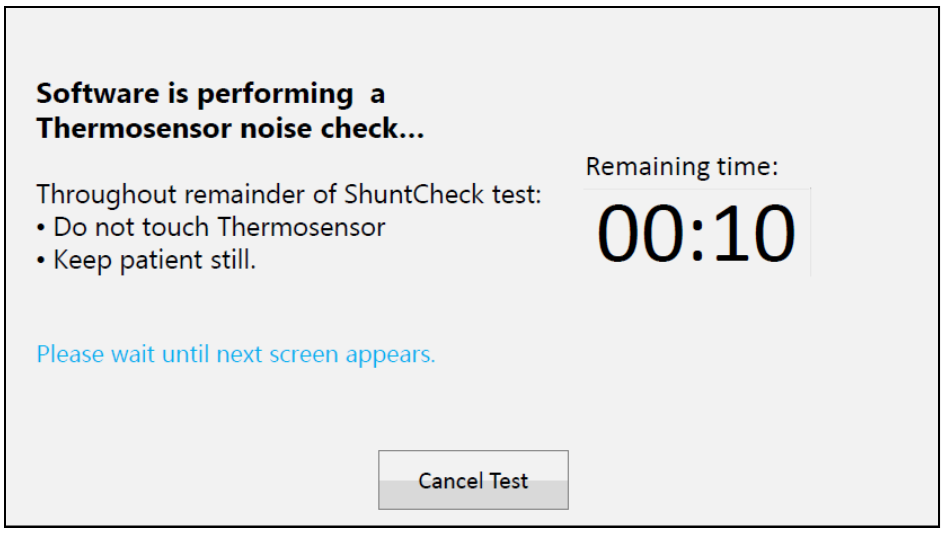



If the Test Type screen appears, select test type Natural Flow by clicking the radio button
(Your facility does not use the Micro-Pumper accessory or the Combined Flow version of the ShuntCheck test)



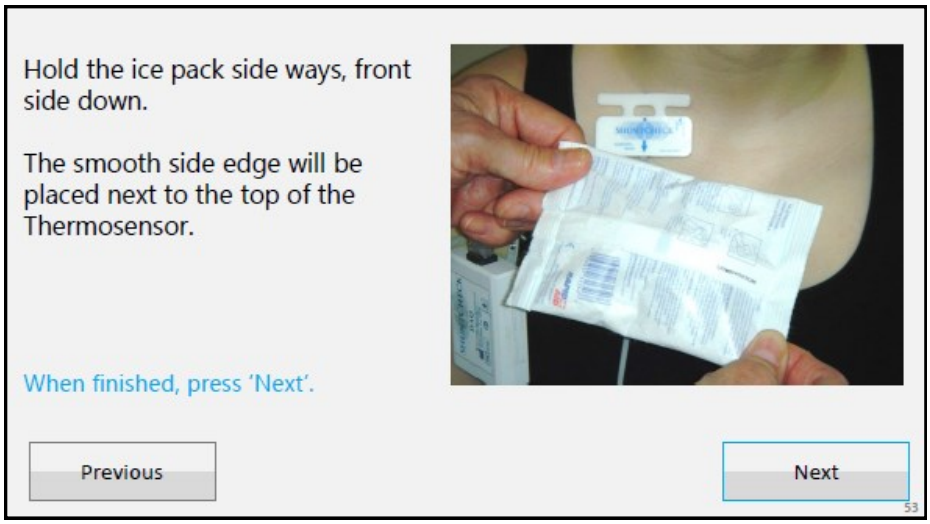



Clip the DAQ to the patient's shirt and plug the thermosensor jack into the DAQ

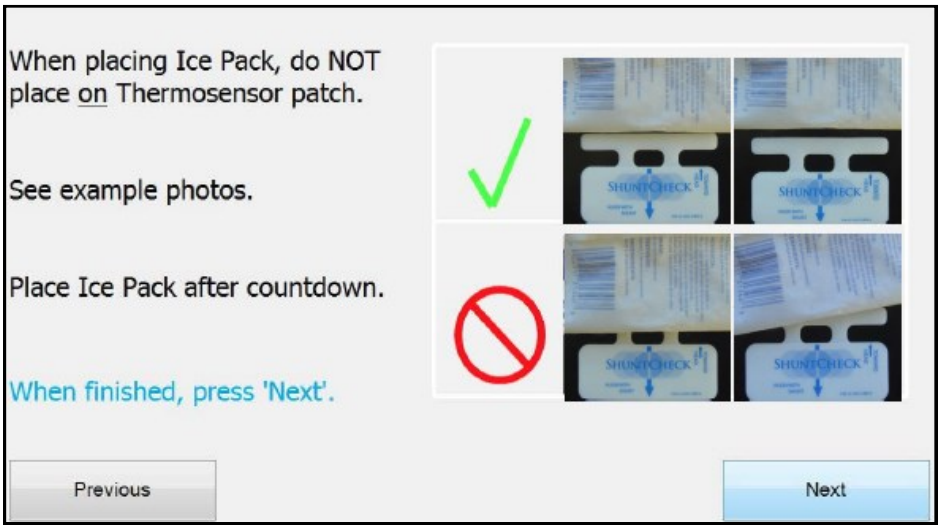



ShuntCheck will then check for good sensor-to-skin contact.
Wait 10 seconds for countdown to complete

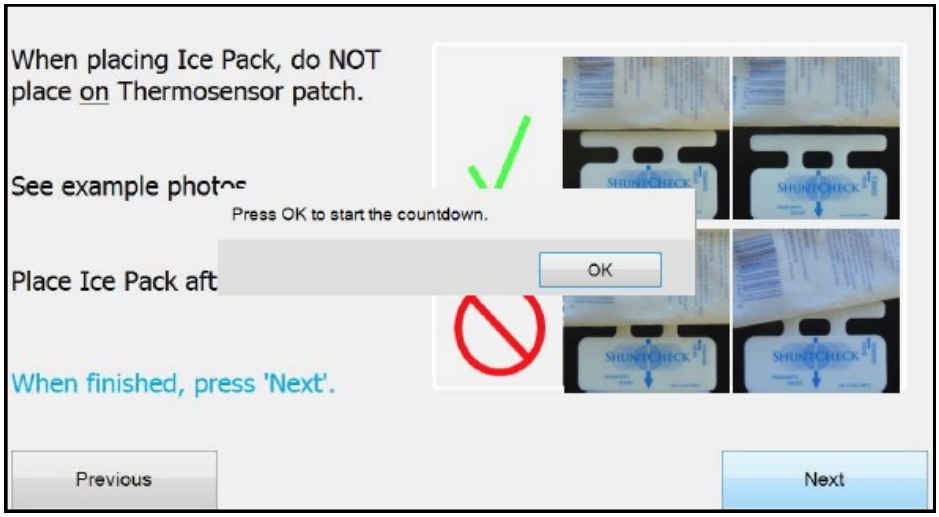
The Instant Ice Pack activates most easily by folding it in half along its long dimension — as shown above



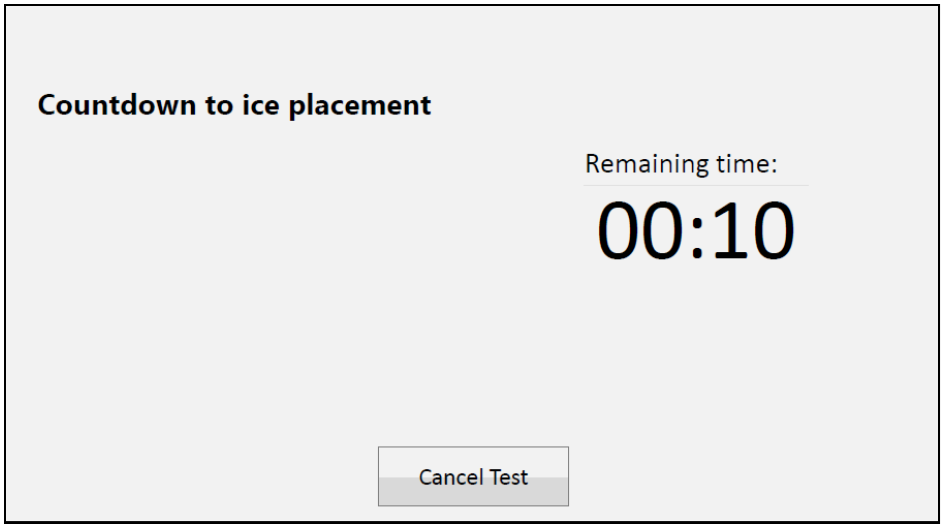
This screen provides a reminder—do not place the ice pack on the sensor

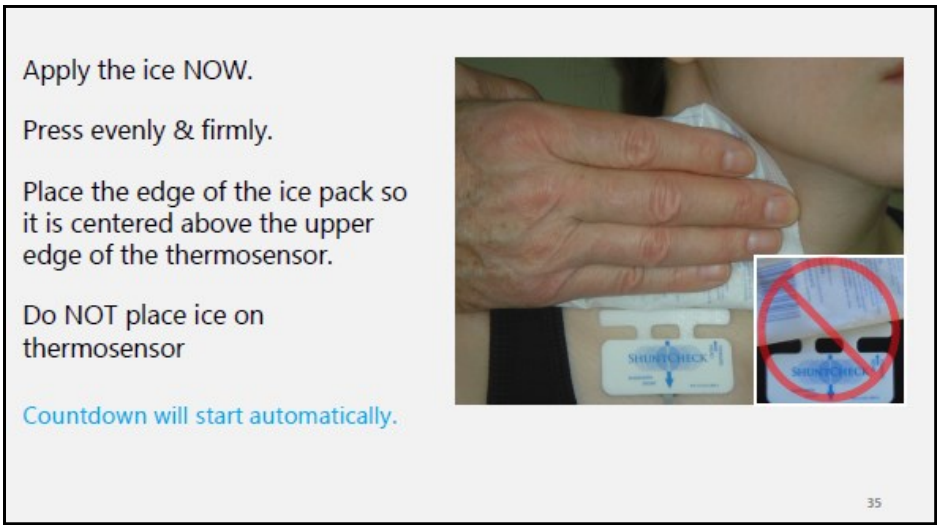



When the ice pack is ready, click Next and then click OK.



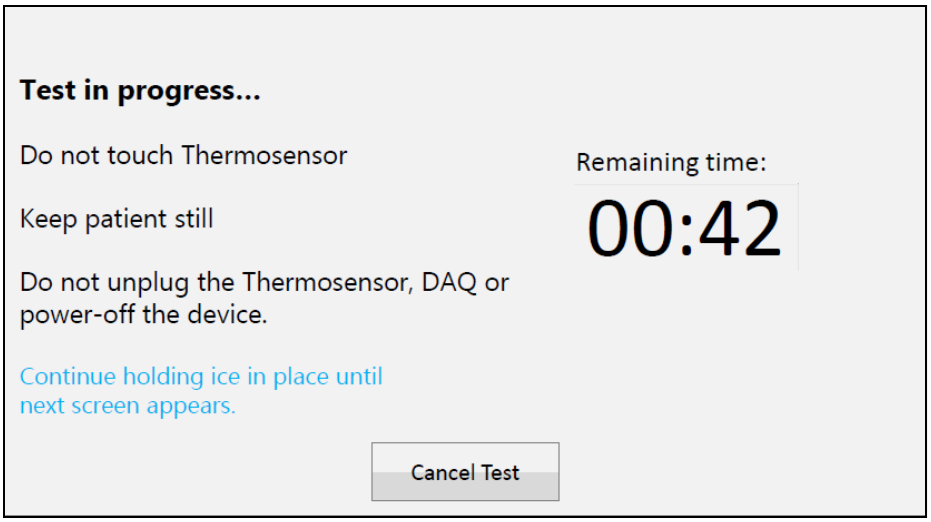

ShuntCheck will provide a 10 second countdown prior to ice application:



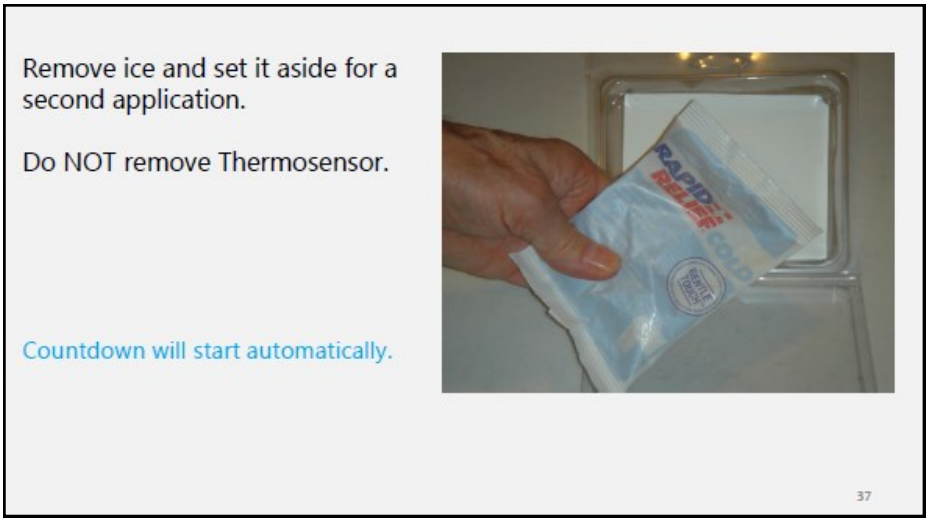




Press *firmly* and *evenly* on the ice and maintain position for 60 seconds to ensure proper cooling of the CSF.

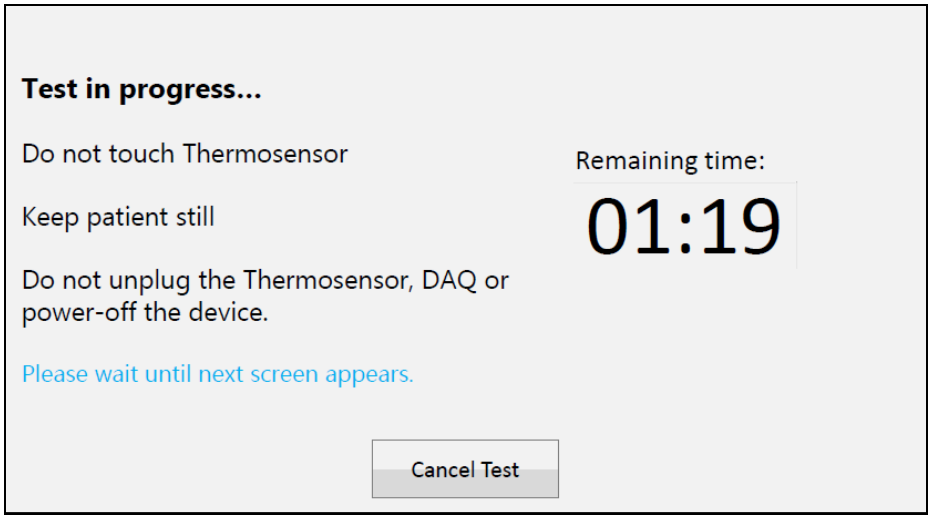
| | |
|---|---|
| ⚠ | *Caution: Do NOT place the ice pack on the thermosensor.* |



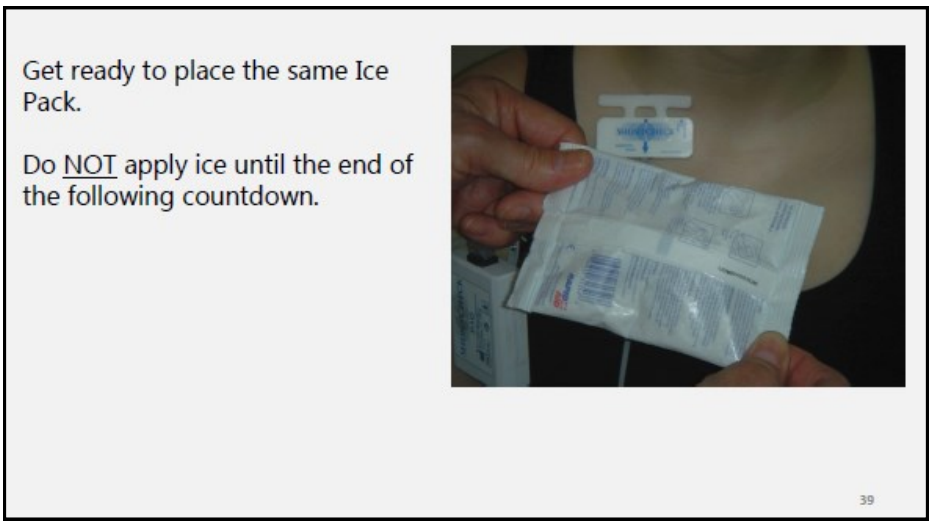

Following the 60 second ice application time, the user will be prompted to remove the ice.




Set aside ice pack for second application

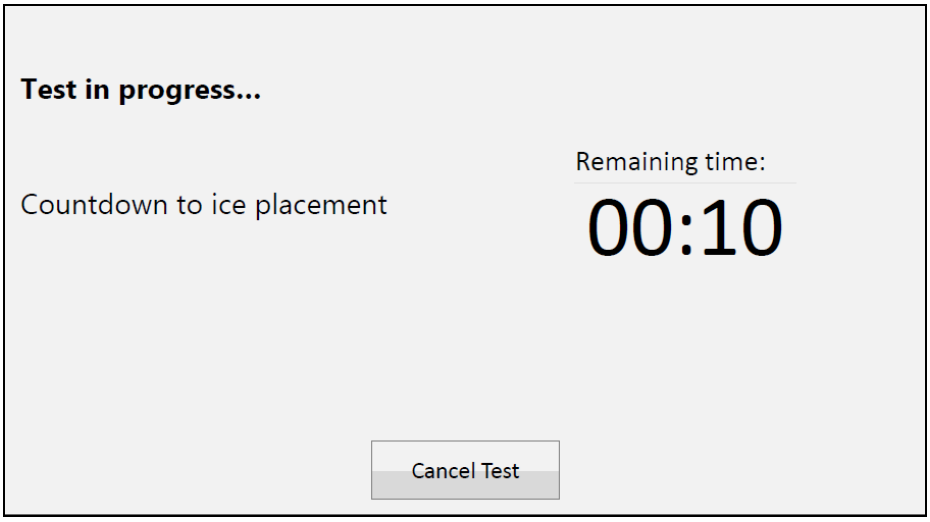



*Caution: The patient must remain still throughout the testing period.*

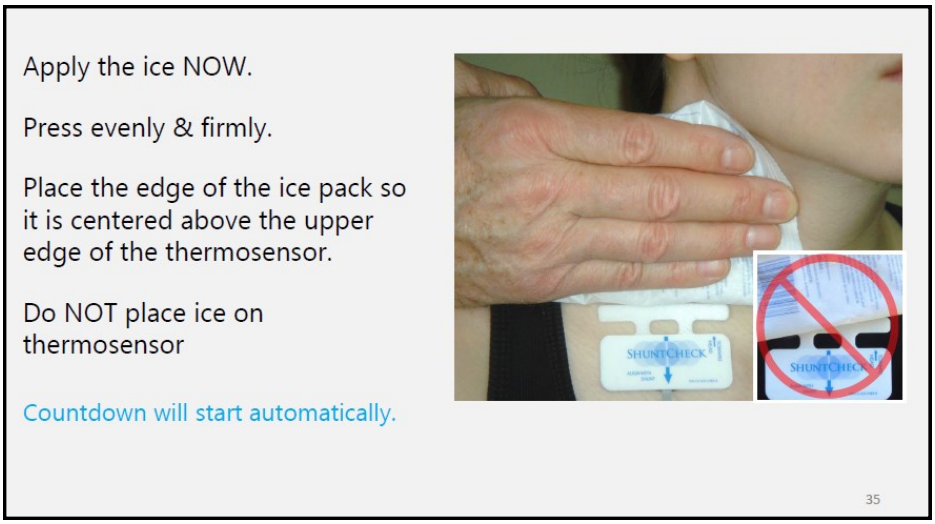



The computer will play an audible note to signal the time to prepare for second ice placement

*Caution: Ensure that the computer's sound is turned up so that this signal can be heard.*



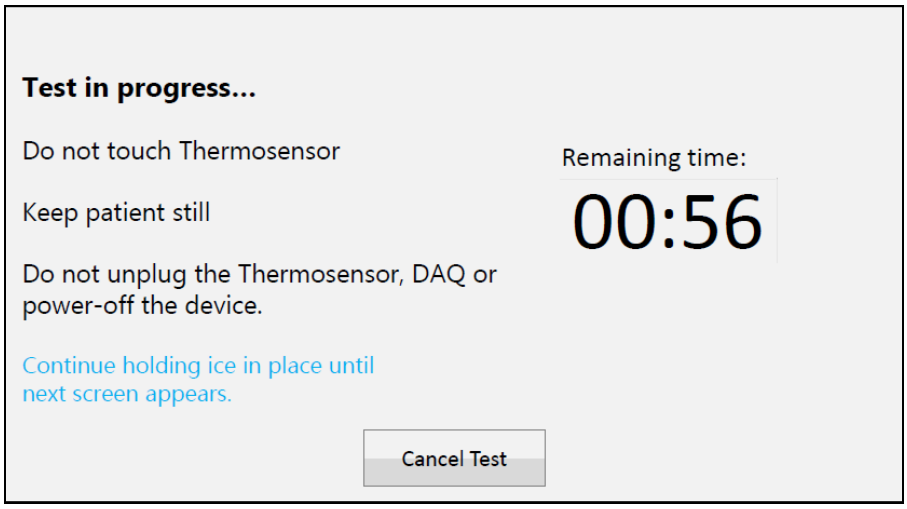

ShuntCheck will provide a 10 second ice countdown




Press *firmly* and *evenly* on the ice and maintain position to ensure proper cooling of the CSF.

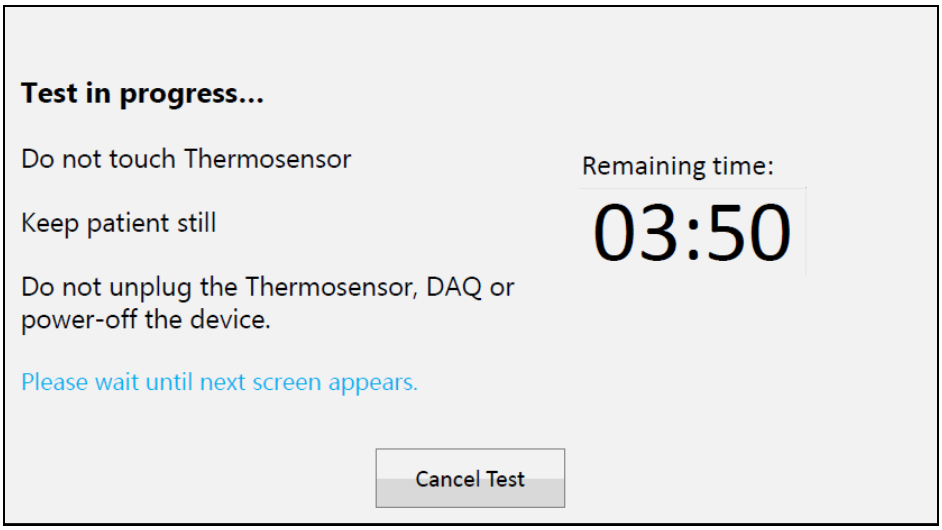
> *Caution: Do NOT place the ice pack on the thermosensor.*

A 120 second countdown will appear.

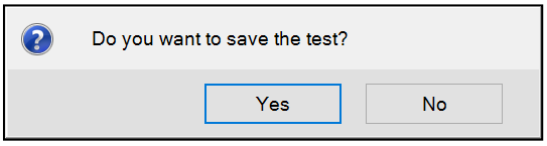



The ice pack can be discarded after this second placement

Click Next  to reach countdown (which is already in progress)

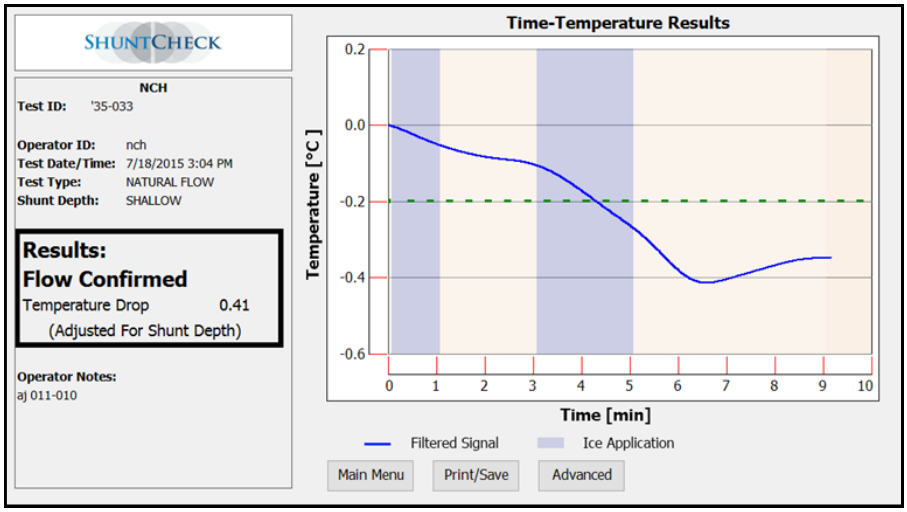



Following the final countdown, ShuntCheck will ask if you wish to save the test




If so, click Yes and then OK on a subsequent pop up.
The device will save the test results and then run through a series of error checks.
If not, click no and the device will ask to retest the patient

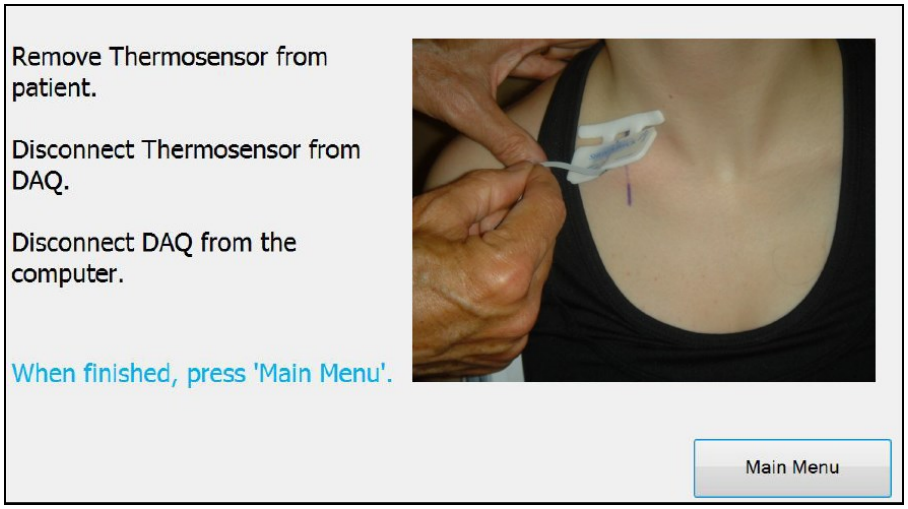
ShuntCheck will then analyze the time-temperature test data and present a results screen.




The panel on the left summarizes patient and test information (Patient ID, date/time of test, type of test, shunt depth) and reports test results ('Flow Confirmed' or 'Flow NOT Confirmed' plus the temperature drop (0.41°C on this test) generated during testing. The panel on the right presents the time-temperature graph generated by the test.

The blue line tracks the ShuntCheck temperature and shows dropping temperature due to CSF flow. The dotted green line is the threshold for Flow Confirmed. (Since the temperature line in this test exceeded the threshold, the Results section in the left panel indicates "Flow Confirmed"). The blue bars indicate the timing of the ice pack placement.

***NOTE:*** *ShuntCheck is an aid to the detection of flow in implanted cerebrospinal fluid (CSF) shunts. ShuntCheck cannot alone diagnose CSF shunt function or malfunction. The clinical diagnosis of CSF shunt function or malfunction, incorporating the flow information from ShuntCheck, should be made only by a qualified neurosurgeon.*




If error checking identifies no test problems, remove the sensor by pulling up on the cable.

Used thermosensors, instant ice packs and a skin markers can be disposed of in regular waste per institutional policies.

## Repeating a ShuntCheck test

A ShuntCheck test may be repeated for a number of reasons:

- To re-run a test which generated an error
- To confirm the finding of the first test
- To assess flow change due to a valve adjustment or positional change

## Skin Rewarming

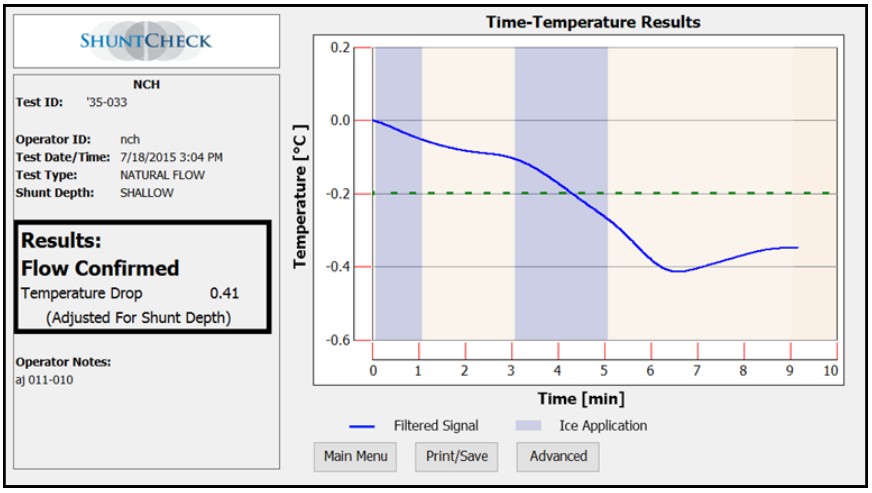
The patient's skin temperature should return to normal before the test is repeated.
In particular, elderly patients' skin rewarms very slowly[1]
Skin rewarming can be used to speed up the timing of a repeat test.
The recommended procedure is:

1. At the completion of the first test, place a warm towel or a warm-pack on the patient's skin where the cold pack had been placed
2. Hold in place for 60 seconds
3. Wait 5 minutes before beginning the next test (to allow the skin to equilibrate)

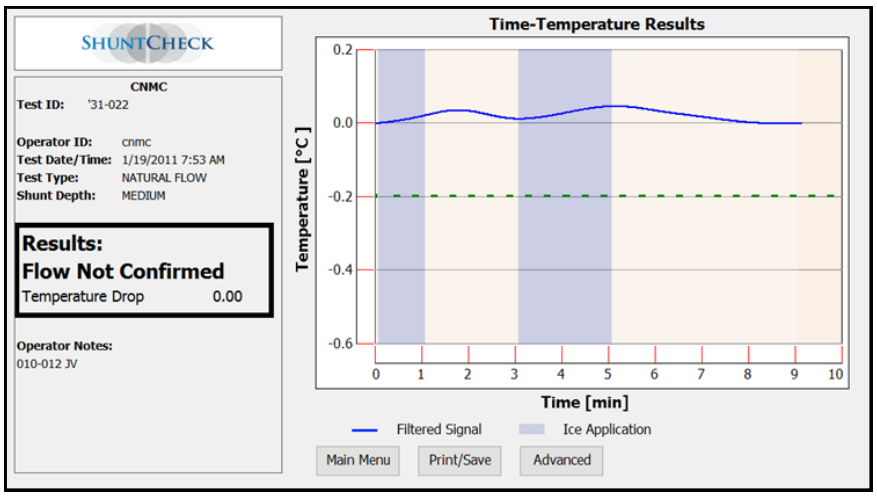
1. Nagashima, Y, et al; *Evaluation...measuring skin blood flow in elderly subjects during cooling load: comparison with younger subjects;* Int J Biometrorol (2003) 47:139-147

## Viewing Graphical Data

Natural flow testing generates results similar to these:



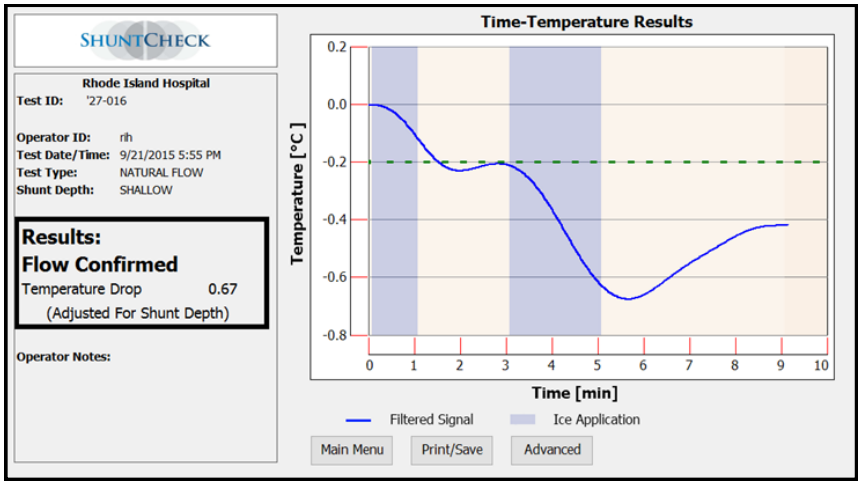

The ice placement periods are shown in blue (The first ice placement for one minute, the second is for two minutes).
In the test above, the Time-Temperature line shows a drop in temperature ≥0.2°C following ice placement, indicating CSF flow. This test is Flow Confirmed.



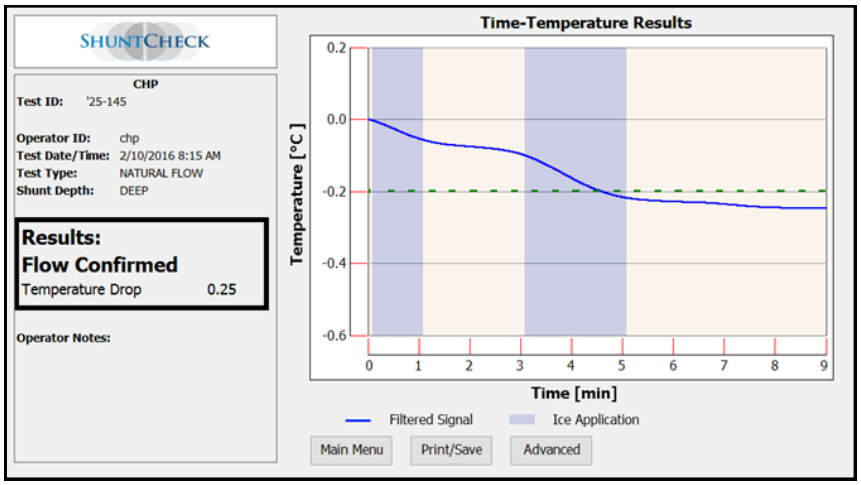

Low CSF flow of 3.5ml/hr or lower will generate a temperature drop of <0.2°C and generate a Flow Not Confirmed test result.

## Viewing Shallow & Deep Shunt Test Graphical Data

Shunt depth impacts the ShuntCheck thermal response.
Shallow shunts respond more quickly and show larger temperature changes.
ShuntCheck software adjusts these larger temperature changes down to make them comparable to Medium depth shunt test results.
The test below shows a flowing shallow shunt

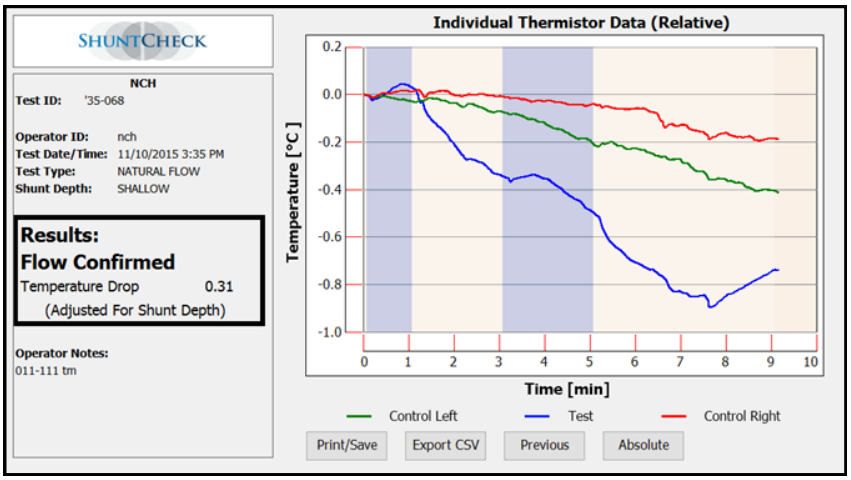



Deep shunts respond more slowly with less temperature change.
The test below shows a flowing deep shunt with a very gradual and muted thermal response.

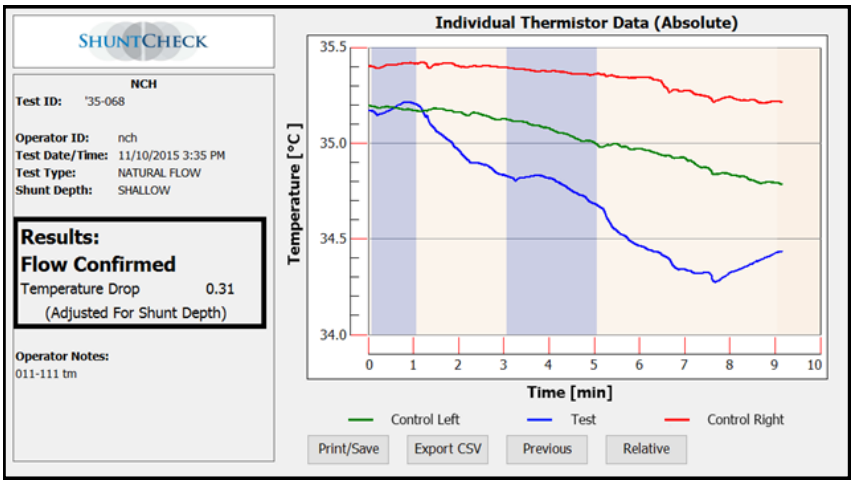


## Viewing Advanced Graphical Data

Click on Advanced to obtain individual thermistor (test, control left, control right) time-temperature graphs




The graph shows the test sensor (blue), control left (green) and control right (red) with all initial temperatures adjusted to zero. Click Absolute to switch to show the actual skin temperatures recorded by each thermistor

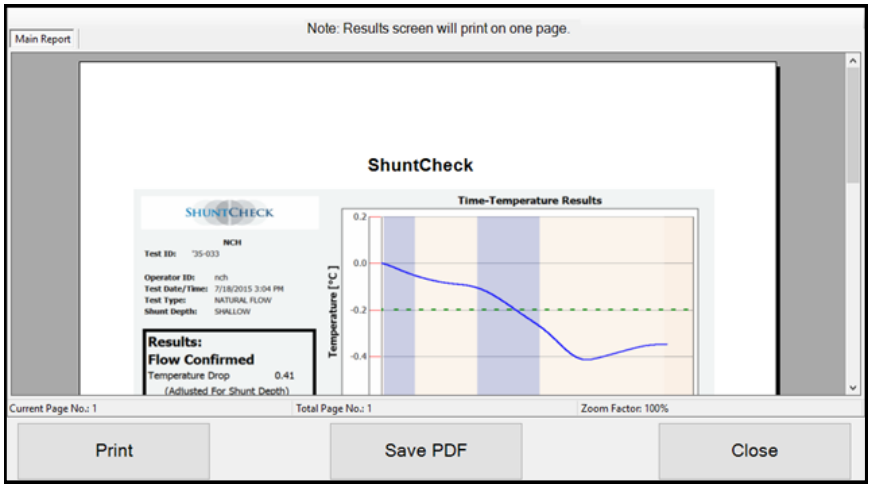



The temperature drop due CSF flow is visible on the blue line.

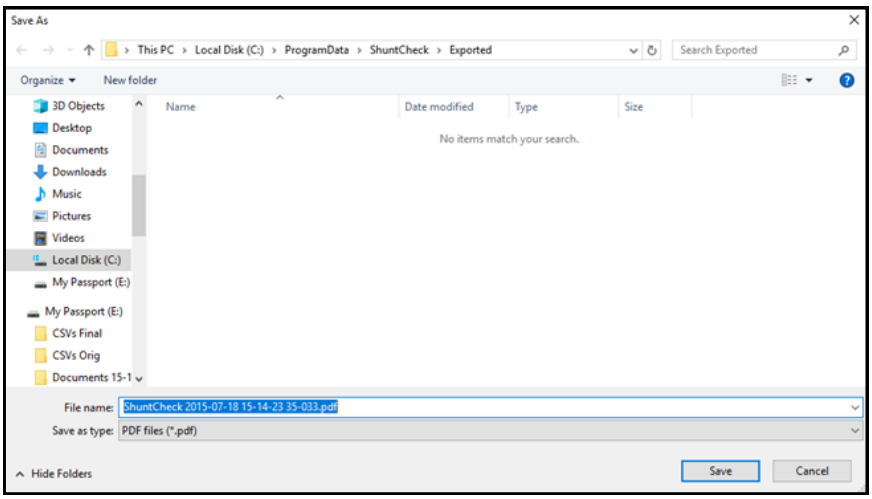
Click Relative to switch to the prior graph.
Click Previous to return to the main results screen.

## Printing & Saving Test Data

Click Print/PDF to reach the print or export screen

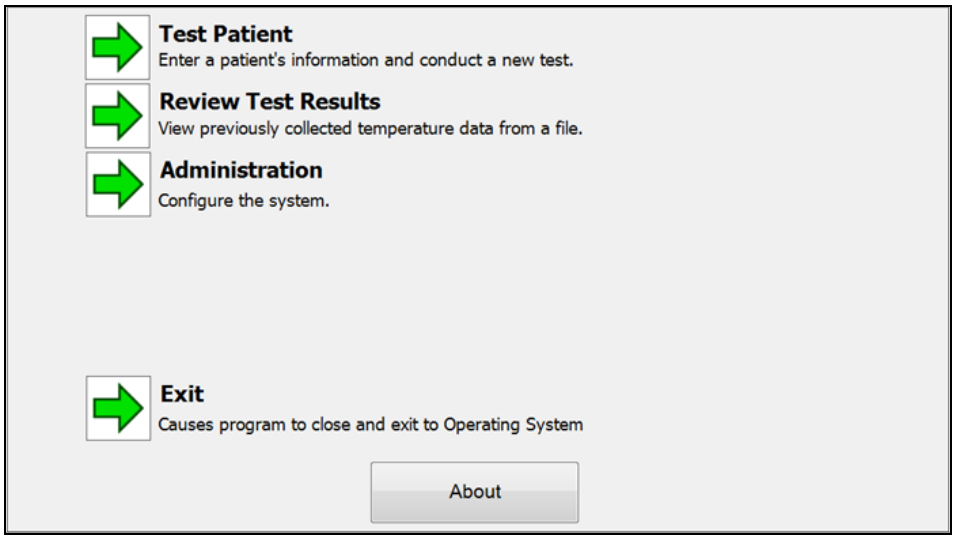



Click Print. The results screen will be printed on the computer's default printer.
Click Save PDF to save a PDF of the screen in ShuntCheck PDF file (default) or to another file accessible by the computer.

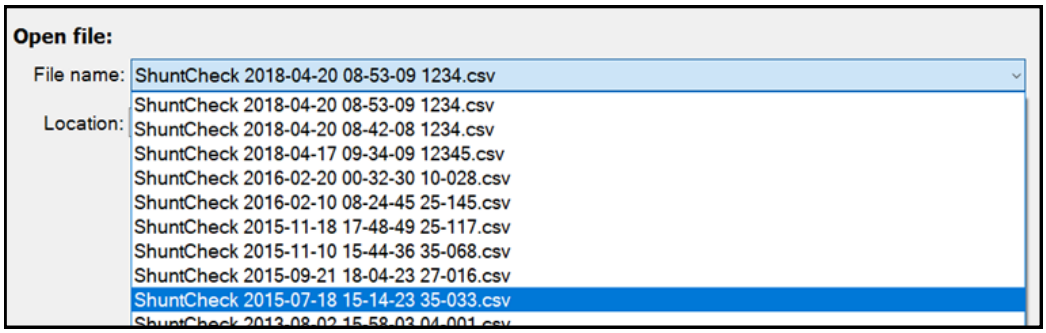


## Viewing Graphical Data of Previous Patients

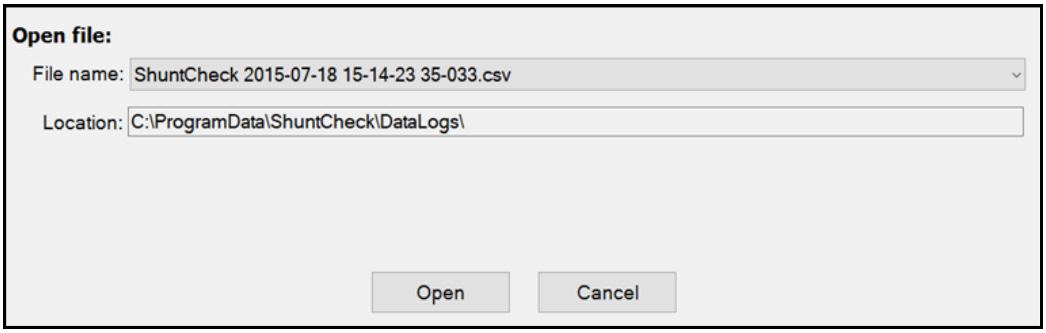
If the user wishes to review the ShuntCheck data of past patients in a time-temperature graph format, this can be done by tapping the ‘Review Test Results” option in the initial ‘Test Patient” screen.



Click on the patient ID from drop down menu

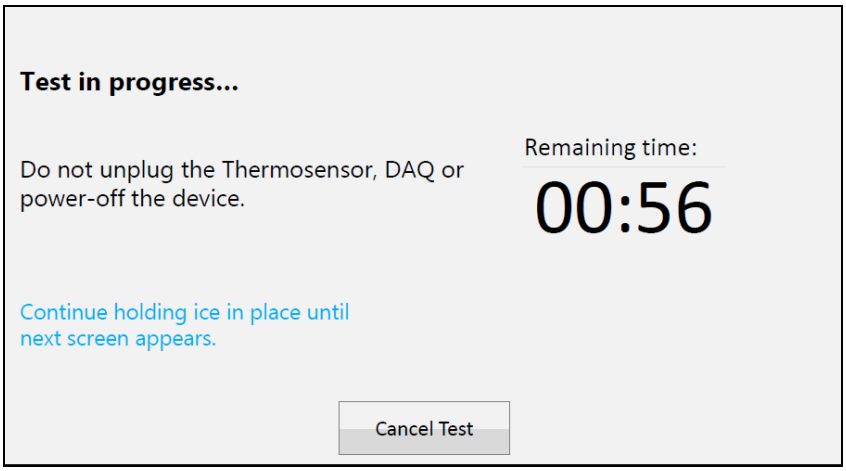



Click Open

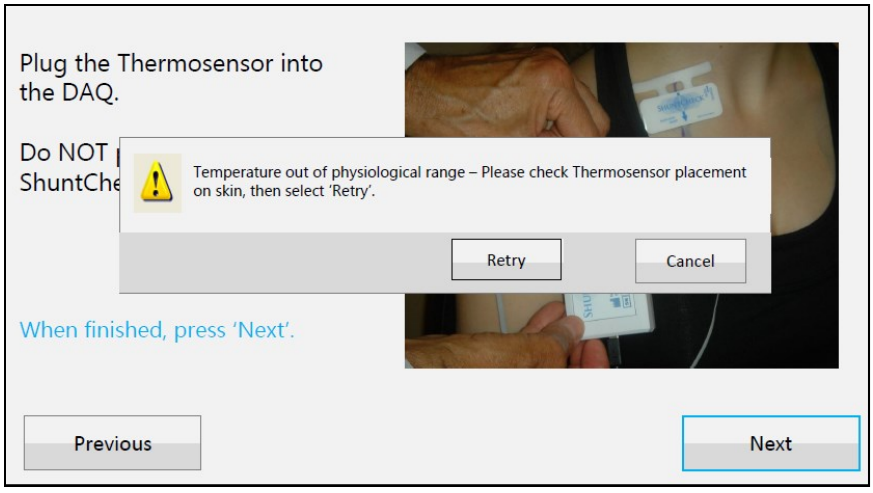


## Troubleshooting, Error Messages, Restarting a ShuntCheck Test

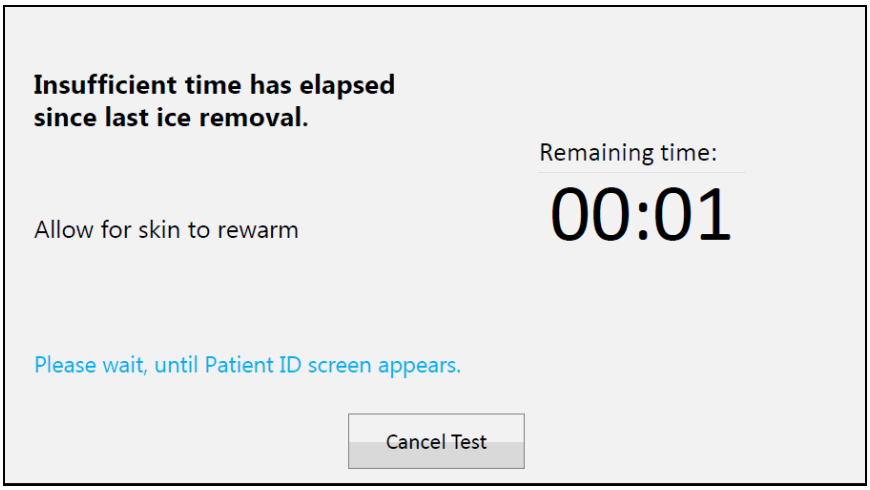
If a ShuntCheck test needs to be restarted due to the sensor patch being dislodged or a procedural error, the test can be restarted by clicking 'Cancel Test' on any of the countdown screens



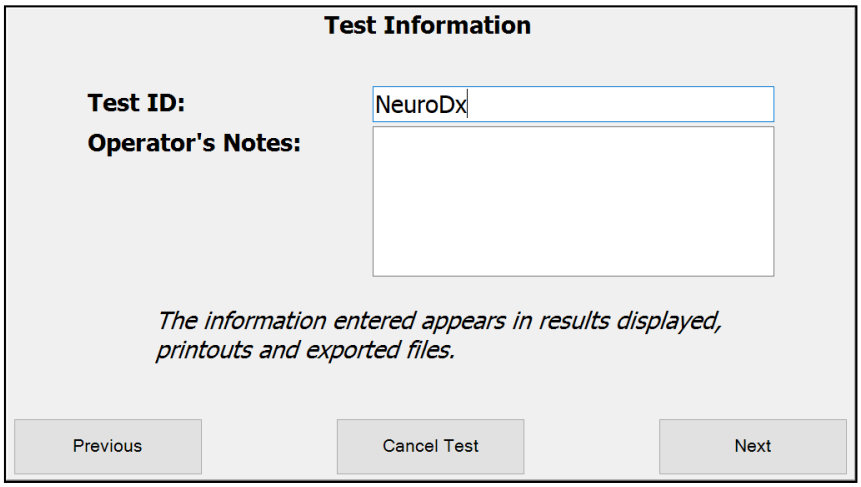

Additionally, ShuntCheck checks for test errors at two points—before the initial ice placement and at the end of the test.
If an error is detected before ice placement, it can be corrected and testing can be resumed. If detected at the end of the test, error must be corrected and the test must be repeated.
Error messages take the form of pop-up messages:



If a test is to be repeated, the device will determine if skin rewarming is required and provide a rewarming countdown.

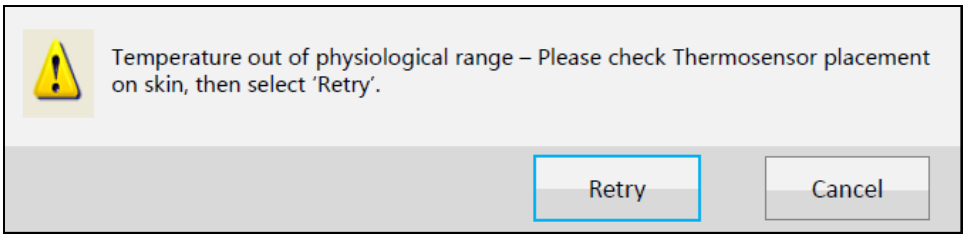



The Test ID will appear at the completion of this countdown.

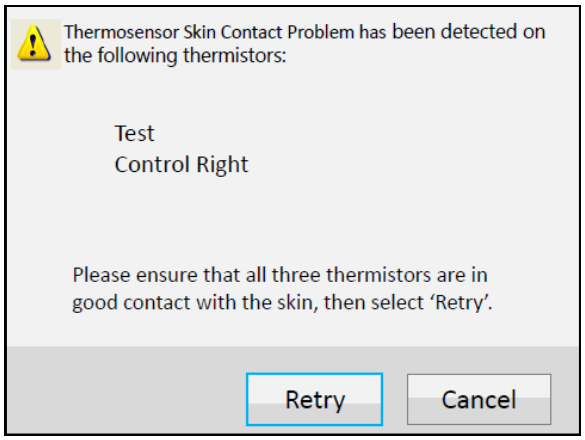



The test can be repeated from this point

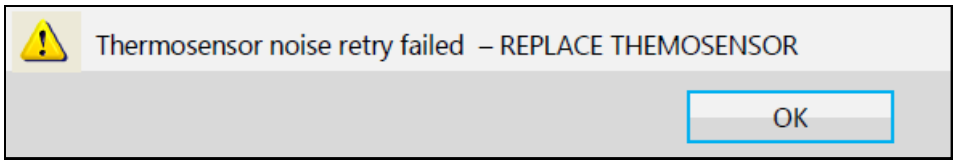
## Error Messages Types



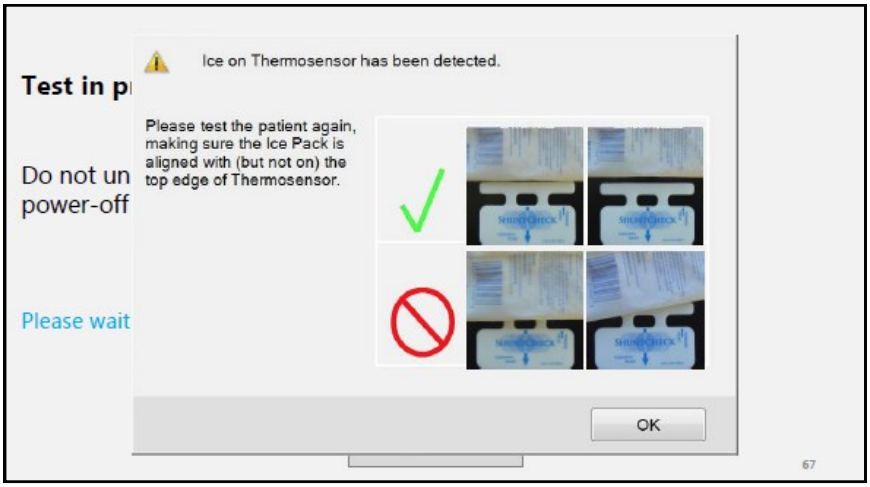

The sensor is reading skin temperatures which are either too high or (most likely) too low. Ensure that the sensor is in good contact with the skin.



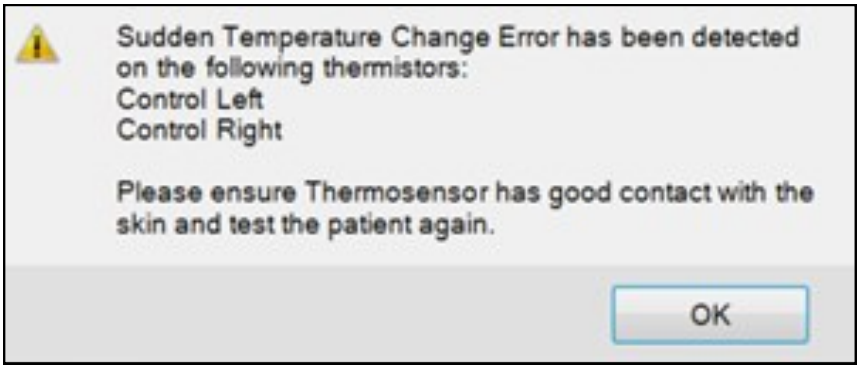

ShuntCheck has detected poor contact between the sensor's thermistors (electronic thermometers) and the patients skin—in this example, the test (middle) and right thermistors are making poor skin contact. Ensure better contact and click Retry



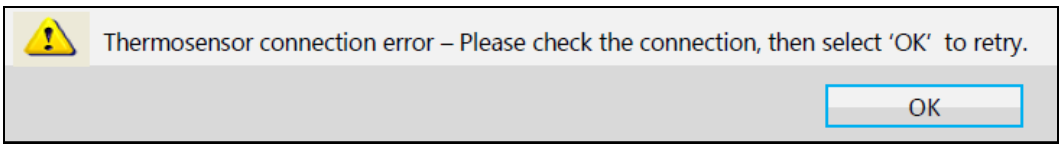

If ShuntCheck continues to detect poor sensor to skin contact, it will provide this warning. Replace the sensor and restart the test



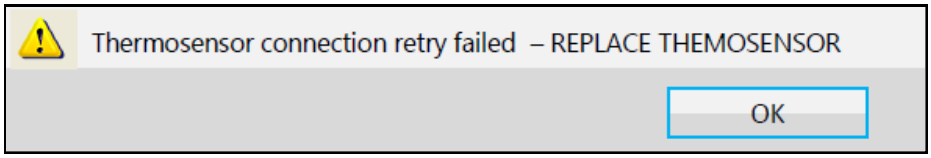

ShuntCheck has detected that the ice pack was contacting the sensor patch during the ice application. This negatively impacts the accuracy and reliability of the ShuntCheck test result.
Click ok.
ShuntCheck will recommend that you test the patient again.



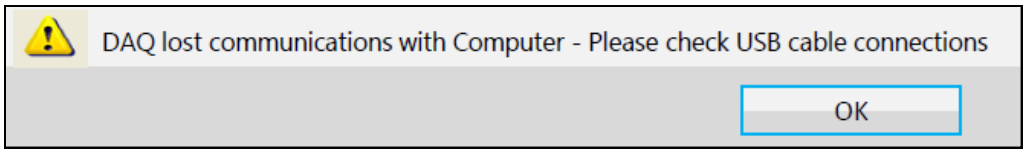

ShuntCheck has detected a sudden change in a control sensor reading.
Check the Thermosensor skin contact and click ok.
ShuntCheck will recommend that you test the patient again.



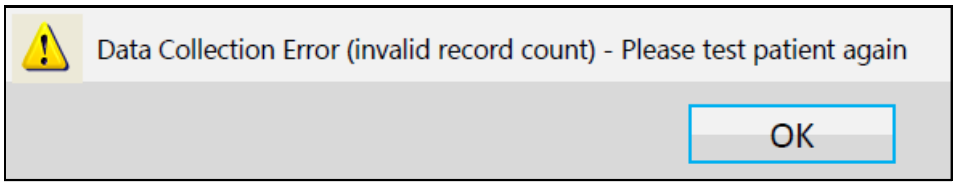

This error is presented if the sensor is not connected to the DAQ. Check the connection and click OK




If the sensor is still not making connection with the DAQ, ShuntCheck will provide this warning. Replace the sensor and restart the test



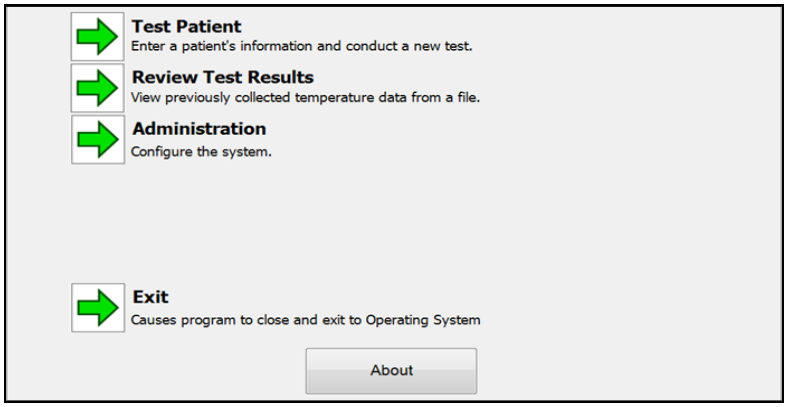

If the DAQ loses connection with the computer (eg if the USB cable is accidentally unplugged, ShuntCheck will provide this warning. Unplug and replug the USB cable into the computer and into the DAQ and click OK



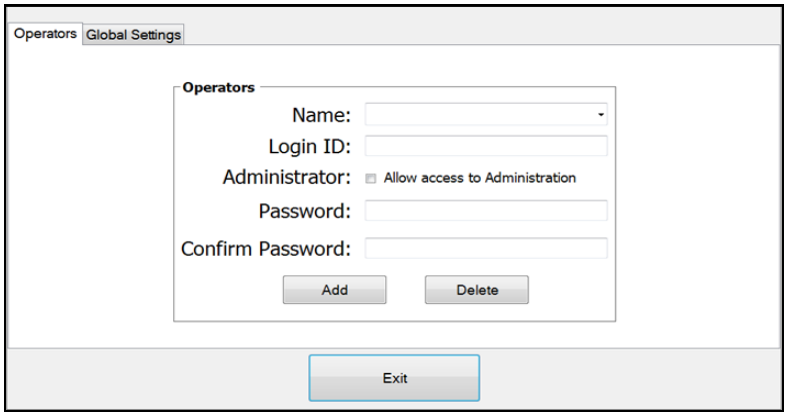

This warning indicates a data recording problem in the test . Click OK and rerun the test

## Administration

The ShuntCheck device can be configured in “Administration”
Click Administration on the Test Patient screen:




Re-enter password shuntcheck and the Operators screen appears




**Add Operators**

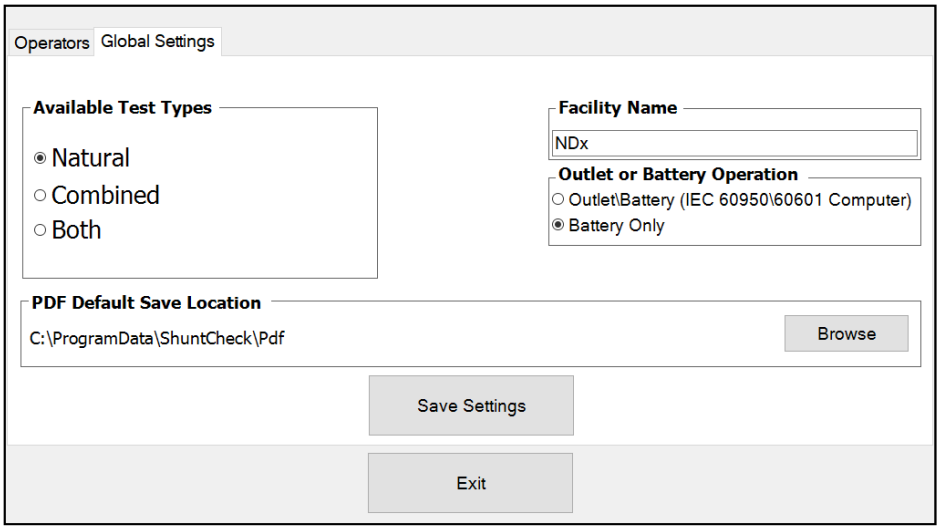
- Add user name in Name field (existing users names appear in a dropdown menu in this field)
- Add user ID in the Login ID field
- If user is to have Administrative authority, check Administrator box
- Add password in Password field and reenter in Confirm field

**To Change or Delete User**

- Select user from dropdown menu in Name field
- To change any field, click Change, enter revisions and click Save Settings
- To delete user, click Delete

## Administration

Click Global Settings




**Select Available Test Types**

- Default setting is Natural Flow (excluding Micro-Pumper).
- Combined (including Micro-Pumper) or Both (Natural and Combined Flow) may be selected by the user)
- To remove a test option, select the other option

**Facility Name**

- Add facility name in Facility Name field (Name will appear on Results Screen)

**Outlet or Battery Operation**

- If software is installed on an IEC 60601/60950 computer, click Outlet/Battery
- If software is installed on a non-60601/60950 laptop or tablet, click Battery Only

**PDF Default Save Location**

- Default setting is PDF Report within the ShuntCheck program
- To select another location, click Browse and select location

**Save Settings**

- After completing additions and changes, click Save Settings
- Click Exit to return to Main Menu

## EMC Guidance

| Guidance and manufacturer's declaration - electromagnetic emissions | | |
|---|---|---|
| The ShuntCheck System is intended for use in the electromagnetic environment specified below. The customer or the user of the ShuntCheck System should assure that it is used in such an environment. | | |
| Emissions test | Compliance | Electromagnetic environment - guidance |
| RF emissions CISPR 11 | Group 1 | The ShuntCheck System 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 A | |
| Harmonic Emissions IEC 61000-3-2 | Not Applicable | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Not Applicable | |
| | | The ShuntCheck System is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning: This equipment is intended for use by healthcare professionals only. This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the ShuntCheck System or shielding the location.** |

| Guidance and manufacturer's declaration - electromagnetic immunity | | | |
|---|---|---|---|
| The ShuntCheck System is intended for use in the electromagnetic environment specified below. The customer or the user of the ShuntCheck System should assure that it is used in such an environment. | | | |
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±6 kV contact ±8 kV air | | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30% |
| Electrical fast transient/burst IEC 61000-4-4 | ±2 kV for power supply lines ±1 kV input/ output lines | Not Applicable . Cable length less than 1[m] | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ±1 kV line(s) to line (s) ±2 kV line(s) to earth | | Mains power quality should be that of a patient environment. |
| Voltage dips, short interruptions and voltage variations on power supply inputs lines IEC 61000-4-11 | <5% Ut (>95 % dip in Ut) for 0,5 cycle 40% Ut (60% dip in Ut) For 5 cycles 70% Ut (30% dip in Ut) For 25 cycles <5% Ut (>95% dip in Ut) for 5 sec | | Mains power quality should be that of a patient environment. If the user of the ShuntCheck System requires continued operation during power mains interruptions, it is recommended that the ShuntCheck System be powered from an interruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | | Power frequency magnetic fields should be at levels characteristic of a typical location in a patient environment |
| Note Ut is the a.c. mains voltage prior to application of the test level. | | | |

| Guidance and manufacturer's declaration - electromagnetic immunity | | | |
|---|---|---|---|
| The ShuntCheck System is intended for use in the electromagnetic environment specified below. The customer or the user of the ShuntCheck System should assure that it is used in such an environment. | | | |
| 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 | Portable and mobile RF communications equipment should be used no closer to any part of ShuntCheck System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance<br>$d = [1.2]\sqrt{P}$<br>$d = [1.2]\sqrt{P}$ 80 MHz to 800MHz<br>$d = [2.3]\sqrt{P}$ 800 MHz to 2,5 Ghz<br>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).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b]<br>Interference may occur in the vicinity of equipment marked with the following symbol: |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2,5 GHz | 3 V/m | |
| NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.<br><br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ShuntCheck System is used exceeds the applicable RF compliance level above, the ShuntCheck System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ShuntCheck System. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

**Recommended separation distances between portable and mobile RF communications equipment and the ShuntCheck System**

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

| Rated maximum output power of transmitter W | Separation distance according to frequency of transmitter m | | |
|---|---|---|---|
| | 150 KHz to 80 MHz $d = [1,2]\sqrt{P}$ | 80 MHz to 800 MHz $d = [1,2]\sqrt{P}$ | 800 MHz to 2,5 GHz $d = [2,3]\sqrt{P}$ |
| 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 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

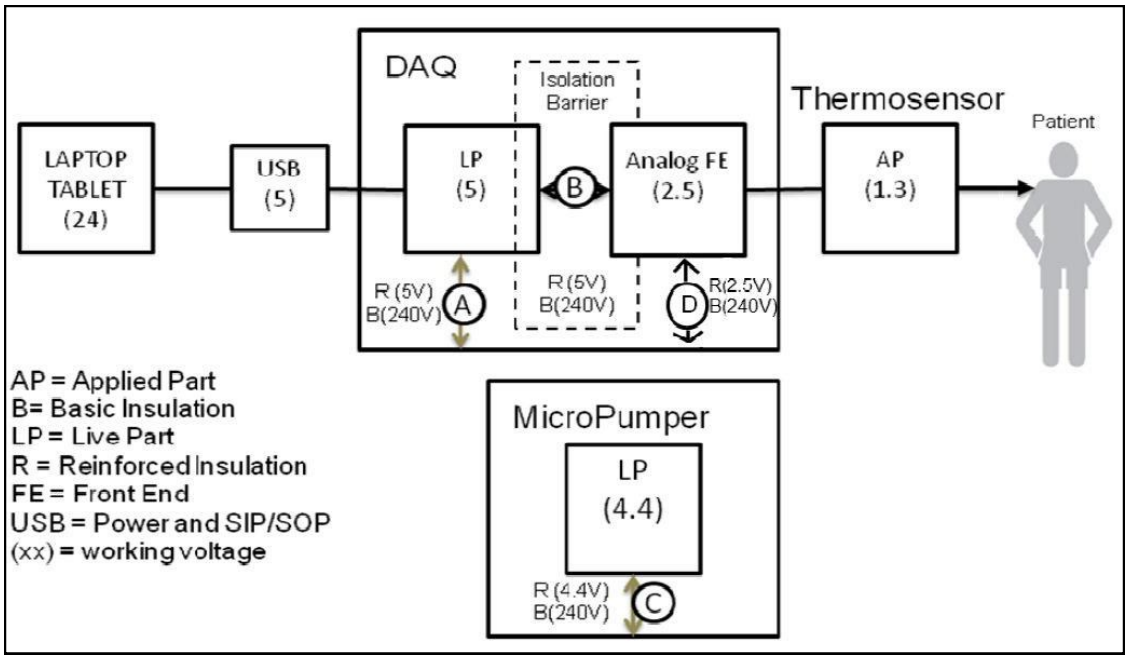
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

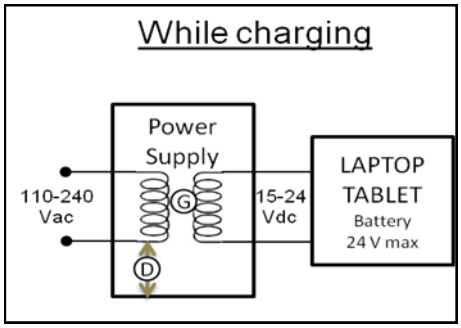
NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

NOTE 3 An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## Isolation Diagram



## Cleaning & Maintenance

***Cleaning DAQ***

To clean after test use, wipe the device with 70% isopropyl alcohol using a soft cloth. Dry thoroughly.

***Charging if laptop or tablet used in ShuntCheck testing***

- The laptop/tablet should be turned off and charged whenever it is not in use.
- Do not begin conducting a test if the battery is low.
- Do not charge in operating theater.
- Disconnect the DAQ from the computer before charging

*Warning: Do not attempt to breach the DAQ or any reason. Do not pour isopropyl alcohol into the device.*

In the event of difficulties with the ShuntCheck device or software, please contact NeuroDx Development, LLC

info@neurodx.com

www.neurodx.com

## Symbol Chart

| | |
|---|---|
| Caution / Warning | Manufactured By |
| DC Current | REF Catalog Number |
| Do Not Reuse | LOT Lot Number |
| Type BF applied part, device will contact patient or operator | Lower / Upper Temperature Limitations |
| Refer to Instruction Manual | SN Serial Number |

# SHUNTCHECK

III

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NEURODX DEVELOPMENT

Operating Manual
12-1382-2 Rev R(1807-01)

Revised July 2018