RIGISCAN® PLUS

User Guide

for Generation 4 Systems

GOTOP MEDICAL

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Chapter 1: Introduction

The RigiScan system allows you to measure the duration, frequency, and degree of rigidity and tumescence of the penis. This device provides a graphical and tabular display of base and tip penile rigidity and tumescence data for the physician's interpretation. The system is suitable for nocturnal data collection or data collection during various provocative interventions that are intended to produce an erectile response. Testing may be conducted in a stand-alone Ambulatory mode or in a Real-time monitoring mode when connected to a computer or tablet running a Windows 7-11 operating system.

This User Guide contains important information which must be observed to ensure patient safety and proper operation of the RigiScan system. Please read this User Guide in its entirety before attempting to use the RigiScan system.

Contraindications

- DO NOT use the RigiScan Monitor for male patients under 18 years of age.
- DO NOT use the RigiScan Monitor in men who have communicable skin or venereal diseases or men who have any rash or lesions on the penis or surrounding area.
- DO NOT use in men with impaired mental capacity unless the testing period is directly supervised by appropriate medical personnel.
- DO NOT use the RigiScan Monitor in men undergoing treatment for Peyronie's Disease as the safety of such testing has not been evaluated.

Warnings

Adequate education is required to assure safe operation of the RigiScan.

- DO NOT use the RigiScan Monitor if the Tension Guides are loose, the cable is kinked or curled, or the Tension Guide is crushed or broken. The cable must slide smoothly through the Tension Guide sleeve. Use of worn or damaged Tension Guides may result in patient injury.
- DO NOT use the RigiScan Monitor with improperly or incompletely installed Tension Guides. The Tension Guides must be inserted in the monitor with the Tension Guide pin fully seated in the slot on the top of the housing. Use of a RigiScan with improperly inserted Tension Guides may result in patient injury.
- DO NOT operate the RigiScan Monitor near sources of intense pulsed or conducted electrical or magnetic fields such as Magnetic Resonance Imaging (MRI), CT scan, X-ray, electrocautery, electrocoagulation, telemetry equipment, high power transmitters, electric blankets, electric razors, power tools, microwave ovens, hair dryers or cellular phones. Items such as these may interfere with operation of the monitor and cause erroneous readings.

Warnings *(continued)*

- Patients MUST NOT bath or shower while wearing the RigiScan Monitor. Getting the monitor wet may cause electrical shock to the patient or damage to the monitor.
- Patients MUST NOT engage in any sexual activity, such as intercourse, oral sex or masturbation, during RigiScan testing. Doing so may result in patient injury or erroneous data.
- Patients with impaired penile sensation are at greater risk of exposure to maximum compressive forces should the system fail to operate properly.
- DO NOT turn the RigiScan Monitor "on" until the loops have been placed on the penis. Turning the monitor on before placing the loops will cause continuous rigidity sampling and may result in patient discomfort, pain, irritation or bruising.
- The RigiScan Monitor must be turned "off" prior to urination. The monitor may be turned off for a continuous period of up to 15 minutes without interrupting the monitoring session. Urinating with the monitor on may cause pain, urethral irritation or hematuria.
- The RigiScan Monitor must be turned "off" prior to readjusting the position of the loops on the penis. Adjusting the loops with the monitor on may cause continuous rigidity sampling and result in patient discomfort, pain, irritation or bruising.
- Reuse of disposable loop covers may result in patient injury or transmission of communicable disease.
- When the RigiScan system is to be used in a Real-time Monitoring Mode (RTM), the host PC must be operated in battery mode and should not be connected to a wall outlet (i.e., mains). Failure to do so may result in a safety hazard.
- Exercise care when considering testing patients with Peyronie's Disease and/or painful erections as the forces exerted by the loops used to measure penile tumescence and rigidity may cause pain, discomfort, or bruising.
- The terminals of any 9V batteries inside the RigiScan carrying case MUST be covered. 9V batteries with uncovered terminals pose a fire risk and must not be used. GOTOP recommends Duracell Industrial 9V batteries because they provide the service life necessary for the nocturnal monitoring and they also include terminal covers.
- It can be unsafe to use accessories, detachable parts or materials not described within this User Guide.
- It is recommended to place the RigiScan monitor inside a protective bag. The protective bag protects the monitor from ingress of fluids which could possibly cause malfunction.
- Do not attempt to modify the RigiScan. GOTOP Medical Inc. can not be held responsible for any injury, damage, or other effects caused by a modification of the RigiScan device or its software.

Cautions

- Ingestion of coffee, tea, cola, alcoholic beverages, sedatives, tranquilizers, muscle relaxants or sleeping pills in the period immediately preceding nocturnal testing with the RigiScan may affect test results by interfering with normal sleep patterns.
- Care must be taken to remove the Tension Guides from the RigiScan monitor slowly and gently to avoid damage to the cables or internal mechanisms. Removing the Tension Guides too quickly may damage the monitor or result in an "out-of-phase" condition and inability to re-insert the Tension Guides.
- Be careful when inserting Tension Guides. Accidentally inserting the Base Tension Guide into the port for the Tip Tension Guide will release an engagement pin and cause the motors to fall out of registry. If this occurs, the RigiScan cannot be used. The instrument must be returned to GOTOP for service.
- USE ONLY the communications cable supplied with the RigiScan system. Alternate communications cables are not compatible with the system and may damage the RigiScan Monitor.
- USE ONLY Duracell 9-volt disposable alkaline or GOTOP approved rechargeable 9-volt batteries. Other batteries may not have sufficient power to complete a Monitoring session.
- In the event that any serious incident has occurred in relation to the device, it should be reported immediately to GOTOP Medical, Inc. and the competent authority of the Member State in which the user and/or patient is established.

Side Effects and Complications

The side effects and complications listed below have been reported with use of the device:

- Penile pain, redness, bruising, abrasion or cuts of the penile skin from action of the loops
- Urethral bleeding
- Hematuria

1.2 Principles of Operation

The RigiScan Monitor is a data logging unit that measures and records penile rigidity and tumescence. It is linked by cable to a Windows PC, which downloads and processes the data before storing it for review and printout. The monitor uses tip and base penile loops that adjust by tightening slightly at discrete time intervals to measure and record penile rigidity and tumescence. Each loop contains a cable that moves freely inside a conduit. Each loop takes a measurement every 15 seconds. The loop gently tightens with a linear force of 4 ounces (114g) and then immediately releases and the tissue rebounds to its unloaded state. The RigiScan Monitor then takes a tumescence measurement. After the tumescence measurement is taken, it is compared to the previous samples. When a 6 mm increase in tumescence is detected, representing possible erectile activity, the RigiScan Monitor takes a second measurement every 30 seconds. After tumescence is measured, the loops tighten a second time around the circumference of the penis with a linear force of 10 ounces (283.5g). The RigiScan Monitor takes a measurement when this force is applied to record a cross sectional response to radial compression. This is how rigidity is measured.

1.3 The RigiScan Plus Monitoring System

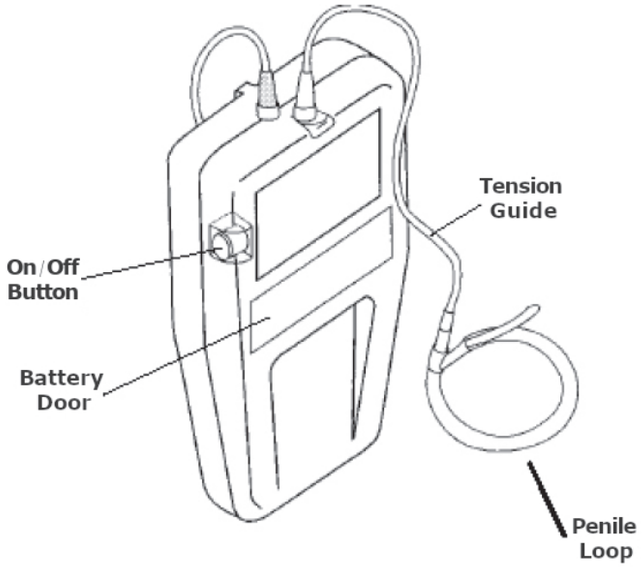
A new RigiScan System consists of the following components and accessories:

- RigiScan Monitor
- RigiScan Windows Software
- Carrying Case
- Box of Leg Straps (disposable)
- USB Communications Cable
- RigiScan Plus User's Manual
- Set of Tension Guides
- Box of Loop Covers (disposable)
- Box of Duracell 9-volt Batteries
- Pack of Protective Plastic Bags (disposable)

Optional Accessories for purchase from GOTOP Medical Inc.:

- Rechargeable Batteries and Charger
- Event Marker Cable
- Reusable Leg Strap
- Waist Strap Extender

NOTE: *Excluding the customer provided IEC 62368-1 compliant PC, all components of the RigiScan system are suitable for use in the patient environment.*



RigiScan Plus Monitor

Fig. 1-1

Chapter 2: Setting Up the RigiScan Plus System

2.1 System Requirements

Before you can install the RigiScan Software, you must assemble the following hardware components:

- IEC 62368-1 Compliant Windows PC equipped with:
  - Microsoft Windows 7 or newer (Windows 8, 8.1, 10 and 11)
  - Hard-disk with at least 1 GB of free disk space
  - At least 1 GB of random-access memory (RAM)
  - Available USB 2.0 port
- Supplied USB Flash Drive

Note: Windows DPI setting should be 100% for optimum display. "Unsupported DPI" warning may appear at launch when using other DPI setting. To check your DPI settings in Windows 7, click the Start button and type "dpi". Click on "Make text and other items larger or smaller" and it will show what is currently selected. On Windows 10, click the Start button and type "dpi". Click on "Display Settings" and check the percentage after the text "Change the size of text, apps, and other items".

2.2 Setting Up the Hardware

The RigiScan Monitor connects to your computer with the supplied communication cable. The 15-pin male connector attaches to the RigiScan Monitor (Fig. 2-1) and the USB plug attaches to an available USB 2.0 port on the computer (Fig. 2-2).

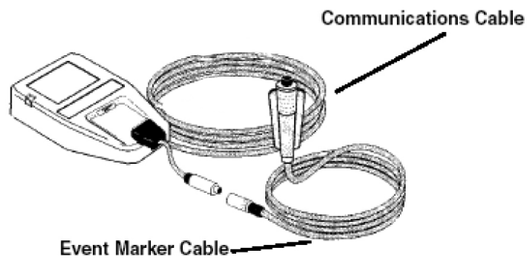
Fig. 2-1

Fig. 2-2

2.3 Connecting the Event Marker (Optional)

You can use the optional Event Marker to mark pertinent points in the patient data.

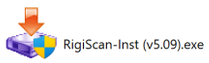
To connect the Event Marker cable: Connect the small, round 4-pin connector on the communications cable to the round connector on the Event Marker cable. To disconnect the Event Marker cable, pull back on the metal connector sheath.



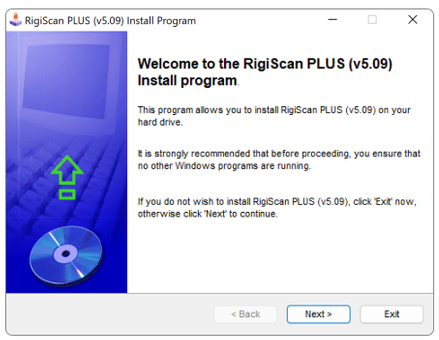
2.4 Installing the RigiScan Plus Software

To install RigiScan Software:

1. Insert the USB Flash Drive into an available USB port on your computer.
2. Allow Windows time to recognize the USB Flash Drive and install driver if necessary.
3. Use Windows Explorer to navigate to the Flash Drive's root directory.
4. Double click the **RigiScan-Inst (v5.09).exe** file.

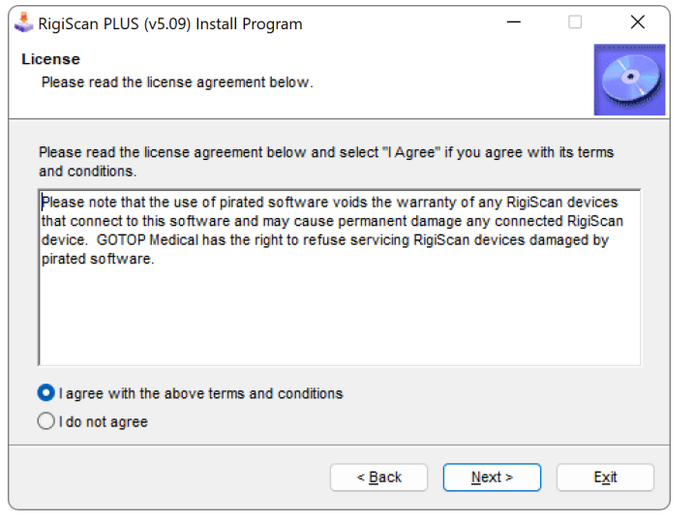


5. When prompted, click **Next** in the installer window to begin installation.

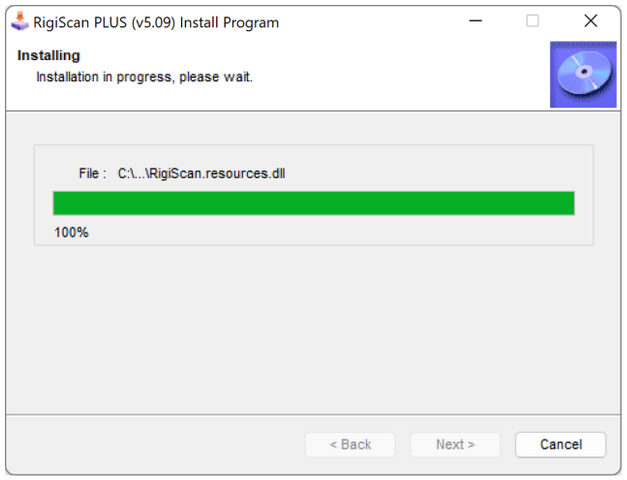


Note: *You may need Administrator Privileges to install software in Windows.*

6. To continue with installation, you must read, understand, and agree with the terms of the license agreement set forth by GOTOP. To do so, click the radio button next to "I agree with the above terms and conditions". Then click **Next**.



7. The RigiScan Software will begin installing as indicated by a progress bar.



8. When the progress bar reaches 100%, a second installer window will appear for the installation of the required Microsoft .NET Framework. If your computer already has the installed version or newer, just click **Close**. If your version of the .NET Framework is older than the required version, you need to agree to the terms before clicking **Install**. The installer will begin installing the necessary Framework. Once complete, click **Close** to close the second installer window and returning you to the RigiScan installer window.

9. Once the .NET Framework is installed, the USB to Serial Driver will automatically begin. It will display a command prompt (black window with white font) for just a couple seconds while the driver is added to the system. No user interaction is necessary for this part of the installation.

10. When installation of the USB to Serial driver is complete, click **Exit** to finish installation.

11. A license file must be in the same folder as the RigiScan program to allow communication with the RigiScan devices. To register the device with this particular computer installation, locate the file "Devices.adl" on the USB Flash Drive and copy it into the same folder as the RigiScan program. The default location for the RigiScan program to be installed into is:

    C:\GOTOP\Rigiscan\

Note: *RigiScan devices must be registered via a "Devices.adl" file to operate with the application. This file is required for your RigiScan device to communicate with the application.*

If you don't have a "Devices.adl" file, contact GOTOP customer service for one via the "contact us" tab on the www.gotopmedical.com website or via email: info@gotopmedical.com

If outside of the United States, contact your local GOTOP customer service representative.

Chapter 3: Software Operation

3.1 Starting RigiScan Plus

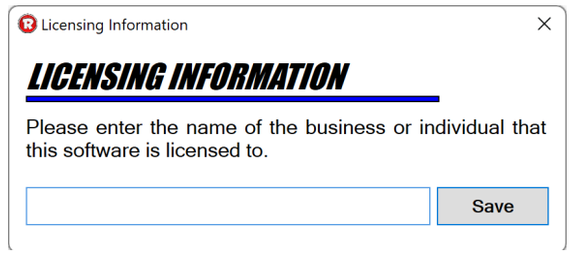
To start the RigiScan application:

1. Double-click the RigiScan icon on the desktop

or

1. Click the **Start** button on the task bar
2. Navigate to **All Programs -> GOTOP Medical RigiScan PLUS**
3. Click **RigiScan**

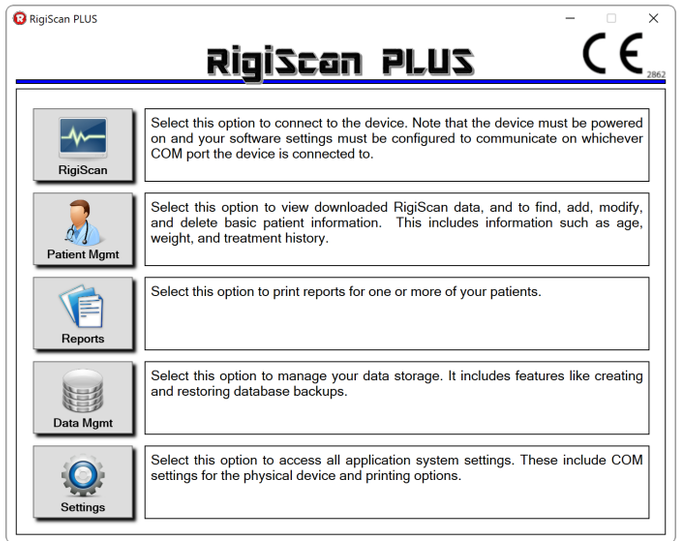
When running the RigiScan application for the first time you may be prompted to enter licensing information.



Enter the name of the business or individual to whom the software is licensed, then click **Save.**

3.2 The RigiScan Plus Home Screen

When you start the RigiScan Software, the RigiScan Home Screen will appear in a new window. A column of buttons, along with functional descriptions of each are provided.



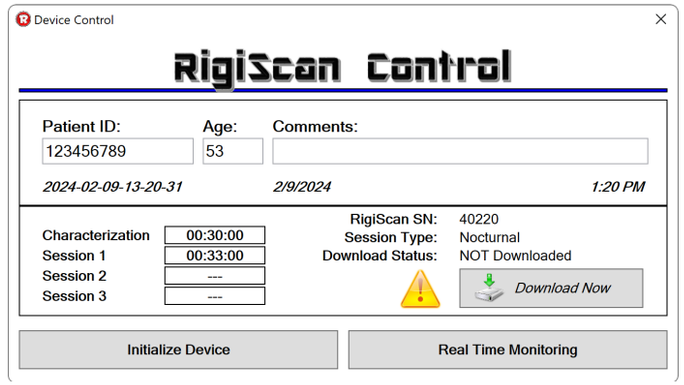
- RigiScan - opens the RigiScan Control window (see Section 3.3)
- Patient Mgmt - opens the Patient Management window (see Section 3.4)
- Reports - opens the Report Manager window (see Section 3.5)
- Data Mgmt - opens the Data Management window (see Section 3.6)
- Settings - opens the RigiScan Settings window (see Section 3.7)

3.3 RigiScan Control Window

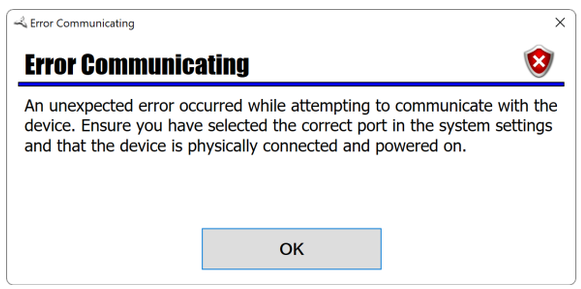
Clicking the **RigiScan** button on the RigiScan Home Screen opens the RigiScan Control window.

Note: *For the RigiScan monitor to communicate with the program, the appropriate port must be selected in the RigiScan Settings Window. See Chapter 3.7 below.*

Here the user may download session data from a previous ambulatory or real-time monitoring session, initialize the device for a new patient, or start a Real-Time Monitoring session.



If clicking the RigiScan button on the RigiScan Home screen opens the Error Communicating pop-up window, click **OK**, verify that the monitor is turned on and properly connected to the PC, and check that the correct communication port is selected in the Setting window (see Section 3.7). It may be necessary to turn the monitor off and then back on again.



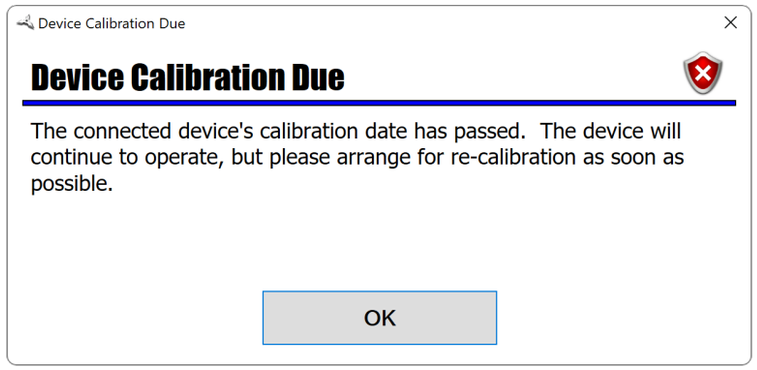
If clicking the RigiScan button on the RigiScan Plus Home screen opens either the Retrieval Error pop-up window or the Device Not Registered pop-up window, then registration of the currently connected device could not be verified. Click **OK**, verify that the device registration file ("Devices.adl") is located in the installation directory (typically C:\GOTOP\Rigiscan\) and verify that the connected device has been registered for use on this PC with GOTOP. See Section 2.4 for installation and registration details. If problem persists, contact GOTOP customer service at 1-651-641-3621, via the "contact us" tab on the www.gotopmedical.com website, or via email: info@gotopmedical.com. If outside of the United States, contact your local GOTOP customer service representative.

Note: *Software may still be used to view existing patient records, generate reports, and manage data storage without a registered device*

If clicking the RigiScan button on the RigiScan Plus Home screen opens the Device Calibration Due pop-up window, arrange re-calibration of the device as soon as possible by contacting GOTOP customer service at:

Email:info@gotopmedical.com or
TEL: 651-641-3621

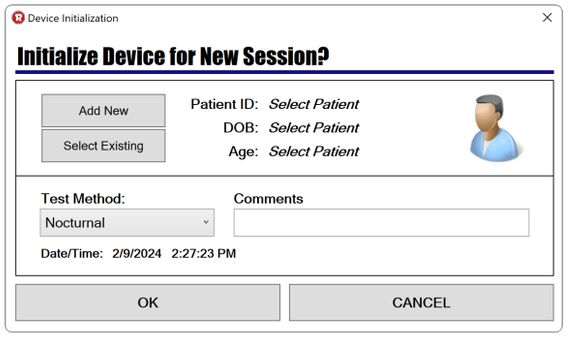
The serial number of your RigiScan monitor will be needed to arrange re-calibration. The serial number is found on the label within the battery compartment. It is potentially dangerous to use a system that is out of calibration.



Using the RigiScan Plus - Initializing the Monitor

To Initialize the Device (New Patient):

1. Click the **Initialize Device** button in the RigiScan Control window. This opens the Device Initialization window.



2. Click the **Add New** button to add a new patient. This opens the Patient Information window.
3. Enter pertinent information into the Patient Information window (see Section 3.4 for details).
4. Click the  button.
5. Click the  button in the Patient Information window to return to the Device Initialization window.
6. When prompted with the Confirm Close pop-up window, click **OK.**
7. The Patient ID you just entered should now be displayed in the Device Initialization window.
8. Select either **Nocturnal** or **Provocative** from the Test Method drop-down menu.
9. Click **OK** to complete initialization and return to the RigiScan Control window.

To Initialize the Device (Existing Patient):

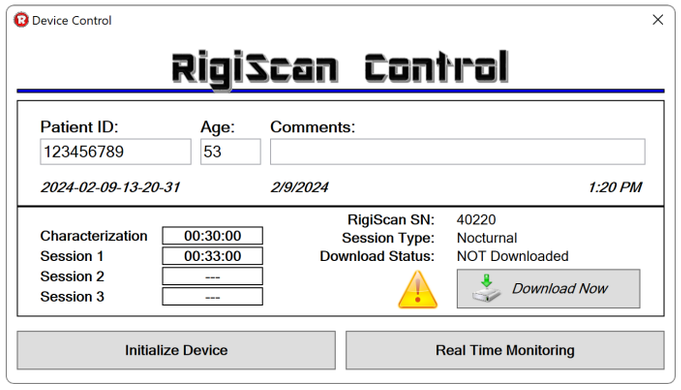
1. Click the **Initialize Device** button in the RigiScan Control window. This opens the Device Initialization window.
2. Click the **Select Existing** button. This opens the Patient Management window.
3. Use the Search and Quick Search features as necessary to locate the desired patient record (see Section 3.4 for Search and Quick Search details).
4. Double-click the desired patient record to close the Patient Management window and return to the Device Initialization window. The Patient ID you selected should now be displayed in the Device Initialization window.
5. Select either **Nocturnal** or **Provocative** from the Test Method drop-down menu.
6. Click **OK** to complete initialization and return to the RigiScan Control window.

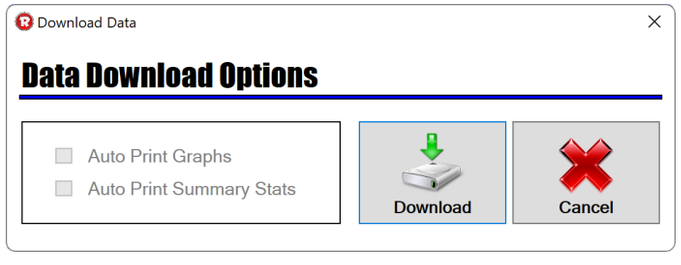
To Start Monitoring Session:

See Chapter 5: Patient Testing for details on starting Real-Time and Ambulatory Monitoring Sessions.

To Download Patient Data (following a monitoring session):

1. Following an ambulatory or real-time monitoring session, connect the device to the PC via the supplied communication cable.
2. Turn the device on, if it isn't already. It may be necessary to turn the monitor off and then back on again to re-establish communications. Also, verify the COM port has been selected in Settings.
3. Navigate to the RigiScan Control window.
4. If the device contains monitoring data not yet downloaded to the PC database, the RigiScan Control window will display "**NOT Downloaded**" in the Download Status area.

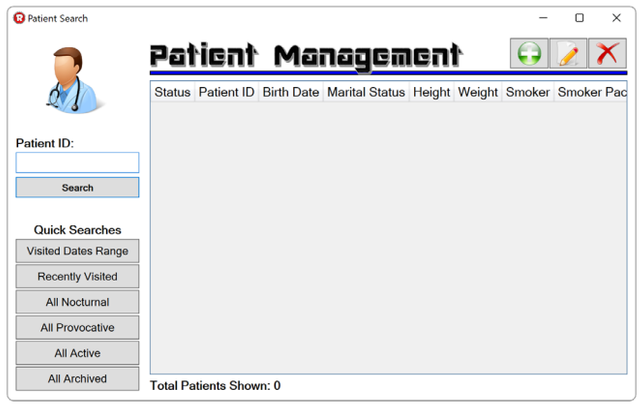




5. Click the **Download Now** button.
6. A **Data Download Options** pop-up window will appear with options to **Auto Print Graphs** and **Auto Print Summary Stats** (both features currently disabled). These options will be set with the default settings. If they are changed, they will only apply for this particular download. The default settings can be changed in the Settings screen (see Section 3.7 for RigiScan Settings Window details).
7. Then, click **Download** to begin downloading session data.
8. A progress bar will appear indicating the downloading status between the PC and the device. This may take over a minute, please be patient while this process in completed.

3.4 Patient Management Window

Clicking the **Patient Mgmt** button on the RigiScan Plus Home Screen opens the Patient Management window. Here, the user may add, view, edit, delete, import, and export patient records.



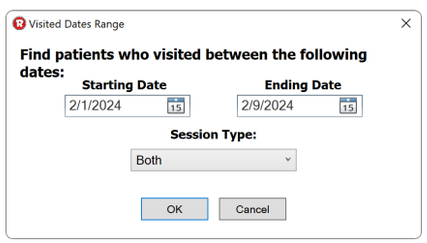
To aid in viewing, editing, and deleting patient records, a search feature as well as quick search buttons are available along the left side of the window.

To Search for an individual patient record:

1. Type a full or partial patient ID number into the Patient ID text box.
2. Click the **Search** button.
3. The total number of patients who contain the any of the searched ID will appear at the bottom of the window.

To view all patients who visited between specific days:

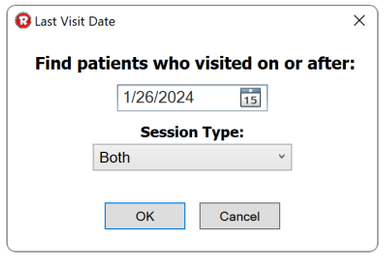
1. Click the **Visited Dates Range** button.



2. When prompted with the Last Visit Date pop-up window, select the starting and ending dates and the Session Type (i.e., Nocturnal or Provocative). Note the dates correspond to the Visit Date in the Treatment History section of the Patient Information window.
3. Click **OK**.

To view all patients who visited on or after a specific day:

1. Click the **Recently Visited** button.



2. When prompted with the Last Visit Date pop-up window, select a date and the Session Type (i.e., Nocturnal or Provocative). Note the date corresponds to the Visit Date in the Treatment History section of the Patient Information window.
3. Click **OK**.

To view all patients with Nocturnal session data:

1. Click the **All Nocturnal** button.
2. Any patient with downloaded RigiScan data with the Nocturnal Session Type will be displayed in the table.

To view all patients with Provocative session data:

1. Click the **All Provocative** button.
2. Any patient with downloaded RigiScan data with the Provocative Session Type will be displayed in the table.

To view all Active patients:

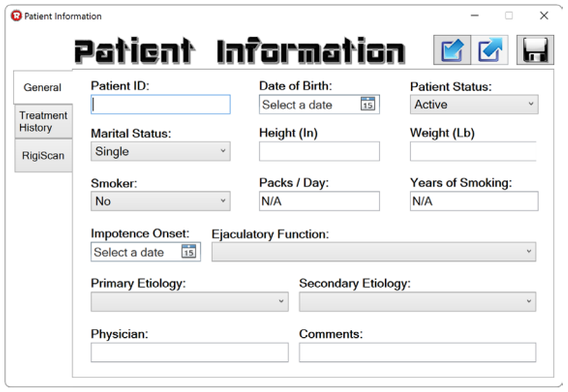
1. Click the **All Active** button.
2. Any patient marked as Active (i.e., not marked as Archived in the Archive Manager) will be displayed in the table.

To view all Archived patients:

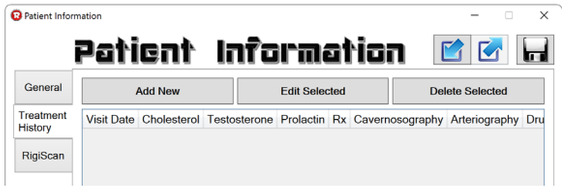
1. Click the **All Archived** button.
2. Any patient marked as Archived (i.e., marked as Archived in the Archive Manager) will be displayed in the table.

To Add A New Patient (Manual Entry):

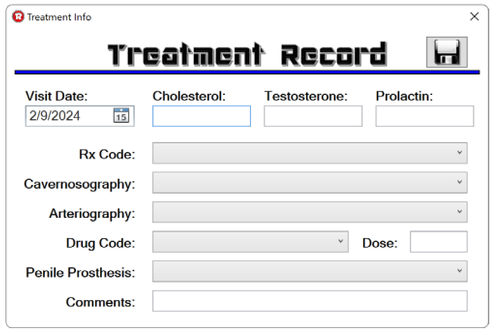
1. Click the  to open the Patient Information window.
2. Fill in pertinent patient information on the General tab.



3. Click the Treatment History tab.



4. Click **Add New** to open the Treatment Record pop-up window.



5. Use text entry fields and drop-down menus to fill in the pertinent treatment history information.
6. Click the  button to save treatment record and return to the Patient Information window.
7. Click the  button in the Patient Information window to save patient data.
8. Click the  button to return to the Patient Management Screen.
9. When prompted with the Confirm Close pop-up window, click **OK.**

To Import a New Patient From File:

1. Click the  button to open the Patient Information window.
2. Click the  button.
3. Use the dialog box to navigate to and select the file to import data from (usually a file with extension ".dat").
4. Click **Open** in the dialog box.
5. Click the  button to save patient record.
6. Click the  button to return to the Patient Management Screen.
7. When prompted with the Confirm Close pop-up window, click **OK**.

To Export an Existing Patient To a File:

1. Click the Patient ID of the record you wish to export, then click the  button to open the Patient Information window.

   or

   Double-click the Patient ID of the record you wish to export to open the Patient Information window.
2. Click the  button in the upper right.
3. Use the dialog box to navigate to the folder the exported patient file is to be saved into.
4. Then, give the file a name to export the data to. It will automatically add a file extension of ".dat" to the file name you give it.
5. Click **Save** in the dialog box.
6. A copy of the patient and all their data will now be successfully exported to your newly created file. Note that this does not remove the patient from the database. If that is desired, follow the instructions in the next section "To Delete an Existing Patient".

To Delete an Existing Patient:

1. Click the Patient ID of the patient you wish to delete, then click the  button to delete the selected patient.
2. Click the **CONFIRM DELETE** button to finalize the deletion of the patient. Otherwise, click the CANCEL button to abort the deletion request.

To Edit an Existing Patient Record:

1. Click the Patient ID of the record you wish to edit, then click the button to open the Patient Information window.

   or

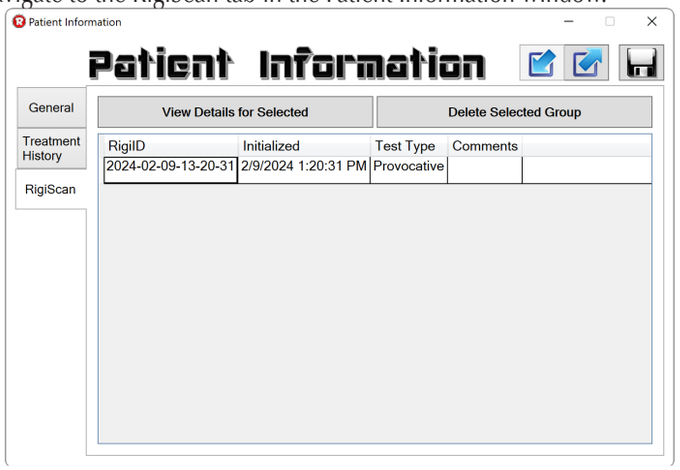
   Double-click the Patient ID of the record you wish to edit to open the Patient Information window.
2. Modify fields in the General tab as necessary.
3. Click the button to save patient record.
4. In the Treatment History tab, use the **Add New** and **Edit Selected** buttons to create or modify treatment records as done in **To Add A New Patient (Manual Entry)** on page 22 of this User Guide.
5. Use the **Delete Selected** button to delete existing treatment records.
6. Click the button to save changes made to treatment records.
7. In the RigiScan tab, use the **Delete Selected Group** button if you wish to remove any RigiScan data from the patient record.
8. Click the button to save changes made to session records.
9. Click the button to return to the Patient Management Screen.
10. When prompted with the Confirm Close pop-up window, click **OK**.

To View Existing Patient Data:

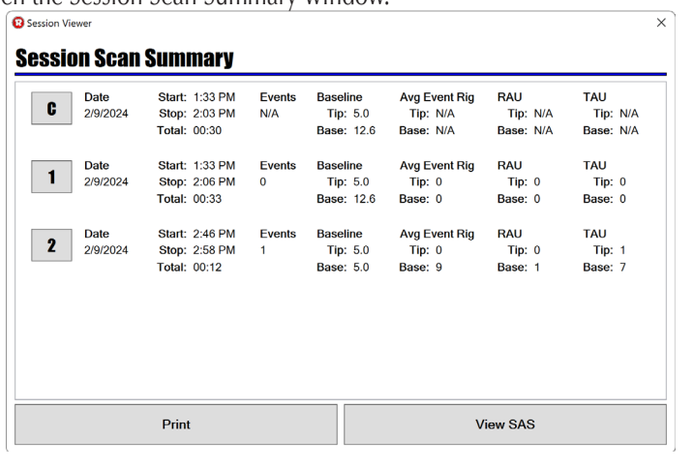
1. Double-click the Patient ID of the record you wish to view.
2. Use the tabs along the left side of the Patient Information window to view General, Treatment History, and RigiScan tabs.

To View Existing RigiScan Plus Monitoring Data:

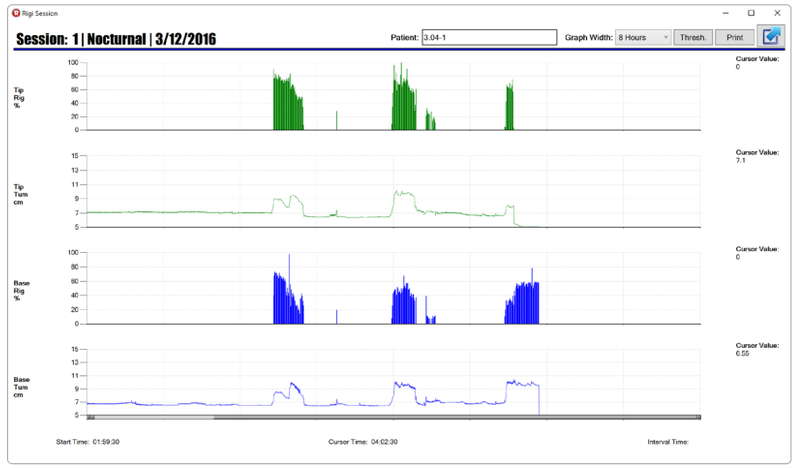
1. Navigate to the RigiScan tab in the Patient Information window.



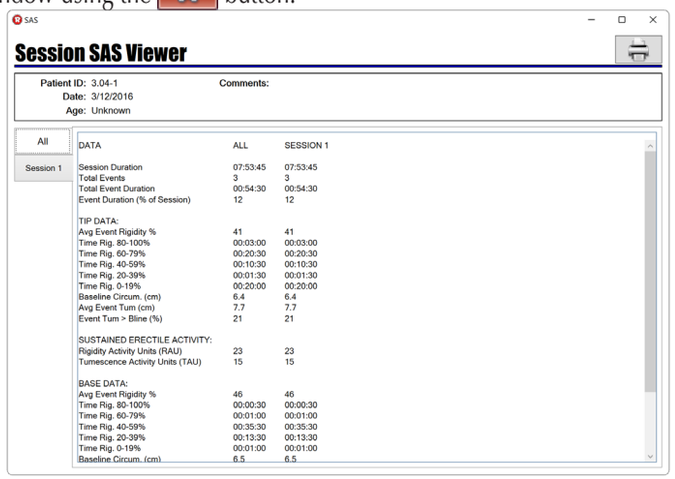
2. Click the RigiScan session you wish to view, then click **View Details for Selected** to open the Session Scan Summary window.



3. Click **C**, **1**, **2**, or **3** to view graphs of the characterization, first, second, or third sessions.



4. From the graph screen, you can set the horizontal scale with the **Graph Width** drop down menu; set a threshold to be displayed on any of the graphs using the **Thresh**. button; print the graphs using the **Print** button; **Export Patient Data as CSV** button so data can be viewed in a spreadsheet; or return to the Session Scan Summary window using the button.



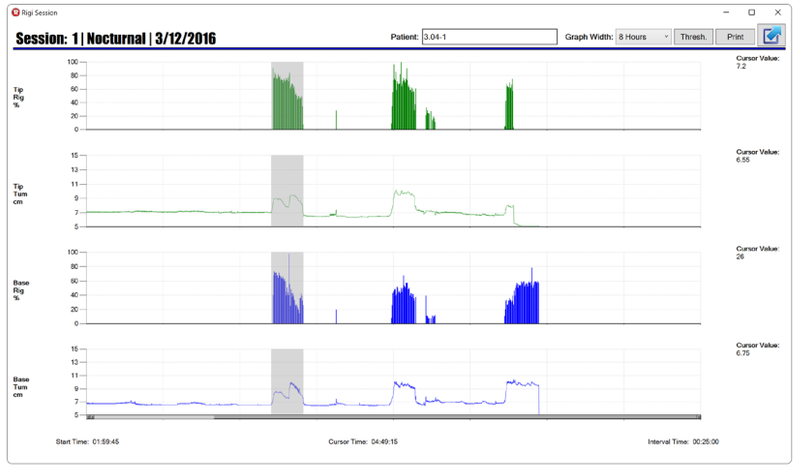
5. From the Session Scan Summary window, you can click the **View SAS** button to open the Session SAS Viewer window.
6. From the Session SAS Viewer window you can view reports for each session individually or a summary report of all session using the tabs on the left.
7. To print an SAS report, click the button, then follow the on-screen instructions to select a printer.

Exporting Patient Data into a CSV File

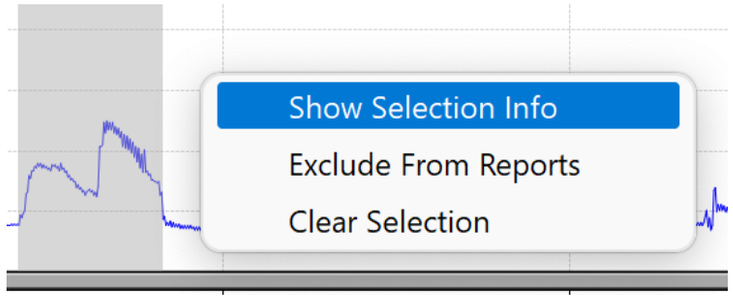
The following information is included when exporting patient data into a CSV file:

- Physician
- Test Method
- Base Tumescense
- Tip Rigidity
- Patient ID
- Sample Number
- Base Rigidity
- Is Sample Marked
- Date
- Sample Time
- Tip Tumescense
- Is Sample Excluded

To Select an Interval to View Selected Information:



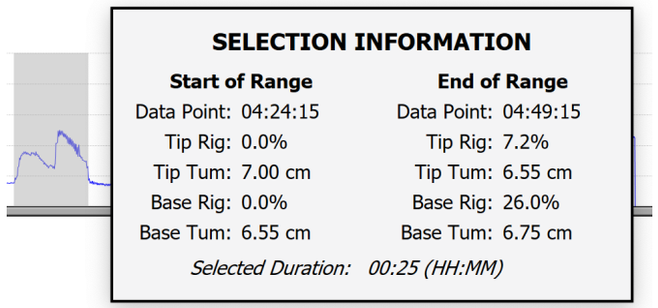
1. In the graph screen, you can get more detailed information by clicking and dragging anywhere in the graph. A gray shaded region will appear. Simply release the mouse button to end the selection of the shaded region and it will then appear on all 4 charts.
2. Also, the **Interval Time:** in the lower right corner will display how long that selected interval is.



3. Right click anywhere on the graph to bring up the context menu. You can then select to either **Show Selection Info**, **Exclude From Reports**, or **Clear Selection**.

To Show Selection Info of the Selected Region

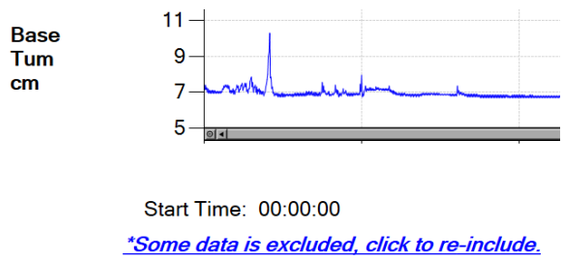
1. Selecting the Show Selection Info from the context menu displays a pop-up giving you more information.



2. From this pop-up, you can see the starting and ending information including the timestamp, tip and base rigidity, tip and base tumescence, and the duration of that interval.

To Exclude the Selected Region from the Reports

1. Selecting this option removes that part of the graph, and all of its recorded samples in that region, from the Session SAS Viewer and Session Scan Summary screens. A confirmation dialog box will appear before excluding any data.



2. The excluded data can be restored by clicking the blue link in the lower left corner of the graph. Clicking **YES** in the confirmation dialog box will restore the data in the graph, Session SAS Viewer, and Session Scan Summary screens.

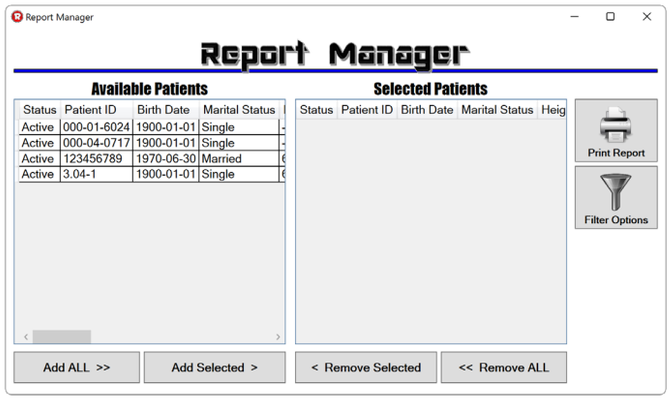
To Clear the Selection in the Graph

1. Selecting this option removes the shaded region on the graph effectively canceling the interval selection.
2. Another way to cancel the interval selection is to just click anywhere on the graph. The shaded region should disappear and the **Interval Time:** should return to a blank value.

3.5 Report Manager Window

Clicking the **Reports** button on the RigiScan Plus Home Screen opens the Report Manager Window. Here the user may generate customized reports for individual or multiple patients.

Clicking the  button in the upper right corner of the Report Manager Window brings the user back to the RigiScan Plus Home Screen.



To add all available patients to the current report:

1. Click **Add ALL.**

To remove all selected patients from the current report:

1. Click **Remove ALL.**

The add an individual patient to the current report:

1. Click the desired patient ID in the Available Patients list.
2. Click **Add Selected.**

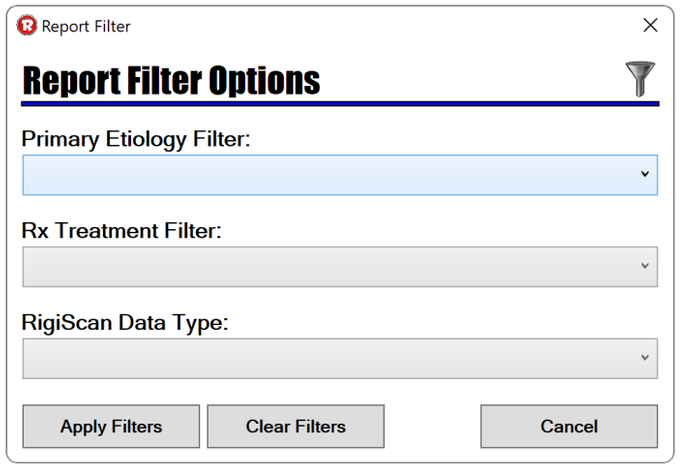
To remove an individual patient from the current report:

1. Click the desired patient ID in the Selected Patients list.
2. Click **Remove Selected.**

Filtering Available Patients

When a large database of patients exists, it may be useful when creating a report to filter the available patients based on certain parameters.

Clicking the **Filter Options** button in the Report Manager window opens the Report Filter Options window, where (via drop-down menus) the user can filter available patients based on Primary Etiology, Rx Treatment, and/or RigiScan Data Type. It is here that the user may also clear previously applied filters to make all patients available again.



Clicking **Apply Filters** will bring the user back to the Report Manager window, where only those patients meeting the filter criteria will be shown in the Available Patients area.

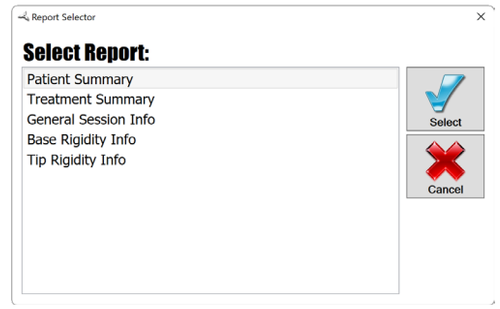
Clicking **Clear Filters** will remove all filtering criteria and bring the user back to the Report Manager window. All active patients in the database will again be shown in the Available Patients area.

Clicking **Cancel** will bring the user back to the Report Manager window without applying any changes to the filtering criteria.

Report Selector

Once the correct Patient IDs have been added to the Selected Patients list, clicking the **Print Report** button in the Report Manager window opens the Select Report window where the user can select from the following report options:

- Patient Summary
- Treatment Summary
- General Session Info
- Base Rigidity Info
- Tip Rigidity Info



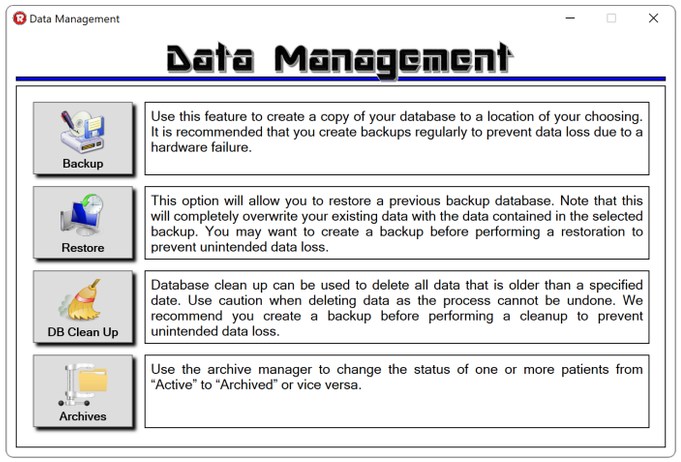
Clicking the **Select** button opens a print dialog box which allows the user to specify the desired printer. Pressing the **Cancel** button closes the Report Selector window.

For details on the information provided in each report, see Chapter 6: RigiScan Plus Reports.

3.6 Data Management Window

Clicking the **Data Mgmt** button on the RigiScan Plus Home Screen opens the Data Management Window. Here the user may backup the database, restore a previous database, cleanup the current database, and specify patient records as active or archived status.

Clicking the  button in the upper right corner of the Data Management Window brings the user back to the RigiScan Plus Home Screen.

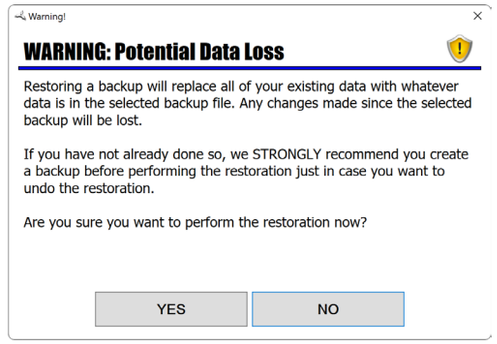


To Backup the database:

1. Click the **Backup** button in the Data Management Window.
2. Select the preferred directory to store the backed up database.
3. Click **OK.**

To Restore a previously backed up database:

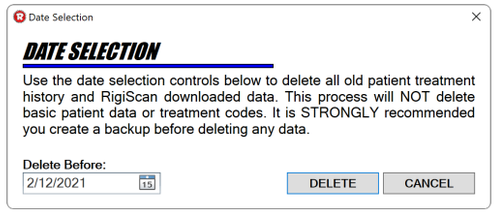
1. To avoid inadvertent loss of data, it is recommended to always backup the current database prior to using the Restore feature. The Restore feature completely overwrites the current database.
2. Click the **Restore** button in the Data Management window.
3. When prompted with the "Warning: Potential Data Loss" pop-up window, click **YES**.



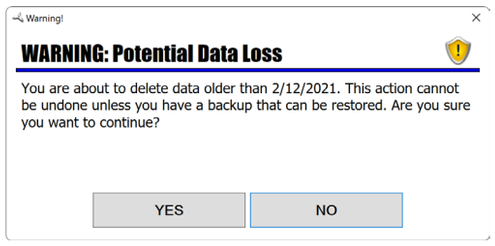
4. Navigate to the directory of the database file you wish to restore.
5. Click **OK**.

To Clean Up database:

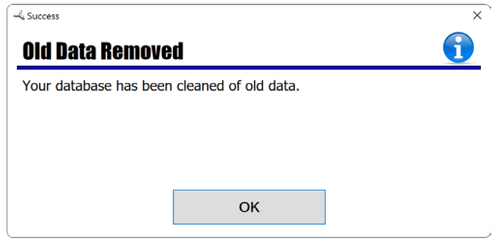
1. To avoid the inadvertent deletion of important data, it is strongly recommended to backup the database prior to using the DB Clean Up feature.
2. Click the **DB Clean Up** button.
3. When prompted, select the "Delete Before:" date. All patient treatment history prior to the selected date will be deleted.



4. Click **DELETE**.
5. When prompted with the WARNING: Potential Data Loss pop-up screen, click **YES.**

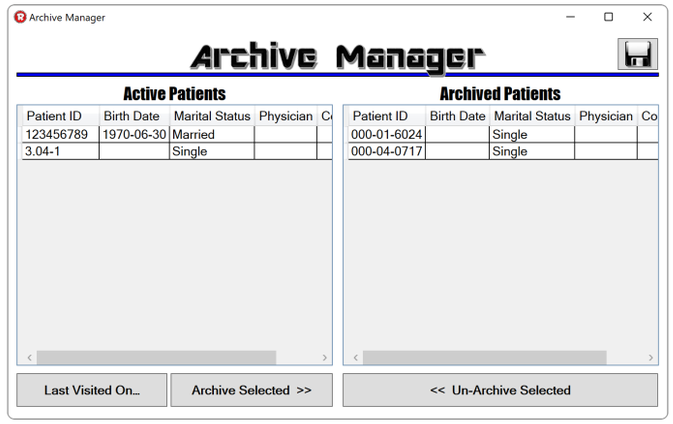


6. When prompted with the Old Data Removed pop-up screen, click **OK.**



To Archive/Un-Archive patients in the database:

1. Click the **Archive** button to open the Archive Manager window.
2. From this window, the user may select patient records to archive or un-archive (set as active).
3. Clicking the  button closes the Archive Manager window and re-opens the RigiScan Plus Home Screen.



To Archive a specific patient record:

1. Click the Patient ID of the desired record to archive.
2. Optional: Ctrl + Click to select multiple patient records
3. Click the **Archive Selected** button.
4. Click the  button to save changes to patients' statuses.
5. Clicking the  button closes the Archive Manager window and re-opens the RigiScan Plus Home Screen.

or

1. Double-click the Patient ID of the desired record to archive.
2. Click the  button to save changes to patients' statuses.
3. Clicking the  button closes the Archive Manager window and re-opens the RigiScan Plus Home Screen.

To Archive all patients whose last visit occurred before a certain date:

1. Click the **Last Visited On...** button.
2. When prompted in the Date Selection pop-up window, select the archive cutoff date.

3. Click the **Archive** button to change the status of all patients whose last visit occurred before the date selected from active to archived and return to the Archive Manager Window.
4. Click the button to save the changes to patients' statuses.
5. Clicking the button closes the Archive Manager window and re-opens the RigiScan Plus Home Screen.

To Un-Archive a specific patient record:

1. Click the Patient ID of the desired record to un-archive.
2. Optional: Ctrl + Click to select multiple patient records.
3. Click the **Un-Archive Selected** button.
4. Click the button to save changes to patients' statuses.
5. Clicking the button closes the Archive Manager window and re-opens the RigiScan Plus Home Screen.

or

1. Double-click the Patient ID of the desired record to un-archive.
2. Click the button to save changes to patients' statuses.
3. Clicking the button closes the Archive Manager window and re-opens the RigiScan Plus Home Screen.

3.7 RigiScan Settings Window

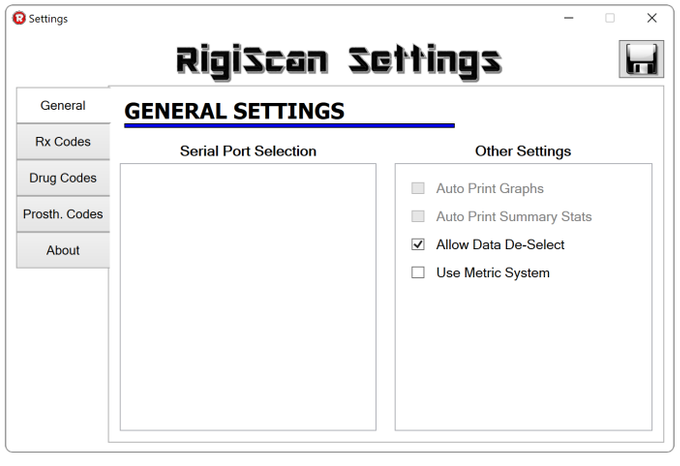
Clicking the **Settings** button on the RigiScan Plus Home Screen opens the RigiScan Settings Window. Click-able tabs along the left side of the window allow the user to navigate to different sections of the Settings Window to customize the RigiScan application for their particular needs.

Clicking the button in the upper right corner of the Settings Window brings the user back to the RigiScan Plus Home Screen.

Below you will find a description of each tab available from the Settings Window:

General Tab

The General Tab allows the user to select the correct serial port used with the monitor, set graphs to automatically print, set summary statistics to automatically print, allow data de-selection, and use metric measurements.



To modify the general settings:

1. Click the desired serial port to highlight it.
2. Click the check box to check or uncheck any other desired settings.
3. Click the button in the upper right corner to save changes and return to the RigiScan Plus Home Screen.

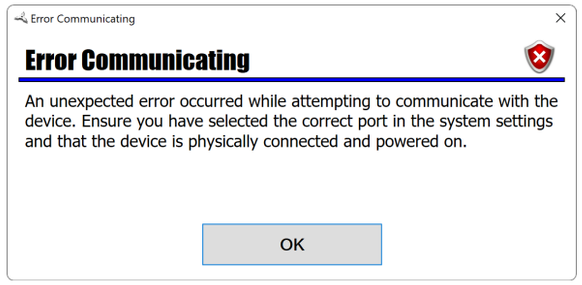
COM Port Selection:

Select the COM port that corresponds with the desired RigiScan. They are identified as "COM#" where the # is a number assigned by the Windows operating system.

NOTE: *USB is an abbreviation for Universal Serial Bus. PC computers and tablets treat USB ports as "Serial" or "COM" ports and assign each port a number (COM1, COM2, COM3, etc…) when a device is plugged in. In some cases, users may need to manually select the correct COM port to establish communication between the RigiScan instrument and the computer/tablet.*

A COM / Serial port may need to be deliberately selected since the application may not automatically select it when it is connected to the PC.

If clicking the RigiScan button on the RigiScan home screen opens the "Error Communicating" pop-up window, click OK, and verify the monitor is turned on and properly connected to the PC/tablet. If the monitor is turned on and properly connected, it may be necessary to manually select a different COM port to correct the problem.



To Modify COM Port Selection:

1. Click on the desired COM port (i.e. COM1) to highlight it.
2. Click the  button to save the setting.
3. Click the  button to exit the Settings menu.
4. Re-try connecting to the RigiScan instrument via the RigiScan button on the main menu.
5. If the Error Communicating message appears again, click **OK** to return to the main menu.
6. Repeat the COM port selection process, choosing a different COM port (i.e. COM2) until communication with the RigiScan is established.

Other Settings:

Auto Print Graphs (feature currently disabled):

This option allows the automatic printing of the Rigi Session Graphs once the downloading of session data is complete. This is where the default setting of this option is set. This setting can be temporarily overridden from the Data Download Options pop-up window (see Section 3.3 for RigiScan Control Window), but the default setting will be used upon the next Data Download.

Auto Print Summary Stats (feature currently disabled):

This option allows the automatic printing of the Summary Analysis Statistics once the downloading of session data is complete. This is where the default setting of this option is set. This setting can be temporarily overridden from the Data Download Options pop-up window (see Section 3.3 for RigiScan Control Window), but the default setting will be used upon the next Data Download.

Allow Data De-Select:

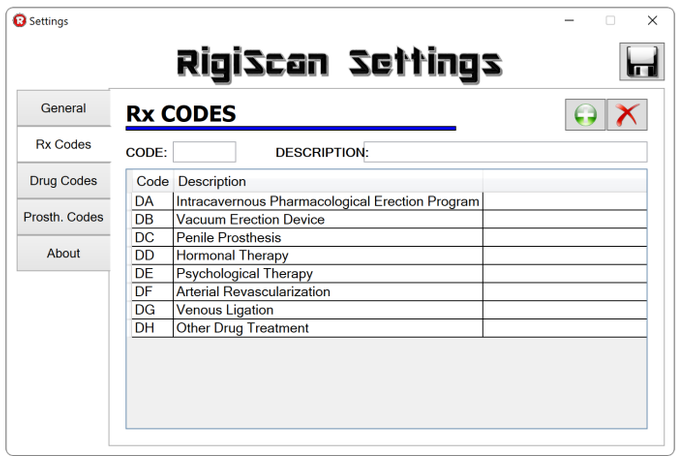
This option allows the removal of data in the graphs. By clicking and dragging anywhere in the graph, a gray shaded region will appear. Simply release the mouse button to end the selection of the shaded region and it will then appear on all 4 charts. Then right clicking anywhere on the graph brings up the context menu. By selecting **Exclude From Reports**, that data will be removed from the graph and those data samples will be removed from the statistics and reports. Multiple regions can be removed, if desired. To restore all of the excluded data, simple click on the blue link in the lower left corner of the graph. Clicking **YES** in the confirmation dialog box will restore the data in the graph and the reports.

Allow Metric System:

This option allows the Height and Weight measurements to switch between the Imperial and Metric systems. Patient's Height and Weight will either be in inches and pounds or they will be in centimeters and kilograms. Checking this box will set the Height to use cm and the Weight to use kg. Unchecking this box will set the Height to use inches and the Weight to use pounds.

Rx Codes Tab

The Rx Codes tab allows the user to enter codes and descriptions of the different physician prescribed treatments used. These codes are then available for use when recording data in a patient record.



To add a new code and description:

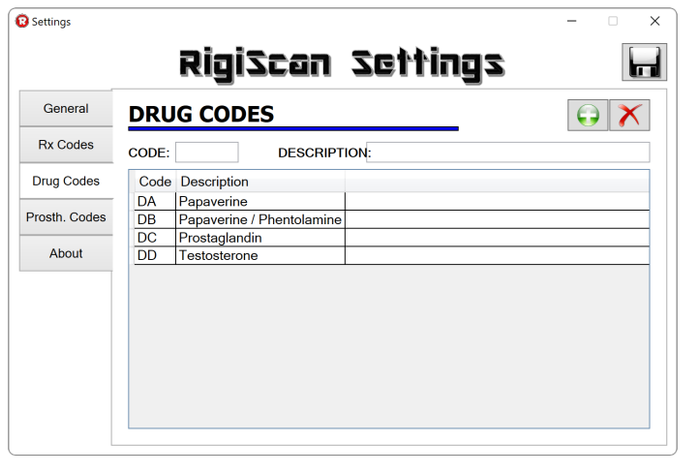
1. Click inside the Code text entry box and type the desired treatment code.
2. Click inside the Description text entry box and type the desired treatment description.
3. Click the button to add the new treatment code and description.
4. Click the button in the upper right corner to save changes and return to the RigiScan Plus Home Screen.

To delete an existing code and description:

1. Click the line you wish to delete.
2. Click the button to delete the selected treatment code and description.
3. Click the button in the upper right corner to save changes and return to the RigiScan Plus Home Screen.

Drug Codes Tab

The Drug Codes tab allows the user to enter codes and descriptions of the different drugs used in treatment. These codes are then available for use when recording data in a patient record.



To add a new code and description:

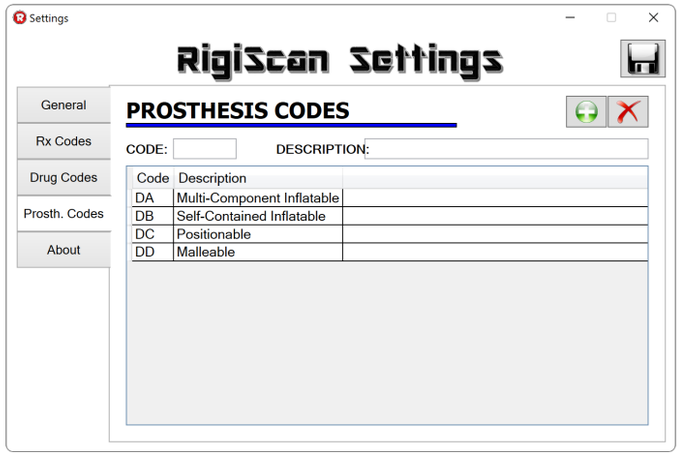
1. Click inside the Code text entry box and type the desired drug code.
2. Click inside the Description text entry box and type the desired drug description.
3. Click the button to add the new drug code and description.
4. Click the button in the upper right corner to save changes and return to the RigiScan Plus Home Screen.

To delete an existing code and description:

1. Click the line you wish to delete.
2. Click the button to delete the selected drug code and description.
3. Click the button in the upper right corner to save changes and return to the RigiScan Plus Home Screen.

Prosthesis Codes Tab

The Prosthesis Codes tab allows the user to enter codes and descriptions of the different types of penile prostheses. If the user selects a penile prosthesis code, that information will then be available in the patient's record.



To add a new code and description:

1. Click inside the Code text entry box and type the desired prosthesis code.
2. Click inside the Description text entry box and type the desired prosthesis description.
3. Click the button to add the new prosthesis code and description.
4. Click the button in the upper right corner to save changes and return to the RigiScan Plus Home Screen.

To delete an existing code and description:

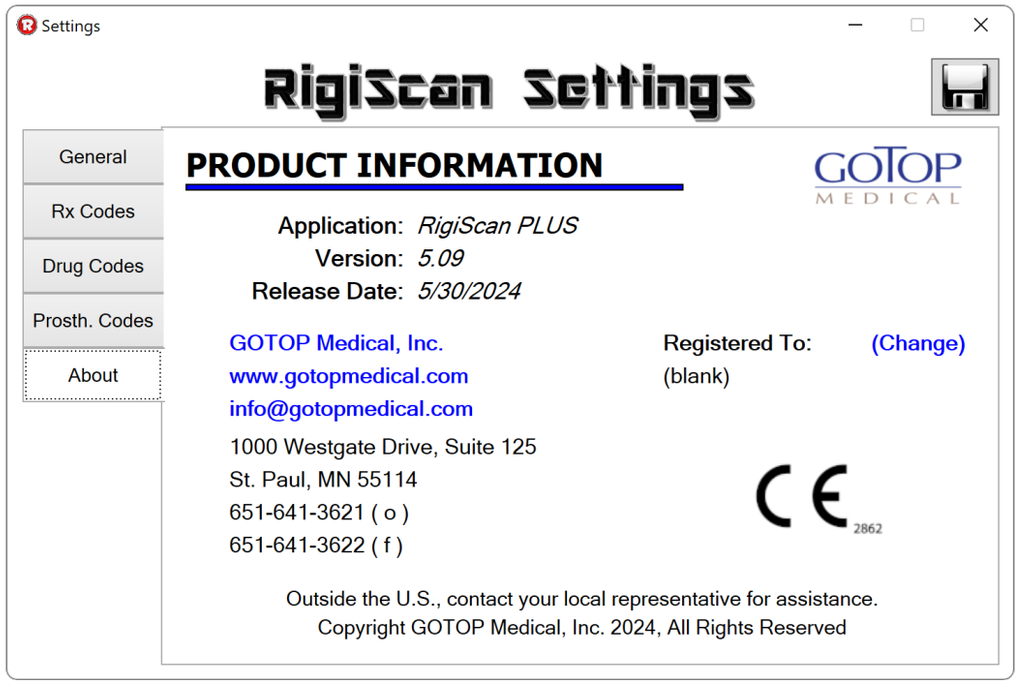
1. Click the line you wish to delete.
2. Click the button to delete the selected prosthesis code and description.
3. Click the button in the upper right corner to save changes and return to the RigiScan Plus Home Screen.

About Tab

The About tab displays product information including

- Application Name
- Application Version
- Application Release Date
- GOTOP Medical Contact Information
- Product Registration Information

It also allows the user to change to whom the software is registered by clicking **(Change)**.



Chapter 4: Preparing the RigiScan Plus System for Patient Testing

NOTE: ***Make certain that the RigiScan monitor is clean and has been disinfected after any prior patient's use. See Chapter 7 below for disinfection instructions.***

4.1 Initialize the RigiScan Monitor for the Patient to be Tested

See subsection "Using the RigiScan Plus - Initializing the Monitor" on page 18 inside Chapter 3.3 called "RigiScan Control Window". Please note that the RigiScan will only record up to 3 sessions. It will not record a fourth. To record additional sessions, download the recorded sessions and again initialize the monitor. Also, note the guide to "Beep cues" on page 56.

4.2 Installing the Tension Guides

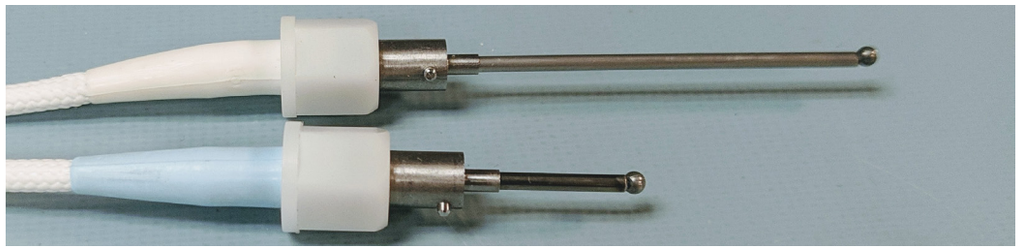
WARNING: Turn the RigiScan Plus Monitor "off" before replacing or removing the Tension Guides/cables.

Prior to each use, inspect the RigiScan monitor's Tension Guides, cables and loops to determine that all parts are in good working order. Tension guides must be handled gently. No tools should be used on the tension guides. The plastic nut on the Tension Guide need only ever be finger tight. Insertion and removal of the Tension Guides from the monitor can be done by hand.

To confirm the Tension Guide is safe to use, remove the loop covers (if installed) and pick up one end of the cable inside the Tension Guide. The tension guide outer sheath should slide down the length of the cable under its own weight. Repeat this several times to confirm the integrity of the Tension Guide.

WARNING: Replace the Tension Guides if the cable does not slide smoothly – if the cable is kinked or curled, the boots are loose, or the Tension Guide is crushed or broken. Use of damaged or worn Tension Guides may result in patient injury.

TIP and BASE Tension Guides are not interchangeable. The TIP Tension Guide is longer than the BASE Tension Guide and has WHITE boots. The BASE Tension Guide has BLUE boots.



It is important that you insert the correct guide into its corresponding port. The TIP Tension Guide (WHITE boot) must be installed in the **TIP** Connector, and the BASE Tension Guide (BLUE boot) must be installed in the **BASE** Connector. Install the TIP Tension Guide (WHITE boot) first since it will only fit in the **TIP** Connector to prevent the BASE Tension Guide from accidentally being installed into the **TIP** Connector Housing potentially damaging the monitor.

WARNING: Damage to the monitor can occur if the shorter base Tension Guide is in the TIP port and the unit is started – the TIP mechanism can enter an "out of registration" state requiring service. Avoid using two BASE Tension Guides on one RigiScan monitor!

The Tension Guides must be inserted in the monitor with the Tension Guide pin fully seated in the slot at the top of the housing. The bayonet fitting must be in place (pushed in, quarter turn). See the figures below for how the ball should be seated for insertion:

NOTE: ***Operating the monitor without the Tension Guides/cables in place may damage the device or result in inability to insert the Tension Guide.***

To install the Tension Guides, follow these steps:

1. Verify that the RigiScan monitor is turned off.
2. Verify that the appropriate Tension Guide (BASE=BLUE, TIP=WHITE) has been selected.
3. Verify that the plastic retention nut on the Tension Guide has been turned fully towards the boot of the Tension Guide and the loop fully expanded such that the ball is seated at the end of the Tension Guide.
4. The ball should be seated against the end of the Tension Guide, as seen below:

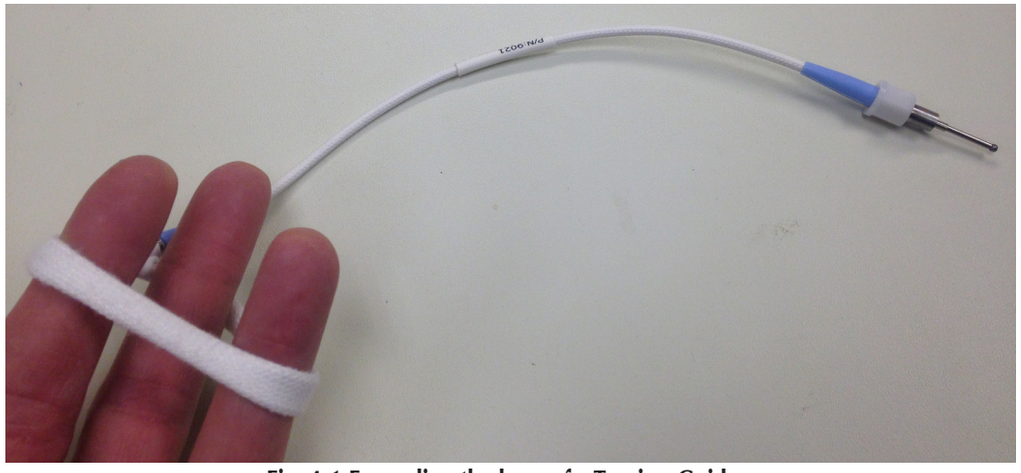


Fig. 4-1 Expanding the loop of a Tension Guide

5. If the end of the Tension Guide appears like Figure 4-2, the loop has not been fully expanded. It should look like Figure 4-3.

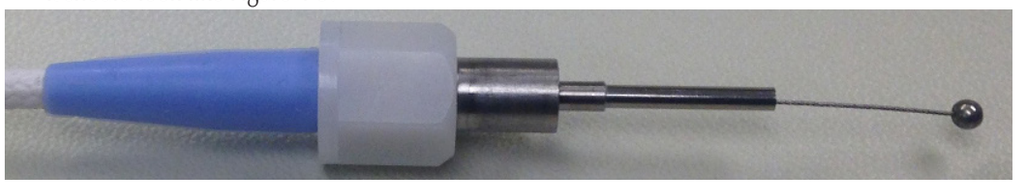


Fig. 4-2 Unseated Ball of a Tension Guide

Fig. 4-3 Seated Ball of a Tension Guide

6. Hold the Tension Guide by the boot at the ball-end of the cable and, while applying tension to pull out the loop cover cable at all times, insert it into the corresponding Tension Guide housing on the Monitor.
7. Align the pin on the Tension Guide with the slot in the housing. Push the Tension Guide into the housing until it is fully inserted and turn approximately 1/4 turn clockwise until the pin is fully seated in the slot.
8. Tighten the plastic retention nut on the Tension Guide until it contacts the Tension Guide housing. (see Figure 4-4)

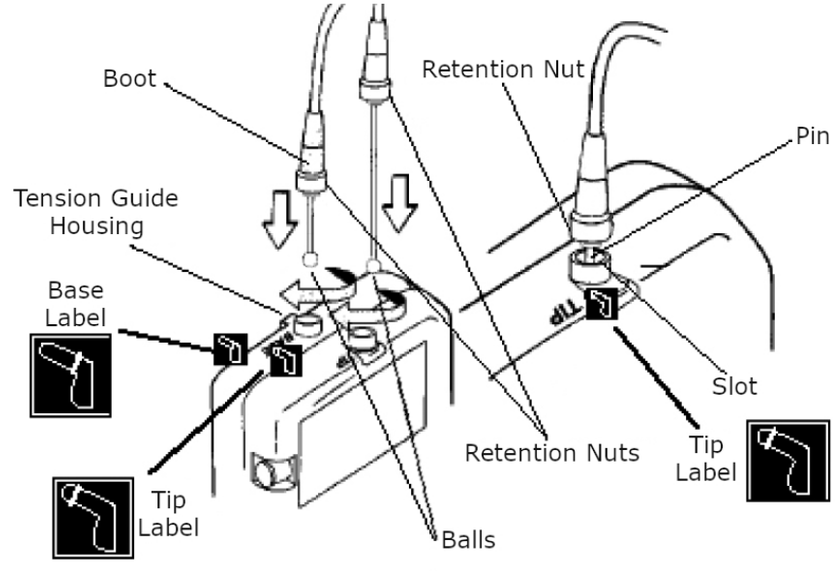


Fig. 4-4 Installing the Tension Guides

4.3 Removing the Tension Guides

1. Verify that the RigiScan monitor is turned off, batteries are removed, and USB disconnected.
2. Unscrew the plastic retention nut on the Tension Guide at the monitor end of the Tension Guide.
3. Expand the loop to its maximum circumference by inserting your fingers in the loop and slowly applying outward pressure until the loop will no longer expand. (see Figure 4-5). If the cable of the tension guide had been drawn into the RigiScan monitor slowly expand the loop; you will be spinning internal gears and motor within the RigiScan.

NOTE: *When removing the Tension Guide, the cable must be fully extended. The bayonet fitting must be in place (pushed in, quarter turn) when manually pulling the cable out to the extended position. Pull slowly.*

4. Push the Tension Guide into the Tension Guide housing on the monitor and turn approximately ¼ turn counterclockwise until the metal pin moves out of the slot at the far right of the housing. If the monitor has not released the cable, this means that the loop was not fully expanded. Carefully reinsert the Tension Guide into the monitor and turn ¼ turn. Again expand the loop fully, and then extract the Tension Guide. Do not attempt to pull the cable out of the monitor with force without the Tension Guide inserted and locked in position – this will only result in damage to the monitor.
5. While applying tension to pull out the loop cover cable at all times, slowly and gently pull on the Tension Guide boot to remove the Tension Guide and cable from the monitor.

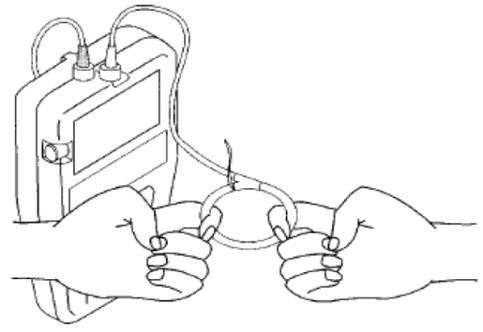


Fig. 4-5 Expanding the Loops

NOTE: To help in use of the RigiScan, below is a link to two videos available on articulate.com:

https://rise.articulate.com/share/wdCHx-razmTdHnKVdzQj1tAhnxZiSa7G

4.4 Installing the Loop Covers

NOTE: *The loop covers are supplied with a clear plastic feeder tube inside the loop. The feeder tube is required for installing the loop cover. DO NOT remove the feeder tube until directed to do so.*

1. Insert the brass barb of the Tension Guide cable securely into the feeder tube at the "Y" connect end of the loop cover. (See Figure 4-6A)

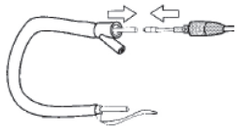


Fig. 4-6A

2. Hold the loop-cover "Y" connect in one hand and gently pull the feeder tube and cable through the loop cover until the "Y" connect is adjacent to the threaded end of the Tension Guide.

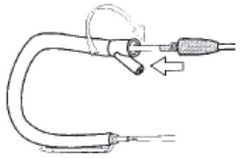


Fig. 4-6B

3. Hold the Tension Guide boot in one hand, the "Y" connect in the other and screw the "Y" connect clockwise until it is securely fastened to the Tension Guide. Do not over tighten. (See Figure 4-6B)

4. Grasp the brass barb of the loop cover and remove the feeder tube. (See Figure 4-6C)

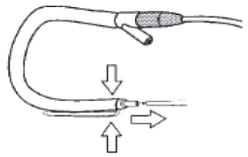


Fig. 4-6C

5. Close the loop by holding the fabric directly behind the release tab and pushing the brass barb into the receptacle on the "Y" connect. (See Figure 4-6D)

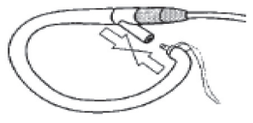


Fig. 4-6D

4.5 Removing the Loop Covers

CAUTION: *Turn the RigiScan monitor "off" before replacing loop covers or removing the Tension Guides/cables. Operating the monitor without the Tension Guides in place may damage the device or result in the inability to insert the Tension Guides.*

1. Expand the loop to its maximum circumference by inserting your fingers in the loop and slowly applying outward pressure until the loop will no longer expand.

2. Open the loop cover by grasping the loop cover "Y" connect in one hand, the release tab in the other, and pulling firmly until the loop cover unsnaps. (Fig. 4-7)

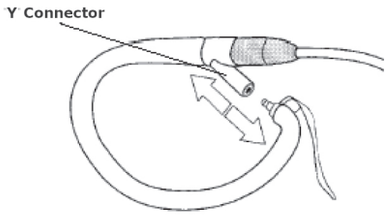


Fig. 4-7

3. Disconnect the loop cover by holding the Tension Guide boot in one hand and turning the "Y" connect counterclockwise until the two detach.

4. Remove and discard the used loop cover in accordance with applicable regulations covering bio-hazardous materials.

4.6 Installing the Batteries

The RigiScan monitor uses either two DURACELL® 9-volt alkaline batteries or two GOTOP approved rechargeable 9-volt batteries. They must either be replaced or have been fully recharged (if using GOTOP approved rechargeable batteries) before of each 10-hour session. When you see the yellow battery indicator light on the top of the RigiScan monitor begin to blink, that signals that the batteries don't have enough power to record another full 10-hour session.

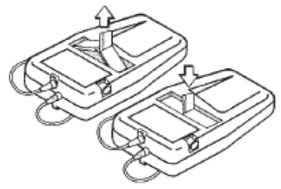


Fig. 4-8

NOTE: *The RigiScan monitor's internal lithium battery must be replaced by a qualified GOTOP Medical service technician a minimum of one (1) time per year.*

4.6 Installing the Batteries *(continued)*

Use Only DURACELL® 9-volt alkaline Batteries or GOTOP approved rechargeable 9-volt batteries

To replace the 9 V batteries, complete the following steps:

1. Open the battery cover by pulling the black tab in the direction of the arrow.
2. Pull up on the black tab in the battery compartment to release the old batteries. (see Figure 4-8)
3. If using alkaline batteries, discard the old batteries in accordance with applicable regulations. If using GOTOP approved rechargeable batteries, place them in GOTOP approved battery charger and allow them to fully charge before re-use.
4. Match the polarity of the new/fully-recharged batteries (+ and –) with those in the battery compartment.
5. Install the new/fully-recharged batteries in the compartment (contact ends first), pressing them down into the compartment with your thumbs and replace the compartment cover.

NOTE*: Remove the 9-volt batteries from the device if the device will not be used for an extended period.*

Chapter 5: Patient Testing

Patient testing entails recording data with the RigiScan monitor while it is attached to the patient. The data that is collected is then downloaded to a Windows PC for evaluation by the clinician. To prepare the RigiScan monitor for a new study, you must be sure that you have initialized the RigiScan monitor with the patient's proper information. For instructions on how to initialize the RigiScan monitor, see Initializing the Monitor in Chapter 3 of this manual.

5.1 Nocturnal and Provocative Collection Modes

Estimating an appropriate baseline for penile circumference is an important parameter in the processing of rigidity and tumescence data by the RigiScan system software. There are two different modes of data collection: Nocturnal and Provocative. Each method processes data differently in order to establish an accurate estimate of the baseline penile circumference, so it is important to select the appropriate mode during initialization before you begin testing the patient. For instructions on how to select the testing mode, see Initializing the Monitor in Chapter 3.

Nocturnal Testing

You should use the Nocturnal Testing mode when you want to monitor nocturnal erections over a period of several hours. This test method can be used while the patient is in a sleep laboratory setting, and also can be used under Ambulatory or Real-time settings. The Nocturnal Mode is used when there are multiple erectile events and there is a periodic return to the flaccid state. This uses the entire session to calculate the baseline.

Provocative Testing

Provocative Testing is performed when the clinician wants to use an intervention to produce a one-time erectile response. This method of testing is performed over a shorter period of time, usually in an office setting. Intervention might include the injection of a pharmacological agent or visual sexual stimuli. This test method can also be used under either Ambulatory or Real-time settings. In the Provocative Mode, the RigiScan system records a baseline penile tumescence during the first fifteen minutes of testing and stores it for later reference. If you are testing in the Real-time mode, the message **CALCULATING BASELINE** will flash at the bottom of the screen while the baseline tumescence is being established. Only when the message **BASELINE ESTABLISHED** appears on the screen indicating the baseline tumescence is calculated and stored may intervention be given to the patient. If you are testing in the ambulatory mode, monitoring must be performed for a period of fifteen minutes to establish a baseline value before intervention is given to the patient.

5.2 Instructing the Patient

When a patient is being tested in the ambulatory mode, you need to explain how to use the RigiScan monitor, including giving instructions on how to put it on, start it, and change the batteries. A Characterization Session is provided for patient education (see section 5.4). Instruct the patient to wear loose fitting clothing when wearing the RigiScan monitor, such as pajamas or boxer shorts. See Appendix B: Patient Instructions at the end of this manual to instruct the patient on how to use the RigiScan monitor. Provide these instructions to your patients to reference when using the RigiScan monitor while not under direct physician supervision.

⚠ ***It is the responsibility of the physician to assure that adequate instructions and orientation regarding use of the RigiScan monitor are given to the patient. Please refer to Appendix B of this User Guide for guidelines on how to properly instruct the patient. These instructions are provided as a reference only and are not intended to replace the instructions given by the physician. Inadequate instruction may result in patient injury.***

Removing the Loops Quickly

Normally the patient would remove the loops by first turning the RigiScan instrument off and then inserting his fingers gently into the loops and pulling outward to expand the loops. However, if the patient experiences pain during testing or needs to remove the loops quickly for any other reason, he can unsnap the loops with the quick release tab. To do this, instruct the patient to follow these steps:

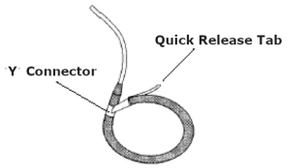


Fig. 5-1A

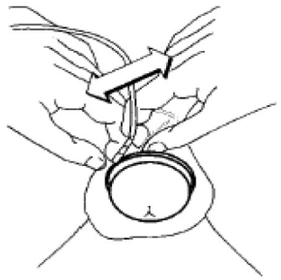


Fig. 5-1B

1. Turn the RigiScan instrument off! The patient MUST turn the RigScan instrument off or testing will continue which will cause damage to the RigScan instrument.
2. With one hand, grasp the loop at the "Y"connector. (See Figure 5-1A)
3. With the other hand, grasp the quick release tab and pull it sharply until the two ends of the loop come apart. (See Figure 5-1B)
4. In general, patients should be discouraged from unsnapping the loops. Simply turning the instrument off should allow the patient to manually expand the loops and quickly relieve any discomfort.

NOTE: *For instructions on reinstalling the loop covers, see Installing the Loop Covers in Ch 4.*

Attaching the Leg Strap Wearing Pajamas or Clothing

To attach the leg strap to the patient's thigh, follow these steps:

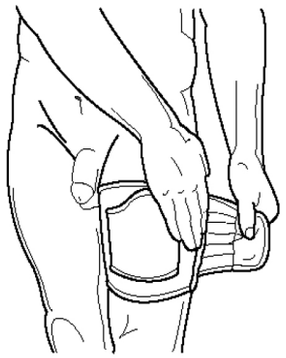


Fig. 5-2 Attaching the Leg Strap

1. Have the patient complete these steps in a standing position wearing pajamas or loose fitting clothing.
2. Wrap the leg strap (supplied in the carrying case) around the thigh of either leg, with the opening pointing toward the patient's penis (see Figure 5-2). If the patient sleeps on his left side, you should attach the RigiScan monitor and strap to the left thigh. If he sleeps on his right side, you should attach the RigiScan monitor and strap to the right thigh. The strap should be comfortably snug.
3. After fitting the strap securely, slide the RigiScan monitor into the holster of the strap.

NOTE: *If physical disabilities prohibit the patient from attaching the leg strap to his thigh, an optional waist strap is available to allow the patient to wear the RigiScan monitor around his abdomen. Connect the two straps together and wrap them around the patient's waist, with the pocket centered over his penis. Insert the RigiScan monitor into the pocket with the Tension Guides pointing down toward his penis.*

5.3 Testing Patients Using the Real-time and Ambulatory Modes

Real-time Testing

Real-time Monitoring permits the clinician to view data recorded during sessions immediately on the computer screen. Either Nocturnal or Provocative testing can be performed using the Real-time Monitoring Option. Battery life during RTM is not an issue since it is being powered by the USB cable.

NOTE: *The optional Event Marker can be used to mark pertinent points in the data for later reference, for example when a pharmacological agent is given to the patient. At anytime after the data stream begins you can press the button on the Event Marker cable to place vertical cursor line on the graph. This line becomes a permanent part of the patient's record, so it will appear in the session reports. See Connecting the Event Marker in Chapter 2 for instructions on how to connect the Event Marker.*

To collect patient data in the Real-time mode, follow these steps in the exact order given.

WARNING: *It is IMPORTANT to follow the instructions in the precise order given. Performing these operations in the wrong sequence may result in improper sampling and cause patient discomfort.*

1. Connect the RigiScan monitor to your computer's communications cable. See Setting Up the Hardware in Chapter 2.)
2. Initialize the RigiScan monitor. (See Initialize the Monitor in Chapter 3.)
3. Attach the RigiScan monitor to the patient's leg. (See Attaching the Leg Strap in the previous section.)
4. Attach the RigiScan monitor Loops to the patient's penis: First, fit the BASE Loop (blue boot) over the patient's penis and position it at the base of the penis. Second, fit the TIP Loop (white boot) over the patient's penis and position it at the tip of the penis just below the glans.

WARNING: *DO NOT turn the RigiScan monitor on until the loops have been placed on the patient's penis. Turning the monitor on before placing the loops will cause continuous rigidity sampling and may result in patient discomfort, pain, irritation or bruising.*

Real-time Testing *(continued)*

5. Turn the RigiScan monitor on.
6. If it is not already open, open the RigiScan Control window. (See RigiScan Control Window in Chapter 3.)
7. Click the **Real Time Monitoring** button. If you initialized the patient data for provocative testing, the Provocative Real-time Mode Graphs screen will appear. Otherwise, the Nocturnal Real-time Mode Graphs will appear.
8. Hold the loops in their proper positions until the RigiScan monitor tightens them. The Base Loop will tighten first, followed by the Tip Loop. The loops will not tighten until you have clicked **Real Time Monitoring**.
9. To stop the Real-time Monitoring session, click  button to exit the Real-Time Mode screen.
10. Wait for the RigiScan monitor to beep. Then turn off the RigiScan monitor's power.
11. Remove the loops from the patient's penis.
12. Download the patient's data to the computer. (See To Download Patient Data in Chapter 3.)

Ambulatory Testing

Ambulatory monitoring allows the RigiScan monitor to collect data without being connected to the computer. The loops must be placed on the penis correctly and the two 9-volt batteries must be replaced (or recharged) before each nocturnal session. Regardless of whether you are using alkaline or rechargeable batteries, they will only have enough battery life for a single session. Replace or fully recharge batteries before each session. It is also recommended to do a Characterization Session in the office so the patient has some experience operating the device before using it without physician supervision (see section 5.4).

WARNING: ***It is IMPORTANT to follow these instructions in the precise order given. Performing these operations in the wrong sequence may result in improper sampling and cause patient discomfort.***

To collect patient data in the ambulatory mode, follow these steps in the exact order given.

1. Connect the RigiScan monitor to your computer's communications cable. (See Setting Up the Hardware in Chapter 2.)

Ambulatory Testing *(continued)*

2. Turn the RigiScan monitor on.
3. Open the RigiScan Control Window. (See RigiScan Control Window in Chapter 3.)
4. Initialize the RigiScan monitor. (See Initialize the Monitor in Chapter 3.)
5. Click  to return to the RigiScan Plus Home Screen.
6. Turn off the RigiScan monitor.
7. Disconnect the communications cable.
8. Attach the RigiScan monitor to the patient's leg. (See Attaching the Leg Strap in Chapter 4.)
9. Attach the RigiScan monitor Loop to the patient's penis: First, fit the BASE Loop (blue boot) over the patient's penis and position it at the base of the penis. Second, fit the TIP Loop (white boot) over the patient's penis and position it at the tip of the penis just below the glans.

WARNING: ***DO NOT turn the RigiScan monitor on until the loops have been placed on the patient's penis. Turning the monitor on before placing the loops will cause continuous rigidity sampling and may result in patient discomfort, pain, irritation, or bruising.***

Conduct an in-office Characterization Session Not to Exceed 15min:

A Characterization Session is most helpful for patients to understand the use of the RigiScan monitor. Please see section 5.4 for important information regarding the Characterization Session.

10. Turn the RigiScan monitor on.
11. Hold the loops in their proper positions until the RigiScan monitor tighten them. The Base Loop will tighten first, followed by the Tip Loop.

CAUTION: ***DO NOT allow the Characterization Session to last more than 15 minutes.***

12. When the session is complete, turn off the RigiScan monitor and remove the loops from the patient's penis.
13. Instruct the patient on the proper use of the RigiScan system for noctournal testing. Be sure to review the patient instructions in Appendix B of this User Guide and provide the patient with a copy of these instructions for their use without physician supervision. Be sure not to push the power button on or off during patient instruction as this may cause errors. After the characterization session, the RigiScan instrument should only be turned on when the patient is ready to begin his first nocturnal monitoring session.
14. Download the patient's data when the patient returns the RigiScan after 2 to 3 nights of testing. (See To Download Patient Data in Chapter 3.)

Beep Cues

Each time the patient turns the RigiScan monitor on, it will emit a series of beep tones to indicate that the device is active and which session it is ready to record. The buzzer is not loud. It is located within the case, in the lower right corner of the RigiScan. For example, the first session is indicated by a single beep, the second by two beeps, and so on. When the RigiScan monitor has reached its maximum storage capacity (three sessions), it will emit a 5-second beep tone. At this point, you need to download the date and re-initialize the RigiScan monitor before it can record any further sessions.

5.4 The Characterization Session

A Characterization Session is the first session of recording performed after the RigiScan monitor has been initialized. It is conducted in the physician's clinic and intended for patient orientation before the patient uses the system at home for nocturnal testing. A Characterization Session is used to instruct the patient on the proper use of the RigiScan monitor and to familiarize the patient with the sensation of the loops contracting on his penis. Conducting the Characterization Session in the office under the supervision of a medical professional reassures the patient that the sensations experienced are a normal part of the RigiScan test and not harmful. In addition to helping acclimate the patient to the test, a Characterization Session establishes baseline tumescence data that is used to maintain the loops at the proper diameter for the patient's penis so that the loops remain in place during nocturnal testing. The RigiScan monitor is programmed to automatically record the first 15 minutes of monitoring as a Characterization Session. After the monitor is initialized, the first power on will trigger the start of monitoring. If the RigiScan is turned off within 15 minutes, the data recorded will be stored as a Characterization Session and reflect the measurements obtained during the in-office session. If, after the first power on, the RigiScan monitor is allowed to run for more than 15 minutes, the instrument will NOT record a Characterization Session. Instead, the instrument is programmed to begin monitoring for the first full session (Session 1). If this occurs, the RigiScan will use the first 30 minutes of data collected and categorize that data as a Characterization Session and then continue monitoring for up to a total of 10 hours.

5.5 Downloading Data from the Monitor

When the patient has completed up to three sessions in either ambulatory or Real-time mode, you must download the data from the RigiScan monitor to the computer. It is important to remember once you connect the RigiScan monitor to the computer and initialize the RigiScan monitor with new patient information, all data stored previously in the RigiScan monitor will be erased and replaced by the new initialization data. For instructions on how to download data from the RigiScan monitor to your computer, see To Download Patient Data in Chapter 3.

Chapter 6: RigiScan Plus Reports

6.1 The Session Scan Summary Report

The RigiScan Session Scan Summary Report allows you to see the results of previously downloaded sessions. These are the fields that appear on the Session Scan Summary Report.

Patient ID. This field displays the identification number of the patient you selected on the Session Scan Summary screen.

Visit Date. This field shows the visit date you selected on the Session Scan Summary screen.

Comments. This field displays any comments you entered when you initialized the monitor.

Session. This field displays the session numbers for the current patient's record. C represents a Characterization Session, and 1, 2, and 3 represent subsequent sessions.

Date. This field displays the date, start and stop times and the duration of each session.

Number of Events. This field displays the total number of qualified events recorded during each session. See Glossary for the definition of a qualified erectile event.

Baseline Tumescence. This field shows the baseline, or flaccid circumference for penile base and tip.

Average Event Rigidity. This field shows average rigidity during qualified events for the base and the tip measured as a percentage.

Sustained Erectile Activity. These fields show the Rigidity Activity Unit (RAU) and Tumescence Activity Unit (TAU) measurements during qualified events for base and tip data. The RAU value represents the area under the rigidity curve during an event. The TAU value represents the area under the tumescence curve based on the percent increase in tumescence over baseline during an event. Refer to the Glossary for information on how these values are calculated.

6.2 The Summary Analysis Statistic Report

The RigiScan Summary Analysis Statistics Report provides a comprehensive review of the duration of events, their averages, and baselines. It includes as many as three data collection sessions, and provides individual and composite views for all three sessions. These are the fields that appear on the Summary Analysis Statistics Report:

Start and Stop Times and Duration. These fields tell session duration and when a qualified event began, when it stopped, and how long it lasted. This report is valid for individual sessions as well as a composite view. Base and tip data is reported in convenient rows and columns. The categories are as follows:

Average Event Rigidity. These values indicate average rigidity measured as a percentage during qualified events in a composite of all sessions as well as individually.

Timed Rigidity Percentages. These values show the length of time in minutes that a qualified erectile event was at a certain percent level of rigidity. This report is valid for individual sessions as well as a composite view.

Baseline Circumference. This field shows the baseline, or non-tumesced circumference.

Average Event Tumescence. These values indicate average tumescence measured in centimeters during qualified erectile events for base and tip. This report is valid for individual sessions as well as a composite view.

Event Tumescence Percentage Greater than the Baseline. These values show the increase from baseline tumescence measured as a percentage for qualified events. This report is valid for individual sessions as well as a composite view.

Sustained Erectile Activity. These fields show the Rigidity Activity Unit (RAU) and Tumescence Activity Unit (TAU) measurements during qualified events. The RAU value represents the area under the rigidity curve during an event. The TAU value represents the area under the tumescence curve based on the percent increase in tumescence over baseline during an event. This report is valid for individual sessions as well as a composite view. Refer to the Glossary for information on how these values are calculated.

6.3 Printing Session Scan Summary and Summary Analysis Statistics Reports

To Print the Session Scan Summary Report:

1. Navigate to the RigiScan tab of the Patient Information window.
2. Select a RigiScan Session and click **View Details for Selected**.
3. Click **Print**.
4. Select the check boxes of the items you wish to print, then click **SELECT**.
5. Follow on-screen instructions to select your preferred printer.

To Print the Summary Analysis Statistics Report:

1. Navigate to the RigiScan tab of the Patient Information window.
2. Select a RigiScan Session and click **View Details for Selected**.
3. Click **View SAS.**
4. Click the  button.
5. Follow on-screen instructions to select your preferred printer. Some versions of Windows have a "Microsoft Print to PDF" printer you can select to save as a PDF instead of printed paper.

6.4 Patient Summary Report

Patient Summary Reports list the information you entered in the Patient Information window (see Patient Management in Chapter 3) for any number of patients. These reports cannot be displayed on screen, but they can be printed through the Reports window (see Reports in Chapter 3). The following fields appear on the Patient Summary Report:

Patient ID. This field displays the patient's identification number.

Birth date. This field displays the patient's birth date.

Height. This field displays the patient's height (in. or cm selectable via the Settings screen).

Weight. This field displays the patient's weight (lbs. or kg selectable via the Settings screen).

Smoking History fields. This field contains subfields that show whether he is a smoker or not, how many packs a day has he smoked, and for how many years.

Ejaculatory Function. This field shows the code for the patient's ejaculatory function. The legend of codes for this field appear on the last page of the Treatment History report.

Etiology fields. These fields show the codes for the primary and secondary impotence etiology of the patient. The legend of codes for these fields appears on the last page of the Treatment History report.

6.5 Treatment Summary Report

Treatment Summary Reports list the information you entered in the Treatment Record window (see Patient Management in Chapter 3) for any number of patients. These reports cannot be displayed on the screen, but they can be printed out through the Reports window (see Reports in Chapter 3). The following fields appear on the Treatment Summary report:

Patient ID. This field displays the patient's identification number.

Visit Number. This field displays the visit number and visit date selected in the patient's record.

Test fields. These fields display the patient's cholesterol, testosterone and Prolactin levels you entered for the visit date displayed in the Visit Date field.

Treatment and Drug fields. These fields display the impotence treatment, drug and dosage, and prosthesis type you entered for the date displayed in Visit Date field. The legend of codes for these fields appears on the last page of the report.

Cavernosography Code. This field displays the test results entered for the date displayed in Visit Date field.

Arteriography Code. This field displays the test results entered for the date displayed in Visit Date field.

RigiScan Data on File. This field indicates whether or not a scanning session was performed and downloaded for the date displayed in the Visit Date field.

6.6 General Session Info Report

General Session Reports list the information recorded during scanning sessions for any number of patients. These reports cannot be displayed on screen, but they can be printed out through the Reports window (see Reports in Chapter 3). The following fields appear on the General Session report.

Patient ID. This field displays the patient's identification number.

Visit Date. This field displays the visit number and visit date selected in the patient's record.

Session Number. This field displays session number for each patient.

Session Duration. This field displays the duration of each session.

Event Duration. This field displays the duration of all qualified events in the listed session.

Event Percentage of Session. This field displays length of time for all qualified events in a session measured as a percentage of the total session duration.

Number of Events. This field displays number of qualified events recorded during each session.

Average Event Rigidity. This field displays the values for average base and tip rigidity of all qualified events recorded during each session.

Sustained Erectile Activity. These fields show the Rigidity Activity Units (RAUs) and Tumescence Activity Units (TAUs) measurements during qualified events for base and tip data. The RAU value represents the area under the rigidity curve during an event. The TAU value represents the area under the tumescence curve based on the percent increase in tumescence over baseline during an event. Refer to the Glossary for information on how these values are calculated.

Event Tumescence Increase. This field displays increase of tumescence from the baseline expressed as a percentage during qualified events for the base and tip of the patient's penis.

6.7 Base Data Report

The information printed on this report shows the rigidity time measured in hours and minutes as a function of percent of rigidity, and sustained erectile activity measured in RAUs and TAUs for the base of the patient's penis.

6.8 Tip Data Report

The information printed on this report shows the rigidity time measured in hours and minutes as a function of percent of rigidity, and sustained erectile activity measured in RAUs and TAUs for the tip of the patient's penis.

Chapter 7: RigiScan Plus Cleaning and Disinfection

CAUTION: *The RigiScan uses disposable loop covers to ensure patient comfort during testing. These items are single use only and must NOT be used by different patients.*

CAUTION: *Ambulatory testing requires the use of a leg strap to properly secure the RigiScan monitor during patient testing. GOTOP Medical offers both Disposable Leg Straps and Re-useable Leg Straps:*

- *Disposable Leg Straps are single use only and must not be used by different patients.*
- *Re-useable Leg Straps must be properly disinfected before re-use. Please refer to the IFU supplied with Re-useable Leg Straps for instructions on proper disinfection.*

7.1 Instructions for Disinfecting the RigiScan Plus Monitor:

NOTE: *The RigiScan monitor must be sanitized after patient use, before it is used by a different patient.*

1. Remove and discard all loop covers that are attached to the RigiScan monitor or included in the carrying case.
2. Remove and discard any 9V batteries in the RigiScan monitor or included in the carrying case.
3. Clean the RigiScan monitor of any visible soiling or particulate by wiping with a cloth moistened with a mild detergent solution or alcohol.
4. Wipe the RigiScan monitor and its components (i.e. the pushbutton, the battery ribbon, the tension guides and tension guide cables) with germicidal sanitizing wipes.

GOTOP Medical suggests the use of germicidal sanitizing wipes saturated with Quaternary Ammonium Compounds to disinfect the RigiScan monitor.

WARNING: *Do NOT immerse the RigiScan monitor or permit liquid to enter the instrument when disinfecting.*

Chapter 8: Maintenance

8.1 Maintenance

The two 9-volt DURACELL® batteries (or two GOTOP approved rechargeable batteries) must be replaced (or fully recharged) before the start of each 10-hour session.

Should the loops or Tension Guides be bent or damaged, install new Tension Guide/cables prior to use.

CAUTION:
Do not use the monitor if the loops or Tension Guides/cables are damaged in any way.

8.2 Annual Calibration

The RigiScan monitor should be calibrated annually to make certain that the forces applied to the penile loops are in specification for patient safety and comfort and for accurate results.

The calibration procedure includes replacement of the internal lithium battery. If you receive lithium battery error messages, or if the Red LED inside the battery compartment, is illuminated, contact GOTOP Medical Customer Service. The lithium battery limits the shelf life of the RigiScan monitor to one year.

Calibration must be performed by a qualified GOTOP Medical Service Technician. Contact GOTOP Medical Customer Service at:

Email:info@gotopmedical.com or
TEL: 651-641-3621

Outside the United States, contact your local representative. The serial numbers of your devices will be needed to arrange re-calibration. The serial number is found on the label within the battery compartment of each RigiScan.

8.3 Expected Service Life

The Expected Service Life of the RigiScan monitor System is 5 years, when the annual maintenance is respected.

Glossary

Ambulatory. The activity of using the RigiScan monitor to collect data when it is independent of the PC.

Baseline Tumescence. The estimated circumference of the penis in the resting, or flaccid, non-erect condition.

Characterization Session. A Characterization Session is the first session of recording performed after the RigiScan monitor has been initialized. It is conducted in the physician's clinic and intended for patient orientation before the patient uses the system at home for nocturnal testing. A Characterization Session is used to instruct the patient on the proper use of the RigiScan monitor and to familiarize the patient with the sensation of the loops contracting on his penis. Conducting the Characterization Session in the office under the supervision of a medical professional reassures the patient that the sensations experienced are a normal part of the RigiScan test and not harmful. In addition to helping acclimate the patient to the test, a Characterization Session establishes baseline tumescence data that is used to maintain the loops at the proper diameter for the patient's penis so that the loops remain in place during nocturnal testing. The RigiScan monitor is programmed to automatically record the first 15 minutes of monitoring as a Characterization Session. After the monitor is initialized, the first power on will trigger the start of monitoring. If the RigiScan is turned off within 15 minutes, the data recorded will be stored as a Characterization Session and reflect the measurements obtained during the in-office session. If, after the first power on, the RigiScan monitor is allowed to run for more than 15 minutes, the instrument will NOT record a Characterization Session. Instead, the instrument is programmed to begin monitoring for the first full session (Session 1). If this occurs, the RigiScan will use the first 30 minutes of data collected and categorize that data as a Characterization Session and then continue monitoring for up to a total of 10 hours.

Downloading. Transferring data stored in the RigiScan monitor to the PC for analysis, printout, and storage.

Initialization. This procedure prepares the RigiScan monitor for the next patient. It erases all data from the RigiScan monitor's memory and stores the next patient's profile, including the Patient ID and date and time of initialization.

Loops. The circular penile sensors that attach to the penis (base and tip) to measure rigidity and tumescence. They accommodate a range in penile circumference from 5.0 cm to 15.0 cm.

Monitoring. This term refers to the collecting of rigidity and tumescence data with the RigiScan monitor. It can be ambulatory or Real-time.

Nocturnal Mode. A testing mode conducted at night while the patient sleeps. This mode uses the entire session to calculate a baseline for evaluation.

Provocative Mode. A testing mode that monitors a patient's erectile response to a provocation intervention, such as pharmacological injections or visual sexual stimuli. This mode uses only the first fifteen minutes of tumescence data to calculate a baseline for evaluation.

Qualified Erectile Event. Periods of erectile activity are considered qualified events when a 20 percent increase in tumescence over the baseline tumescence occurs persisting for a period of at least three minutes then returning to the baseline for at least five minutes.

Real-time. The output of data on the computer screen as the RigiScan monitor collects it. This can be done in both the nocturnal and provocative modes.
Note: While the data is being displayed on PC, it is not being saved. To capture/save the displayed Real-Time data, you must end the Real-Time session, re-establish communication, and then download the session.

Rigidity. The degree of hardness of the penis. The RigiScan Software measures rigidity as a percentage.

Rigidity Activity Units (RAU). This value is a time intensity measurement that represents the area under the rigidity curve during a qualified event. The Rigidity Activity Unit is calculated by summing the rigidity values for the duration of a qualified event and dividing by 2 times 100. The value 2 is used because there are two rigidity samples taken per minute, and the value 100 is used to remove the percent.

Session. A monitoring period between fifteen minutes and ten hours in length. The RigiScan monitor will store the data from three sessions and one Characterization Session in its memory. The RigiScan monitor may be intermittently turned off for periods of up to fifteen minutes to allow time for the patient to urinate. If the RigiScan monitor is turned off for less than fifteen minutes, monitoring will resume in the same session when the monitor is turned back on. If the monitor is turned off for more than fifteen minutes, the current session ends and the monitor will begin the next session when it is turned on again. In order for data collected during any one of the three nocturnal monitoring sessions to be permanently stored in the RigiScan monitor Memory, it must first be qualified. A session is qualified when the RigiScan monitor is allowed to gather at least fifteen minutes of data before ending the session. If the monitor does not collect a minimum of fifteen minutes of data before the session ends (the monitor is turned off for more than 15 minutes), the session is not qualified and the data will be overwritten the next time the monitor is turned on (this does not apply to the Characterization Session).

Tension Guides. A Tension Guide is an assembly comprised of an internal steel wire and an external protective sheath. The steel wire is terminated with a ball on one end and a brass barb on the other end. The wire is housed inside a sheath that allows the wire to move freely inside the assembly. The Tension Guides are formed into loops using disposable cloth covers to enable patient monitoring. The RigiScan uses two different Tension Guides which are not interchangeable. The Tip Tension Guide is longer than the Base Tension Guide. It is important to insert the correct Tension Guide into the correct port. See Section 4.2 for additional information on Tension Guide identification and installation.

Tumescence. The circumference of the penis, measured in centimeters.

Tumescence Activity Units (TAU). This value is a time-intensity measurement that represents the area under the tumescence curve above the baseline during qualified events. It is proportional to the percent increase in tumescence over baseline. The Tumescence Activity Unit is calculated by summing the tumescence value minus the baseline tumescence and dividing by 4 times the baseline. The value 4 is used in the calculation because there are four tumescence samples taken per minute.

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Appendix A: Product Specifications

Physical Dimensions

Size
Width: 13.34 cm
Length: 21.60 cm
Height: 5.08 cm

Weight
0.862 kg

Power Source

Battery
Two DURACELL
9V Alkaline Batteries
or
Two GOTOP Approved
Rechargeable 9V Batteries

Temperature

Operating	Storage/Transit
5° to +40° C	-25° to +70° C

- time required to warm from the minimum or cool from the maximum storage temperature until ready for use when the ambient temperature is 20 °C: 15 minutes

Measurement Range

Rigidity: 0% to 100%
Tumescence: 5 cm to 15 cm

Humidity

Operating/ Storage/ Transit
0% to 90% non-condensing

Atmospheric Pressure

Operating/ Storage/ Transit
700 hPa - 1060 hPa

Ingress Protection Rating

IP22

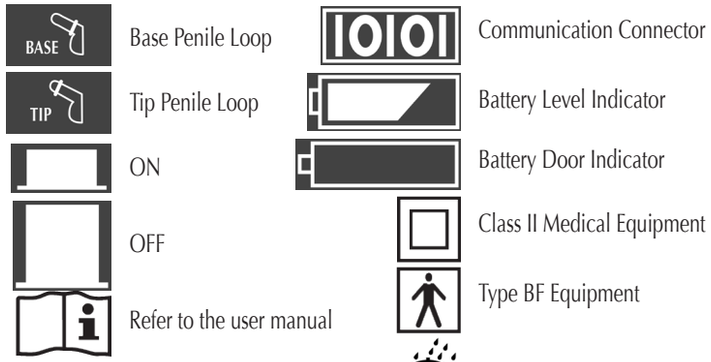
IP Rating from solid objects is rated 2 (Protected against solid objects over 12 mm, e.g. persons fingers).

IP Rating from liquids is rated 2 (Protected against direct sprays of water up to 15° from the vertical).

Motors

12V ⎓	0.9 W
Micromo Electronics	1624 E Ø 125
Gearhead	16/5 262:1

Indicators



Base Penile Loop
Tip Penile Loop
ON
OFF
Refer to the user manual
Communication Connector
Battery Level Indicator
Battery Door Indicator
Class II Medical Equipment
Type BF Equipment
Keep Dry

This is intended to alert the user to the presence of important operating and maintenance instructions in the literature accompanying the product

This exclamation point within a triangle is intended to alert the user that there is a caution

This is a warning symbol

GOTOP Medical, Inc.
1000 Westgate Drive, Suite 125
St. Paul, MN 55114, U.S.A.
Phone: 651.641.3621 Fax: 651.641.3622

EC REP
Atlantico Systems Ltd.
34 Oldfield - Kingston, Galway
Republic of Ireland. Tel: +353 91 443609
SRN: IE-AR-000000208

CCYY-MM Manufactured Date

MD Medical Device

CCYY-MM Expiration Date

CE 2862 CE Mark

℞ Use only when prescribed

Dispose of Properly in Accordance to Local and Federal Laws

Appendix B: Patient Instructions

The following pages lists instructions for the patient to follow in the use of the RigiScan monitor. Provide these instructions to the patient for times not under direct physician supervision.

WARNING: ***It is the responsibility of the physician to assure that adequate instructions and orientation regarding use of the RigiScan monitor are given to the patient. These instructions are provided as a reference only and are not intended to replace the instructions given by the physician. Inadequate instruction may result in patient injury.***

Patient Instruction Sheet

Warning! The RigiScan system is for use only on order of a licensed physician.
Warning! The RigiScan system is for use only by male patients of at least 18 years of age.
Warning! DO NOT turn on the RigiScan monitor until you have placed the loops on your penis. Doing so may result in penile pain, irritation or bruising.
Warning! DO NOT remove or loosen cables from the RigiScan monitor. If the cables are not firmly connected to the monitor, patient injury may result from over tightening of the loops.
Warning! DO NOT use the RigiScan system if the loops or connecting cables are worn or damaged in any way. Doing so may result in patient injury from over tightening of the loops.
Warning! DO NOT engage in any sexual activity, such as intercourse, oral sex or masturbation during RigiScan testing. Doing so may result in patient injury or erroneous data.
Warning! DO NOT bath or shower while wearing the RigiScan monitor. Getting the monitor wet could cause electrical shock or damage to the monitor.
Warning! Turn off the RigiScan monitor before urinating. Urinating with the monitor on may cause pain, irritation or blood in the urine.
Warning! DO NOT use electric blankets, electric razors, power tools, microwave ovens, hair dryers or cellular phones while operating the RigiScan system. These appliances may interfere with operation of the monitor or cause erroneous recordings.
Warning! DO NOT wear the loop covers continuously for more than 24 hours.

Placing the RigiScan Plus Monitor into Protective Bag

Slide the RigiScan monitor in the protective bag so that the resealable flap is on the back (see Figure B-1). Then, cut the flap from the top by the resealable adhesive lip straight down towards the middle of the tension guides (see Figure B-2).

Fig. B-1 Placing the RigiScan into the Protective Bag

The flap needs to be cut so each side can fold around the two tension guides coming out from the top of the RigiScan. Fold the flaps down around the front of the RigiScan and around the tension guides.

Fig. B-2 Cutting the Flap for access to the Tension Guides

Putting on the RigiScan Plus Monitor

Stand comfortably. Wearing loose fitting clothing or pajamas, wrap the leg strap (supplied in the carrying case) around the thigh of either leg with the pocket opening toward your penis (see Figure B-5). If you sleep on your left side, attach the strap to your left thigh, and if you sleep on your right side, attach the strap to your right thigh. The strap should be comfortably snug.

Slide the RigiScan monitor, now sealed into a protective bag, into the leg strap pocket.

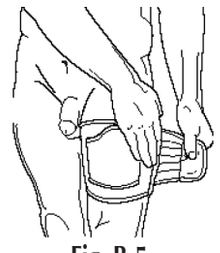


Fig. B-5

The loops are labeled on the wide end of the RigiScan monitor as BASE and TIP . The Base Loop has the blue end and the Tip Loop has the white end. Place the Base Loop around your penis approximately 1/4″ (6 mm) from the base of your penis. Place the Tip Loop around the end of your penis about 1/4″ (6 mm) from the glans or head of your penis (see Figure B-6). You may have to stretch your soft penis to place the loops properly. If the loops are too small to let you put them on comfortably, insert two fingers into the loop and gently pull outward to widen them (see Figure B-7). The RigiScan monitor will adjust the loops when it is turned on.

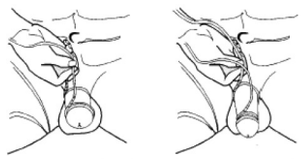


Fig. B-6 Placing the Base and Tip Loops

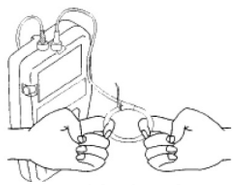


Fig. B-7 Widening the Loops

Starting a RigiScan Plus Session

To turn the RigiScan monitor on, press the on/off button until it clicks and the button stays in. To turn off the RigiScan monitor, press the on/off button until it clicks and pops out (see Figure B-8). The RigiScan monitor will beep once when activated the first night, twice the second night, and three times the third night. Once you have the RigiScan monitor and loops in place, hold the loops while you turn on the RigiScan monitor to make sure the loops stay in place on your penis. Once the RigiScan monitor is turned on, the base loop, followed by the tip loop, will slowly become smaller to fit snugly around your penis. Once the unit has adjusted the loops, you can let go of them. The loops will squeeze gently around your penis every 15 seconds and will continue through the full session (up to ten hours). This is how the RigiScan monitor measures your erections. Be careful not to kink or bend the cables sharply. To interrupt the session for any reason, such as using the toilet, press the on/off button to turn off the RigiScan monitor. You can leave the monitor off for up to fifteen minutes. Be sure to hold the leg strap and monitor in place when standing or walking. When you are ready to go back to sleep, turn the monitor on again.

Fig B-8 Turning on the RigiScan monitor.

NOTE*: You may leave the loops in position when urinating, but remember to turn off the RigiScan monitor before urinating. Hold the leg strap and monitor in place when standing or walking. Make sure to turn the monitor back on within fifteen minutes.*

Removing the Loops Quickly

Normally, you would remove the loops by first turning the RigiScan instrument off and then inserting your fingers gently into the loops and pulling outward to expand the loops as shown in Figure B-7. However, if you experience pain during testing or need to remove the loops quickly for any other reason, you can unsnap the loops with the quick release tab. To do this, follow these steps (see Figures B-9A and B-9B).

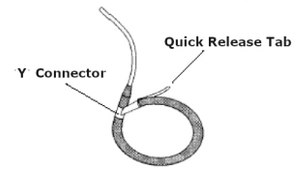


Fig. B-9A

1. Turn the RigiScan instrument off! The patient MUST turn the RigScan instrument off or testing will continue which will cause damage to the RigScan instrument.
2. With one hand, grasp the loop at the “Y” connector.
3. With the other hand, grasp the quick release tab and pull it sharply until the two ends of the loops come apart.
4. In general, patients should be discouraged from unsnapping the loops. Simply turning the instrument off should allow the patient to manually expand the loops and quickly relieve any discomfort.

If you had to remove the loops quickly due to pain or discomfort, please discontinue testing and contact your physician’s office for further instruction.

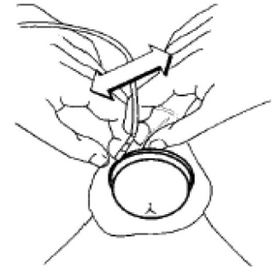


Fig. B-9B Removing the Loops quickly

If you accidentally pulled the loops apart or they somehow accidentally separated, please turn the RigiScan system off and reassemble the loop or loops. Next, place the loops back onto your penis and turn the RigiScan on. Hold loops in place until both the base and tip loops are under gentle tension. Testing should return to normal. However, if testing appears abnormal or you experience pain as testing resumes, please turn off the RigiScan monitor and contact your physician’s office for further instruction.

When you Wake the Next Morning

When you wake the next morning first turn off the RigiScan monitor.

Ease the loops off your penis by gently inserting your fingers into the loops and pulling slightly outward to widen them.

Remove the RigiScan monitor from the leg strap pocket and remove the leg strap from your leg. To replace the batteries, open case. Place the strap and RigiScan monitor back in the carrying case.

Wipe the RigiScan Monitor with a moist cloth if any debris or build-up are observed.

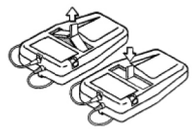


Fig. B-10 Replacing the Batteries

REMEMBER! If you have any questions, do not hesitate to contact your doctor's office. If further assistance is needed in setting up or using the RigiScan, or to report unexpected operation or events, contact GOTOP Medical or your local GOTOP Medical representative. Contact GOTOP Medical via http://gotopmedical.com/contact-us.html, or Email:info@gotopmedical.com

Replace/recharge the batteries before each session. If using alkaline batteries, fresh batteries are supplied in the carrying case. Dispose of used alkaline batteries in accordance with applicable regulations. If using rechargeable batteries, place them into the approved battery charger so they are fully charged for the next session. Remove the old batteries by pulling on the black ribbon between the two batteries, and insert new batteries as indicated by the image inside the battery cavity.
(see Figure B-10)

Appendix C: Troubleshooting Guide

Below are some potential issues which may be encountered.

Communication Error Message?
Port not selected or wrong port selected; See User Guide 3.3 RigiScan Control Window (page 15) and 3.7 RigiScan Settings Window (page 37).

If possible, try connecting the cable to a different USB port, and then select that port.

USB extension cable or USB hub used that causes signal interference.

Non-USB communication cable used? The earlier generation communications cable does not work with the Gen 4 RigiScan, also not with an external USB adapter.

USB communication cable defective? If so, requires replacement or repair. Contact GOTOP Customer Service.

Security block of port? Are the security settings of the computer blocking access to the communication ports? Contact your institution's IT department.

Is it a Generation 4 RigiScan? The Gen 4 version of the RigiScan uses the same "D" connector as earlier generations of the RigiScan. The Gen 4 supports communication via a USB port on the computer. Although the Gen 4 USB communication cable mechanically fits earlier generations, it will not provide communication over the USB. GOTOP offers upgrades of the electronics, and software for earlier generations to the current Gen 4. Contact GOTOP Customer Service.

Device not registered Message?
See User Guide 3.3 RigiScan Control Window (page 15). The "devices" file is like a license "key" to allowing the software to work with specific serial numbered devices. Contact GOTOP Customer Service.

Calibration Due Message?
See User Guide 3.3 RigiScan Control Window (page 18). The calibration due date referenced by the software is not carried in the RigiScan monitor, but rather in the devices.adl file corresponding to the unit. When a RigiScan is calibrated by GOTOP Medical, a new devices file is supplied. That file needs to replace the old devices file in the same folder as the RigiScan program.

RigiScan will not run?
Has the monitor been initialized for the patient? The RigiScan Monitor will only record 3 sessions in memory. It will not record a 4th without being initialized. See User Guide 3.3 Initializing the Monitor (page 18). There is a beeper inside the RigiScan Monitor which gives cues as to how many sessions are already recorded, or if it is full. See User Guide 5.3 Beep Cues (page 56). The beeper is not very loud. It is located on the right side near the thin end of the case.

9V Batteries dead? See User Guide 4.6 Installing the Batteries (page 49). The Yellow LED indicator light may be on when the battery is low.

Battery contact smashed? The spring contacts for the 9V batteries may have been deformed and need to be retensioned to make contact with the battery terminals.

Red LED is on? If the red LED in the 9V battery box is on, the internal Lithium battery is low and needs to be replaced. Contact GOTOP Customer Service.

Bad results?
Check the tension guides. Remove the Tension Guides from the monitor. Does the steel cable slide smoothly through the guide? To test the friction of a Tension Guide, if you pick it up at the ball or the male crimp then the outer guide should slide down the cable under its own weight. If the cable is kinked, or if the Teflon liner tube is kinked, the cable may not slide smoothly and the tension guide needs to be replaced or repaired. If the inner liner tube has come loose and is extending at either end of the Tension Guide the Guide needs to be replaced or repaired.

Cannot install Tension Guide?
Note that the Tension Guide for the Base and Tip are different. The Tip Tension Guide will not fit in the port for the Base Guide.

If RigiScan was allowed to run with Base Tension Guide installed at Tip position or a Tension Guide was improperly removed, the Tip may be "out of registry". This requires repair of the RigiScan. Contact GOTOP Customer Service.

Cannot remove Tension Guide?
When removing a tension guide, the bayonet fitting has to be left in the port and locked until the cable within the tension guide is pulled out all the way. If not, the internal mechanics are locked in place and pulling with force only damages the tension guide.

If you cannot turn the bayonet fitting, make sure that the plastic nut used to "lock" the fitting is unscrewed far enough.

Appendix D: References

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12. Levine LA, Carroll RA: Nocturnal penile tumescence and rigidity in men without complaints of erectile dysfunction using new quantitative analysis software. J. Urol. 1994, Oct., 152(4), p 1103.

Appendix E: Electromagnetic Declaration

Notes and Cautions

This symbol means: Attention, consult accompanying documents.

This symbol indicates Type BF equipment.

CAUTIONS:

This device is not intended for use in the presence of flammable mixtures.

This device requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.

This device may be affected by portable and mobile RF communications equipment.

This device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the RigiScan should be observed to verify normal operation.

NOTE ON CLASSIFICATION:

This device is classified as internally powered.

This device is classified Type BF equipment for protection against electrical shock.
This device is classified as ordinary equipment without protection against ingress of water.
This device is classified as suitable for continuous operation

NOTE ON DISPOSAL:

This device contains electronic components and should be disposed of according to local, state and national regulations. Please contact your local authorities for proper disposal of small electronics devices. Remove batteries and recycle them according to regulations as well. Many retail outlets that sell batteries provide for free recycling.

Guidance and manufacturer's declaration - electromagnetic emissions

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

Emissions Test	Compliance	Electromagnetic environment — guidance
RF emissions CISPR 11	Group 1	The RigiScan Plus uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Group B	The RigiScan Plus is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic IEC 61000-3-2	TBD	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	TBD	

Guidance and manufacturer's declaration - electromagnetic immunity

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

IMMUNITY test	Compliance		Electromagnetic environment – guidance –
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air		Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power Supply lines ± 1 kV for input/output lines	±2 kV for power Supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(S) ± 2 kV line(s) to earth	± 1 kV line(s) to line(S) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % (IT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in U-1) for 5 cycles 70 % (IT (30 % dip in UT) for 25 cycles <5 % UT 180° (>95 % dip in UT) for 0.5s	<5 % (IT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in U-1) for 5 cycles 70 % (IT (30 % dip in UT) for 25 cycles <5 % UT 180° (>95 % dip in UT) for 0.5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the RigiScan Plus requires continued operation during power mains interruptions, it is recommended that the RigiScan Plus be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration - electromagnetic immunity

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

IMMUNITY test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance –
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the RigiScan Plus, including cables, than the 'recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1.20 d = 1.24P 80 MHz to 800 MHz d = 2.30 800 MHz to 2.3 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range*. Interference may occur in the vicinity of equipment marked with the following symbol**: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

*Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the RigiScan Plus is used exceeds the applicable RF compliance level above, the RigiScan Plus should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the RigiScan Plus.
**Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the RigiScan Plus

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

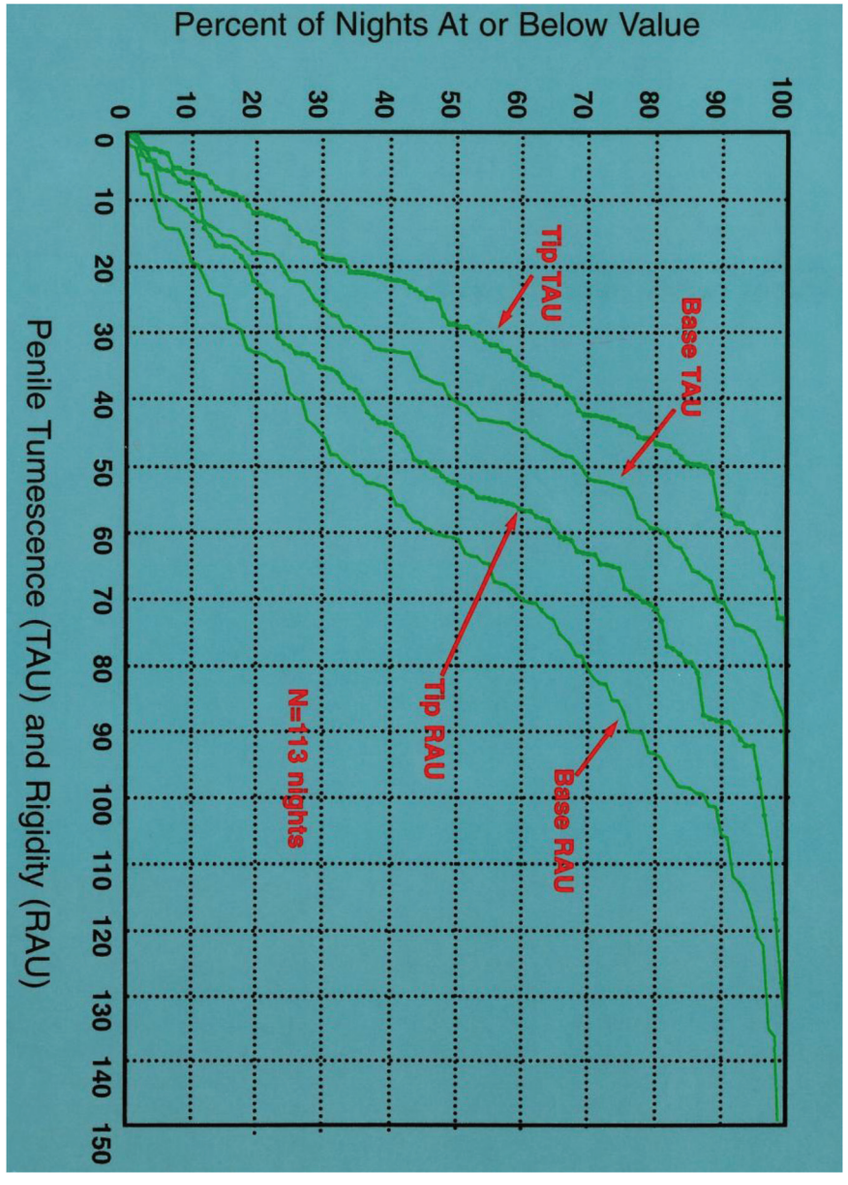
Rated maximum output power of 150 kHz to 80 MHz (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz d= 1.2 P	**80 MHz to 800 MHz** d = 1.2 P	**800 MHz to 2.5 GHz** d = 2.3 P
0.01	0.12m	0.12m	0.23m
0.1	0.38m	0.38m	0.76m
1	1.2m	1.2m	2.3m
10	3.8m	3.8m	7.6m
100	12m	12m	23m

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

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

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Appendix F: RigiScan Plus Nomogram



Appendix G: Limited Warranty

RIGISCAN® PLUS SYSTEM AND ACCESSORIES

A. This limited warranty applies only to the hospital or physician (hereinafter referred to as "CUSTOMER") purchasing the RigiScan Plus System from GOTOP Medical , Inc.

This is limited warranty assured the CUSTOMER the GOTOP Medical, Inc. will replace or repair any RigiScan Plus System which malfunctions in the course of normal operations within one year from the date of invoice due to defects in parts or workmanship. Ancillary components, consumable, computer support equipment or peripherals are not warranted by GOTOP Medical.

B. THE FOREGOING WARRANTY IS IN LEIU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED. INCULDING WITHOUT LIMITATION WARRANTIES OF MERCHANTABILITY AND FITNESS FOR ANY PURPOSE.

LIMITATIONS OF REMEDIES:

1. THE SOLE AND EXCLUSIVE REMEDY FOR GOTOP Medical, INC. AND LIABILITY OF ANY KIND INCLUDING LIABILITY OR NEGLIGENCE WITH RESPECT TO PRODUCTS SHALL BE LIMITED TO THE REMEDY PROVIDED IN THIS WARRANTY.
2. GOTOP Medical, INC. SHALL NOT BE LIABLE, IN ANY EVENT, FOR CONSEQUENTIAL OR SPECIAL DAMAGES IN CONNECTION WITH SERVICE, PARTS AND LABOR HEREUNDER OR RESULTING FROM ANY USE OR FAILURE INCLUDING, WITHOUT LIMITATION, LIABILITY FOR CUSTOMER'S EXPENSE OR LOSS OF INCOME WHILE SYSTEMS ARE OUT OF OPERATION.
3. GOTOP Medical, INC. SHALL NOT BE LIABLE FOR ANY MEDICAL EXPENSES OR DAMAGES RESULTING FROM THE USE OF THIS SYSTEM OR THE INTERPRETATION OF THE DATA CAUSED BY ANY FAILURE OR MALFUNCTION OF THE PRODUCT.

To qualify for the remedy provided by this limited warranty, the CUSTOMER must meet the following conditions:

- The instruction for use in the RigiScan Plus Users Guide must be followed.
- No modification, adjustments, repairs or alteration shall have been made to any of the software, monitor, or ancillary components supplied by GOTOP Medical, Inc.

A warranty determination cannot be made until repairs have been completed. Accordingly, the CUSTOMER may be responsible for the cost of non-warranted service, parts and freight.

Upon determination of the nature and cause of the malfunction, GOTOP Medical, Inc. will issue a "no charge" invoice for services and parts covered by the warranty. Charges not covered by warranty will be invoiced to the purchaser at the GOTOP Medical, Inc. current rates for labor and materials.

Examples of components not covered by this limited warranty include, but are not limited to:

- Monitor loop/cable replacements required due to normal wear and soiling.
- Monitor loop/cable replacements required due to improper disinfection techniques, physical damage, and stains or stretching of the Tension Guides.
- Electronic components damage resulting form the fluids inside the monitor.
- Communication cables, leg straps, carrying case, batteries, disk, AC/DC adapter
- Routine calibration of the monitor.

Address all questions regarding this warranty to a GOTOP Medical, Inc. Service Representative at 651-641-3621

NOTES:

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GOTOP MEDICAL

GOTOP Medical, Inc.,
1000 Westgate Drive, Suite 125,
St. Paul, MN 55114
U.S.A.

P 651.641.3621
F 651.641.3622

www.gotopmedical.com

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