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The logo for SHUNT CHECK features the words "SHUNT CHECK" in a blue, serif font. The text is centered over a background of five overlapping circles in shades of gray. A vertical white line bisects the circles and the text.

# SHUNT CHECK

III

## **Operating Manual**

For

### **ShuntCheck Natural Flow Test**



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### 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 charge computer in 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 

### 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 a 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

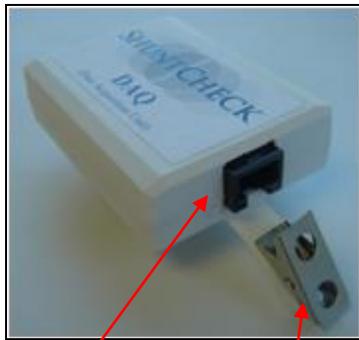
The ShuntCheck Data Acquisition Unit (DAQ) has a top, front, and back panel. Each panel's various functions are described below.

**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
<b>Thermosensor</b>	
Size & Weight	Length 24" x Width 2.5" X Height 1.5", 20 grams
Material	EVA patch with medical grade adhesive
<b>Accessories</b>	
Instant Cold Pack	Rapid Relief, Instant Cold Pack, #31346 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 tablet or laptop computer running ShuntCheck software provides step-by-step instructions, analyzes the temperature readings and displays test results

ShuntCheck Computer	Specification
Power	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**

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

**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.
- Do not place the Micro-Pumper over open wounds or recently implanted shunt valves.
- 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 laptop or tablet 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.

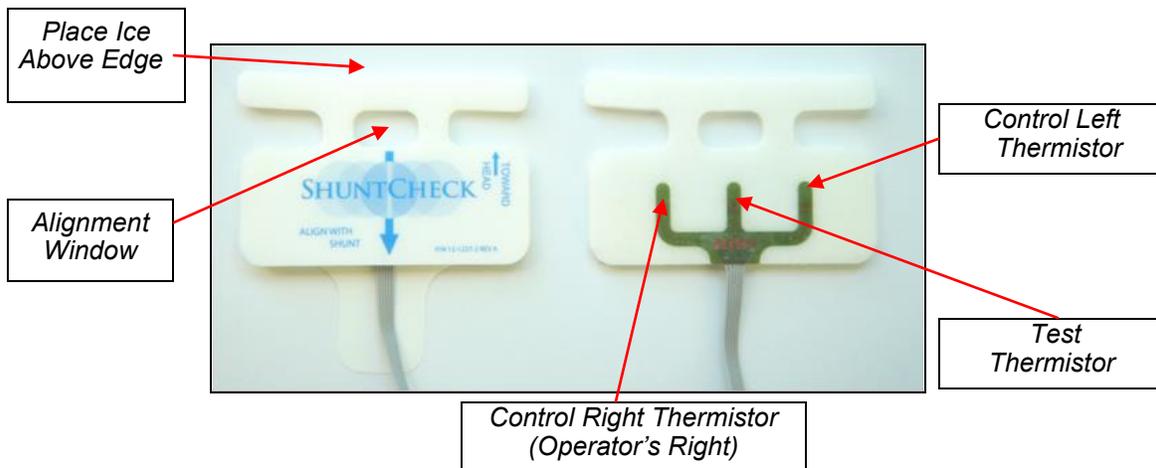
Prior to conducting the test, ensure the patient is sitting up comfortably with back support. The patient position may be changed during the test as directed by a physician.

### 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





The image shows a login dialog box titled "ShuntCheck III". It contains two input fields: "Login ID" and "Password". Below the fields are two buttons: "Login" and "Cancel".

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 the device is charging.*

The image shows the main menu screen of the ShuntCheck III software. It features four menu items, each with a green arrow icon:

- Test Patient**: Enter a patient's information and conduct a new test.
- Review Test Results**: View previously collected temperature data from a file.
- Administration**: Configure the system.
- Exit**: Causes program to close and exit to Operating System

At the bottom of the menu is an "About" button.

Click Test Patient





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

Patient should be seated with back support.

Palpate for the shunt over the clavicle.



When finished, press 'Next'.

Cancel Test      Next

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

**Assess Shunt Depth**

**Determine Patient's Shunt Depth as either:**

- Shallow (can see catheter ridge)
- Medium (not visible but easy to palpate)
- Deep (difficult to palpate)

*This information will be entered after Patient ID.*

When finished, press 'Next'

Previous      Next





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: Do not 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





Ensure complete adhesion by pressing down firmly over entire Thermosensor.



When finished, press 'Next'

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

Ensure complete adhesion by pressing down firmly over entire Thermosensor.



 Is the Thermosensor placed correctly over the shunt?

When finished, press 'Next'





**Patient Information**

**Patient ID:**

**Operator's Notes:**

*The information entered appears in results displayed, printouts and exported files.*

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

**Shunt Depth**

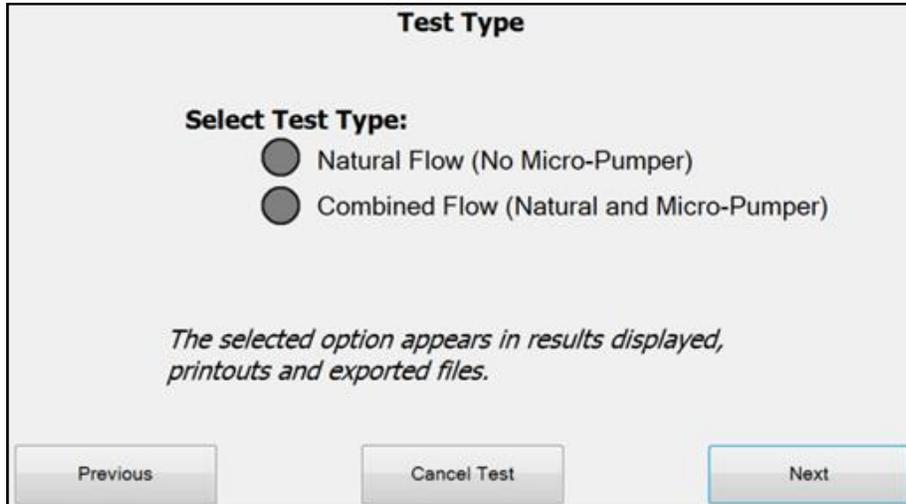
**Select Shunt Depth:**

- Shallow (can see catheter ridge)
- Medium (not visible but easy to palpate)
- Deep (difficult to palpate)

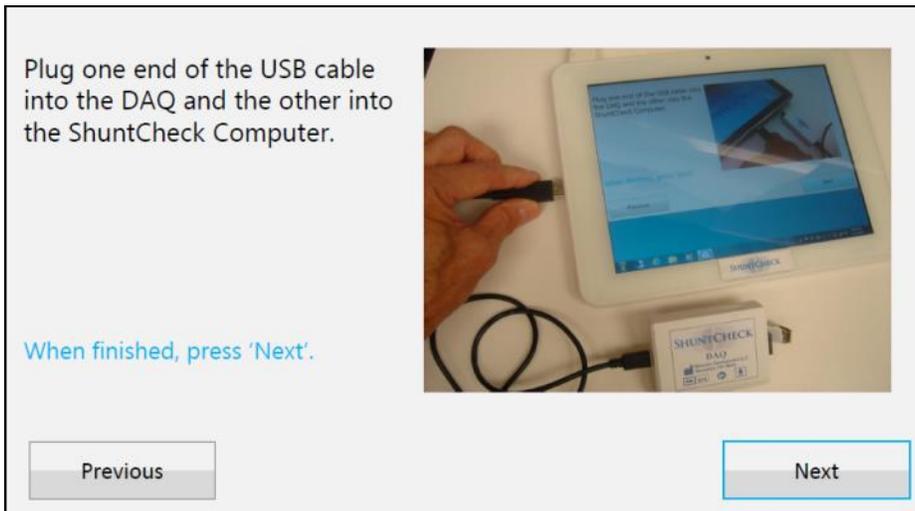
*The selected option appears in results displayed, printouts and exported files.*

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)





Plug the Thermosensor into the DAQ.

Do NOT plug it directly into the ShuntCheck Computer.

When finished, press 'Next'.



Previous Next

21

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

**Software is performing a Thermosensor noise check...**

Throughout remainder of ShuntCheck test:

- Do not touch Thermosensor
- Keep patient still.

Remaining time: **00:10**

Please wait until next screen appears.

Cancel Test

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





Prepare Instant Ice Pack:

- Squeeze to activate cooling
- Shake vigorously for 20 seconds

When finished, press 'Next'



Previous Next

30

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

Hold the ice pack side ways, front side down.

The smooth side edge will be placed next to the top of the Thermosensor.

When finished, press 'Next'.



Previous Next

53

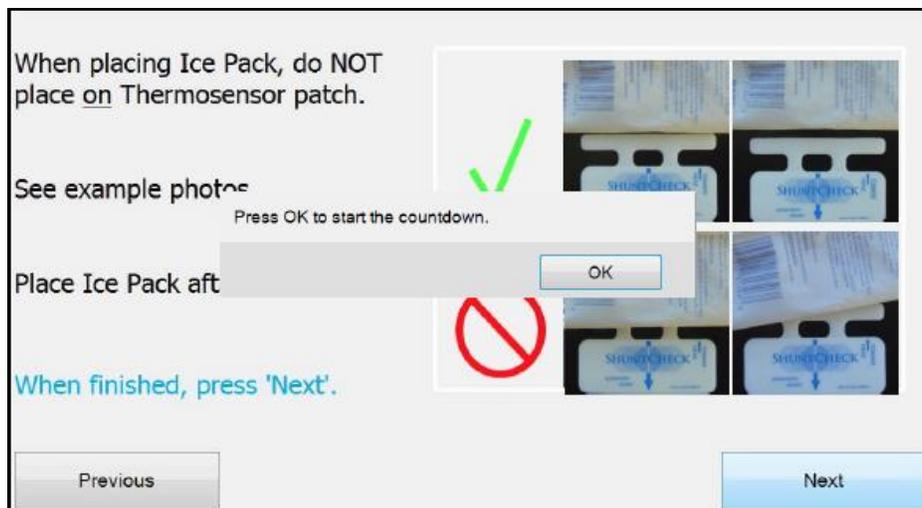




This screen provides a reminder—do not place the ice pack on the sensor



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



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





**Countdown to ice placement**

Remaining time:  
**00:10**

Cancel Test

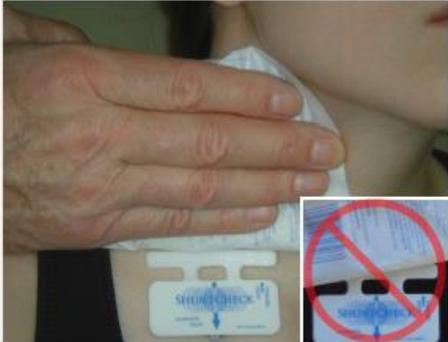
Apply the ice NOW.

Press evenly & firmly.

Place the edge of the ice pack so it is centered above the upper edge of the thermosensor.

Do NOT place ice on thermosensor

Countdown will start automatically.



35

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.**





**Test in progress...**

Do not touch Thermosensor

Keep patient still

Do not unplug the Thermosensor, DAQ or power-off the device.

Remaining time:  
**00:42**

Continue holding ice in place until next screen appears.

Cancel Test

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

Remove ice and set it aside for a second application.

Do NOT remove Thermosensor.

Countdown will start automatically.



37

Set aside ice pack for second application





**Test in progress...**

Do not touch Thermosensor

Keep patient still

Do not unplug the Thermosensor, DAQ or power-off the device.

Remaining time:

**01:19**

Please wait until next screen appears.

Cancel Test

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

Get ready to place the same Ice Pack.

Do NOT apply ice until the end of the following countdown.

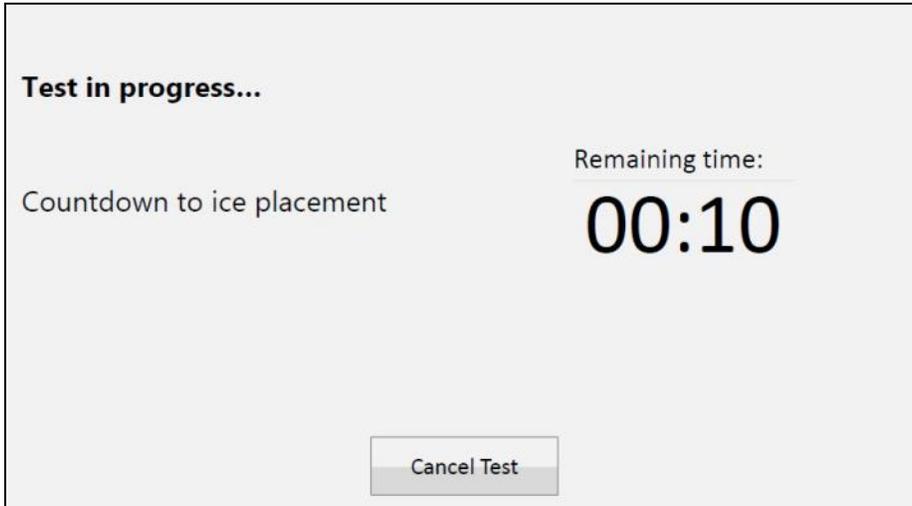


39

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

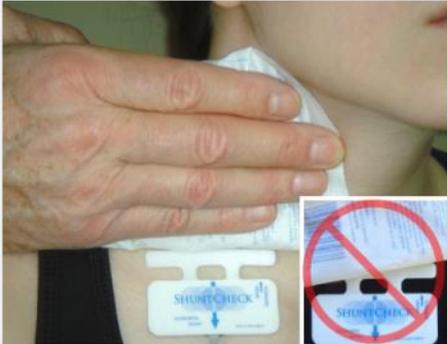
Apply the ice NOW.

Press evenly & firmly.

Place the edge of the ice pack so it is centered above the upper edge of the thermosensor.

Do NOT place ice on thermosensor

Countdown will start automatically.



35

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.

**Test in progress...**

Do not touch Thermosensor

Keep patient still

Do not unplug the Thermosensor, DAQ or power-off the device.

Remaining time:  
**00:56**

Continue holding ice in place until next screen appears.

Cancel Test

The ice pack can be discarded after this second placement

Discard the ice pack.

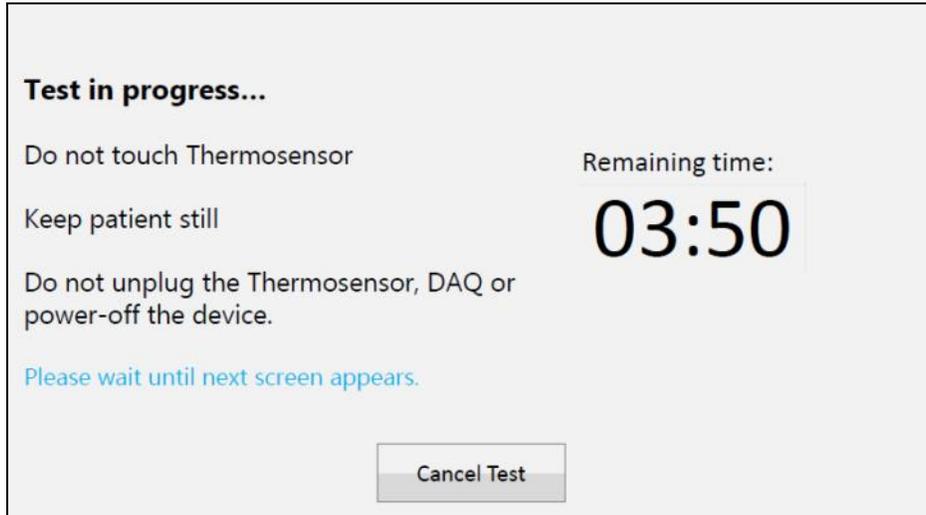


42

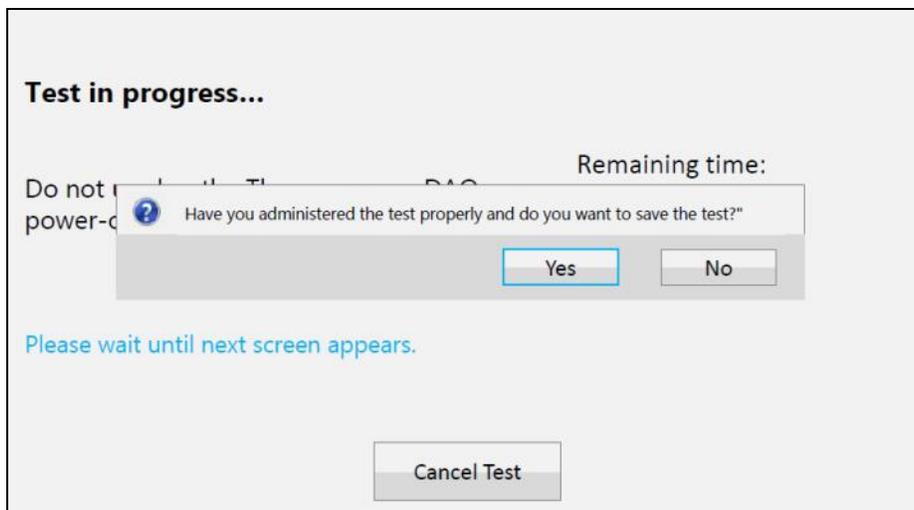




Click Next to reach countdown (which is already in progress)



Following the final countdown, ShuntCheck will ask if the test was administered correctly.

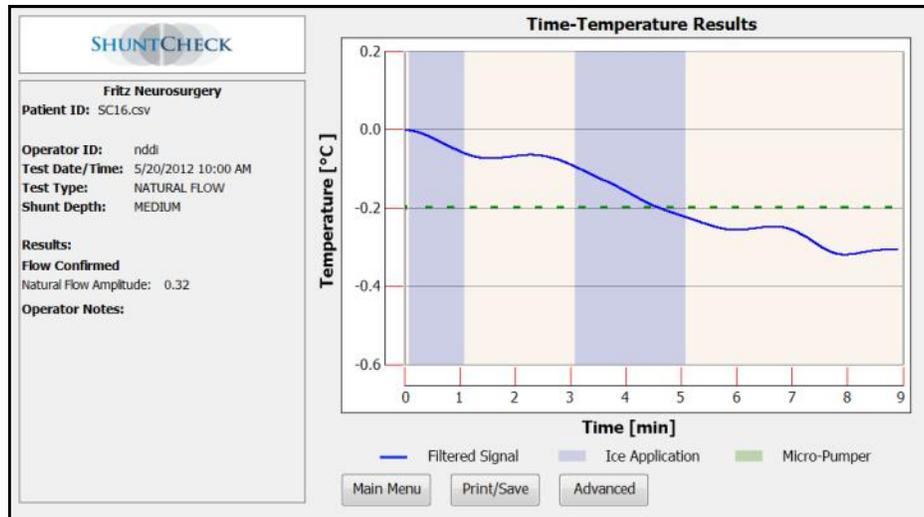


If so, click Yes and then OK on a subsequent pop up.  
The device will save the test results and then run through a series of error checks.  
If not, click no and the device will ask to retest the patient





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 amplitude (0.32°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.





Remove Thermosensor from patient.

Disconnect Thermosensor from DAQ.

Disconnect DAQ from the computer.

When finished, press 'Main Menu'.



Main Menu

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<sup>1</sup>

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)

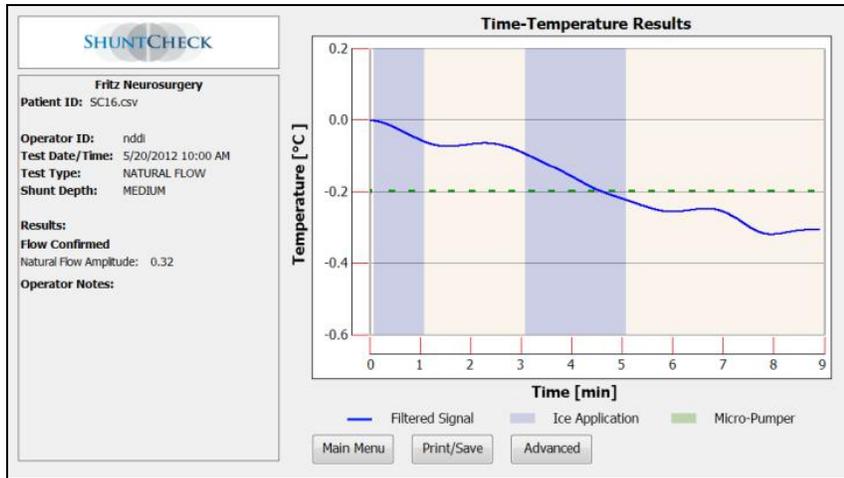
1. Nagashima, Y, et al; *Evaluation...measuring skin blood flow in elderly subjects during cooling load: comparison with younger subjects*; Int J Biometrorol (2003) 47:139-147



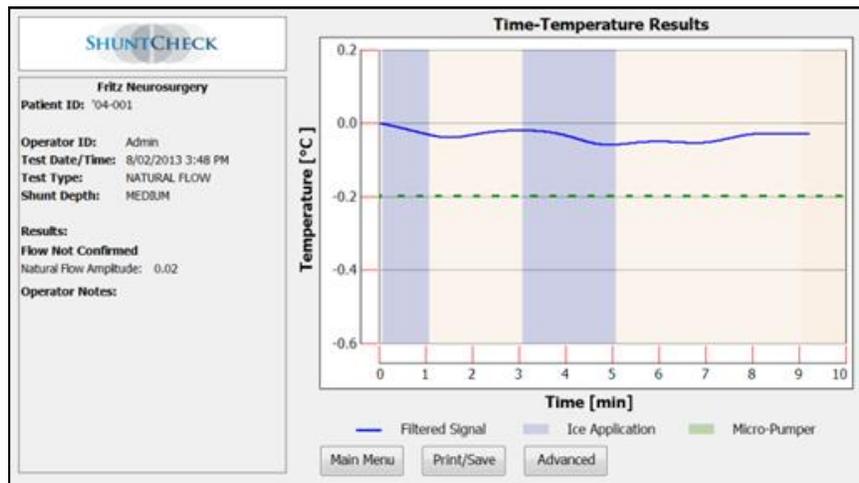


### Viewing Graphical Data

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  $\geq 0.2^{\circ}\text{C}$  following ice placement, indicating CSF flow. This test is Flow Confirmed.



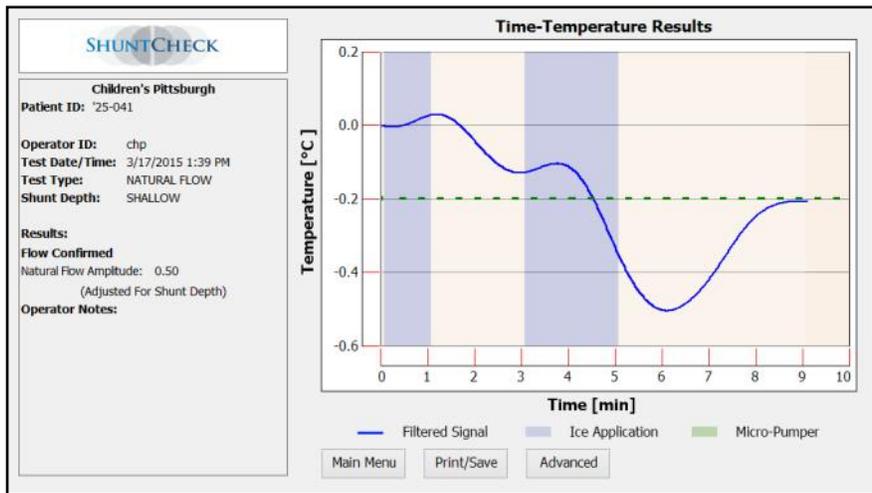
Low CSF flow of 3.5ml/hr or lower will generate a temperature drop of  $< 0.2^{\circ}\text{C}$  and generate a Flow Not Confirmed test result.



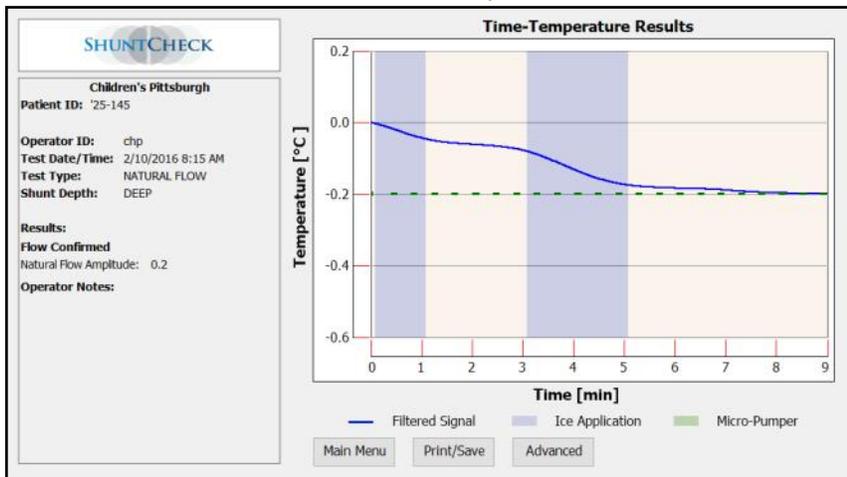


### Viewing Shallow & Deep Shunt Test Graphical Data

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



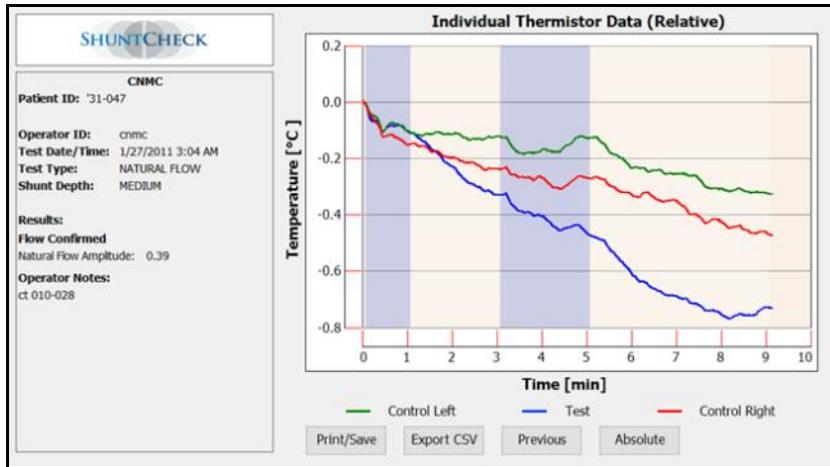
Deep shunts respond more slowly with less temperature change. The test below shows a flowing deep shunt with a very gradual and muted thermal response.



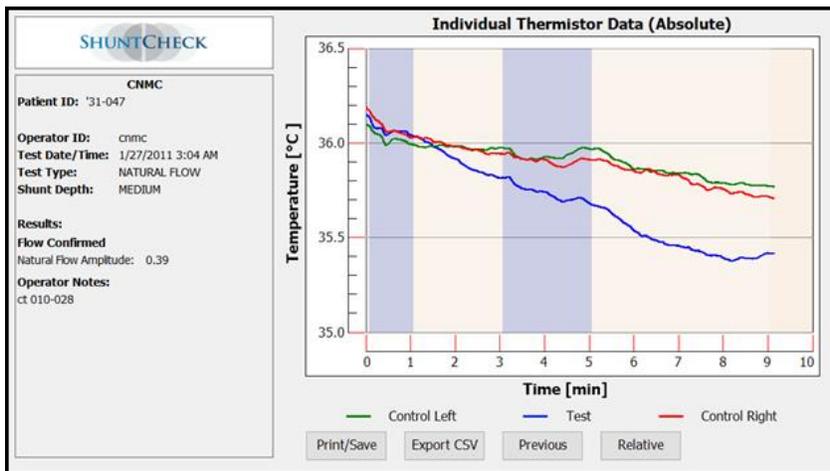


### Viewing Advanced Graphical Data

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 a graph which shows the actual skin temperatures recorded by each thermistor



The temperature drop due CSF flow is visible on the blue (test)

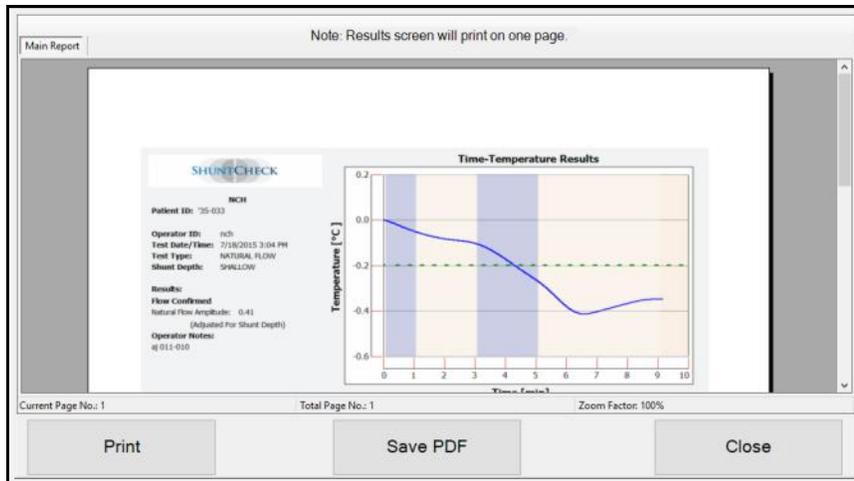
Click Relative to switch to the prior graph.  
Click Previous to return to the main results screen.



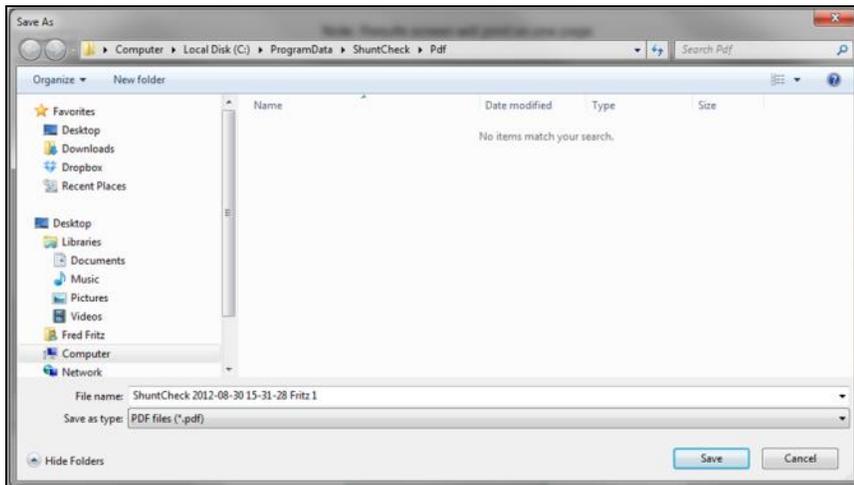


### Printing & Saving Test Data

Click Print/PDF to reach the print or export screen



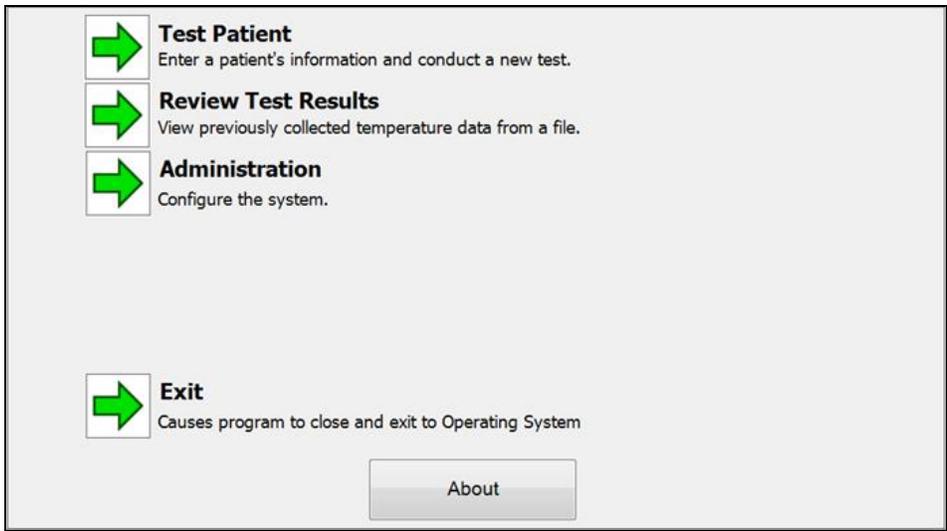
Click Print. The results screen will be printed on the computer's default printer.  
Click Save PDF to save a PDF of the screen in ShuntCheck PDF file (default) or to another file accessible by the computer.





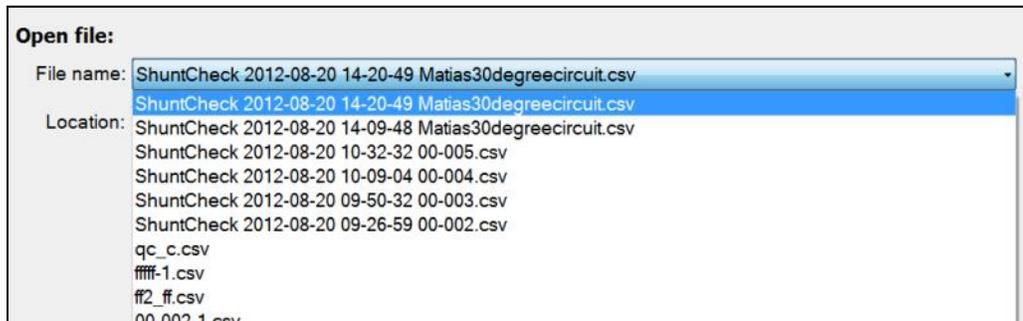
### Viewing Graphical Data of Previous Patients

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.

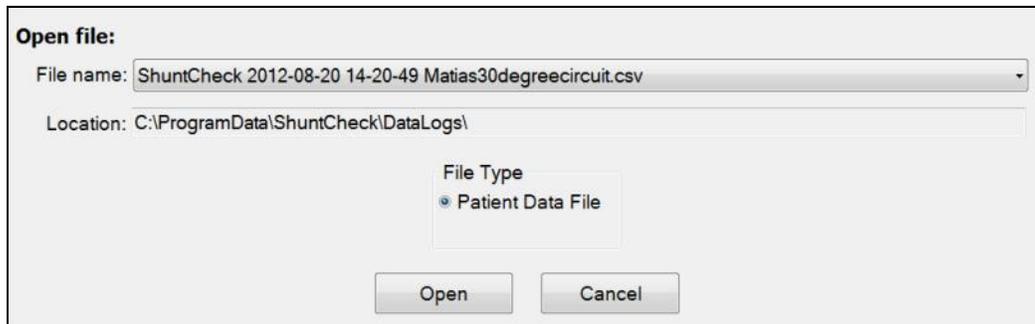




Click on the patient ID from drop down menu



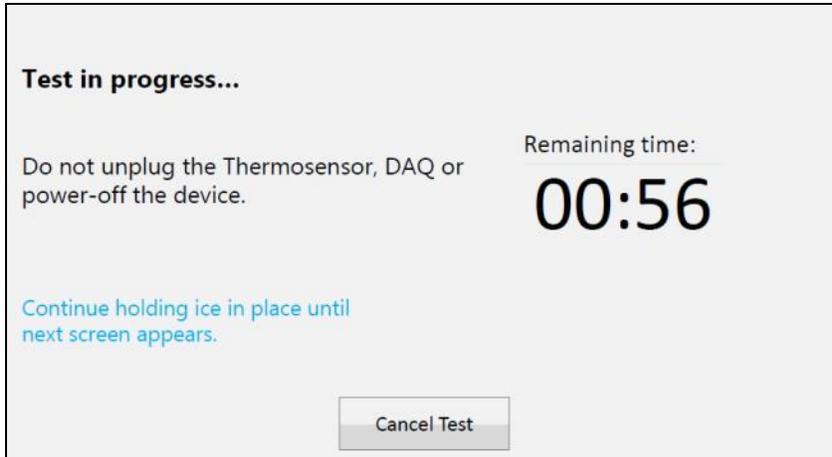
Click Open



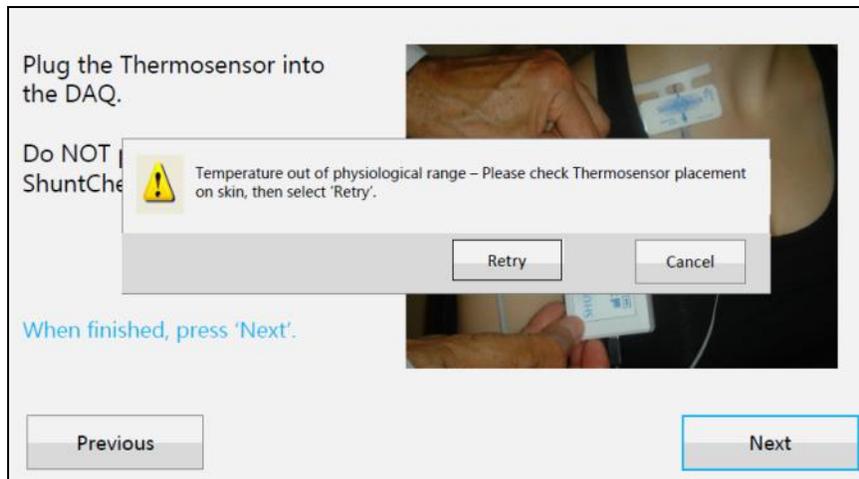


**Troubleshooting, Error Messages,  
Restarting a ShuntCheck Test**

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.

**Insufficient time has elapsed since last ice removal.**

Allow for skin to rewarm

Remaining time:  
**00:01**

Please wait, until Patient ID screen appears.

Cancel Test

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

**Patient Information**

**Patient ID:** 10254512 John Smith

**Operator's Notes:**

*The information entered appears in results displayed, printouts and exported files.*

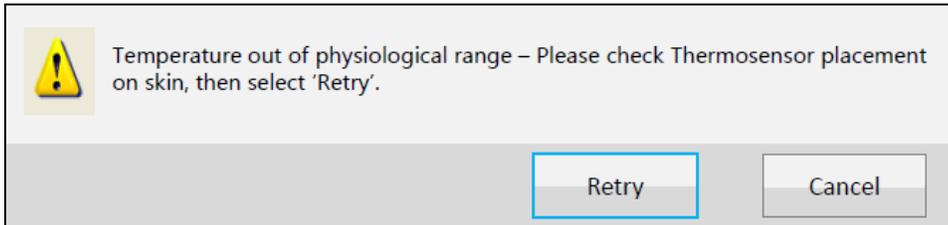
Previous Cancel Test Next

The test can be repeated from this point





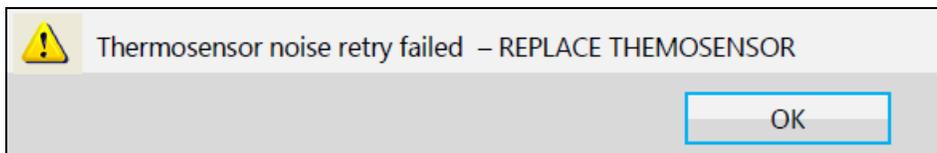
**Error Messages Types**



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.

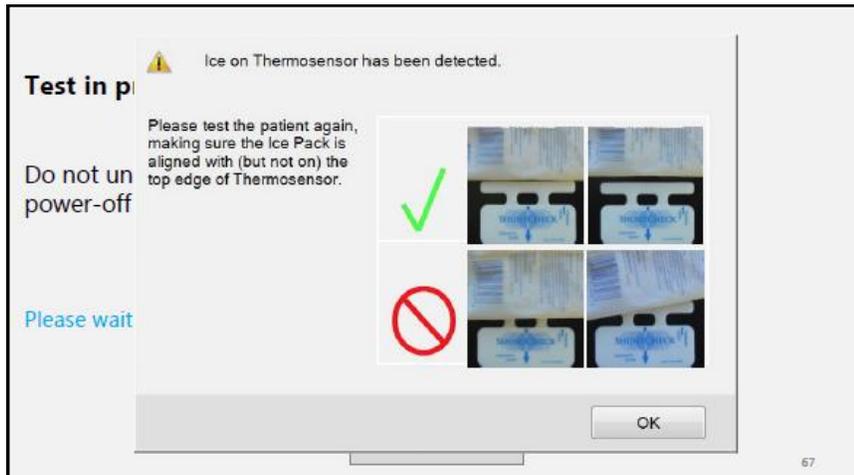


ShuntCheck has detected poor contact between the sensor's thermistors (electronic thermometers) and the patients skin—in this example, the test (middle) and right thermistors are making poor skin contact. Ensure better contact and click Retry



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.

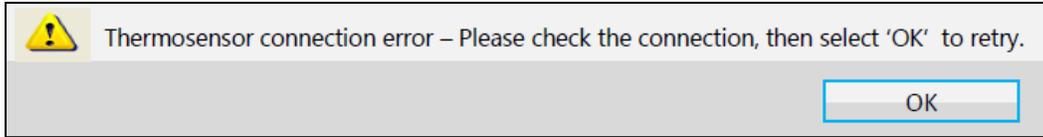


ShuntCheck has detected a sudden change in a control sensor reading.

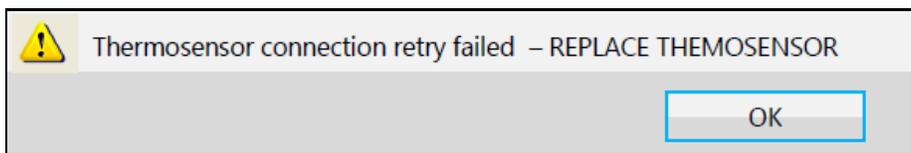
Check the Thermosensor skin contact and click ok.

ShuntCheck will recommend that you test the patient again.

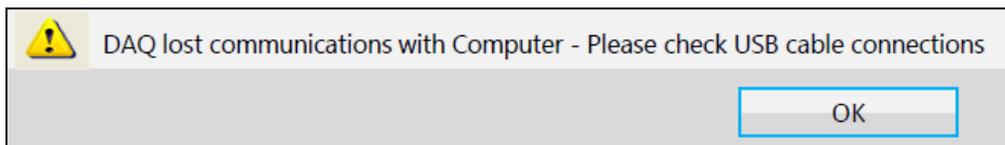




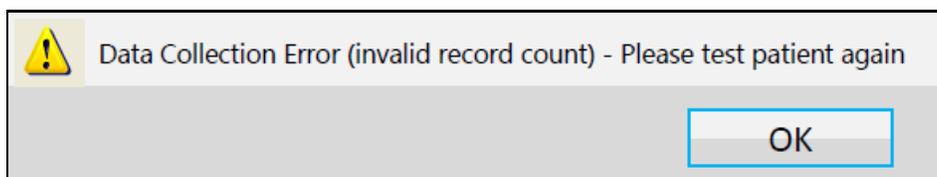
This error is presented if the sensor is not connected to the DAQ. Check the connection and click OK



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



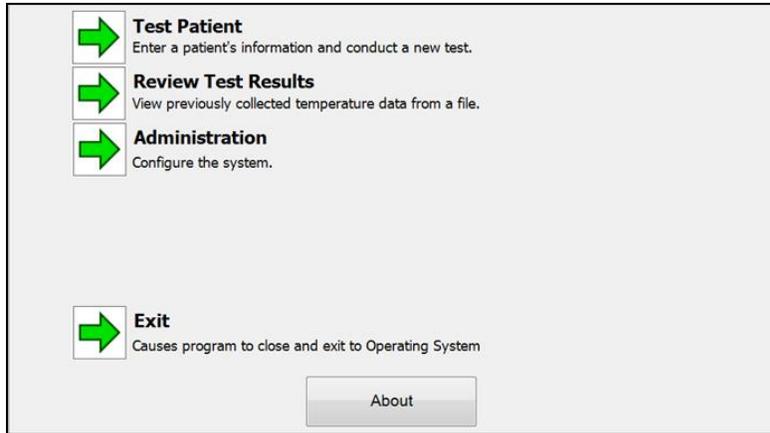
This warning indicates a data recording problem in the test . Click OK and rerun the test





## 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





**Administration**

**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

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)

**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**

<b>Guidance and manufacturer's declaration - electromagnetic emissions</b>		
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: <b>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 re-orienting or relocating the ShuntCheck System or shielding the location.</b>





<b>Guidance and manufacturer's declaration - electromagnetic immunity</b>			
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	Not Applicable. Device is not connecte to a.c. mains while in use.	Mains power quality should be that of a typical commercial or hospital 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	Not Applicable. Device is not connecte to a.c. mains while in use.	Mains power quality should be that of a typical commercial or hospital 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	Not Applicable. Device is not connecte to a.c. mains while in use.	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital 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
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2,5 GHz</p>	<p>Not Applicable</p> <p>3 V/m</p>	<p>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.</p> <p>Recommended separation distance</p> $d = [1.2]\sqrt{P}$ <p><math>d = [1.2]\sqrt{P}</math> 80 MHz to 800MHz</p> $d = [2.3]\sqrt{P}$ <p>800 MHz to 2,5 Ghz</p> <p>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).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p>
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
<p><sup>a</sup> 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. <sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.</p>			



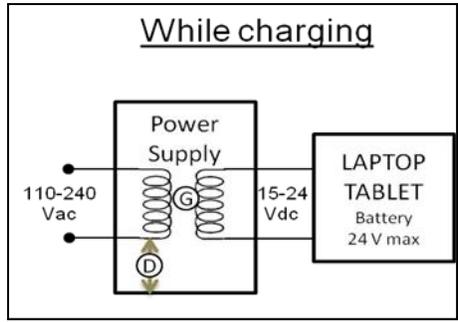
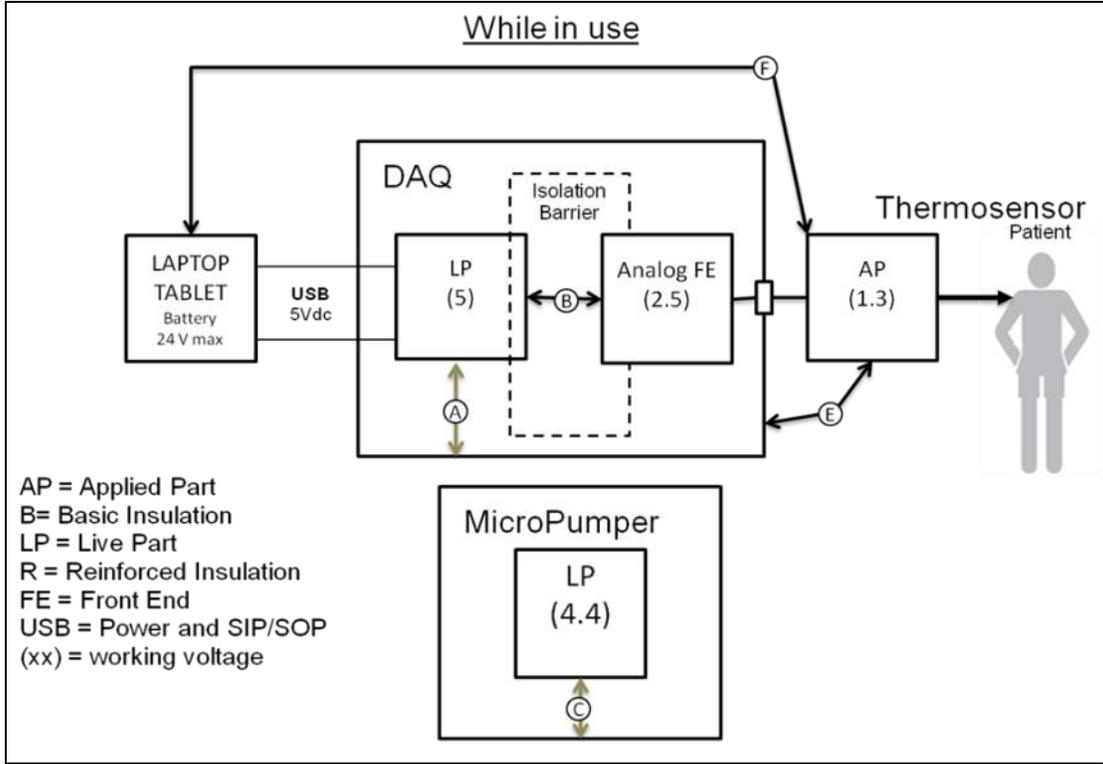


Recommended separation distances between portable and mobile RF communications equipment and the ShuntCheck System			
The ShuntCheck System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ShuntCheck System can help 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	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = [1,2]\sqrt{P}$	$d = [1,2]\sqrt{P}$	$d = [2,3]\sqrt{P}$
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 the 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	 Catalog Number
 Do Not Reuse	 Lot Number
 Type BF applied part, device will contact patient or operator	 Lower / Upper Temperature Limitations
 Refer to Instruction Manual	 Serial Number



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The logo for SHUNT CHECK features the words "SHUNT" and "CHECK" in a blue, serif font. The text is centered over a background of five overlapping circles in shades of gray. A vertical white line bisects the circles and the text.

# SHUNT CHECK

III

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