WR TESTWORKS
Autonomic and Peripheral | Labs and Software

Neurological Testing Management Software

Version 3.2
User Guide

Contents

Overview 5
About WR-TestWorks™ 5
Important Concepts 6
Warnings and Cautions 7
Technical Support 8
Disclaimer of Warranties and Limitations 8
Software Installation 9
Installing WR-TestWorks™ 9
Software Setup – Institution, User & Study Management 12
Institution Management 12
Study Management 13
Physician Management 14
Technician Management 15
Data Location 16
Within SQL 16
Within WR-TestWorks 16
General Navigation and Controls 17
Patient/Test Browser 17
System Menu 18
General Tab 19
Devices Tab 20
Q-Sweat Configuration 20
Cardiac Configuration (HRV) 21
CASE Configuration 22
Patient List Control 23
Editing Patient Data 23
Deleting / Un-Deleting Patients, Test, and Analyses 24
Test Tab 25
Changing Chart Properties 26
Test and Analysis-Specific Information 28

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Editing Time Markers 28
Cardiac Component 29
Heart Rate Response to Deep Breathing 31
Tilt Table 36
Valsalva Maneuver 39
Q-Sweat Component 42
Q-Sweat Device Preparation 42
Performing Q-SWEAT Recordings 43
Q-SWEAT ANALYSIS TECHNIQUES 44
CASE Component 46
Performing CASE IV Vibration Test – Sample Protocol 47
Performing CASE-IV Heat-Pain NRA-NS Test – Sample Protocol 52
Smart Somatotopic Quantitative Sensation Testing (S-ST-QST) of Body Sites - Touch Pressure and Heat as Pain 5 (QST TP and HP5) 56
Overview 57
QST TP Monofilaments Available for Testing and Estimating Threshold: 57
The 2 Alternative Forced-Choice Stepping Algorithm for QST TP – Sample Protocol: 57
Testing Scores 58
Sites and Progression 59
Site Number 59
Site 59
Site Number 61
Advances To 61
Special Instructions for Touch Pressure Hand & Foot Sites 61
Order of Test Execution 61
Example Test 62
Smart Somatotopic Sensation Test (S-ST-QST) 64
Somatotopic Heat as Pain Test 68
Data Export 72
Report Generation 73
Single Report Viewing 73
Combined Report Generation 73

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Report Completion 75
Adding Notes 75
Saving 76
EHR Export 77
Data Import 80
Exporting Out of WR-TestWorks 2.x 80
Converting from WR-TestWorks 2.x to 3.x 84
Importing into WR-TestWorks 3.x 85
License Agreement 88

CE 0413

EC REP

Medical Device Safety Service (MDSS) GmbH
Schiffgraben 41
30175 Hannover
Germany

Overview

About WR-TestWorks™

The WR-TestWorks software operates and/or acquires data from several devices manufactured by WR Medical Electronics, and interfaces with other FDA approved devices. The software accepts demographic data and captures patient physiological data for peripheral sensory, cardiac, and autonomic nervous system testing. Physicians can reference physiological events recorded during patient monitoring or while a patient undergoes specific maneuvers. The software will record, display, save, analyze, and generate reports.

Devices supported:

Q-Sweat™ - Quantitative Sweat Measurement System

CASE IV™ - Computer Aided Sensory Evaluator

HRV Acquire – ECG and patient feedback

BMEYE NexFin™ and **NexFin HD™** - Continuous finger arterial pressure measurement system, with brachial pressure waveform reconstruction.

CNSystems CNAP 500 - Continuous finger arterial pressure measurement system, with brachial pressure waveform reconstruction.

SMT – Sniff Magnitude

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Important Concepts

Data Organization:

- *Study*- A study is a collection of patients, visits and tests. Studies are intended to be a convenient collection of patients or tests.
- *Patient*- A patient is a person who undergoes tests within a study by means of one or more visits. Patient attributes include demographic data such as name, date of birth, gender, and so on (data that never changes or changes infrequently).
- *Visit*- A visit can consist of one or more tests and has certain information about the patient associated with it (such as height and weight). Typically, all tests within a visit take place on the same day or within a short period of time.
- *Test*- A test is a single session of collecting data from a patient. The test has a date associated with it, a technician, a set of raw data, etc.
- *Analysis*- An analysis is an interpretation of raw test data. The same set of raw test data can be analyzed in more than one way. Each analysis may have different analysis parameters and/or use different analysis techniques.
- *Report*- A report is a presentation of an analysis or group of analyses. Reports are typically previewed in a window before being printed or exported. A single analysis can be represented in more than one report. For example, a full report, a summary report, etc.

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Warnings and Cautions

Please refer to the hardware manual(s) of each device used for any warnings, cautions, indications, and contraindications.

User Responsibilities:

The WR Medical WR-TestWorks software will perform in conformity with the description thereof contained in this manual and accompanying documentation, when used with properly assembled, operated, maintained, and repaired devices connected to the system. Parts that are missing or damaged shall be replaced immediately.

The user of this software shall have the sole responsibility for any malfunction, which results from improper use, not following device maintenance instructions, or improper repair.
Clinical judgment should always be used when interpreting the results of any test. As with any monitored parameter, artifacts and poor signal quality may lead to inappropriate values.
Please read and adhere to the following considerations regarding the use of the software:

- WR-TestWorks is to be used and operated by qualified personnel only.
- If the accuracy of any reading is questionable, first check the patient's vital signs by alternate means and then check the that the connected device is functioning properly.
- WR-TestWorks software is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

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Technical Support

For questions regarding the WR-TestWorks software please contact:

Technical Support / Help Desk
WR Medical Electronics Co.
1700 Gervais Avenue
Maplewood, MN 55109
Phone: 651-604-8400 (Toll Free US: 800-635-1312)
Fax: 651-604-8499
Email: neuro@wrmed.com
Web: www.wrmed.com

The Help Desk is available during normal business hours (8:00am to 4:30pm, Central Time)

Disclaimer of Warranties and Limitations

WR Medical Electronics Co. makes no warranty or representation, either express or implied, with respect to the WR-TestWorks Software, its quality, merchantability, or fitness for a particular purpose. The software is provided as is. No oral or written information or advice given by either party or its employees shall create a warranty or make any modification, extension or addition to the warranty.

WR Medical Electronics Co. shall not be liable for any direct, indirect, incidental or consequential damages, including lost profits and damages for personal injury or property damage, arising from or in the connection with the licensed rights or its use whatsoever.

In no case shall WR Medical Electronics Co.'s liability exceed the purchase price for the software. Information in this document is subject to change without notice and does not represent a commitment on the part of WR Medical Electronics Co.

Software Installation

Installing WR-TestWorks™

Minimum Recommended System Requirements:

- Microsoft Windows 7 x64
- Core i5 2 GHz Processor*
- 8 GB RAM
- 10 GB Free Disk Space
- 1920 x 1080 Screen Resolution
- 1 USB port per attached device (Do not use a USB hub)

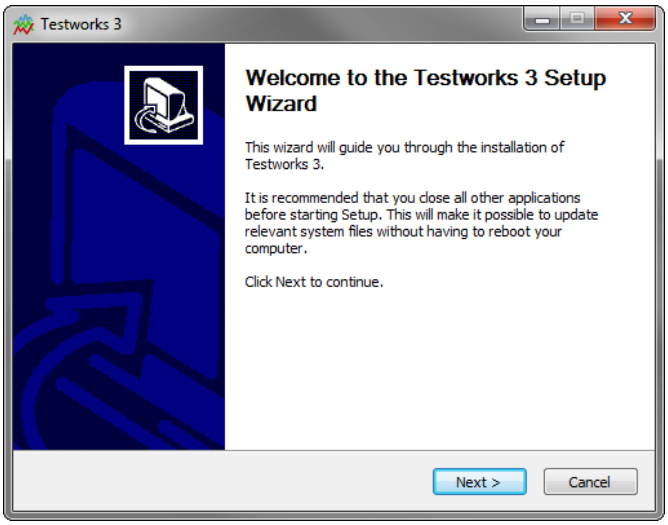
*Note: For HRV sampling at rates above 200 Hz, it is recommended to use a higher end processor and more memory.

Recommended System Requirements for high end sampling (1 kHz):

- Microsoft Windows 10
- Core i7 6850K 3.6 GHz Processor (or higher)
- 32 GB RAM
- 10 GB Free Disk Space
- 1920 x 1080 Screen Resolution
- 1 USB port per attached device (Do not use a USB hub)

Begin the installation by inserting the WR-TestWorks CD-ROM in the CD-ROM drive.

Follow the on-screen instructions and enter the requested information…



Close all other applications, then click “Next”.

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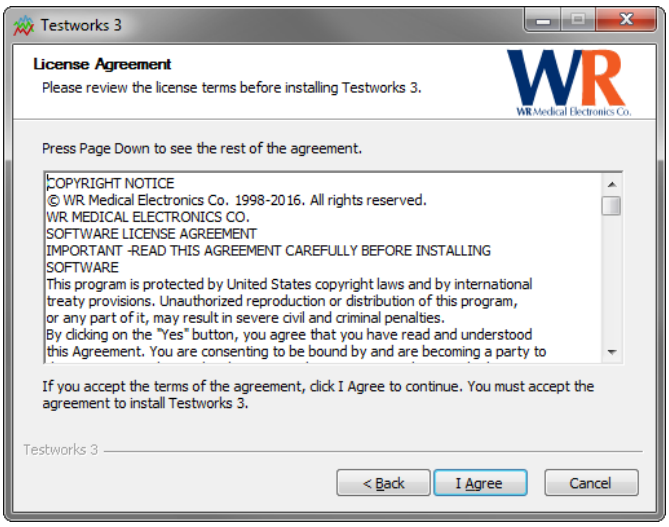
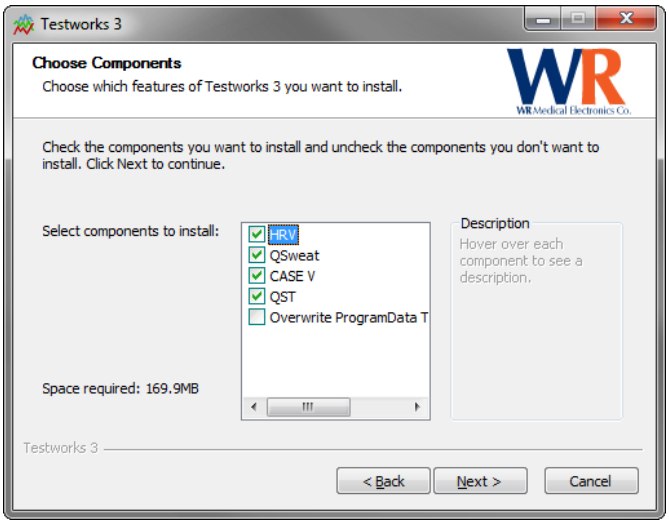


Review the license agreement, also found in the appendix. Choose “I Agree” to continue, or do not accept and cancel the installation.



Choose the relevant components to your installation, depending on the equipment available to you. You can also choose to overwrite any program data (applicable to an upgrade, not a new installation) that currently exists if you would like to revert to the default program data for this version of software.

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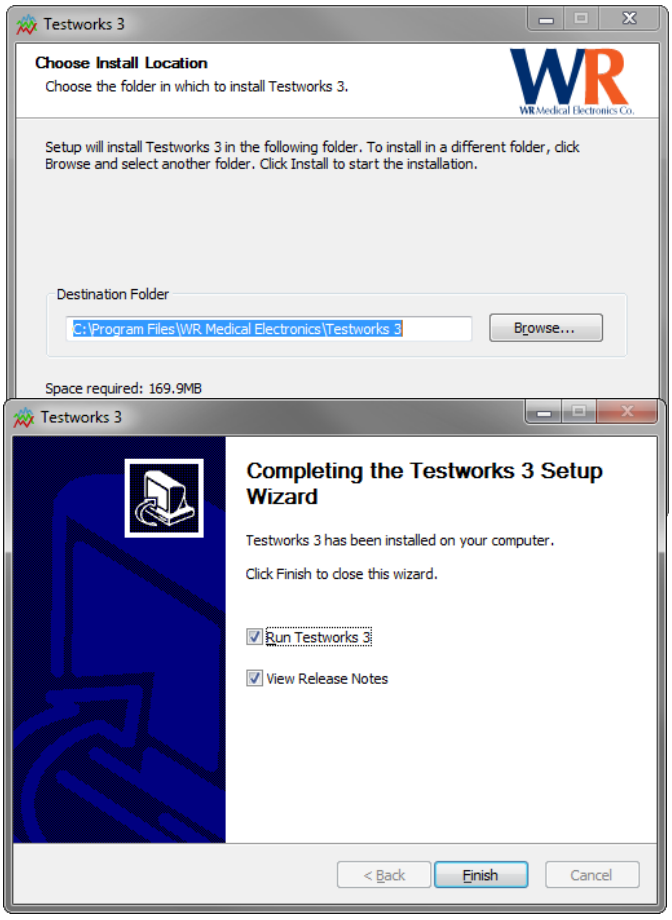

Choose the program destination folder by selecting the “Browse” button and selecting the desired drive location. The default location will create a new WR Medical Electronics folder under the Program Files on the C: drive. A local drive is recommended for better performance.

Click “Finish” to complete the installation.

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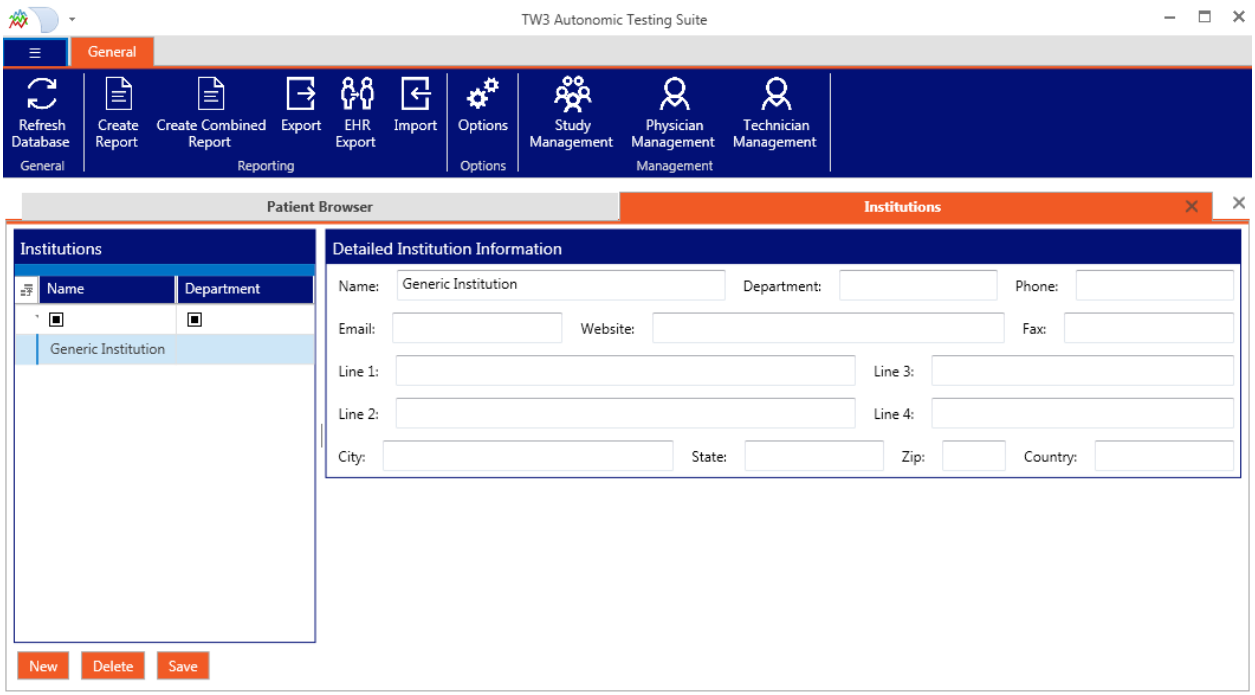
Software Setup – Institution, User & Study Management

Institution Management



Institutions can be added, edited, or deleted within the Institution Management dialog box (accessible under the System Menu button - ☰).

To add a new Institution, select “New” in the lower left corner of the screen and enter the Institution information in the ‘Detailed Institution Information’ window. When finished entering the institution information, click “Save”.

To edit or delete an existing Institution, select the Institution from the list, then the desired operation button.

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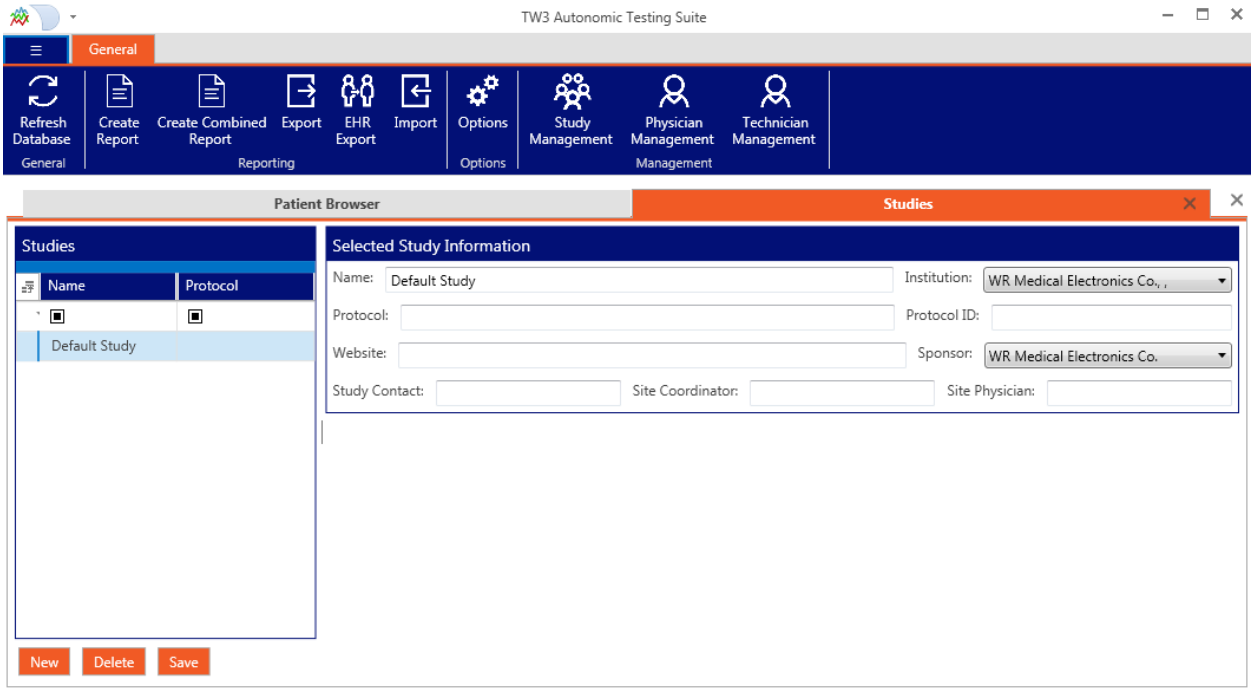
Study Management



A “Study” contains a collection of patients that are tested. The “Study” may be used for drug trials or studies, but at least one must exist within WR-TestWorks. The Study Management dialog box (accessible in the main toolbar under the ‘General’ tab or from within the System Menu) is used to create/edit studies.

To add a new study, select “New” in the lower left corner of the screen and enter the study information in the ‘Selected Study Information’ window. When finished entering the study information, click “Save”.

To edit or delete an existing study, select the study in the list, then the desired operation button.

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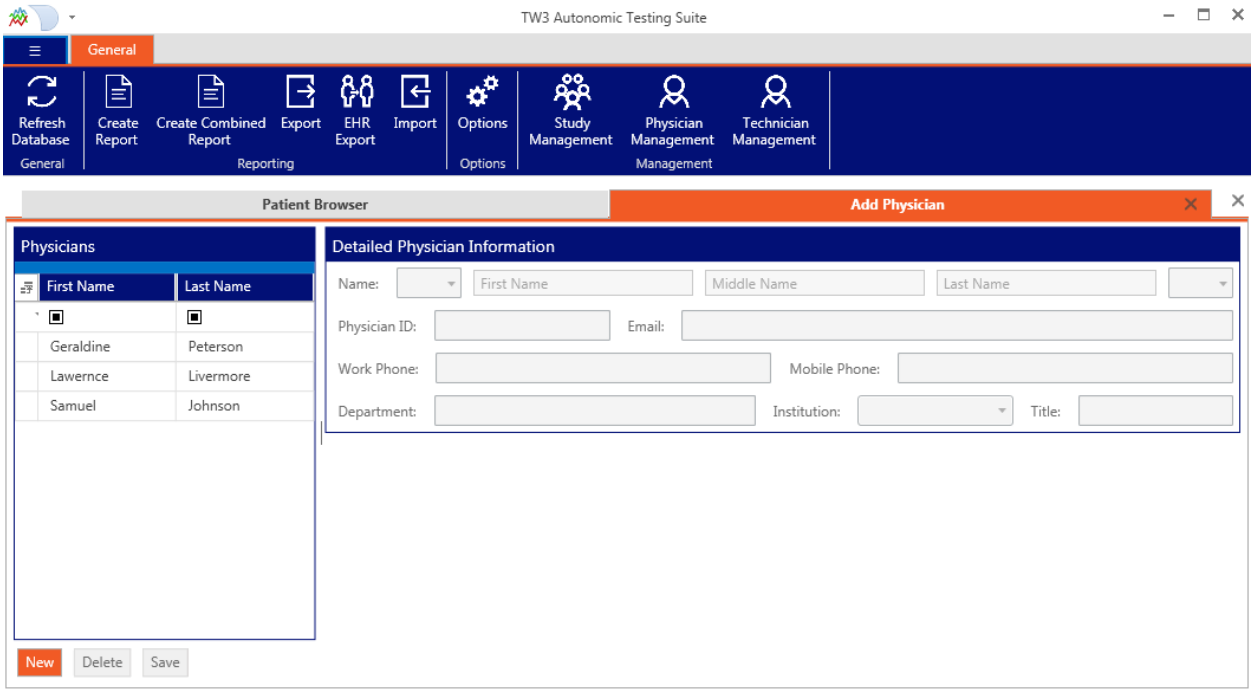
Physician Management



Physicians can be added, edited, or deleted within the Physicians Management dialog box (accessible in the main toolbar under the 'General' tab or from within the System Menu). Each user of WR-TestWorks should have a separate login to identify the tests or analyses performed by that individual.

To add a new user, select "New" in the lower left corner of the screen and enter the user information in the 'Detailed Physician Information' window. When finished entering the user information, click "Save".

To edit or delete an existing user, select the user in the list, then the desired operation button.

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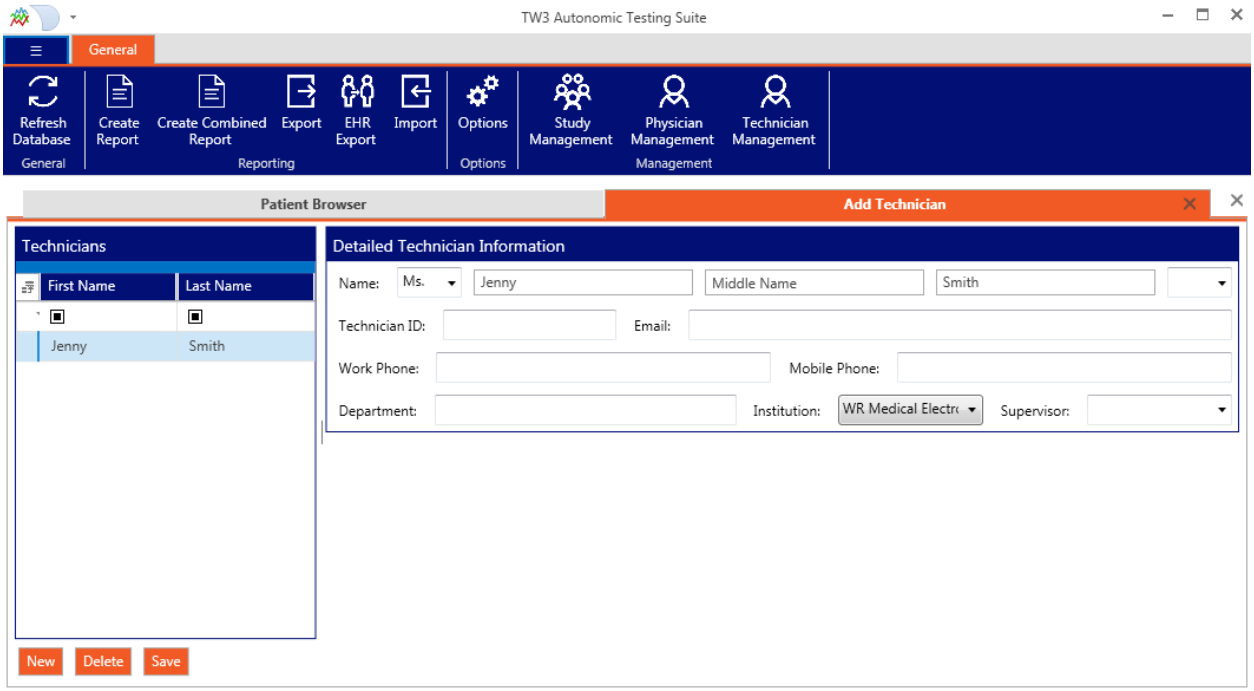
Technician Management



Technicians can be added, edited, or deleted within the 'Technician Management' dialog box (accessible in the 'Management' toolbar under the 'General' tab or from within the System Menu). Each user of WR-TestWorks should have a separate login to identify the tests or analyses performed by that individual.

To add a new user, select "New" in the lower left corner of the screen and enter the user information in the 'Detailed Technician Information' window. When finished entering the user information, click "Save".

To edit or delete an existing user, select the user in the list, then the desired operation button.

If it is

desired to record which technician has conducted testing or analyses, set the technician by selecting the technician from the drop-down list in the lower left corner and clicking "Set Technician":

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Data Location

By default, WR-TestWorks saves data to a local SQLite flat file. WR-TestWorks also supports networked data locations of the following database types:

SQL Server 2005
SQL Server 2008 and 2008 R2
SQL Server 2012

To connect WR-TestWorks to an external SQL Server, the following steps must be taken:

Within SQL

1. Create a new database
2. Create a single service user with permissions to the database

Within WR-TestWorks

1. Click “Options” 

in the main toolbar at the top of the screen or from the System Menu.
2. Click the ‘Database’ tab from the Option Categories on the left.
3. Set the ‘Database Source’ from SQLite (default) to the version of SQL Server being used.
4. Set the ‘Database Host’ to the address of the SQL Host in the format HostName\SQLName.
5. Set ‘Username’ to the name of the service user created above with permissions to the database.
6. Set ‘Database Name’ to the applicable database title within SQL.
7. Set ‘Password’ to the password for the service user (created above) with permissions to the database.
8. Click “Save”, and the program will automatically close and re-open.
9. Once re-opened, WR-TestWorks will prompt to be allowed to create the tables within the database, click “Yes.”

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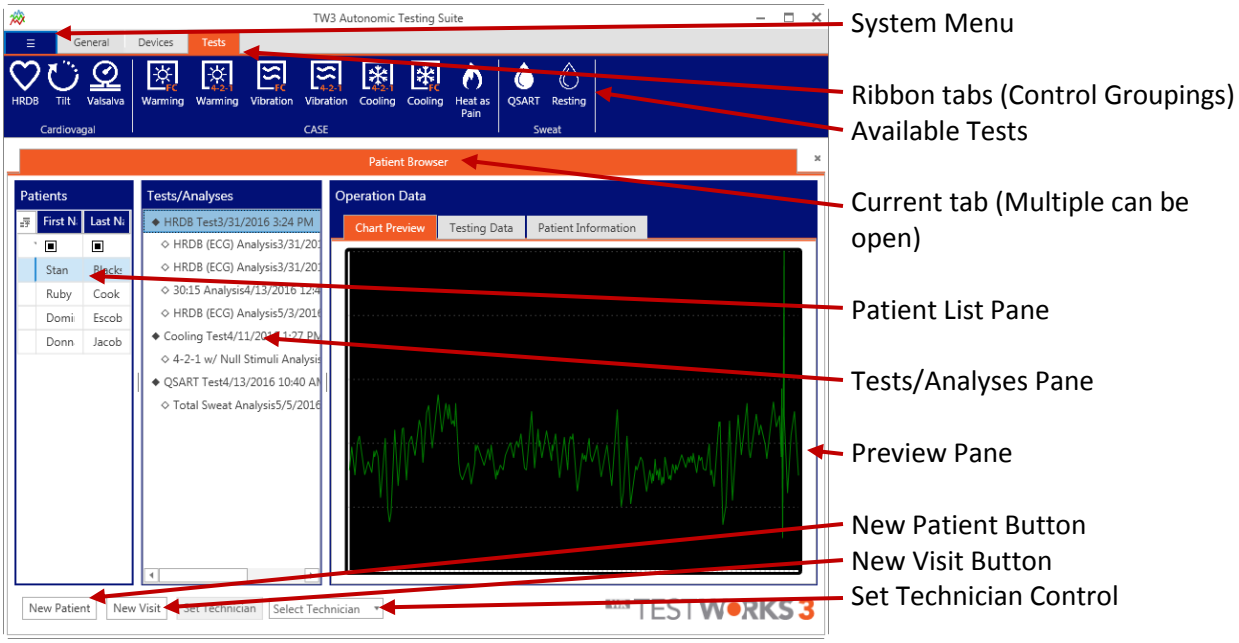
General Navigation and Controls

Patient/Test Browser



Nearly all operations within WR-TestWorks are available from the Patient Browser through the main control ribbon and its associated tabs.

The Patient Browser displays three panels of information; a patient list, a test list (for the selected patient), and either the selected test's chart preview, calculated testing data, or summary of patient information. The user has control over the patient list via sorting, filtering and searching. These panes may be resized by dragging the splitter bars between the panes.

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System Menu

- **About** – Program and license information.
- **Refresh Database** (also in General Tab) – If needed, manually refresh the program against its database contents.
- **Options** – Options menu (also in General Tab), which includes General, License, Database, EHR Support, Reports, and Custom Fields information and settings.
- **Study Management** – Create, edit and delete studies. See "Software Setup – Institution, User & Study Management" section.
- **Physician Management** – Create, edit and delete physicians. See "Software Setup – Institution, User & Study Management" section.
- **Technician Management** – Create, edit and delete technicians. See "Software Setup – Institution, User & Study Management" section.
- **Institution Management** – Create, edit and delete institutions. See "Software Setup – Institution, User & Study Management" section.
- **EHR Export** – Export EHR
- **Import** – Opens Import Manager.
- **Available Commands** – When XML test and analysis files are available, this menu lists and explains all available commands for writing tests and analyses.
- **Help** – Program help menu.
- **Exit** – Exit the program.

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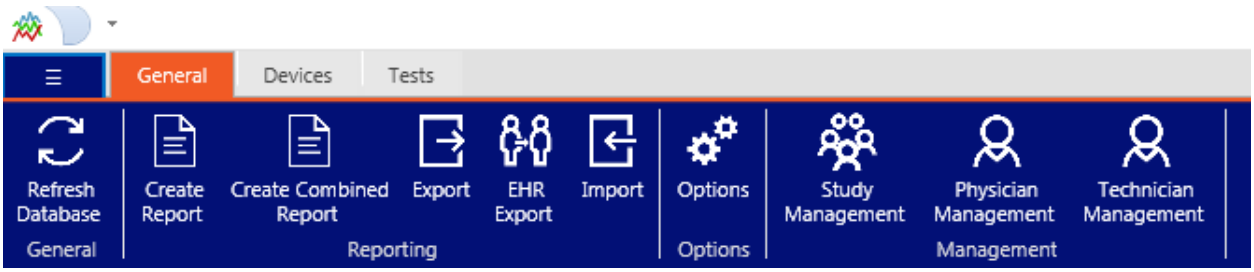
General Tab



- **Refresh Database** – If needed, manually refresh the program against its database contents.
- **Create Report** – Creates a report based on the currently selected analysis. See "Report Generation" section.
- **Create Combined Report** – Launches the report generation menu, allowing you to create a report containing any combination of tests across patients, dates, etc. See "Report Generation" section.
- **Export** – Data export. See "Data Export" section.
- **EHR Export** – Export of results directly to a patient record system. See "EHR Export" section.
- **Import** – Data import. See "Data Import" section.
- **Options** – Options menu (also in System Menu), including license, database location, EHR, and report settings.
- **Study Management** – Create, edit and delete studies. See "Software Setup – Institution, User & Study Management" section.
- **Physician Management** – Create, edit and delete physicians. See "Software Setup – Institution, User & Study Management" section.
- **Technician Management** – Create, edit and delete technicians. See "Software Setup – Institution, User & Study Management" section.

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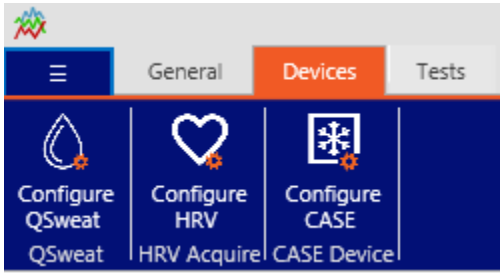
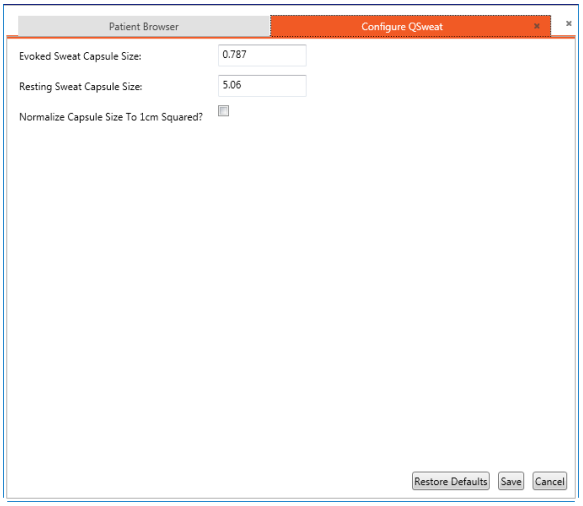
Devices Tab



Device settings can be found in the main ribbon under the 'Devices' tab.

Q-Sweat Configuration



Enter the values desired to correspond to the capsule size for both Evoked and Resting sweat test types. The standard sizes can be restored by clicking the "Restore Defaults" button.

The 'Normalize Capsule Size to 1cm Squared' checkbox may be selected to normalize the rate and volume data based upon the capsule sizes entered. (**NOTE**: Previous versions, and papers have used absolute values.)

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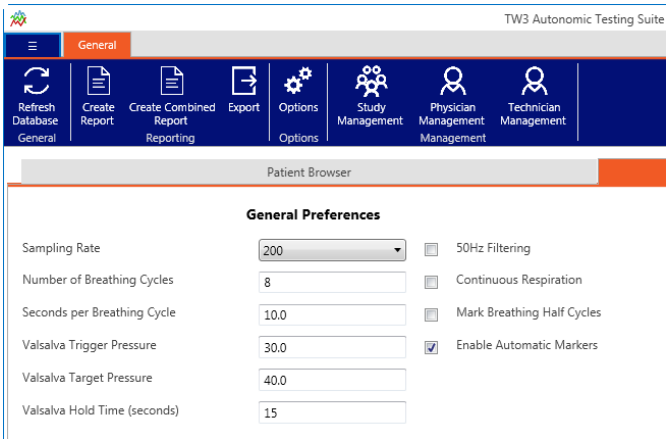
Cardiac Configuration (HRV)



HRV Acquire Configuration Table:

ECG Setup -		
Operating Frequency	Sets internal DSP line filter	Default 60 Hz, check for 50 Hz (Line Freq.)
Sample Rate	Analog signal acquisition rate (samples/second)	Default – 200 Hz
HRDB Metronome Settings -		
Respiration Cycles	Number of breathing cycles to perform (in a set) or continuous	Default - 8 cycles
Respiration Time	Breathing cycle time (in/out total)	Default - 10 seconds
Mark Respiration Half Cycles	Mark each respiration (in & out)	Default - No
Continuous Respiration	Ignores Respiration cycles, permanently cycles HRDB cue.	Default - No
Valsalva Settings -		
Trigger Pressure	Pressure to start hold timer	2-50 mmHg (30 mmHg typical)
Target Pressure	Desired expiratory pressure	2-50 mmHg (40 mmHg typical)
Hold Time	Time to hold pressure at target	1-30 seconds (15 sec typical)
General Settings -		
Enable automatic event markers	Generate event markers within WR-TestWorks recordings	Default - Yes
Tilt Sample Points	BP and HR sample point times (in seconds) in Tilt Test	Default – 1, 3, 5, 10

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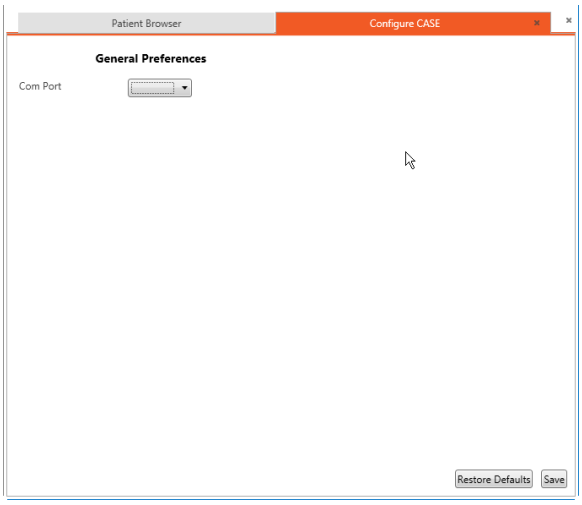
CASE Configuration



Enter the COM Port that the device is connected to.

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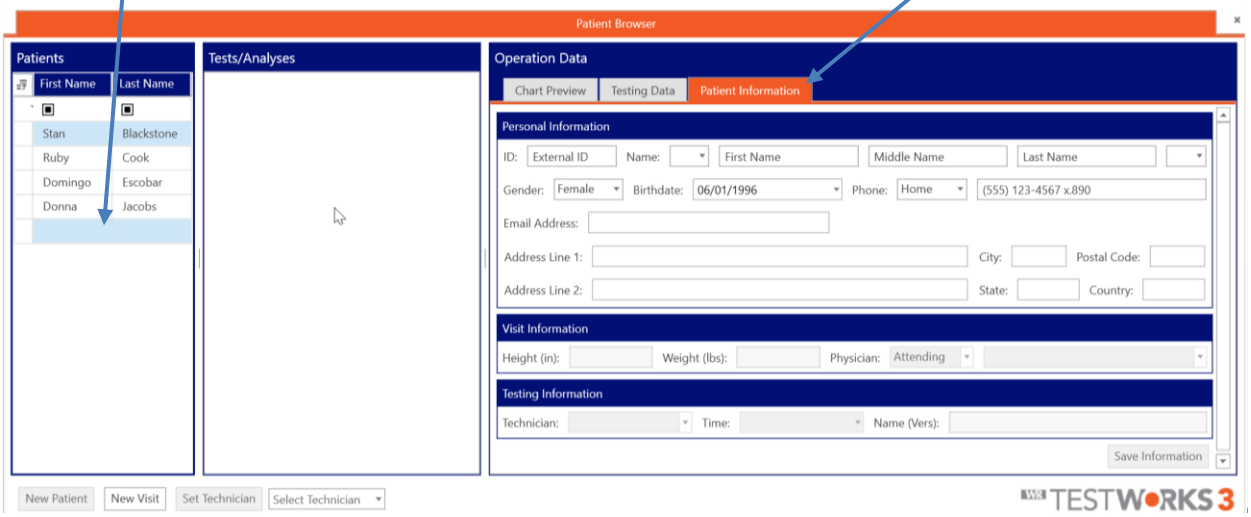
Patient List Control

Entering patient data is the first step users will take when testing a patient. Patients are added by pressing the “New Patient” button at the bottom left corner of the main window.

A blank row will be added to the patient list, and the ‘Patient Information’ tab will open for this new patient:



Once the relevant personal information is input, click the “Save Information” button at the bottom right corner of the screen.

Editing Patient Data

Occasionally, users may need to revise existing patient data. This is done by right-clicking the patient in the patient list and selecting “Edit”. The ‘Patient Information’ tab will be displayed, and the fields within can be modified. Once finished, click the “Save Information” button, or changes will be erased.

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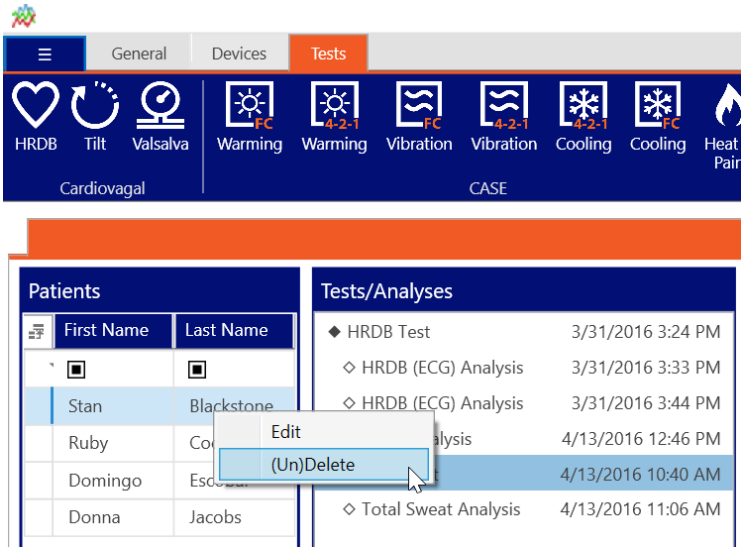
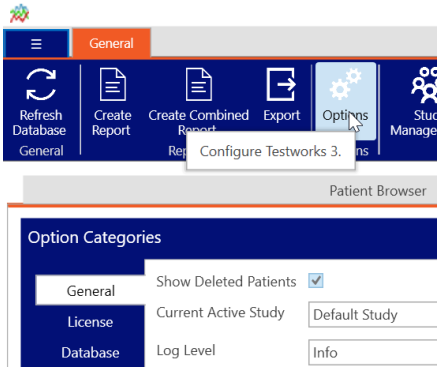
Deleting / Un-Deleting Patients, Test, and Analyses

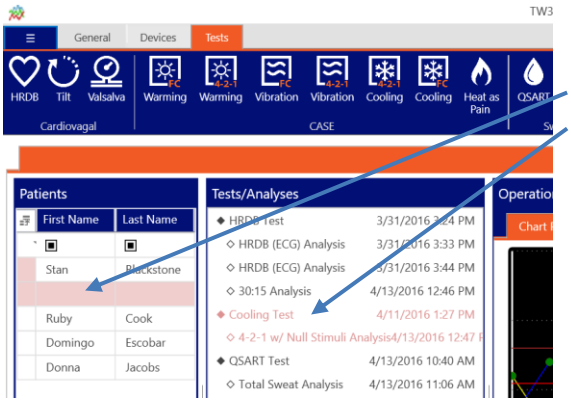
Once recorded and saved, all patient study data within WR-TestWorks cannot be erased and cannot be changed. However, items may be "deleted" to remove them from view in the Test Explorer panels and to exclude them from Copy, Export, and Report operations.



To delete (or un-delete) items, select one (or more) items, then right-click and select '(Un)Delete' from the context menu or select '(Un)Delete' from the appropriate main menu root (Patient, Test, or Analysis).



To be able to view items that were previously deleted, navigate to the 'General' tab and click "Options". In the General options category, check the 'Show Deleted Patients' box. Then click "Save" in the lower right corner of the screen.



When the "Show Deleted Patients" box is checked, deleted patients and tests will show up in red.

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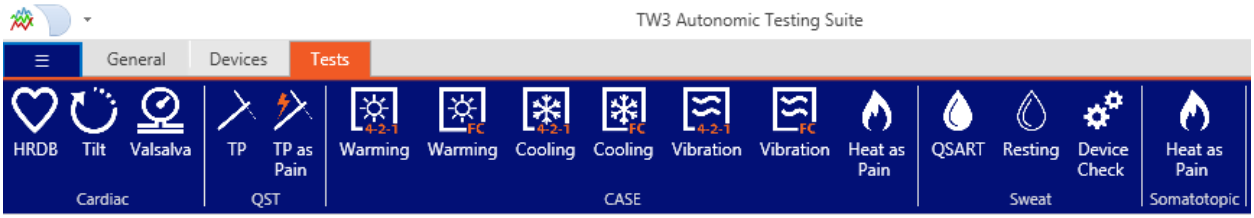
Test Tab



Test / Analysis Window

The test window provides a graphical display of test recording using one or more charts. Several test types and most analysis methods also include a data panel under the charts to display (or enter) other pertinent information.

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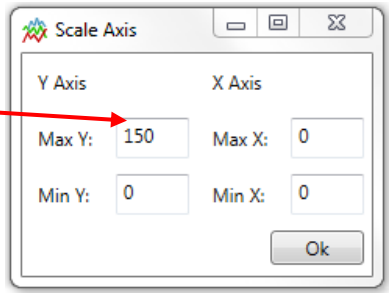
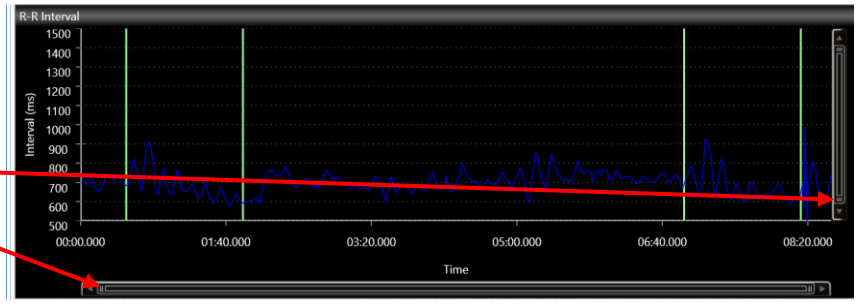
Changing Chart Properties

The relative sizes of individual charts may be adjusted by dragging the 'Chart Splitter' located between the chart panes.



It is possible to change the scale of the Y (vertical) axis during or after recording. Double-Click on the chart to display the Chart Properties dialog box. Adjust the minimum and maximum scale values as desired, or click the Auto Scale. Click Apply or the OK button.

Chart X and Y scales can also be modified using the sliders at the ends of the scroll bars on the bottom and right side of each chart.



Zoom in

Zoom Out

Reset zoom to full scale (both x and y axis)

Synchronize Charts (sets the x and y scale for all other charts to match the scale of the chart in which this control is pressed)

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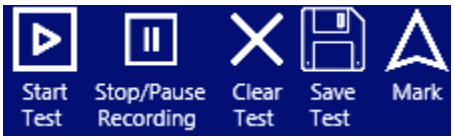
Test Toolbar

The Test Toolbar consists of various buttons to control the test operations during data acquisition (recording) and analysis. Test controls are dependent on the device in use, and the selection of controls available may be different per test.



Start Test: Begins recording test data, or launches any pre-recording controls.

Stop/Pause Recording: Stops recording data. Recording can then either be finished and saved, or recording can be started again (pause).

Clear Test: Clear the existing test data and start over. Cannot be done until the user has chosen to finish recording the test.

Save Test: Save test data. Cannot be done until the user has finished recording the test.

Mark: Place a mark on the testing chart. Some tests may do this automatically (HRV Acquire).

TEST NOTES

Notes can be added to a test before saving the test. Simply open the notes area in the bottom right of the screen.

Visit Notes: General comments relevant to entire set of tests in the visit.
Test Notes: Remarks specific to the current open test.
Analysis Notes: Comments specific to the current open analysis (if any).

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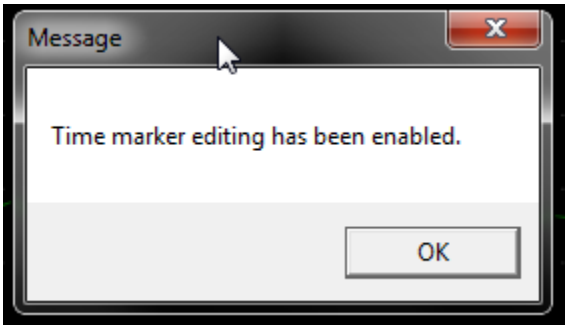
Test and Analysis-Specific Information

Editing Time Markers

Time markers placed during testing can be added, deleted or moved. Before starting an analysis, click the 

button. The following notification will be presented indicating that time markers can now be edited:



Time markers can now be removed via mouse right-click, and placed via mouse left-click.

When finished, click the 

button again to toggle this mode off, and continue with your analysis.

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Cardiac Component

Cardiac Test Types

HRDB (Heart Rate Deep Breathing)

Tilt Table

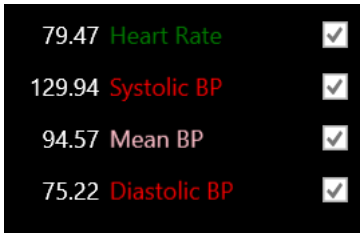
Valsalva Maneuver

Cardiac Specific Test Toolbar buttons

Start/Stop Metronome:  Starts/Stops metronome display on HRV device.

Charted Signals

Beat-to-beat Heart Rate (Beats/Min):
Beat-to-beat Systolic BP (mmHg):
Beat-to-beat Mean BP (mmHg):
Beat-to-beat Diastolic BP (mmHg):



Beat-to-beat R-R Interval (Milliseconds):

Continuous ECG Data (mVolts):
Continuous Arterial BP (mmHg):
Chest Expansion Data (arbitrary units):
Valsalva Expiratory Pressure (mmHg):

NOTE: The HRV Acquire display will be blank between the time of entering a testing screen and pressing the "Start Test" control on the ribbon of the test. This is normal operation.

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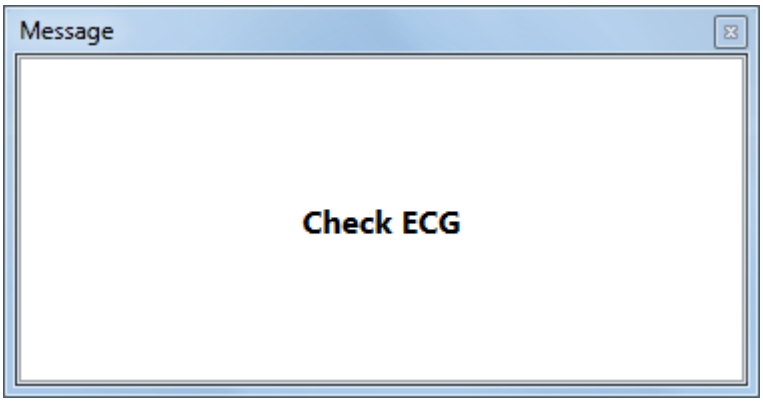
HRV Acquire device only:

If the HRV Acquire device is unable to detect heart beats, a “Check ECG” message will be displayed in the bottom chart window.



Check to see that the electrodes are fresh and the cables are connected properly.

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Performing HRDB – Sample Protocol

Several items affect Heart-Rate Deep Breathing (HRDB). These must be considered by the technician and controlled in order to maintain standardization and consistency between test subjects and for repeated tests on the same patient.

Instructions:

1. Have the patient come in, relaxed and comfortable, with an empty bladder.
   Patient should be supine for a minimum of 5 minutes prior to starting the test.

2. Attach the ECG electrodes (white on right, black on left, and red is reference). You may want to prepare the skin with an alcohol wipe, NuPrep, or other standard ECG preparation. If you are getting a lot of artifact, remove the pads, prepare the skin, and then start again with fresh pads.
   Two sites for electrode placement (Figure 1) are:
   The interscapular area just medial to the tip of the scapula.
   The supraclavicular areas.
   NOTE: Reference electrode site is not critical.

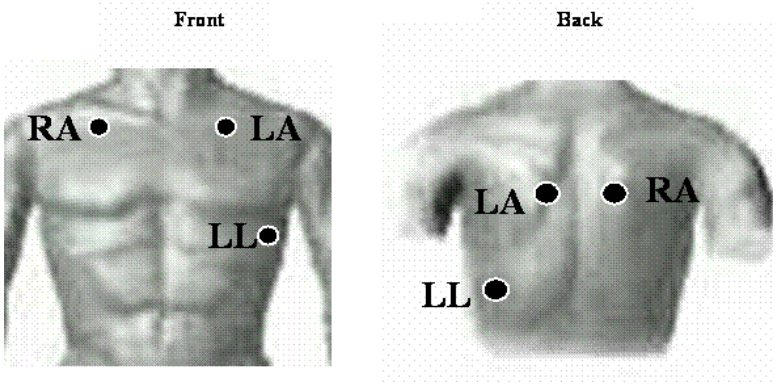

Figure 1: Two sites for ECG electrode site placement for the HRDB test are the insterscapular area just medial to the tip of the scapula and the supraclavicular areas, denoted as RA and LA in the front and back views.

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3. Attach the chest expansion bellows to the patient. To start, expand the bellows by 4-5 inches, stretching it over the patient's chest, with the black bellows material on the front of the patient and the Velcro material on the back (Figure 2). Place on the rib cage, at the location where the greatest expansion is expected. Do not place bellows over the reference ECG electrode as it may cause ECG artifact. Plug the Luer fitting in to the specified location on the HRV Acquire main unit AFTER attaching the bellows firmly to the patient (Figure 3).

Figure 2: Attach chest expansion bellows over the rib cage at the location of greatest expansion.

NOTE: If chest expansion trace is not visible during the recording, disconnect the bellows from the HRV Acquire, ask the patient to breath out completely, and reattach the bellows to the HRV.

Figure 3: Plug the Luer fitting to to the HRV Acquire main unit.

4. Turn on the ECG device and the WR-TestWorks software.
5. Select (or create) the patient in the Test Explorer, and select the HRDB test icon. 

6. Enter visit information, and begin recording. 
7. Explain the procedure to the subject:

"We are going to be testing your autonomic nerves. This test is quite simple. We will ask you to breathe deeply at the same rate as the oscillating bar (or to breathe in and out according to my hand movements) for a total of 8 breaths. After a 5-minute rest, we will ask you to repeat the test with another 8 breaths. It is important to breathe as deeply as possible. You can breathe in through your nose and out through your mouth if that is comfortable for you. Do not hold your breath at any time, but use a full 5 seconds for breathing in and a full 5 seconds for breathing out. We will have you try it for 2 breaths so you can see how it feels."

8. Give the patient a practice test. The practice should be only two breaths. Start/Stop the metronome as needed with the Metronome button on the toolbar. 
9. Let the subject rest 2 minutes after the practice.

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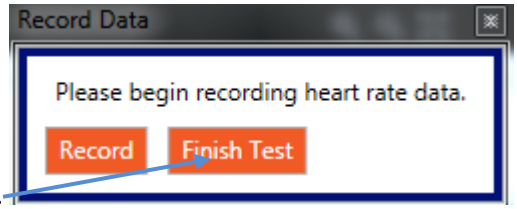
10. Press the Metronome button  to start the metronome operation when the patient has fully exhaled (metronome begins with inspiration phase). Press again to stop metronome after set is completed. If automatic event markers are enabled (default), event marks will be inserted into the recording at the start and stop points.

NOTE: If the HRV Acquire configuration includes a value for the respiration cycles, the metronome will stop automatically after the specified respiration cycles have been performed.

11. Rest for 5 minutes. DO NOT STOP THE TEST IN WR-TESTWORKS, CONTINUE RECORDING.

12. Start the second set. (Additional sets can be done, repeat after rest period)

13. When complete, stop the recording. 

14. Finished the recording. 

NOTE: Keep recording within WR-TestWorks throughout the entire test, even while the patient is resting between sets.

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HRDB ANALYSIS TECHNIQUES

HRDB using HR: 

Analysis based on Heart Rate

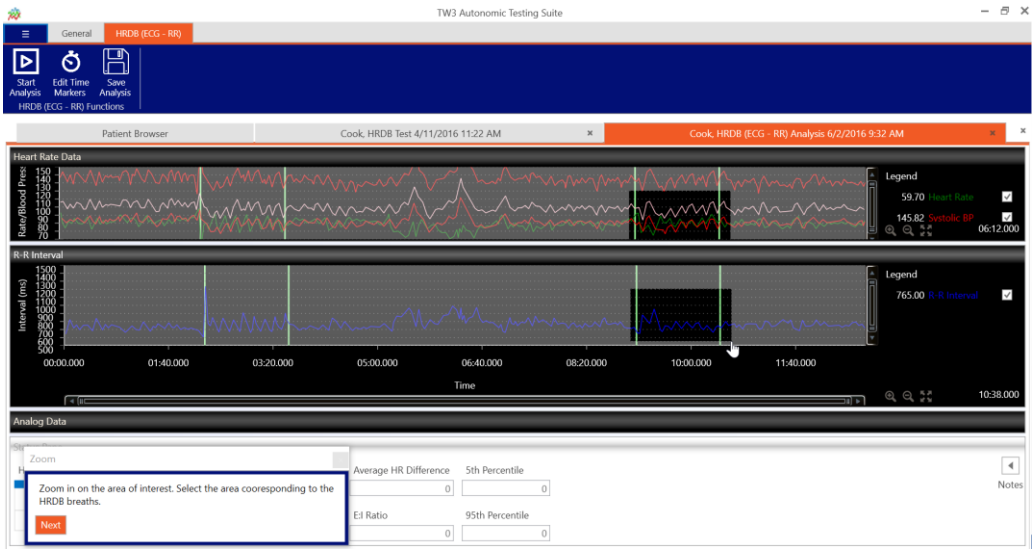
HRDB using R-R: 

Analysis based on the R-R Interval

Spectrum/Frequency Analysis of ECG Signal: 

Select the desired analysis icon from the analysis ribbon. Then, click the "Start Analysis" 

button to begin. Follow the instructions in the dialog box to analyze the test (Figure 4).



Select the desired breathing set by clicking and dragging the mouse within the chart area. **TIP:** Use the mouse scroll wheel or the magnification controls  to back out of any unintended zooming.

Figure 4: Click and drag the mouse around the desired breathing set for HRDB (R-R) analysis of the patient's HRDB test.

In most tests, zooming on charts with calculated values (R-R or HR) will not automatically scale the analog chart as well. Press the  button on any chart to impose its current x-axis and y-axis scale to all other charts.

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Click the “Next” button and the software will choose the highest consecutive 5 valley-peak points shown on the R-R frame (Figure 5).

Figure 5: Select the highest consecutive 5 valley-peak points shown on the R-R frame.

TIP: When analyzing HRDB recordings with small HR or R-R variations, make sure you enlarge the chart by clicking and dragging to the limits of the relevant trace.

Points may be adjusted by removing incorrect points and replacing them with correct points. To remove a point, “right-click” near it (the point closest to the cursor will be removed). Select new points by “left-clicking” on the desired point (marked by the current cursor position).

When the desired points are selected, click the “Next” button and the resulting analysis data is shown in the analysis window (Figure 6).

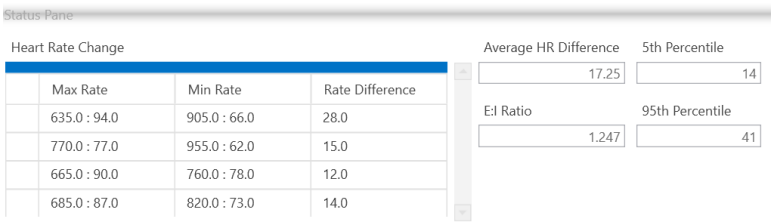

Figure 6: Resulting analysis data for the HRDB (R-R) analysis.

Click the “Finish” button in the user guide, then click “Save”.

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HEAD-UP TILT

A Tilt Table Test is performed to evaluate one of the causes of syncope.

Performing Head-Up Tilt – Sample Protocol

It is important to perform the tilt after the patient has been lying down for a standard amount of time, typically 20 minutes.

Instructions:

1. Have the patient come in, relaxed and comfortable, with an empty bladder.
   IMPORTANT: The patient should be supine for a minimum of 20 minutes prior to starting the test.

2. Attach the ECG electrodes (white on right, black on left, and red is reference). You may want to prepare the skin with an alcohol wipe, NuPrep, or other standard ECG preparation. If you are getting a lot of artifact, remove the pads, prepare the skin, and then start again with fresh pads. Two sites for electrode placement (Figure 7) are:
   The interscapular area just medial to the tip of the scapula.
   The supraclavicular areas.
   NOTE: Reference electrode site is not critical.

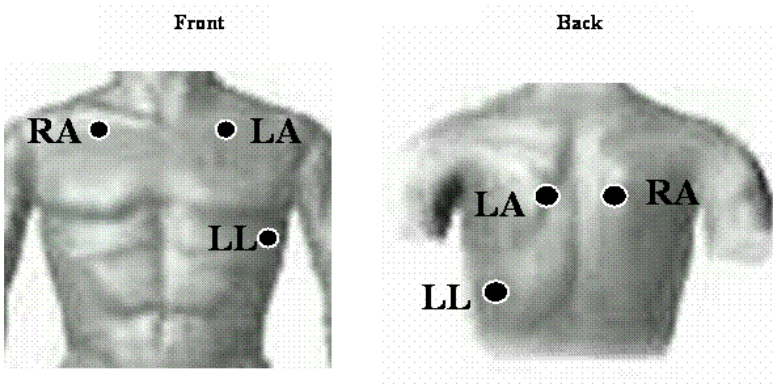

Figure 7: Two sites for ECG electrode site placement for the tilt test are the insterscapular area just medial to the tip of the scapula and the supraclavicular areas, denoted as RA and LA in the front and back views.

3. Connect blood pressure device, where applicable.

4. Turn on the ECG device and the WR-TestWorks software.

5. Select the patient in the Test Explorer (if you need to add new patient, refer to Patient List Control on p. 21), then select the Tilt test icon. 

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6. Enter visit information, then click “Save”.

7. Begin recording. 

8. Explain the procedure to the subject:

   “We are going to be tilting you up to a near vertical position and will be monitoring your heart rate and blood pressure while doing so.”

9. If the tilt test is configured for manual blood pressure entry, enter the baseline blood pressure.

10. After at least a minute of baseline recording, tilt the patient up (to 70 degrees).

11. Press the Mark key  in WR-TestWorks to signify the beginning of the tilt.

12. Press the Mark key  again when the patient is tilted back down. Continue recording at least one minute following the tilt down.

13. When complete, stop the recording. 

14. If providing manual blood pressure, check the entries for accuracy prior to saving the test. Once saved, these values cannot be changed (as they are part of the “recorded” test).

TILT ANALYSIS TECHNIQUES

30:15 using HR: 

30:15 Ratio based on Heart Rate

30:15 using R-R: 

30:15 Ratio based on the R-R Interval

Tilt using R-R: 

Tilt analysis based on the R-R Interval

ECG Spectrum: 

Tilt analysis based on ECG spectrum analysis

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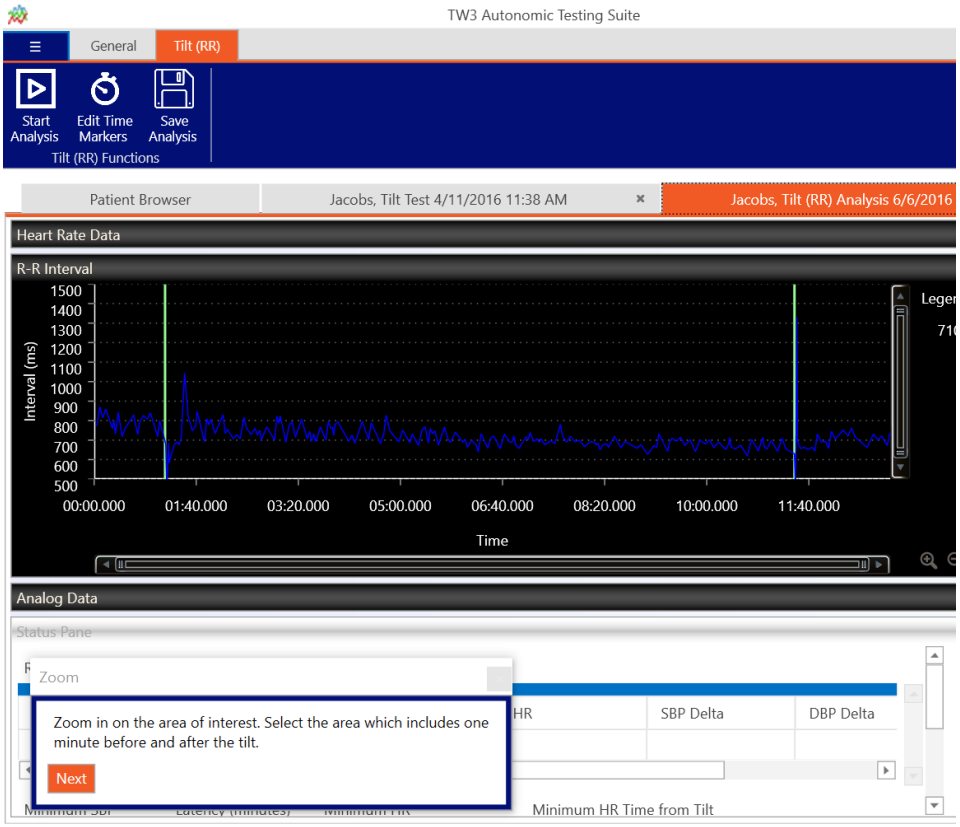
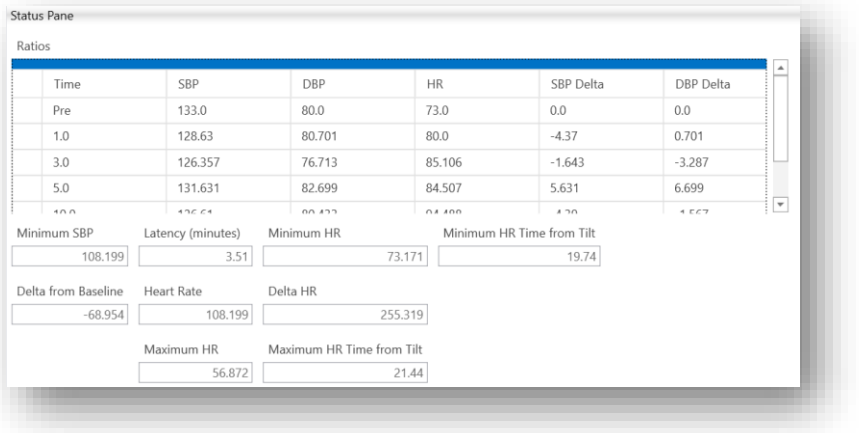
Select the desired analysis icon from the analysis ribbon. Follow the instructions in the dialog box to analyze the test. The Tilt (R-R) analysis can be seen in Figure 8 below.



Using the event markers and tilt configuration settings, the analysis automatically chooses the chart range and sample points. Sample points are displayed on the chart with diamond markers.

Figure 8: The Tilt (R-R) analysis of a tilt table test within WR-TestWorks.



Click the “Next” button to proceed to choosing the minimum SBP level, and again to advance to the selection of the minimum and maximum heart rate points. The resulting analysis is shown in the analysis window.

Click the “Finish” button in the user guide to complete the analysis.

Click the “Save” button to save the analysis, then exit the test and analysis tabs.

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Performing Valsalva – Sample Protocol

The heart is monitored by ECG, pressure recording, or other methods while the patient performs the Valsalva maneuver; cardiac volume decreases in unaffected patients but may dilate in a patient with impaired myocardial reserve; there is a characteristic complex sequence of cardiocirculatory events, departure from which may indicate disease or malfunction.

Several items affect the Valsalva Recording. These must be considered by the technician and controlled in order to maintain standardization and consistency between test subjects, for repeated tests on the same patient.

Instructions:

1. Have the patient come in, relaxed and comfortable, with an empty bladder.
   NOTE: Patient should be supine for a minimum of 5 minutes prior to starting the test.

2. Attach the ECG electrodes (white on right, black on left, and red is reference). You may want to prepare the skin with an alcohol wipe, NuPrep, or other standard ECG preparation. If you are getting a lot of artifact, remove the pads, prepare the skin, and then start again with fresh pads. Two sites for electrode placement (Figure 9) are:
   The interscapular area just medial to the tip of the scapula.
   The supraclavicular areas.
   NOTE: Reference electrode site is not critical.

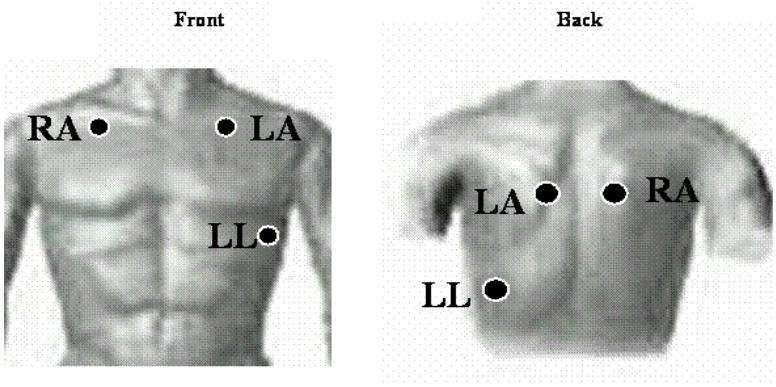

Figure 9:Two sites for ECG electrode site placement for tilt test are the insterscapular area just medial to the tip of the scapula and the supraclavicular areas, denoted as RA and LA in the front and back views.

3. Connect blood pressure device, where applicable.

4. Turn on the ECG device and the WR-TestWorks software.

5. Select the patient in the Test Explorer (if you need to add new patient, refer to Patient List Control on p. 21), then select the Valsalva test icon.

6. Enter visit information, then click “Save”.

7. Begin recording  .

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8. Explain the procedure to the subject:

"We are going to be testing your autonomic nerves. This test is quite simple. We will ask you to exhale into the mouthpiece and cause the light bar to move upwards to the 40 mmHg line and continue blowing for 15 seconds. After a 5 minute rest, we will ask you to repeat the test. It is important to try and reach 40 mmHg of pressure and hold it as steady as possible. Do not hold your breath at any time. We will have you try a practice test so you can see how it feels."

9. Give the patient a practice test.

10. Let the patient rest 2 minutes after the practice.

11. Start the first set. A mark will automatically be placed when the patient's expiratory pressure reaches the target level (300 mmHg by default), and another marker will automatically be placed after the set Valsalva maneuver time (15 seconds by default).

12. Let the patient rest for 5 minutes.

12. Start the second set.

13. When complete, stop the recording.  **NOTE: It is important to continue recording at least 30-45 seconds after the maneuver.**

NOTE: Keep recording on WR-TestWorks throughout the entire test, even while the patient is resting between sets.

VALSALVA ANALYSIS TECHNIQUES

HRDB using HR: 

Analysis based on Heart Rate

HRDB using R-R: 

Analysis based on the R-R Interval

Heart Rate, Blood Pressure Changes with Stimulus: 

Analysis based on Linear Regression

Adrenergic: 

Analysis based on BP

Pressure Recovery Time: 

Analysis based on BP

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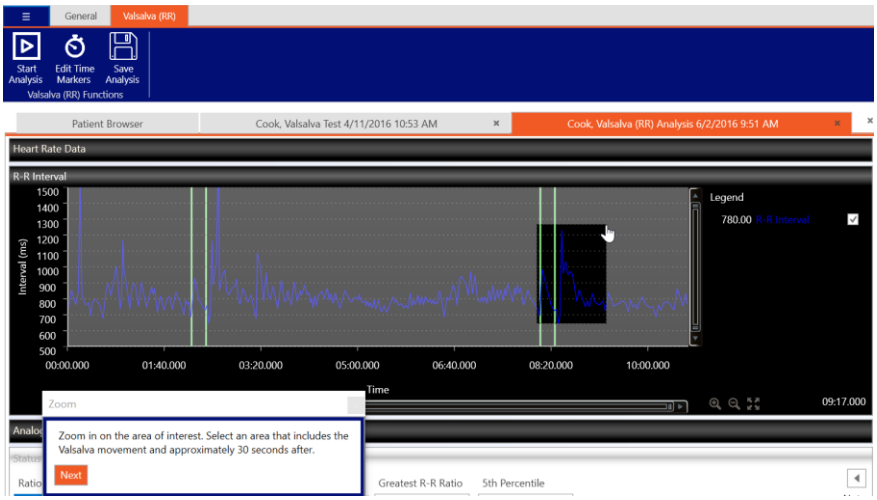
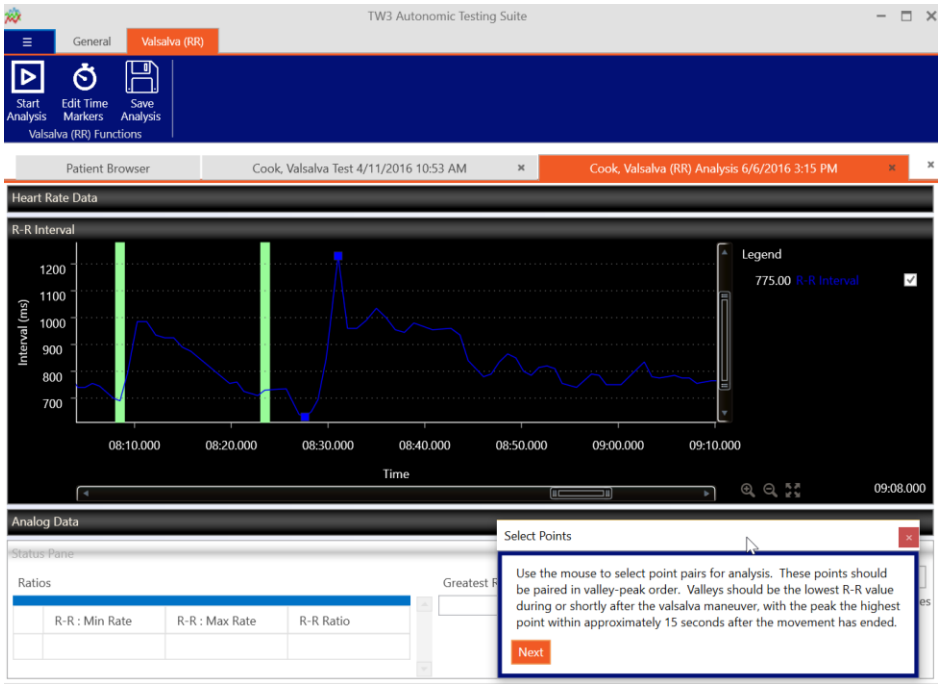
Select the desired test analysis icon from the analysis ribbon. Then, click the “Start Analysis” button to begin. Follow the instructions in the user guide dialog box to analyze the test.
Select the desired Valsalva maneuvers by clicking and dragging the mouse in the chart area. The area to be analyzed should include from the start of the first maneuver to 30-45 seconds beyond the end of the final maneuver.



Click the “Next” button and the software will choose the local maximum and minimum heart rate points for each maneuver (shown on the R-R frame).

Points may be adjusted by removing incorrect points and replacing them with correct points. To remove a point, “right-click” near it (the point closest to the cursor will be removed).
Select new points by “left-clicking” on the desired point (marked by the current cursor position).

On occasion, the auto-selected points will include pairs between maneuvers. Deselect these points using the right mouse button.



When the desired points are selected, click the “Next” button and the resulting analysis data is shown in the analysis window.

Click the “Finish” button in the user guide to complete the analysis.

Press the Save button to save the analysis, then exit the test and analysis tabs.

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Q-Sweat Component

Q-Sweat Test Types

Sweat Response (evoked)

Resting Sweat

Device diagnostic test, used for troubleshooting

Charted Signals

Data Channel 1(nL/min):
Data Channel 2(nL/min):
Data Channel 3(nL/min):
Data Channel 4(nL/min):

Q-Sweat Device Preparation

Prior to starting a test (15-30 min), the Q-Sweat device should be powered on with the capsules seated on the parking fixture to allow the system to purge any accumulated moisture. The desiccant should be checked to determine remaining time (See hardware manual).

TIP: A Q-Sweat test recording may be started to monitor the drying process.

USB version only:

The "Power" LED on the front panel of a USB based Q-Sweat also indicates the operational status:

Steady green	- unit is in use
Pulsing green	- unit is ready for patient testing
Steady amber	- unit is warming up (or drying out)
Flashing yellow	- power-on self-test error* (contact WR Medical)
Light off	- device powered off, or micro not running

*The self-test error is indicated in the device status window of a Q-Sweat test.

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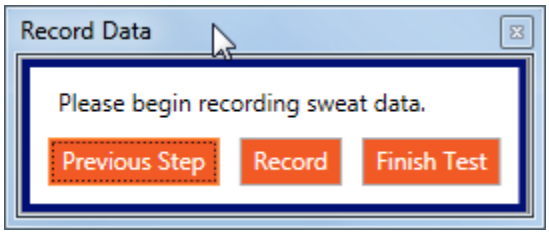
Performing Q-SWEAT Recordings

1. Have the patient come in, relaxed and comfortable, with an empty bladder.
2. Prepare the skin surrounding the area to be tested.
3. Select the patient in the Test Explorer (if you need to add new patient, refer to Patient List Control on p. 21), then select the desired test icon 

or 

.
4. Enter visit information, then click “Save”.
5. Select the start test button  and follow the test dialogue to start recording.



   a. Confirm that the channels have dried sufficiently (sweat rates low and traces flat).
   b. For resting sweat tests, record a minute of baseline rates on the parking fixture.
6. Attach sweat collection capsules using Velcro and/or silicone straps.
   a. Confirm that there are no air leaks, and adjust capsules as needed.
   b. Record a minute of baseline sweat rates.

   NOTE: The baseline sweat rates will not be zero, this is normal. It is best to have a flat baseline prior to starting. This baseline will be subtracted out during the analysis.
7. Press the mark button at the beginning or end of any event. 
8. To end recording press the stop button. 

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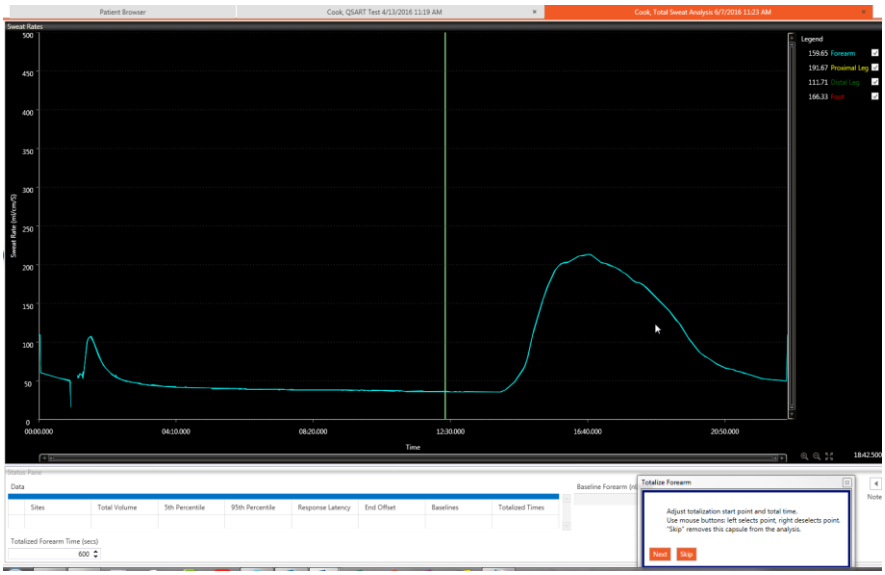
SWEAT TOTAL: 

Perform a totalized sweat analysis (for Sweat Response and Resting tests).

Click the “Start Analysis” icon 

from the toolbar under the ‘Total Sweat’ tab to open the analysis toolbar. Follow the instructions in the dialog box to analyze the test (one channel at a time).



Adjust the start and response points, if necessary, by right-clicking to remove points and left-clicking to select points.

Verify, or adjust, the baseline value (initialized as the lowest 5 second average rate between the auto-selected start and response points).

Click “Next” to calculate and display the total sweat volume.

Use the “Back” button to select different start/response points, to adjust the baseline level, or to return to previous channels.

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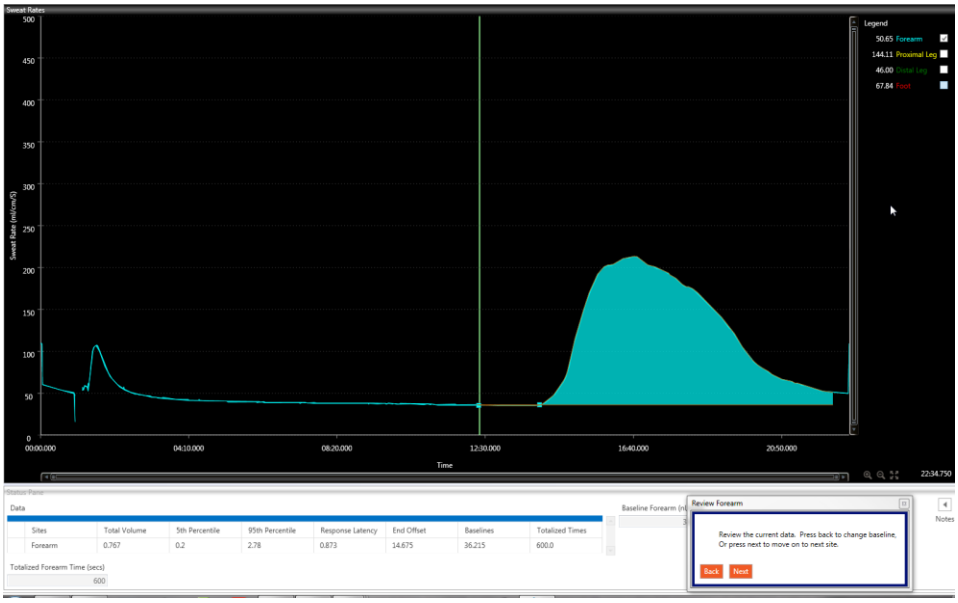

"Skip" removes the current channel from the analysis.

Select "Next" to continue, analyzing each channel.

Click the "Finish" button when all channels are complete.

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CASE Component

Quantitative Sensory Test Types

Warming 4,2,1 with Null Stimuli

Warming Forced Choice

Cooling 4,2,1 with Null Stimuli

Cooling Forced Choice

Vibration 4,2,1 with Null Stimuli

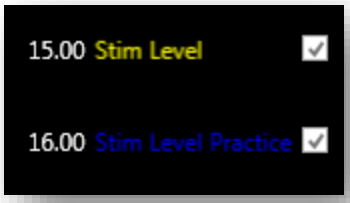
Vibration Forced Choice

Heat Pain NRA with Null Stimuli

Charted Signals

Stimulus delivered:

Practice Stimulus:



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RECORDINGS

Quantitative Sensory Testing (QST) measures vibration and thermal (cooling, warming and heat-as-pain) detection thresholds using stimuli that are specific and sensitive, and testing algorithms that are time efficient. Stimulators are attached or placed on the skin, typically on the foot or hand, and samples are given to familiarize the patient with the stimulus. An automated test is performed and analyzed by WR-TestWorks software. Typically, the test is performed on the left side, unless there are physical abnormalities, loss of intact skin or other issues which require the right side to be tested.

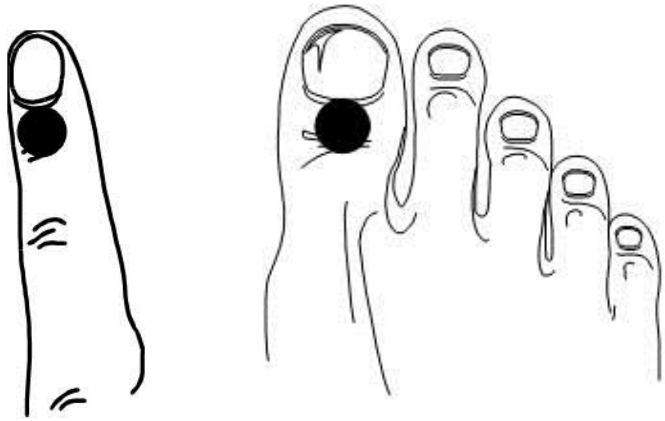
Patient Preparation

- Patients should not use any sedatives or tranquilizers for a time prior to the test as determined by the physician. The test cannot be done on patients with mental retardation, dementia, or when the patient is inattentive, uncooperative, sedated, or too ill to cooperate.
- Compressive stockings, belts, and garments should be avoided the day of the test.
- Do not apply to broken skin or on areas of exfoliating skin conditions.
- Skin temperature should be at least 32 degrees C.
- Patient should be comfortably seated.

Performing CASE IV Vibration Test – Sample Protocol

Test Sites – Vibration (typical)

Midline of first digit, below the nail and above the first joint
Midline of big toe, below the nail and above the first joint



NOTE: Position of the vibration stimulator is important, see illustrations below.
If a test is unsatisfactory, it can be repeated on the same day.

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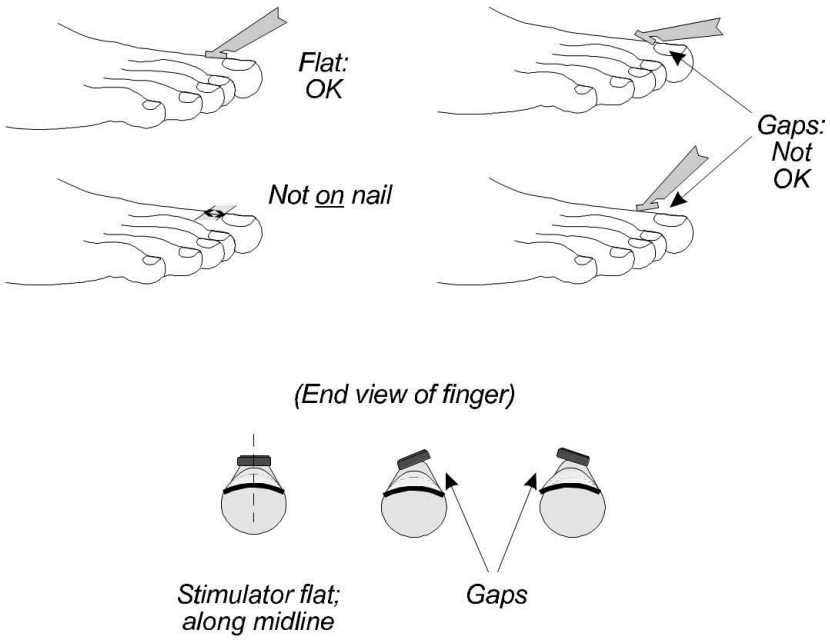
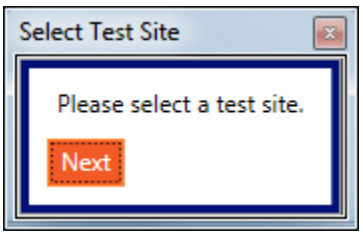


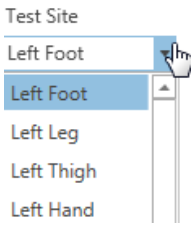
Instructions

1. Select (or create) the patient in the Test Explorer, and select the desired test icon 

or 

.
2. Enter the visit information.
3. Click to start the test  .
4. Select the desired test site from drop-down list.





5. Place the vibration stimulator at the selected test site.

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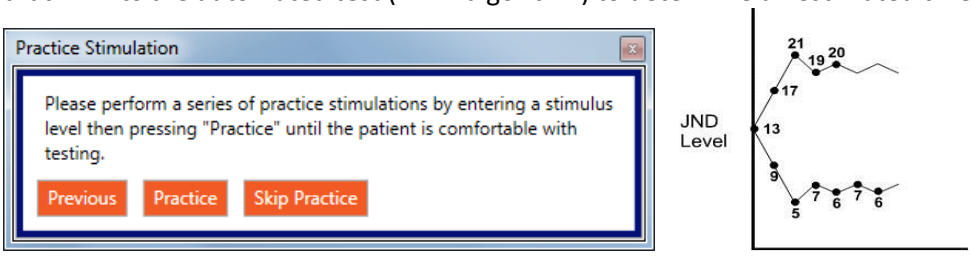
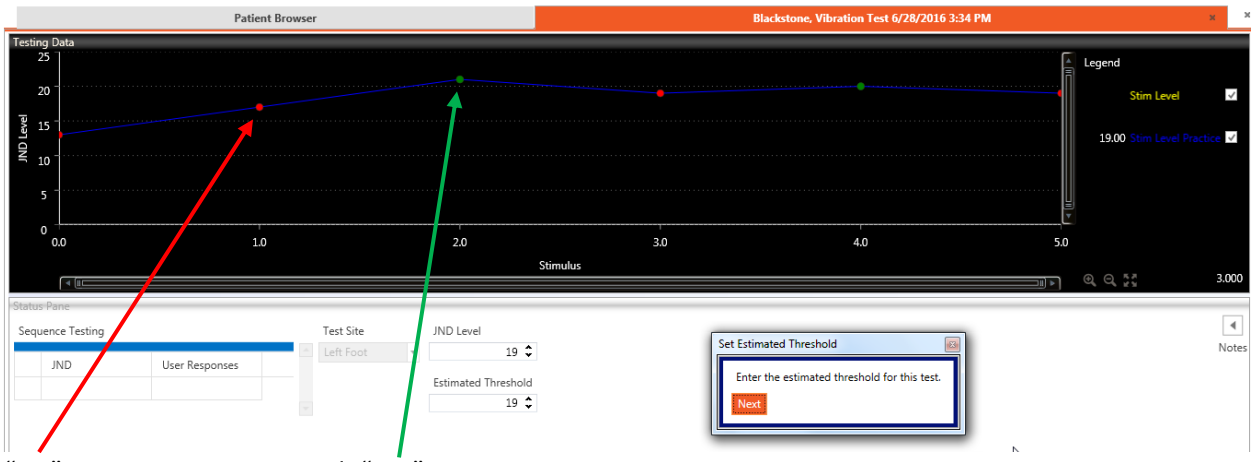
6. Read the appropriate Patient Instructions card(s) to the patient, and give sample stimuli in a way that mimics the automated test (4-2-1 algorithm) to determine an estimated threshold level.



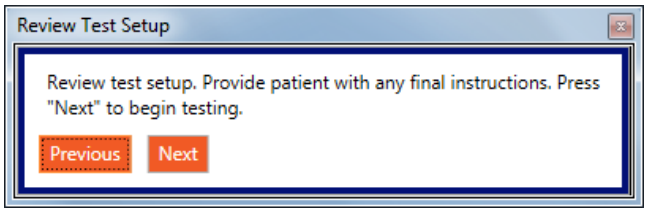
NOTE: The patient will use the response device to enter 'Yes' or 'No' as to whether (or not) they felt the stimulus. If they pressed the response button prior to the end of the stimulus it will not be recognized and must be re-entered.
[For forced-choice tests, they must indicate the period in which they felt the stimulus '1' or '2'.]

7. When the patient understands the test operation, and an estimated threshold has been identified, click "Next" and enter the estimated threshold level for this test.



"No" Patient response in red. "Yes" Patient response in green.

8. Put the headphones on the patient (adjusting volume as necessary) and begin the automated test (by clicking "Next").



9. When testing is completed, remove the vibration stimulator.

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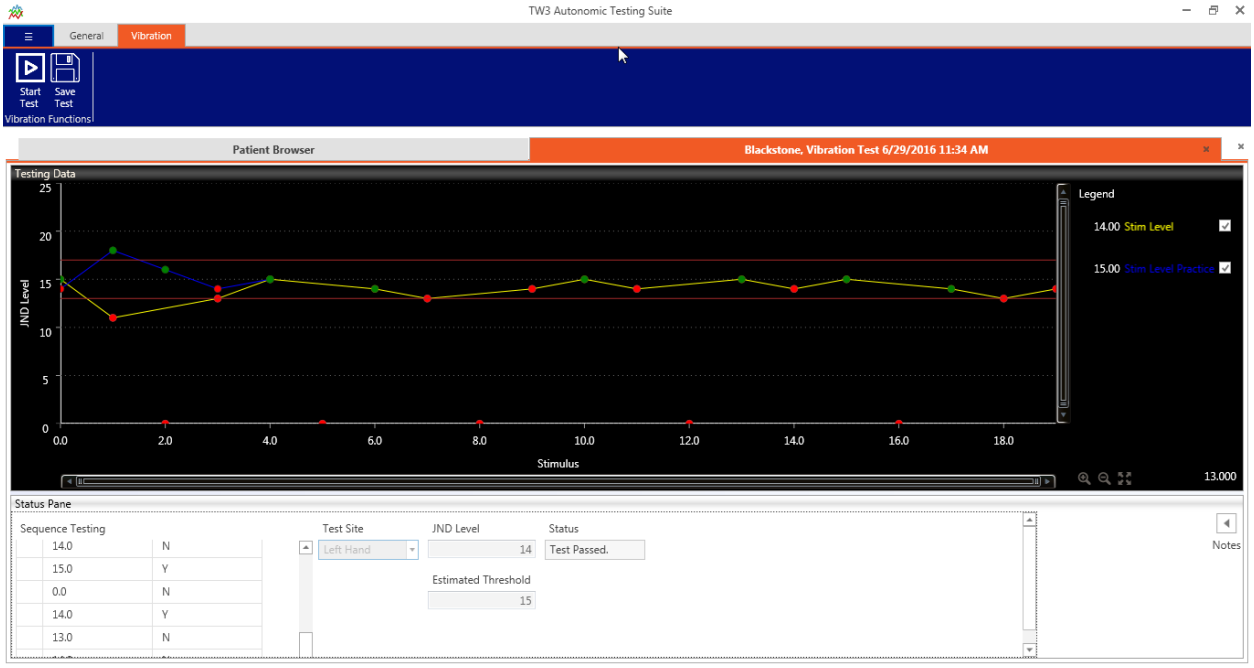

10. Save and close the test.

Note – If a response if not received during testing for greater than 5 minutes, the test will automatically end.

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ANALYSIS

Open a test, and select the analysis button 

, then the start analysis button 
to perform an automated analysis. Results are shown on the chart, as well as numerically.

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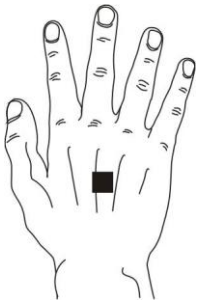
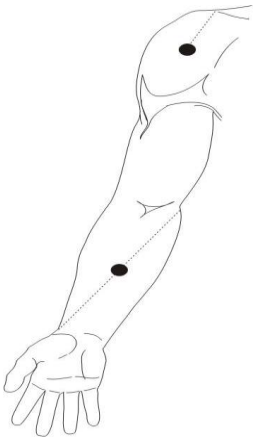
Test Sites - Thermal

Foot: dorsal surface



Hand: dorsal surface

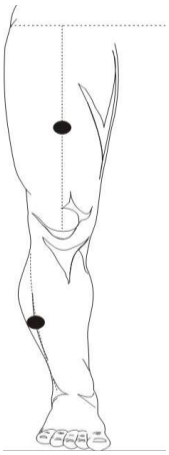


Lateral shoulder: apex of the deltoid muscle - lateral aspect of the shoulder

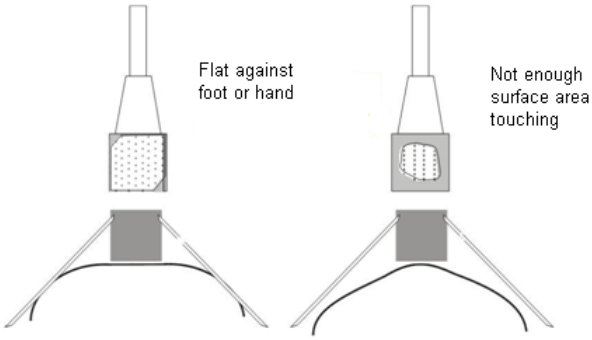
Volar forearm: midpoint between medial epicondyle to radius end

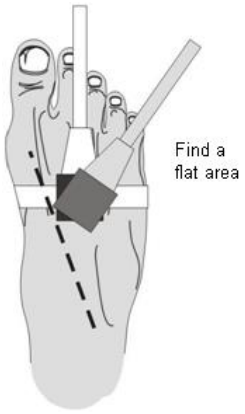
Anterior thigh: midpoint between inguinal crease to midpoint of patella

Lateral leg: midpoint of a line from the tip of the head of the fibula to the tip of the lateral malleolus



Be certain that the stimulator makes good contact with the skin.





Use a stabilizing strap for foot
Warm the foot to 30-32°C., and cover with a sock
Limb should be fully relaxed
Awkwardly positioned limbs may cause numbness

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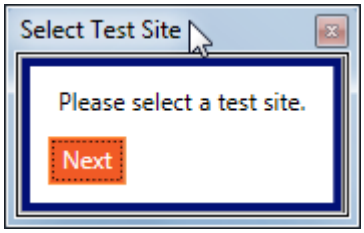
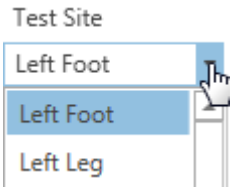
Instructions

1. Select the patient name, select the test icon 

, and enter visit information.

2. Select the start test button  , then follow the command prompts to begin testing.



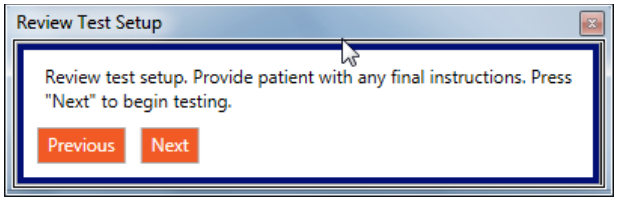


3. Place the thermal stimulator at the selected test site, and continue to be prompted to press the "Enable Thermal Stimulator" button on the CASE IV device.

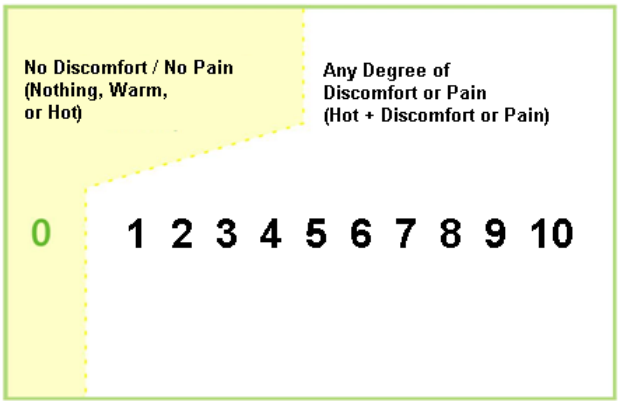
4. Read the Patient Instructions cards to the patient.

   ***NOTE:** NO SAMPLES ARE GIVEN FOR HEAT-PAIN.

5. Begin the automated test (by clicking "Next").



6. The patient will provide answers from the visual analog pain scale, where 0 is no pain or discomfort and 10 being the highest or most painful.



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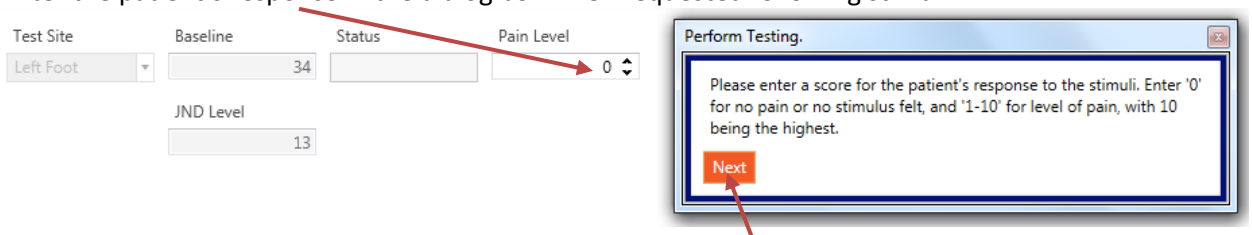
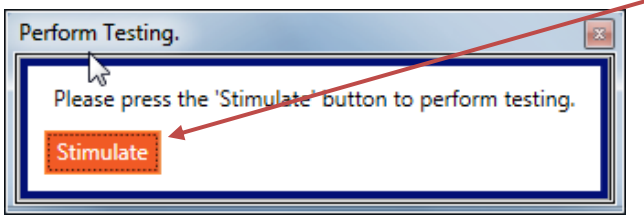
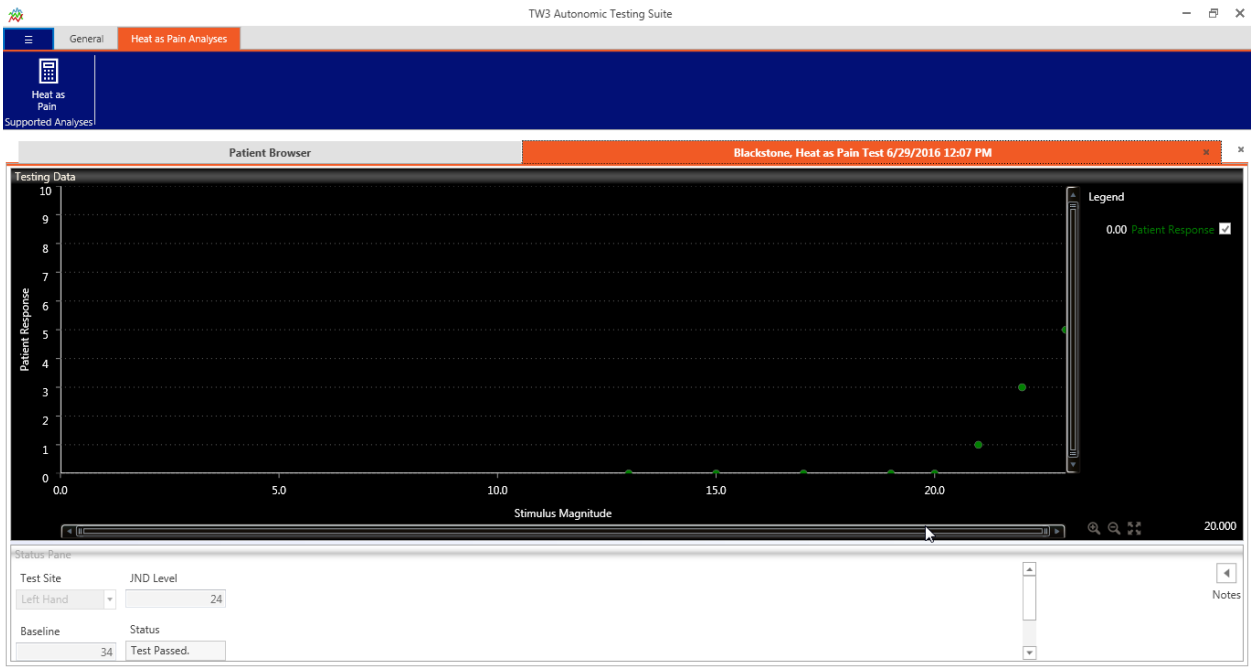
Enter the patient's response in the dialog box when requested following stimuli.



The next stimulation will continue after response is entered, "Next" is pressed, and "Stimulate" is pressed to start the next stimulus.



7. Continue entering responses until testing is completed. Then, remove the thermal stimulator.
NOTE: The test stops if a response is at level 5 or higher.



NOTE: Do not perform this test on the same site within 24 hours.

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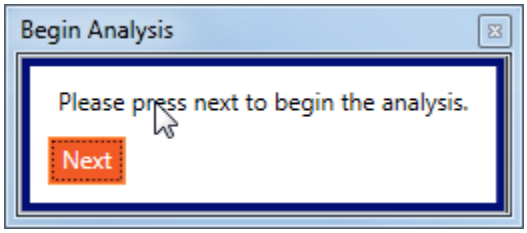
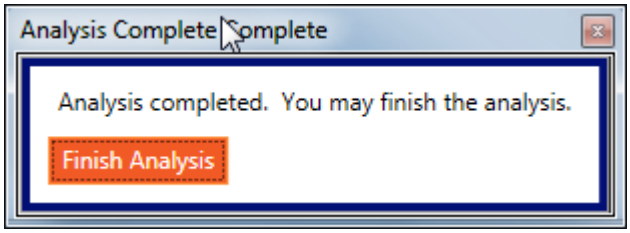
ANALYSIS

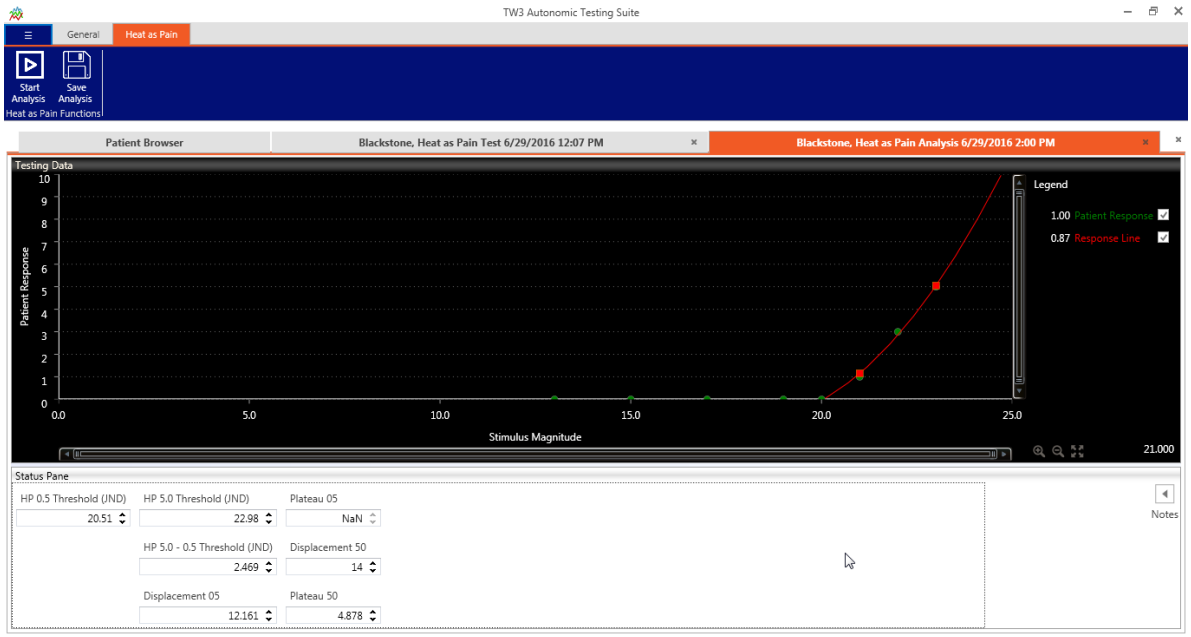
Open a test, and select the analysis button 

, then the start analysis button  to perform an automated analysis.

Press “Next”, then “Finish Analysis” to complete the analysis.







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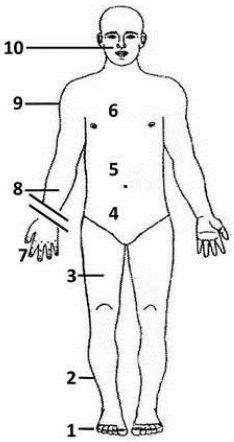
Smart Somatotopic Quantitative Sensation Testing (S-ST-QST) of Body Sites - Touch Pressure and Heat as Pain 5 (QST TP and HP5)

Body Surface Touch-Pressure and Heat as Pain 5 Score ($QST_{BS\ 20}$ TP and HP5)



Objectives:

- Identify 10 standard sites.
- Describe the techniques and computer algorithm to estimate $QST_{BS\ 20}$ TP and HP5.
- Describe test results.

Methodology:

- Touch pressure: Nylon monofilaments A, B, C - - - I, -3, -2, -1 - - - 5 ln gms, 2 alternative forced choice-step testing directed by CASE IV C or PC (algorithm designed by PJD and programmed by WR Medical Electronics, Maplewood, MN). Testing begins at anatomical site 2 and later at site 8 (figure). Testing beyond 2 and 8 depends on responses, i.e. $<95^{th}$, test next at sites 1 and 7; $\geq 95^{th} - <99^{th}$, test sites 1 and 3 and 7 and 9 and $\geq 99^{th}$, test sites 3 and 9 (assume sites 1 and 7 is $\geq 99^{th}$). Test more proximal sites if needed, i.e. contiguous distal site $\geq 95^{th}$.
- HP5: Use Ascending Non-repeating Stepping Algorithm and CASE IV C beginning at sites 2 and 8, and test more distal and proximal sites as described for touch-pressure.

Results for:

- Anatomical site as: percentiles or as NIS* points , i.e. $<95^{th}$ = 0 point; $\geq 95^{th} - <99^{th}$ = 1 point and $\geq 99^{th}$ = 2 points.
- Body surface, i.e. points.
- % of max, i.e. of 80 points.

As a component of composite neuropathic impairment score (ΣNIS):

- $QST_{BS\ 20}$ TP and HP5 can be added to NIS – weakness (points); NIS – reflexes (points); and Σ5NC as points (ulnar CMAP; ulnar SNAP; fibular CMAP; tibial CMAP and sural SNAP).

* NIS = Neuropathy Impairment ScoreΔ, CMAP = compound muscle action potential and SNAP = sensory nerve action potential.

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Overview

The pattern of sensation loss, and the modalities of sensations affected provide useful diagnostic information to physicians. One of the common patterns of sensation loss encountered in peripheral neuropathy is symmetrical and length dependent. This type of sensation loss occurs in diabetes, inherited conditions, vitamin deficiency, alcoholism, industrial and medicinal toxicity, cancer, and various metabolic diseases. The approach developed here is to be used for clinical and research studies of diabetic sensorimotor polyneuropathy and transthyretin polyneuropathy. It is assumed that in TTR amyloid polyneuropathy there are multifocal small regions of involvement which summate distally so that the pattern becomes symmetrical and length dependent.

To make $QST_{BS\ 20}$ TP and HP5 efficient, the same unilateral side is tested on subsequent occasions. This makes sense as it is assumed that the process of sensation loss is symmetrical. A single representative modality of sensation is used to assess large sensory fibers, i.e., touch pressure using monofilaments, and HP5 using CASE IVc assessing small fiber sensory function. A third efficient approach is to begin testing at a defined intermediate level of an extremity and moving distally or proximally but only proximally to the point where sensation becomes normal, i.e., < 95th percentile. The final approach to make the test efficient is to not determine threshold precisely once it exceeds the 99th or 99.9th percentile or falls below the 95tth percentile.

QST TP Monofilaments Available for Testing and Estimating Threshold:

	grams	ln grams
A	0.05	-3
B	0.135	-2
C	0.368	-1
D	1.0	0
E	2.7	1
F	7.4	2
G	20.0	3
H	55.0	4
I	148.4	5

The 2 Alternative Forced-Choice Stepping Algorithm for QST TP – Sample Protocol:

Monofilaments provide nine levels of magnitude of touch-pressure stimuli from A to I (shown above). A brief practice session should be done on hand or forearm with monofilament E, allowing the patient to see how the test is done. Formal testing then begins with use of monofilament E. The patient's eyes must be closed. Ten pairs of randomly assigned stimulus events (a stimulus and a null stimulus) are given for each level of stimulus force tested using restricted randomization so that the same number of stimuli and null stimuli are given in period 1 of the 10 pairs tested. Test the sites to be tested (e.g. dorsal phalanx 3-4 mm from base of nail on each of the five toes) and then test them again with pairs of stimuli. Identify periods 1 and 2 verbally. For the stimulus, make contact with the skin from a distance of one to two mm from the skin and with slow descent. After contact, pressure is increased so that the

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monofilament bends to about 5/6 of its extended length, then pressure is reduced and the monofilament is lifted from the skin. Null stimulation is in every respect similar but contact is not made with the skin. The word "1" then "2", the duration of the interval of testing and the motion of the examiner's hand should be exactly the same for null stimuli and stimuli but for null stimuli contact is not made with the skin. The tone and loudness of the voice should not indicate to the subject which interval of time (1 or 2) has the stimulus.

Each stimulus event should take about 2 seconds. The time between the pair of stimulus events should be 1 to 2 seconds. After a pair of stimulus events is given, ask the patient, "Did you feel the touch in 1 or in 2?" Record the interval chosen. As the test progresses, the examiner's questions may be simplified (e.g. "In 1 or 2?"). The subject must choose 1 or 2. In some patients, the time between the stimulus and when the patient feels it may be delayed because of a disease of the nerves. In these patients, the interval between pairs of stimulus events may be increased, e.g. to 4 seconds.

Testing Scores

A patient receives a result score at the end of each test. This test result is used to generate a percentile from less than 1% to greater than 99%. This percentile result is used then to determine a final patient score of 0, 1, or 2. They are determined as follows:

- If the percentile score is less than 95% a score of 0 is assigned.
- If the percentile score is equal to or greater than 95% but less than 99% a score of 1 is assigned.
- If the percentile score is equal to or greater than 99% a score of 2 is assigned.

At the end of each test, a patient will have a score from 0 to 2, which will be added in determination of a total test score for the patient to all other tests. For each site not tested a score of 0 is assumed, except as noted below. At the end of a full round of testing a patient will have been tested using anywhere from 8 to 40 tests. This results in a set of three scores: the sum of scores from all Somatotopic Touch Pressure tests, the sum of all scores from Heat as Pain tests, and the sum of all scores from Somatotopic Touch Pressure and Heat as Pain tests combined. Each of these is ranked as $\left(\frac{score*2}{total\ possible}\right)$, which results in a percentile for that block of tests. Each of the QST Touch Pressure and Heat as Pain test blocks are out of a possible 40 points, and the total is out of a possible 80 points.

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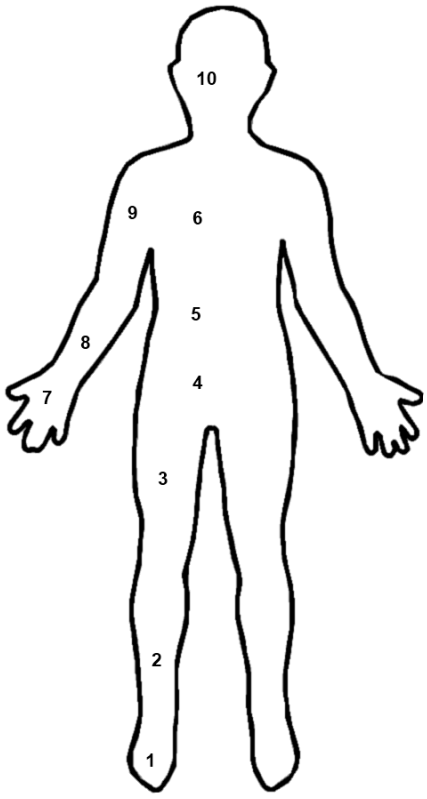
Sites and Progression

There are a total of 10 (ten) sites for testing along the body. These sites are tested in a manner which assumes length dependency with bilateral equivalency in respect to the left or right. These ten sites are the dorsal foot, the lateral leg, the anterior thigh, the lower and upper abdomen, the subclavicular, the dorsal hand, the volar forearm, the deltoid, and the face. Each site also corresponds to a testing site number, starting with site 1 being at the dorsal foot and site 10 being the face.



Site Number	Site
10	*Face*
9	*Deltoid*
8	*Volar Forearm*
7	*Dorsal Hand*
6	*Subclavicular*
5	*Upper Abdomen*
4	*Lower Abdomen*
3	*Anterior Thigh*
2	*Lateral Leg*
1	*Dorsal Foot*

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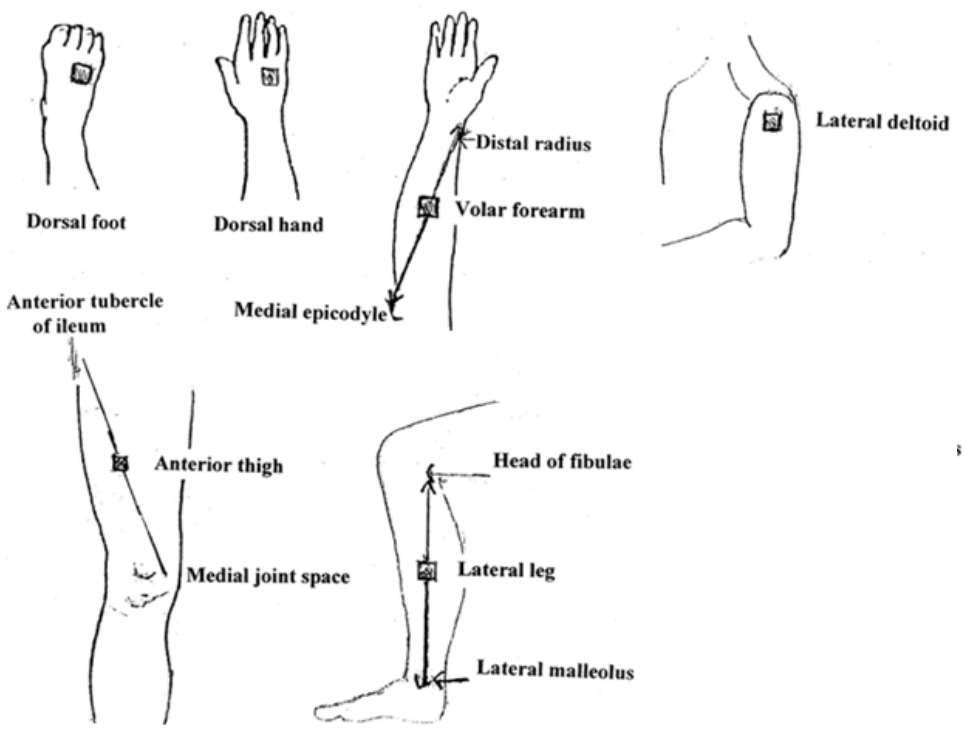

The testing sites are broken up further into two categories: the lower body category, which contains sites 1 through 6, and the upper body category, which contains sites 7 through 10. This is to fully account for length dependency in the testing. Both upper and lower body categories are tested in a similar manner.

Testing typically starts at site 2, the **Lateral Leg**. Testing can then progress to either site 1 or site 3 based upon the score determined from testing. Testing then continues upwards along the body in length dependent fashion until either a test site receives a score of 0 or site 6 is reached. At that point, testing moves to the upper body testing sites and begins testing at site 8. Just as before, testing will move to either site 7 or 9 depending upon the test result and will continue in length dependent fashion until either a site receives a score of 0 or site 10 is reached, whichever occurs sooner. Testing is then finished. A diagram of site progressions is included below (Figure 10). It should be noted that if a patient receives a score of 2 at a site, all sites located distally are automatically assumed to have a score of 2. For example, if the patient receives a score of 2 at site 2, site 1 automatically receives a score of 2. Similarly, if site 8 has a score of 2 site 7 is assumed to have a score of 2 as well.

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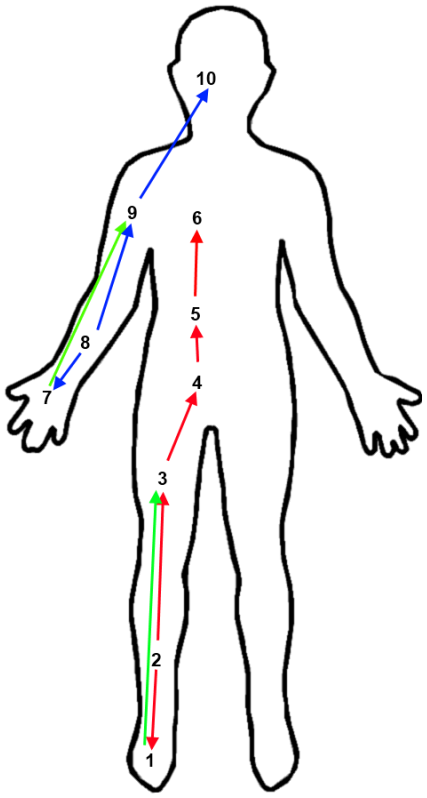
In testing for advancement purposes, a test with a score of 1 or 2 advances to the next site. A test with a score of 0 terminates at that site, except as noted in the cases of sites 2 and 8.



Site Number	Advances To
10	*N/A*
9	*Face (Site 10)*
8	*If tested result is 0/1: Dorsal Hand (Site 7)* *If tested result is 2: Deltoid (Site 9)*
7	*If Site 8 tested as 0: N/A* *If Site 8 tested as 1: Deltoid (Site 9)*
6	*N/A (Continue to Site 8)*
5	*Subclavicular (Site 6)*
4	*Upper Abdomen (Site 5)*
3	*Lower Abdomen (Site 4)*
2	*If tested result is 0/1: Dorsal Foot (Site 1)* *If tested result is 2: Anterior Thigh (Site 3)*
1	*If Site 2 tested as 0: N/A (Continue at Site 8)* *If Site 2 tested as 1: Anterior Thigh (Site 3)*

Figure 10: A diagram of testing site progressions and a related table describing them.

Special Instructions for Touch Pressure Hand & Foot Sites

Touch pressure tests are applied to the finger and toe a few millimeters behind the the nail instead of the dorsal foot and hand. Each set of Null-Stimulus pairs should be applied to a different finger/toe. For example, the first set of Null-Stimulus pairs would start on the thumb. The next pair would be on the pointer finger, then the middle finger, etc.

Order of Test Execution

When testing the patient the testing should begin with QST Touch Pressure testing at site 2. Testing should be performed along the left side of the body. In the event any site cannot be tested along the left side of the body, the patient should be tested for all tests at the same sites on the right side of the body. Continue as directed with QST Touch Pressure tests on the lower body until a termination is reached; then continue with the upper body. With the upper body tests completed using QST Touch Pressure tests testing continues with Heat as Pain tests. These start at the lower body site 2. Continue as directed with Heat as Pain tests on the lower body until a termination is reached; then continue with the upper body. Once the upper body tests are completed testing using QST tests are complete.
HRDB testing can be performed before or after QST testing.

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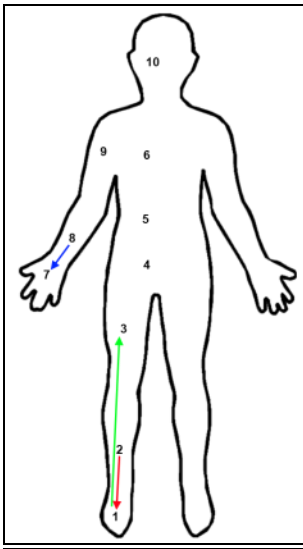
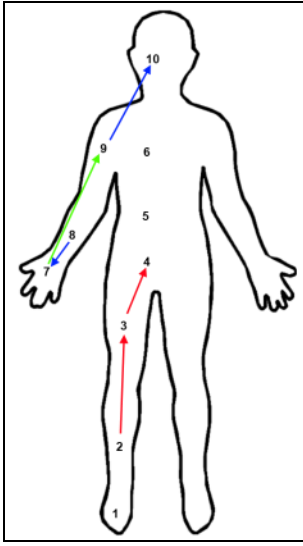
Example Test

Below are several example tests with explanations.

Touch Pressure			
	Site	Range	Score
	10		
	9		
	8	< 95%	0
	7	≤ 95% - < 99%	1
	6		
	5		
	4		
	3	< 95%	0
	2	≤ 95% - < 99%	1
	1	≥ 99%	2

Heat as Pain 5			
	Site	Range	Score
	10	< 95%	0
	9	≤ 95% - < 99%	1
	8	≤ 95% - < 99%	1
	7	≥ 99%	2
	6		
	5		
	4	< 95%	0
	3	≤ 95% - < 99%	1
	2	≥ 99%	2
	1	≥ 99%	2

QST_{20} Touch Pressure	(Sum * 2) / 40	20%
QST_{20} Heat as Pain 5	(Sum * 2) / 40	45%
QST_{20} Heat as Pain 5 & Touch Pressure	(Sum + Sum * 2) / 80	32.5%

In the example above a patient has gone through all the necessary quantitative sensory testing. This has resulted in five tests using the QST Touch Pressure testing and seven tests using the Heat as Pain testing.

Starting with the Touch Pressure tests, testing began at site 2, or Lateral Leg. The testing revealed a percentile value between 95% and 99%, resulting in a score of one. Testing continued at site 1, where a

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score of 2 was received due to testing above the 99th percentile. Since site 2 had a score of 1, testing moved up to site 3. At site 3 testing resulted in a value unequivocally below the 95th percentile giving a score of 0 for the site. Testing finished at the lower limb sites and moved on to site 8. At site 8 a score of 0 resulted, and led to a test of site 7 only. At site 7 the test resulted in a score of 1 due to being between 95% and 99%. Testing with monofilaments stopped at this stage.

Moving on to the Heat as Pain tests, testing began at site 2. Testing revealed the site to be unequivocally above the 99th percentile. Testing moved to site 3, with site 1 being marked automatically as 2. At site 3 testing resulted in a score of 1, and terminated at site 4 with testing indicating the patient scoring below the 95th percentile. Testing advanced to the upper body at this point at site 8. Site 8 scored 1, resulting in testing both sites 7 and 9. With testing at site 7 resulting in a score of 2 analysis continues at site 9. Site 9 also shows a score of 1 for testing between the 95th and 99th percentiles, and site 10 is tested. Site 10 scores 0 for testing below the 95th percentile. As a note, site 10 would terminate regardless of whether it tested 0, 1, or 2.

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Smart Somatotopic Sensation Test (S-ST-QST)

A touch pressure test is launched by clicking the Touch Pressure icon in the Somatotopic toolbar, 

. The launch page is shown below in Figure 11.

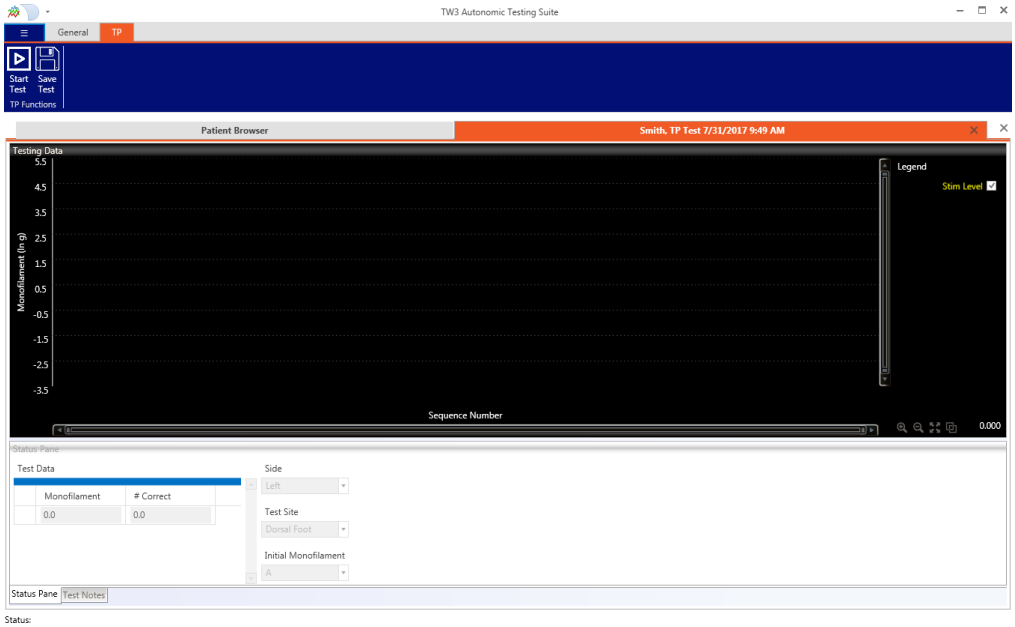

Figure 11: Touch Pressure Test launch page. The "Start Test" button is located in the upper left corner.

Click "Start Test" to open the main test window. The testing sites and the testing side are selected via a drop-down box. The first site to be tested should always be the **Lateral Leg** site (Figure 12). Other sites are chosen based upon guidance that will appear later in testing. Once a site has been chosen, click "Next".

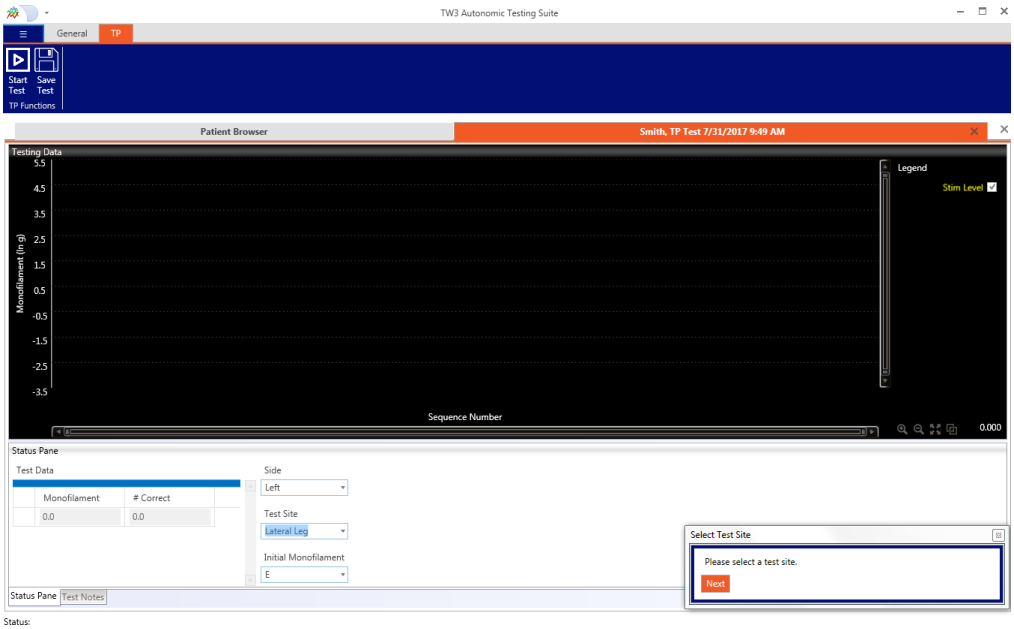

Figure 12: The Lateral Leg should be the first site tested in the Smart Somatotopic Touch Pressure test.

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At this time, the following instructions should be read to the patient:

1. This is a test of your ability to feel touch sensation. The test is not painful and takes about 10 minutes. The object is to identify the smallest touch you can feel.
2. You will need to close your eyes during the test.
3. Testing is done in pairs and I will indicate these two periods of time by saying “1” then “2”. You must say whether you felt the touch in 1 or 2. I will touch you only one time, never in both 1 and 2. If may be difficult for you to judge whether you felt this touch in 1 or in 2 but you must choose 1 or 2. You cannot answer “I’m not sure” or “I don’t know”.
4. Get comfortable and let’s do a practice test.

The program allows for a period in which the user can perform a series of practice steps with the patient. Do a brief practice session on hand or forearm with monofilament E, allowing the patient to see how the test is done. Once practice has been completed, click “Next” in the ‘Practice Stimulation’ prompt and testing will begin.

Please read the following instructions to the patient prior to beginning testing:

1. If at any time during the test you begin to feel drowsy or are having difficulty concentrating, please tell me and I will give you a break.
2. Do you have any questions? Please close your eyes, relax and focus on your hand/foot. Now I will begin the testing.

The program will prompt the user which period (1 or 2) in which the ‘NULL’ and the stimulus should be given. The program will also prompt the user to select the period in which the patient felt the response. Correct answers on the chart are denoted by green circles and incorrect answers are denoted by red circles (Figure 13).

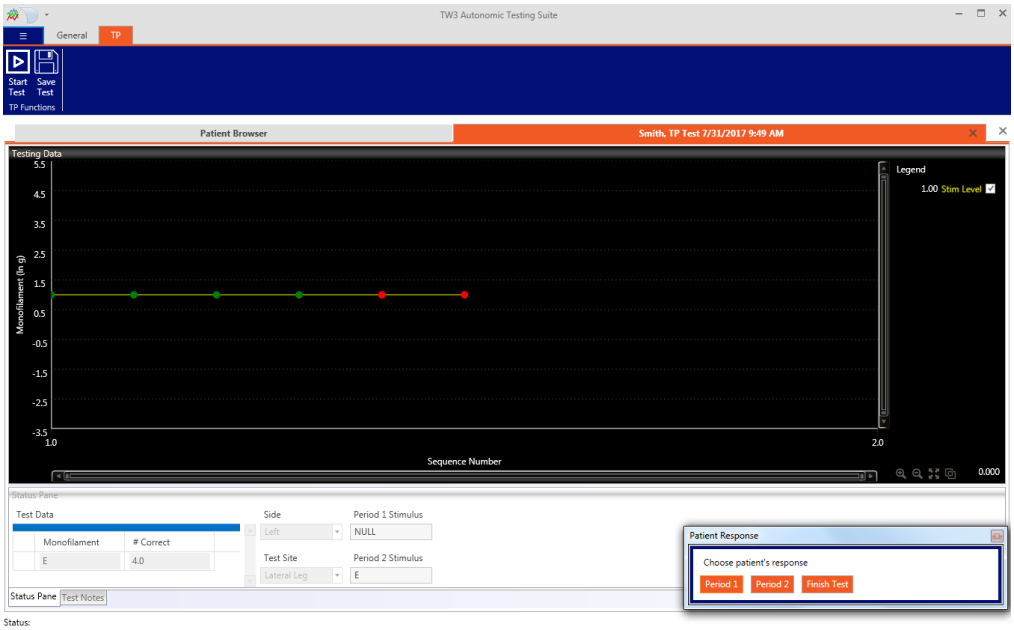

Figure 13: Correct answers are shown in green. Incorrect answers are in red.

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At the end of a round of tests at a given stimulus level, the test will either terminate or advance to another stimulus level (Figure 14).

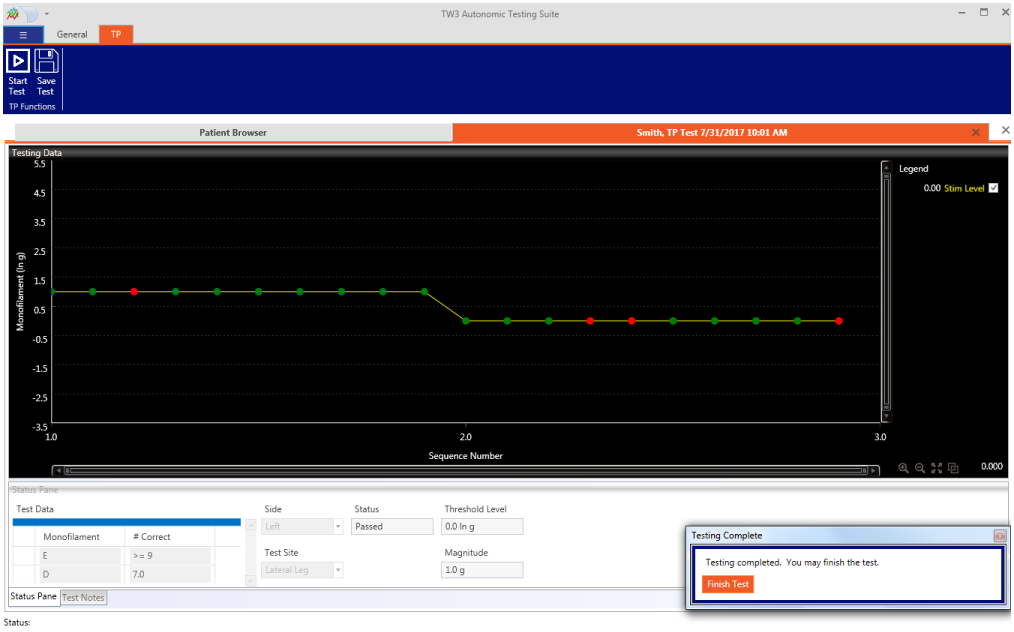

Figure 14: Here, the stimulus level has advanced from stimulus E to stimulus D to continue testing.

After the appropriate number of responses have been collected, a dialog box will inform the user that the test for the current site has been completed. To enable the analysis to determine the next testing site for the Smart Somatotopic Sensation Test:

- Click “Finish Test” in the ‘Testing Complete’ dialog box to close the dialog box.
- Then click “Save Test” in the upper left corner of the main control ribbon.
- Close the current test by clicking the small ‘x’ in the upper right hand corner of the test tab.
- Navigate back to the patient list and open the test that was just completed. At this point, the appropriate analysis is now enabled.
- Click “Dyck Analysis” to open the analysis tab, then click “Start Analysis” and follow the instructions in the dialog boxes. A pop-up box will be displayed, advising the user which site should be tested next.

Repeat the testing process by launching a new test from the main patient browser, using the site that was indicated during the last test. For example, if analysis of the Lateral Leg site test indicated to test the Dorsal Foot next, the user would then choose Dorsal Foot as the testing site for the second test.

Continue this process until the analysis pop-up box displays the message, “Testing finished at site” (Figure 15). At this point, touch pressure testing is complete. Testing then moves to the Somatotopic Heat as Pain Test.

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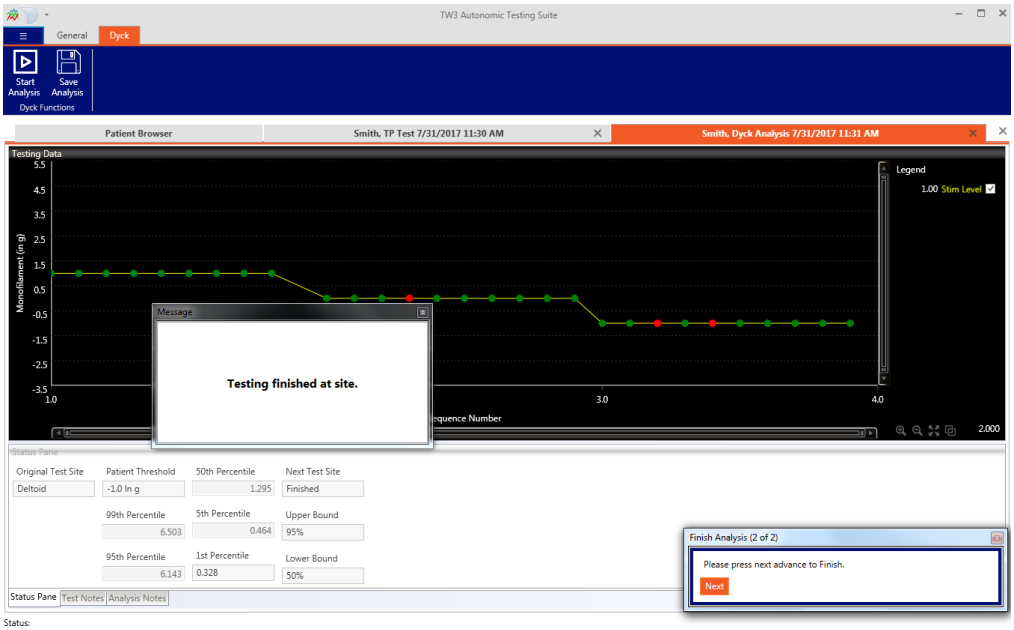

Figure 15: At this point, touch pressure testing is complete.

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Somatotopic Heat as Pain Test

A heat as pain test is launched by clicking the Heat as Pain icon in the Somatotopic toolbar, 

. The launch page is shown below in Figure 16.

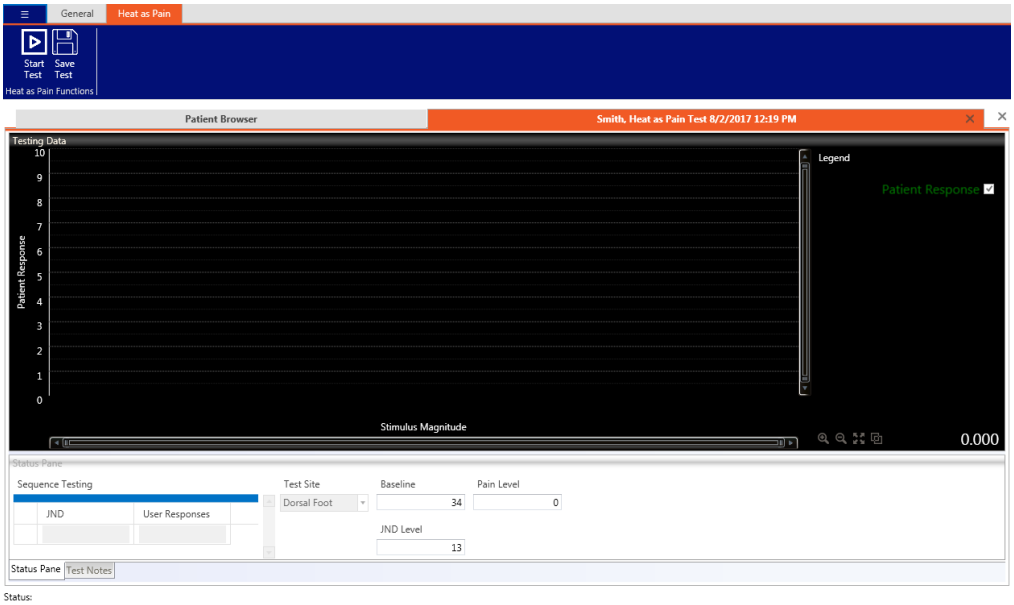

Figure 16: Somatotopic Heat as Pain Test launch page. The "Start Test" button is located in the upper left corner.

Click "Start Test" to open the main test window. After the Somatotopic heat as pain test has been launched, the user is prompted to select a site for the stimuli. As with QST Touch Pressure, the **Lateral Leg** should always be the first site selected when starting a test (Figure 17).

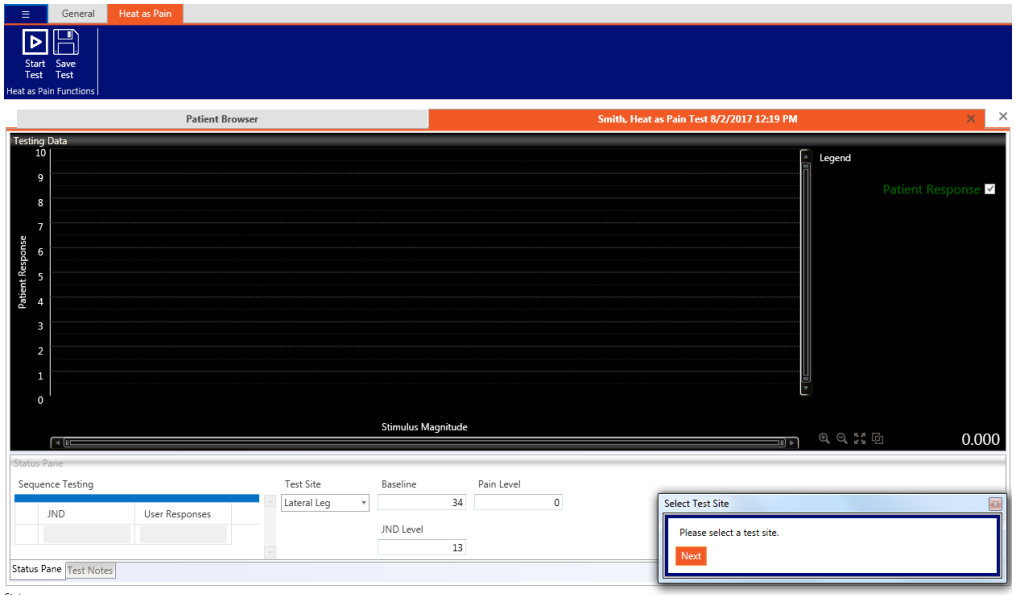

Figure 17: As with the QST TP testing, begin the Heat as Pain test on the Lateral Leg site.

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At this stage, the test prompts the user to position the thermal stimulator upon the patient. After doing this, click “Next”. The test then prompts the user to press the ‘Enable Stimulator’ button on the CASE IV device (Figure 18).

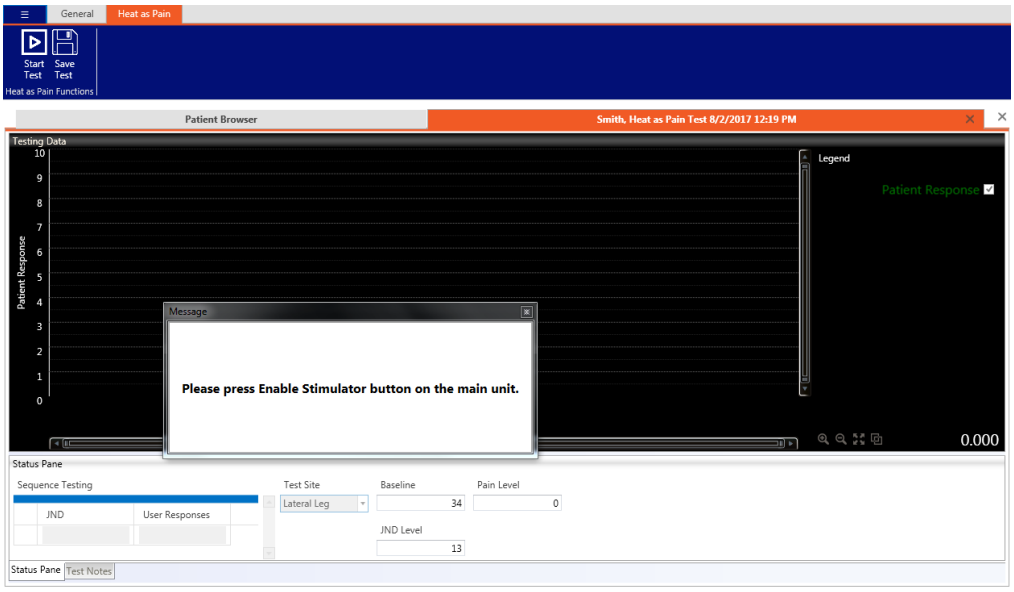

Figure 18: The test will prompt the user to press the ‘Enable Stimulator’ button on the CASE IV device.

After pressing the ‘Enable Stimulator’ button, the thermal stimulator will go through some steps that allow it to warm up appropriately and acclimate to the patient's skin ().

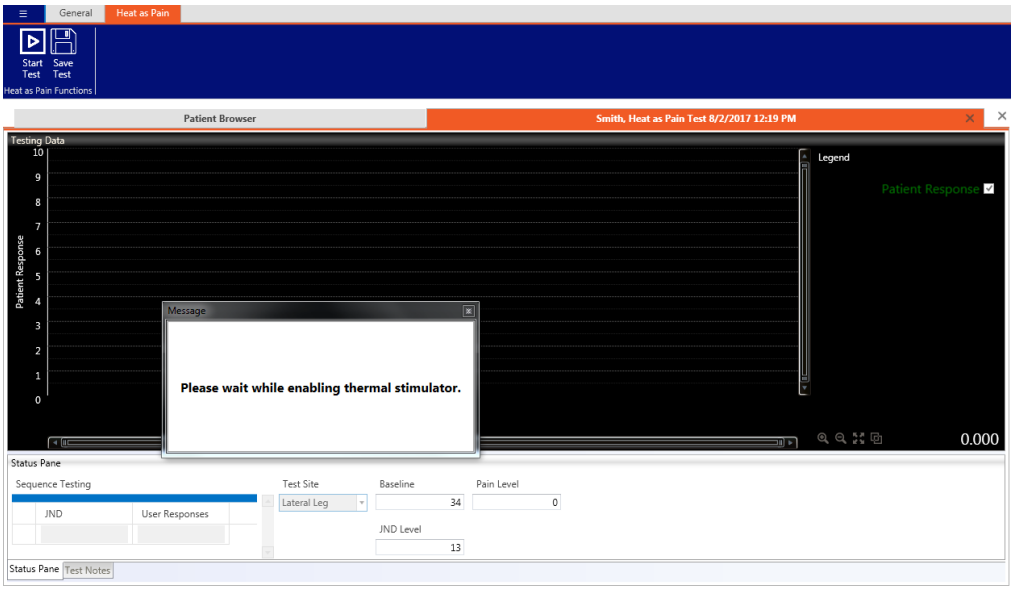

Figure 19: After enabling the CASE IV device, the thermal stimulator will take a little time to warm up.

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Once this is done the user may progress to testing. The patient will be supplied a stimulus by the device. After the stimulus, the user will be prompted to enter the patient's response on a scale of 0 through 10. Enter ‘0’ for no pain or no stimulus felt, and ‘1-10’ for the level of pain, with ‘10’ being the highest.

It should be noted and clarified for the patient that a score of ‘1’ **DOES NOT** indicate simply feeling the stimulus, but rather indicates the point at which the patient begins to feel **PAIN**.

Once the value is entered the test continues. A green circle indicates each valid response or a point at which the patient did not feel the stimulus. An invalid response (stating the feeling of stimuli during a null stimulus) is indicated by a red circle.

Testing continues until a patient reports a score of 5 or above. At this stage the test is complete and ready for analysis (Figure 20).

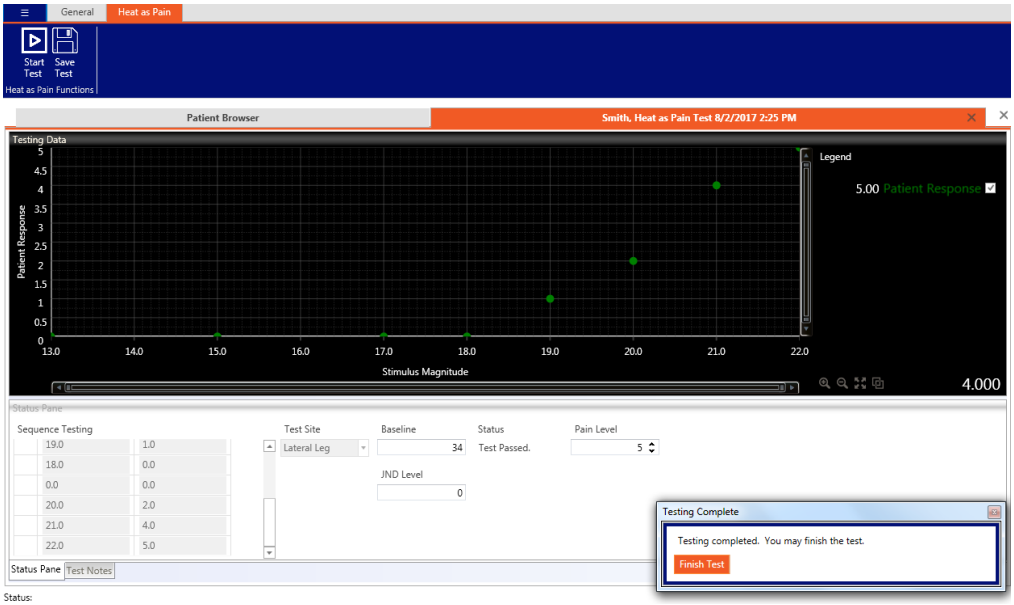

Figure 20: The Heat as Pain test is completed when the patient reports a score of 5 or above to a stimulus.

It should be noted that occasionally during testing, at higher stimulus levels, the thermal stimulator might take a few moments to normalize. A message will pop up (Figure 21) when this occurs and the user should wait for thermal normalization to occur and the pop up message to go away.

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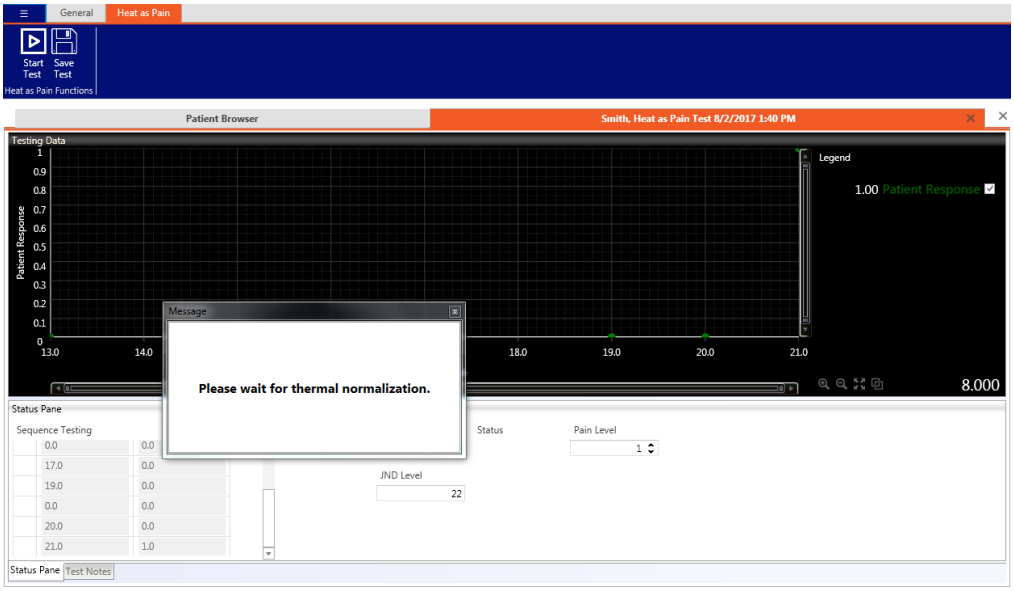

Figure 21: Occasionally, the thermal stimulator will need a moment to normalize before continuing with the test.

Close the test. The full analysis can then be launched by opening the completed test from the patient browser and clicking on the Dyck analysis icon, 

. This launches the full analysis. The analysis will prompt the user with a display indicating the test site to advance to (if appropriate) or to end testing (Figure 22). All necessary patient information is displayed in the bottom chart for the user, and can later be viewed upon a report.

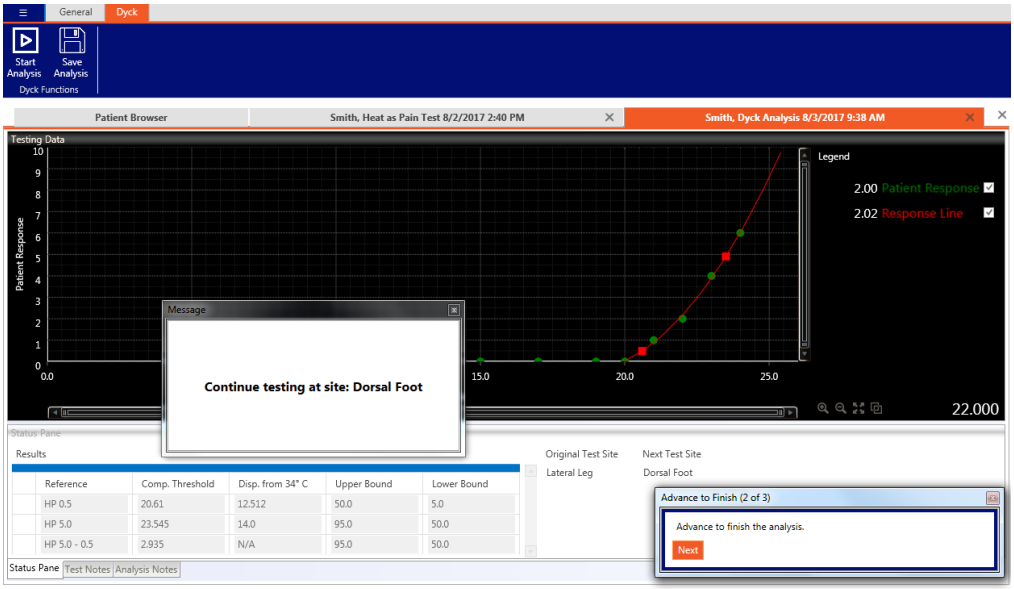

Figure 22: Analysis of the completed test will indicate which site to move to or if testing is considered complete.

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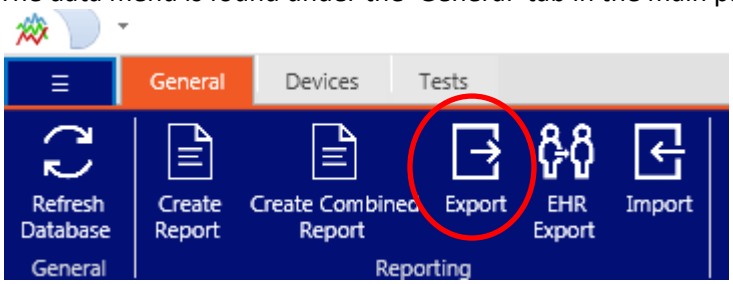
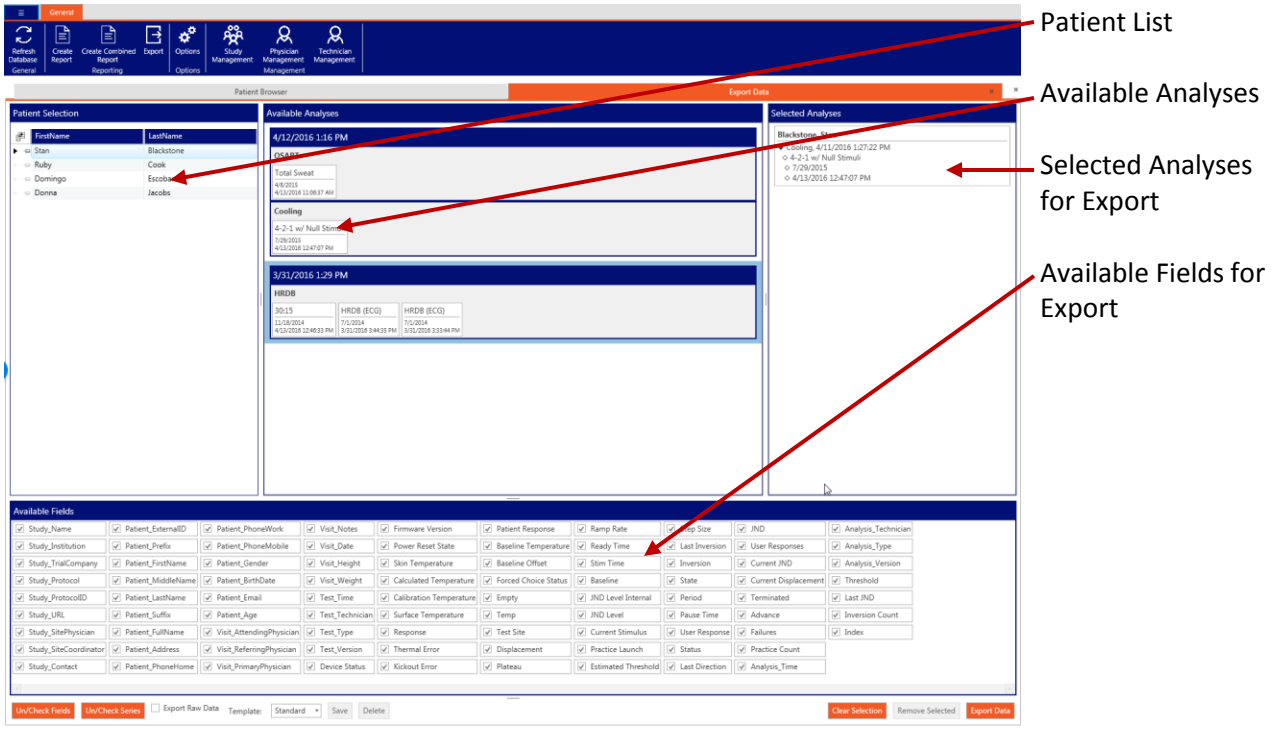
Data Export

The data menu is found under the 'General' tab in the main patient browser window:





Begin by selecting a patient in the patient list. The patient's available analyses will then be displayed in the "Available Analyses" window. Then, click and drag the desired individual analyses, tests, or visits to the "Selected Analyses" pane. Select what fields you would like exported. Also, select whether you would like to export the raw test data (Export Raw Data checkbox). Finally, click "Export Data" in the bottom right. Click "Export Data" and choose a save location. Your data will be saved to a .csv file.

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Report Generation

Single Report Viewing

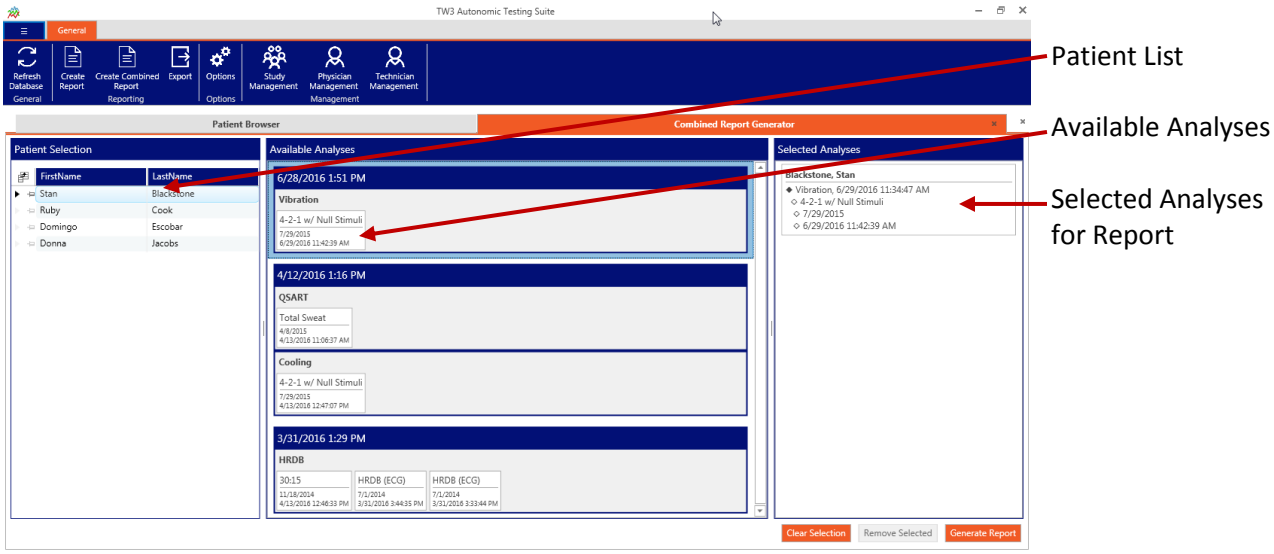
A report for a single analysis can be create immediately from the 'General' tab using the "Create Report" button 

. Please note that an analysis must be selected before pressing this button.

Combined Report Generation

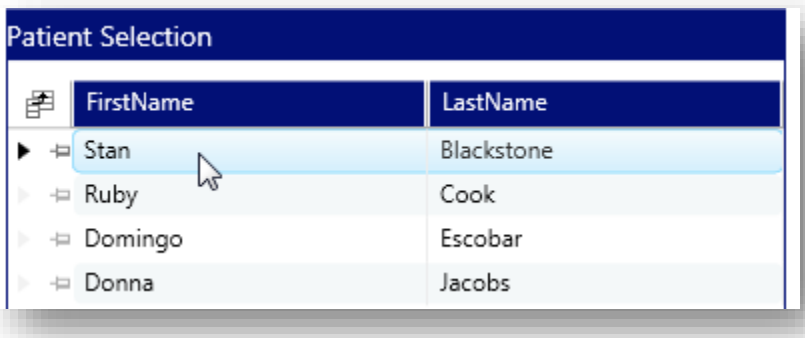
The combined report generator can be launched from the 'General' tab of the main window 

.



Combined reports are generated via the following process:

1. Select a patient or patients:



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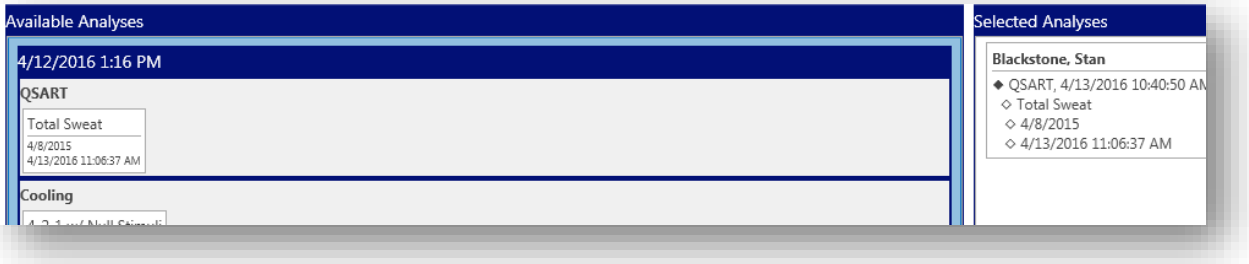
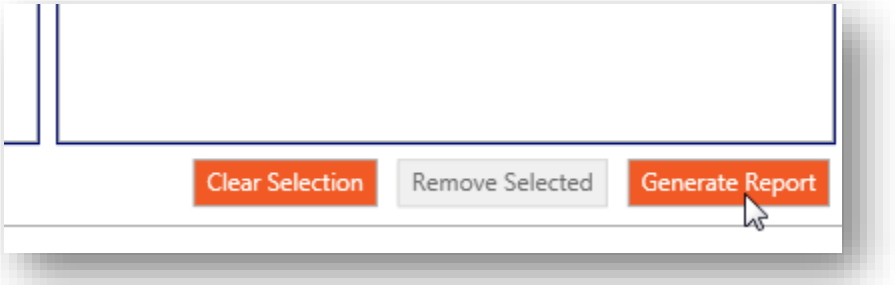
2. Drag an analysis or multiple analyses from the “Available Analyses” pane to the “Selected Analyses” pane:



3. Click “Generate Report”:



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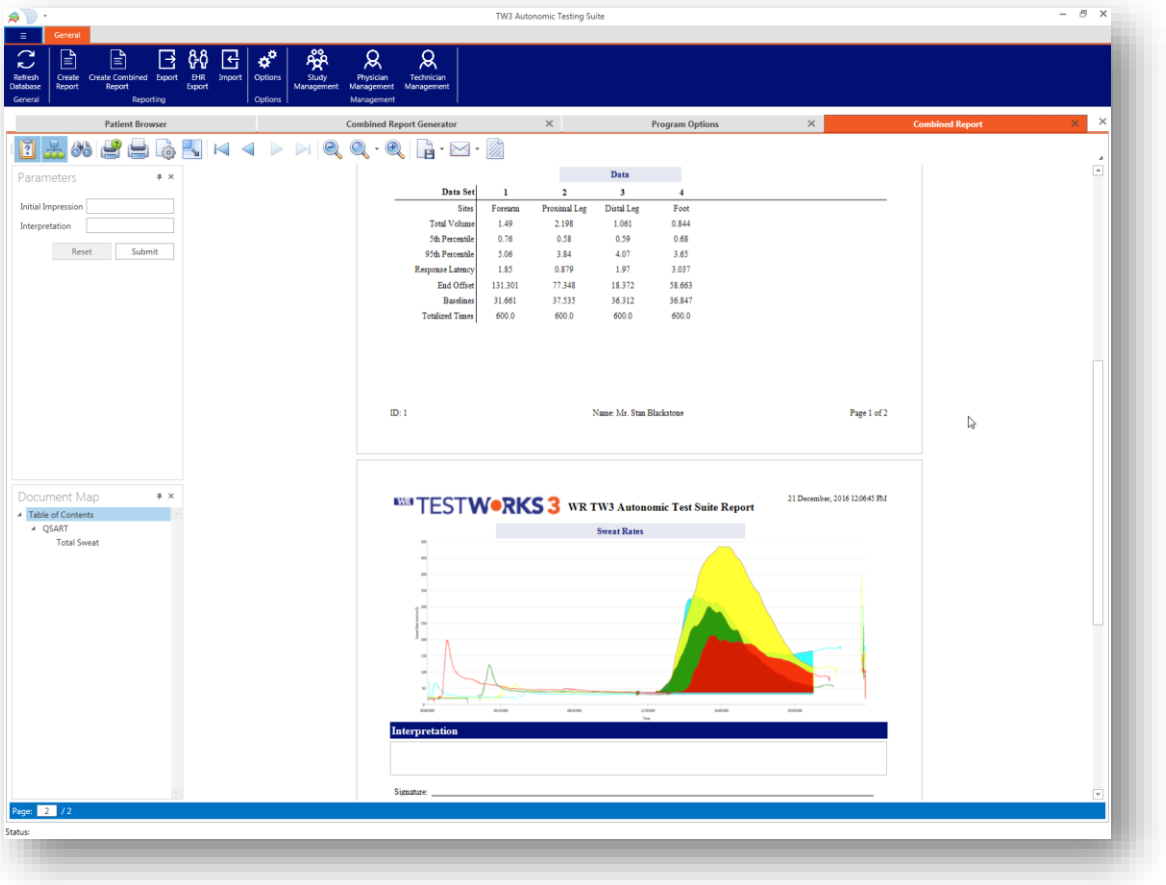
Report Completion

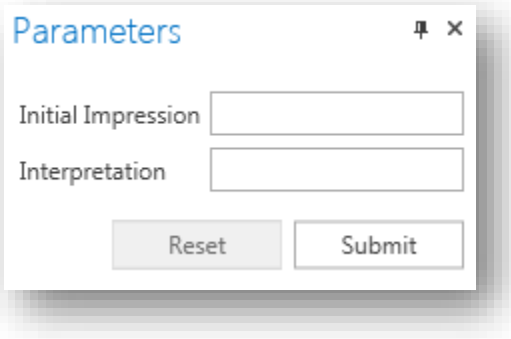


Once the report is generated, it can be viewed, printed, notes added, and exported to multiple formats.

Use the report page controls to browse through the report 

.

Adding Notes



Notes can be added to the report via the bar to the left of screen. Press the “Submit” button to push your notes into the report.

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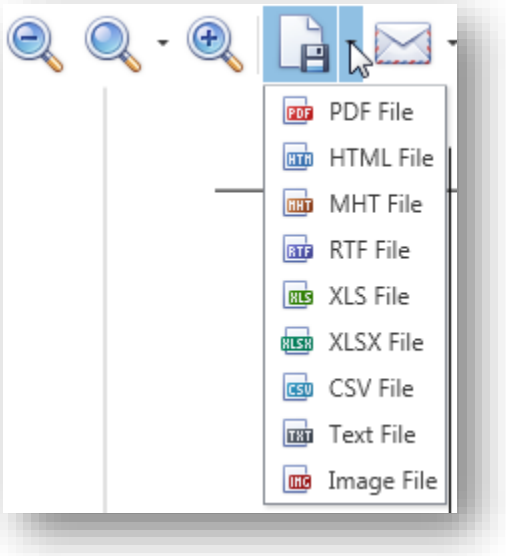
Saving



Reports can be saved directly into PDF and many other formats.

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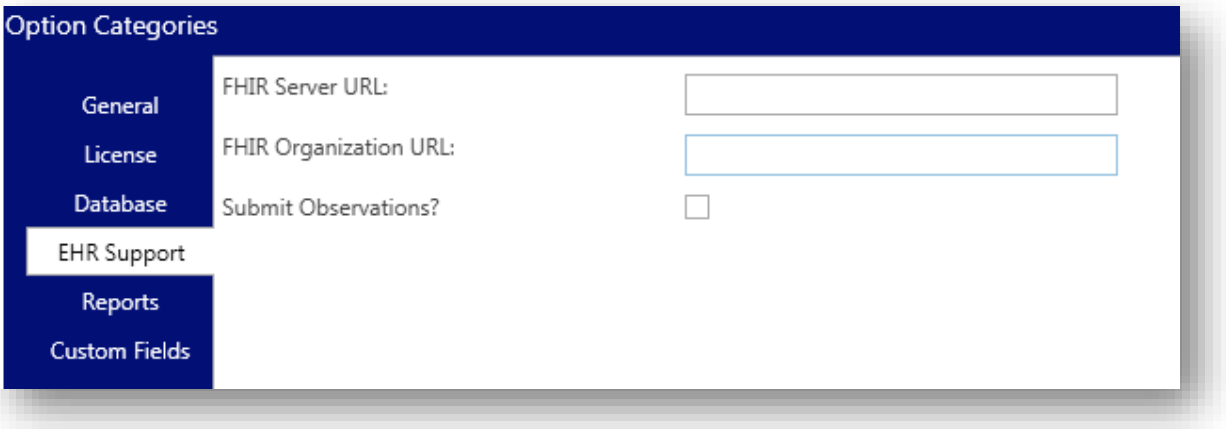
EHR Export

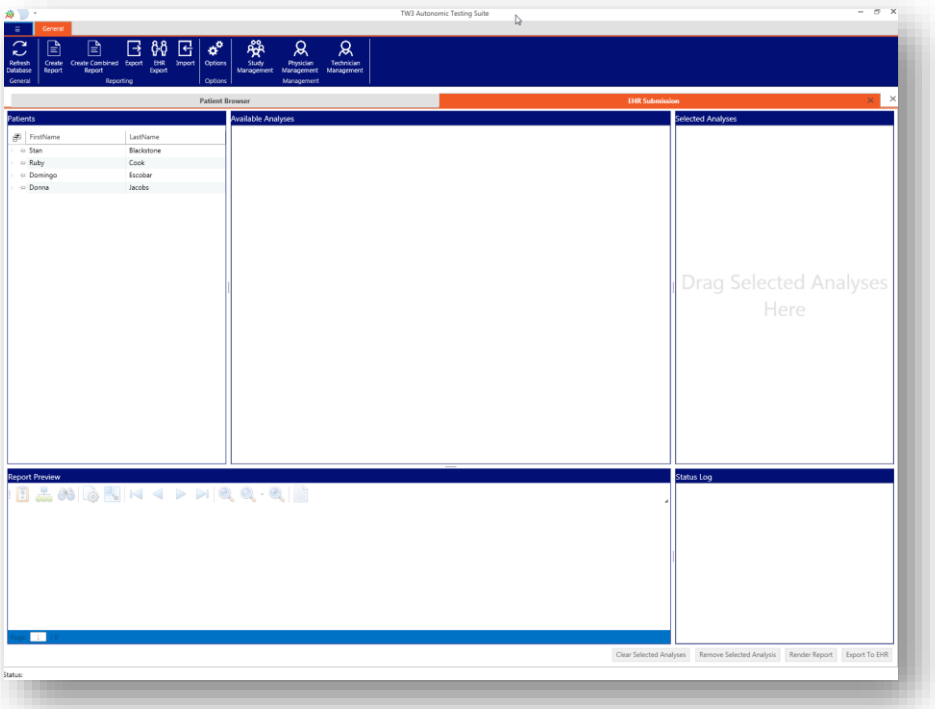
EHR export settings are maintained within the Program Options window:



A Server URL and Organization URL are required. By default, the program sends only a single PDF report as a DiagnosticReport. “Submit Observations?” can be checked if it is desired to send the individual result values from within the report as sub-fields within the DiagnosticReport.

Once configured, results can be sent to the EHR system via the 

button.



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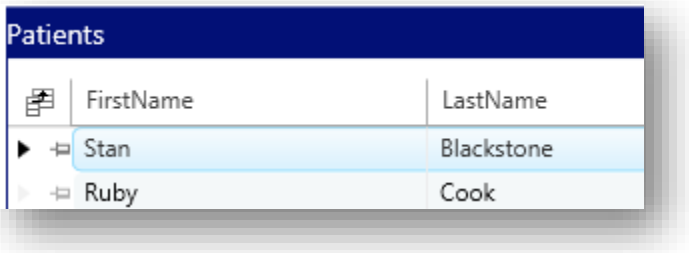
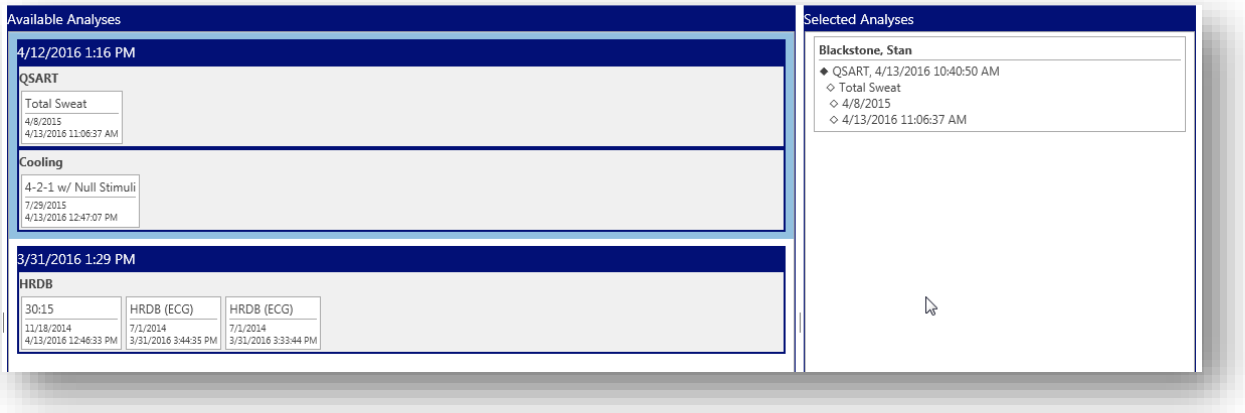
Reports are sent to EHR via the following steps:

1. Select a patient



2. Drag any desired available analyses to the “Selected Analyses” pane



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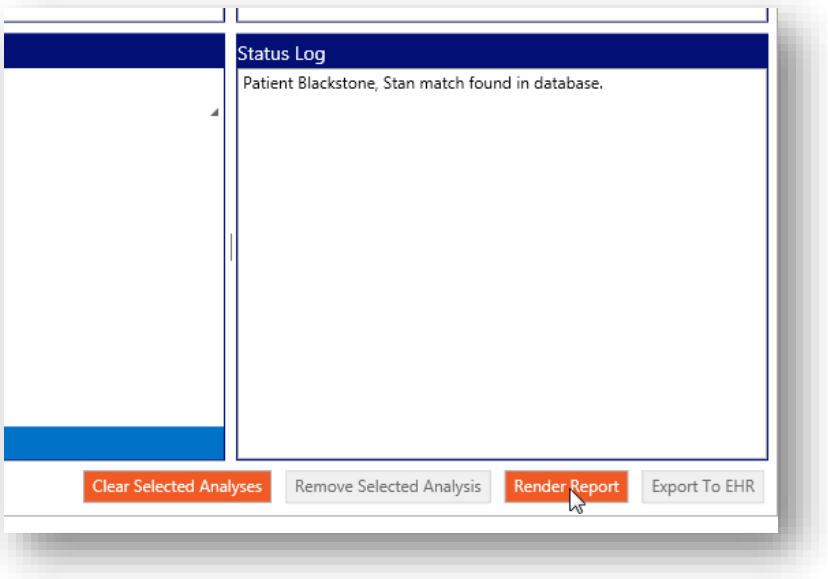
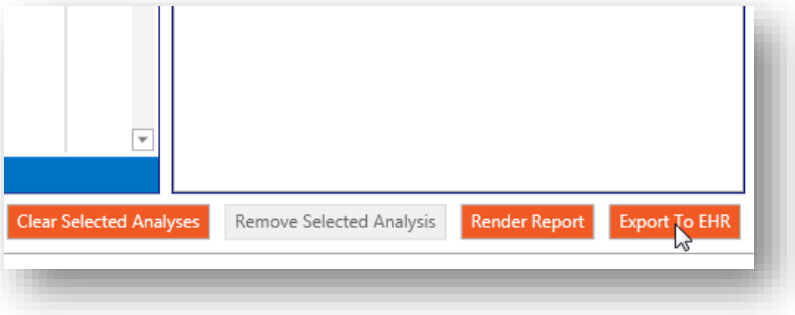
3. Click “Render Report”. A full report preview will be added to the screen, with the ability to review and add notes. See “Report Generation” section for more information.



4. Finally, click “Export To EHR”



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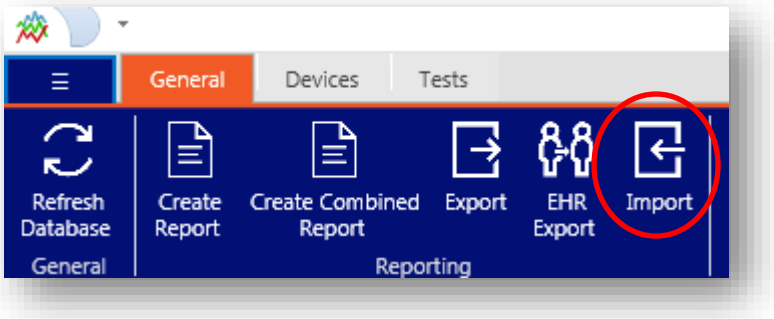
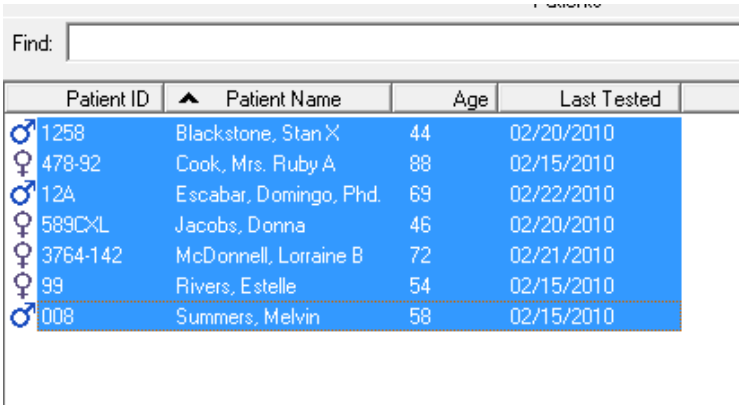
Data Import

The data import menu is found under the 'General' tab in the main patient browser window:



Exporting Out of WR-TestWorks 2.x

Select all patients in WR-TestWorks 2.x you would like to import into WR-TestWorks 3.x



Right-click the selected patient list and select "Export".

Click to define a new Export Format.

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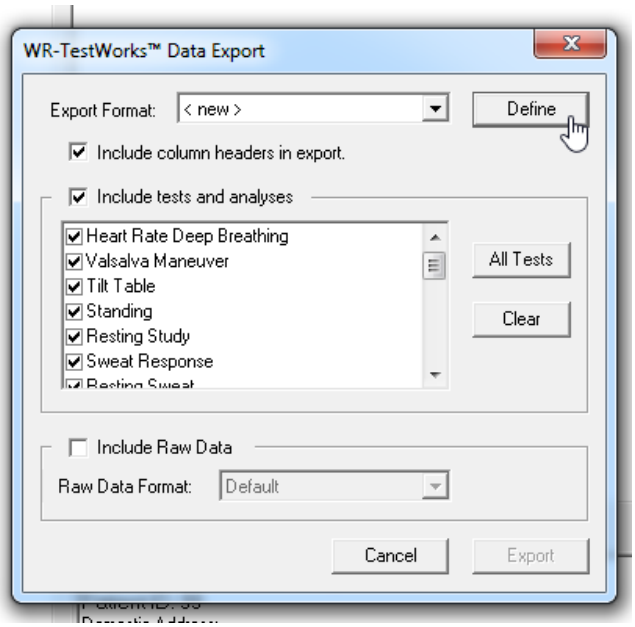
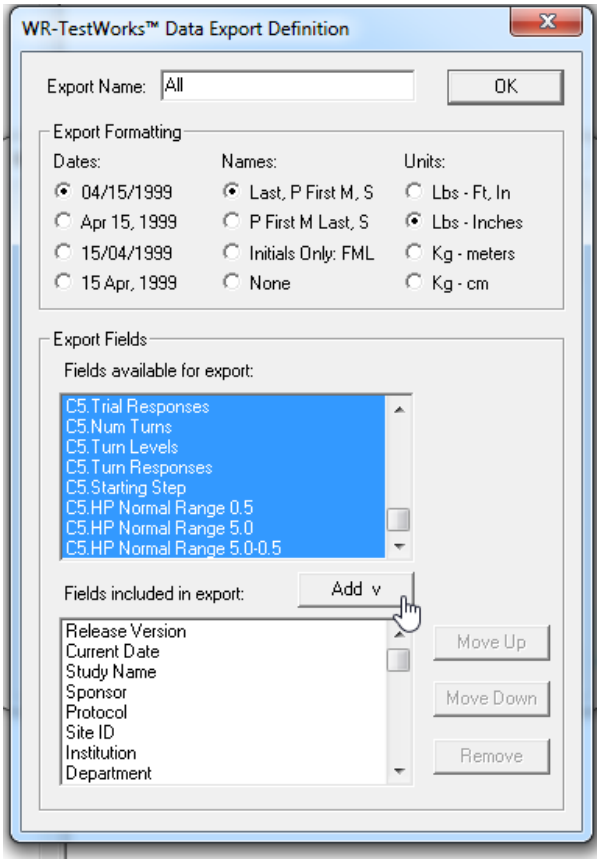


Change units to “Lbs – Inches” and select all export fields.



Ensure that the Export Format you just created is used, and check to Include Raw Data.

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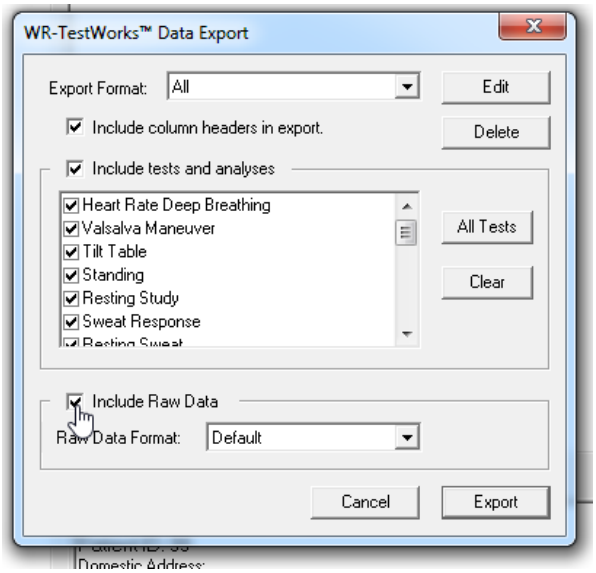

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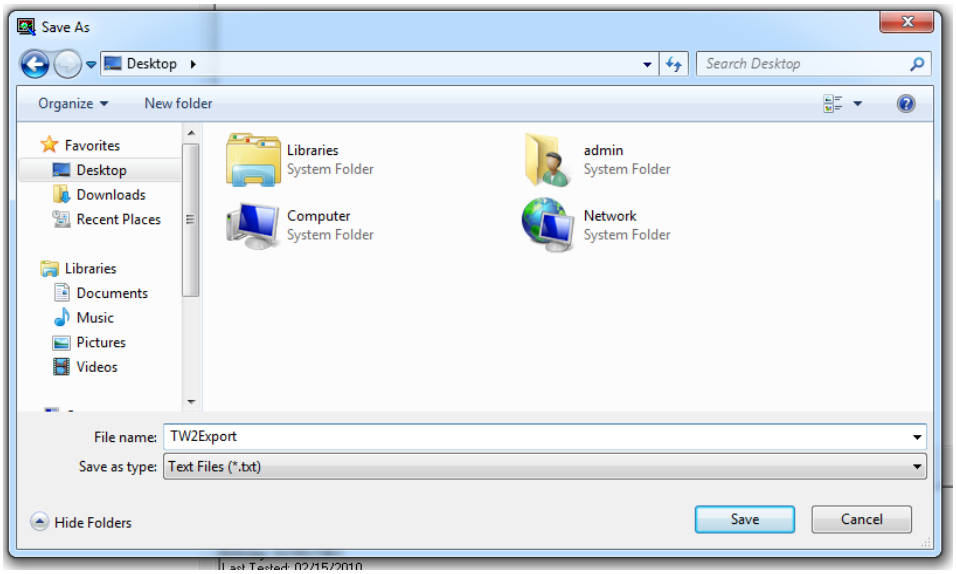
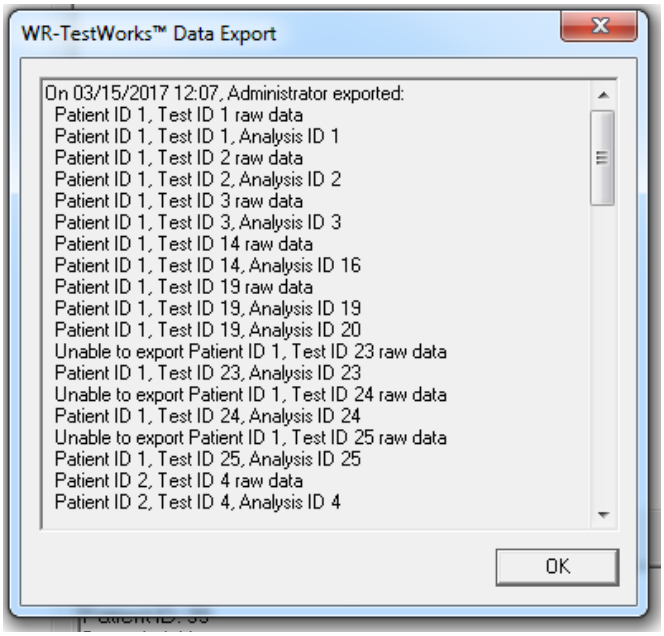
Choose where the export files will be saved. The export will create a main .txt file and a folder of all raw results files.



WR-TestWorks 2.x will confirm the status of Data Export once finished. Please note any failed exports, as they will not be present in WR-TestWorks 3.x. However, CASE IV tests will show that they are unable to export raw data, as there is none for CASE tests (raw data is included in the main export file).



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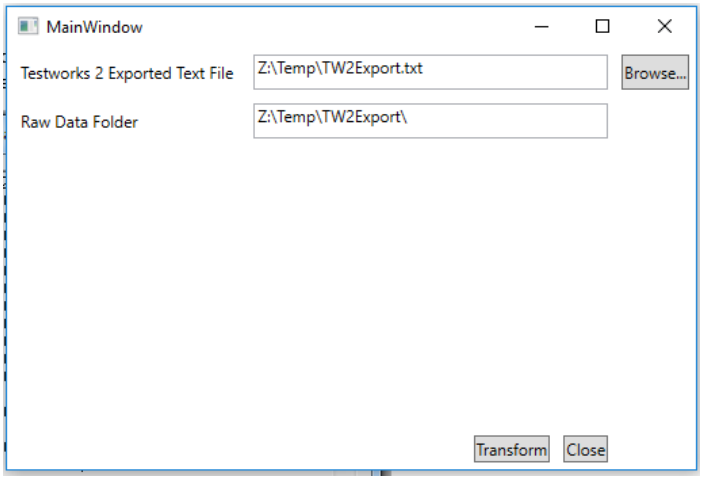
Converting from WR-TestWorks 2.x to 3.x

The data output by WR-TestWorks 2.x must be reformatted to meet the input rules of WR-TestWorks 3.x. An external tool is used for this (TW2_Converter.exe).

Open the executable and locate the main text file and folder containing the raw data files from you WR-TestWorks 2 export.



The converter will confirm whether conversion was successful. If successful, it will create a copy of all WR-TestWorks 2 output files with "_transformed.csv" appended.

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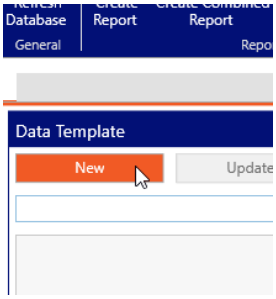
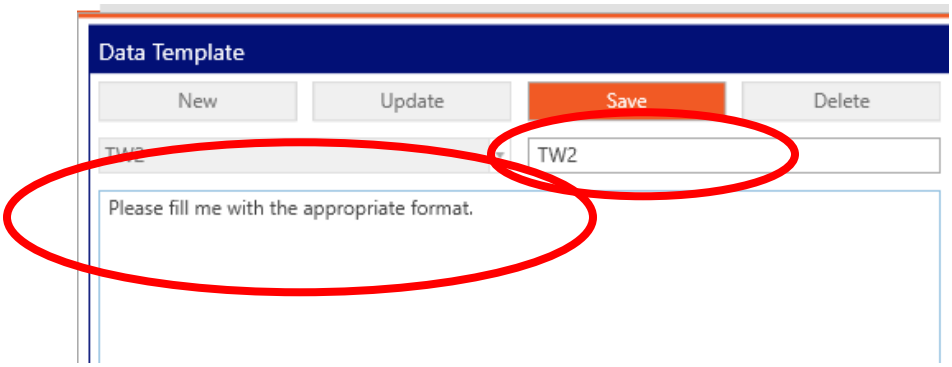
Importing into WR-TestWorks 3.x

Open the Import Manager tab in WR-TestWorks 3. Click “New” to create a new Data Template.



Create and name a Data Template. The data template format is extremely flexible, but it is advisable to begin with the main TW2 template format.



Make sure that the “SelectionFolder” field matches the name of the folder that contains you raw data files.

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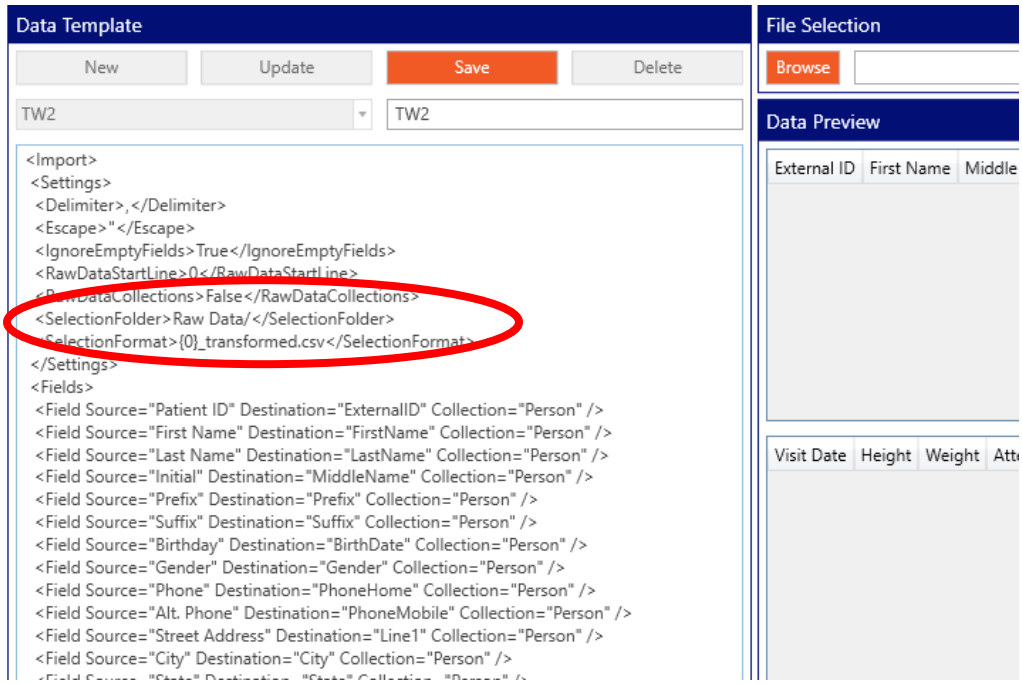

Browse to select you main .csv to import, and press Preview to begin the process of importing. Depending on the file size, this may take some time.

Once complete, you will see a data preview of your import. Please note, **this will only show the first 5 entries**.

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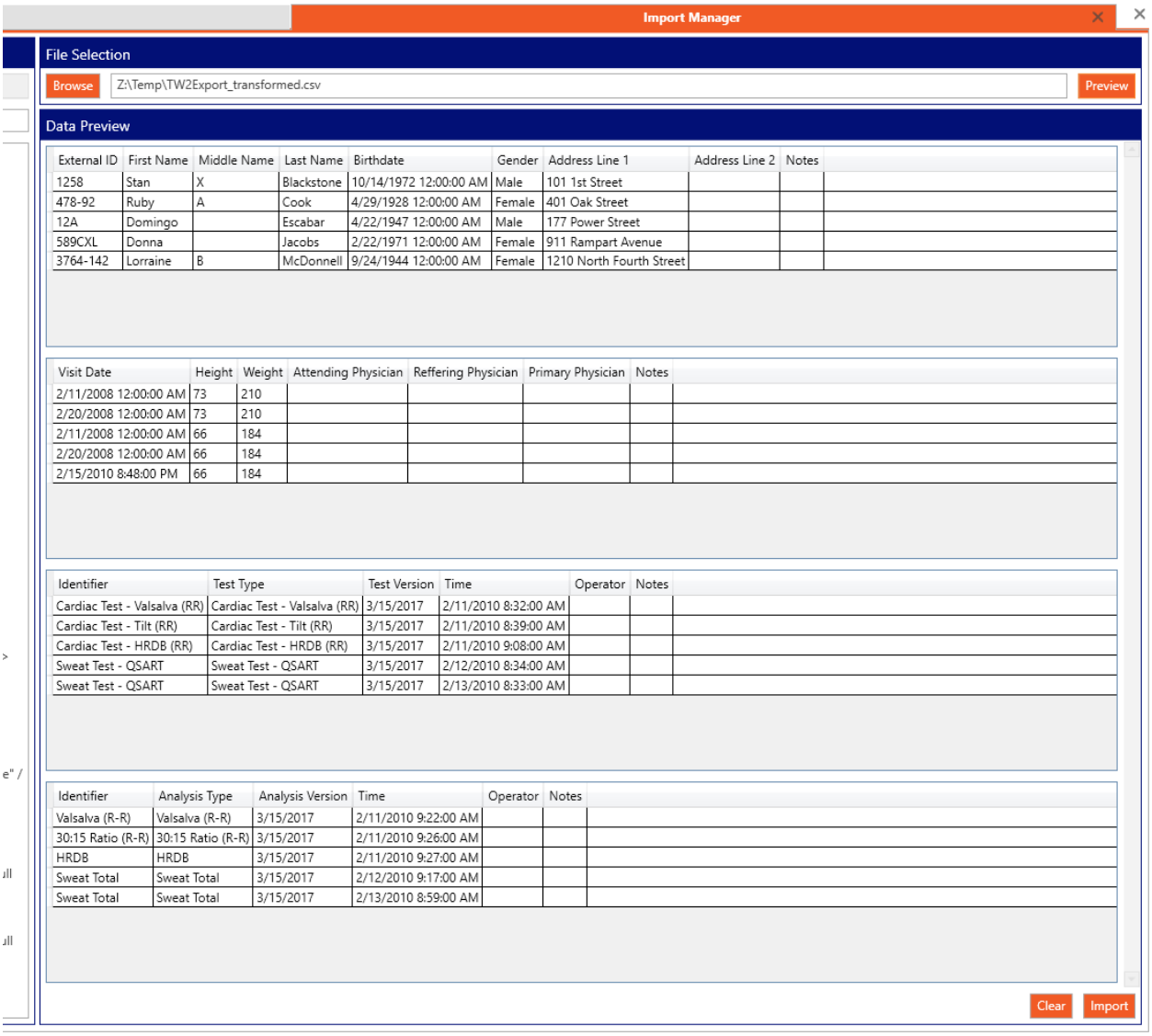

If the previewed data looks acceptable, click Import. The patients and tests will now be present in your Patient Browser, after refreshing the page.

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