



# AUDICOR® Trending System

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## Operating Summary

Software version 1.3



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Other US and foreign patent coverage pending.

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# PREFACE

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## Contact Information



Inovise Medical, Inc.  
8770 SW Nimbus Avenue  
Suite D  
Beaverton, Oregon 97008-7196  
USA



Authorized Representative for the CE Mark:  
Priory Analysts  
The Atrium, Park Street West  
Luton, LU1 3BE, United Kingdom

## Customer Support

### Online Support

Useful AUDICOR TS information (including a downloadable version of this user's guide) and e-mail support.

[www.audicor.com](http://www.audicor.com)

### Telephone Support

Customer Support in English regarding installation and operation of AUDICOR TS.

Telephone:  
1-503-431-3800

Toll-Free USA:  
877-466-8473  
(877-INOVISE)

### Fax and E-Mail Support

FAX: 1-503-431-3801

Email: [productsupport@inovise.com](mailto:productsupport@inovise.com)

World Wide Web  
<http://www.audicor.com>

## Intended Use

**Rx Only** Federal law restricts the sale of the device identified in this manual to, or on the order of, a licensed medical practitioner.

This manual is intended for use by medical practitioners who perform computer-aided phonocardiography, electrocardiography (ECG) and similar tests, and for physicians who interpret heart sounds and ECG data.

The Audicor System, when used with Audicor Sensors on the chest wall, is intended for use in acquiring, analyzing and reporting heart sound data and to provide interpretation of the data in an integrated ACG (acoustic cardiograph) report for consideration by physicians. Audicor systems allow detection, reporting and interpretation of advanced parameters such as Electro-Mechanical Activation Time (EMAT), Left Ventricular Systolic Time (LVST), third heart sound (S3) strength, fourth heart sound (S4) strength, and the Systolic Dysfunction Index (SDI)

The AUDICOR interpretive statements and graphics are designed to enhance the diagnostic process. They are no substitute for the qualified judgment of a properly trained, supervised clinician. ECG and heart sound data offered by the device are only significant when used in conjunction with physician over read as well as with any diagnostic test, always give consideration to patient symptoms, history and other relevant factors.

AUDICOR testing is indicated for patients who present with cardiac symptoms, including shortness of breath, and for patients who are at risk for heart disease.

AUDICOR testing is indicated only for patients 18 years of age or older. AUDICOR TS analyses are not valid for patients under 18 years of age.

# Conventions and Notations in This Book

## Conventions

**text** indicates a button or key that you select or press.

## Notations



**Warning** statements identify conditions or practices that could result in injury to patients or users.



**Caution** statements identify conditions or practices that could result in damage to equipment or other property.



**Notes** provide additional information about a feature or process.



**Tips** convey helpful information about how to use the AUDICOR TS system.

## Related Publications

Publication	Part number
<i>AUDICOR TS Quick Reference Guide</i>	40188

# AUDICOR TS Warnings and Cautions



**Warning** AUDICOR analyses are not valid for patients under 18 years of age.

**Warning** Before performing defibrillation or applying any high frequency surgical equipment to a patient, remove AUDICOR sensors, AUDICOR adapter connector and ECG electrodes from the chest area. Sensors or electrodes trapped under defibrillator pads or paddles during defibrillation or sensors or electrodes in contact with high frequency electrosurgical equipment can cause patient burns.

**Warning** Use only Ag/AgCL-type ECG electrodes with AUDICOR sensors. Other types of electrodes might result in a leads off condition and incomplete AUDICOR or ECG reports.

**Warning** AUDICOR Sensor 4.0 is a single use device. Do not reuse single use devices due to risk of spreading infection, blood born pathogens and contamination.

**Warning** Once the AUDICOR sensors or one or more ECG electrodes are connected to a patient, do not allow patient cable connectors or AUDICOR adapter connectors to meet with any grounded or live parts. Contact could cause unacceptable levels of electrical current to flow to the patient.

**Warning** The quality of ECG and sound signals reported by the AUDICOR TS system may be adversely affected by electromagnetic interference from environmental sources resulting in non-physiological waveforms with the potential for misinterpretation.

**Warning** Do not use in the presence of flammable gasses.

**Warning** Damaged, abused or mishandling of this device could result in delays in diagnosis and treatment as well as electrical shorts and could also create a fire hazard.

**Warning** **Battery may explode or catch fire if mishandled:**

- Do not disassemble or incinerate
- Do not charge except as specified in the instructions
- Do not heat above 60°C (140°F)
- Do not crush
- Do not immerse in water/liquids or cleaning fluids
- Do not abuse or mistreat the battery
- Do not attempt to use a corroded or damaged battery



**Warning** AUDICOR may not be suitable for patients with extremely fragile skin or patients with open wounds/lesions at or immediately adjacent to electrode and sensor positions. AUDICOR may not be appropriate for patients that have skin allergies or are otherwise sensitive to the disposable electrodes and or the AUDICOR sensors used with the system.

**Warning** Should a mild or severe skin reaction to the sensor adhesives occur, discontinue use immediately. In this case the patient may experience notable discomfort, pain or burning sensation or a skin rash in and around the sensor area. Clean the affected area of all adhesive residue and apply topical relief as prescribed by the patient's physician. For ECG electrodes check manufacturer's information for instructions.

**Warning** Connect the AUDICOR TS and printer power supplies only to the power strip provided with the system. Plugging these devices directly into wall power may result in current leakage in excess of limits permitted by IEC-60601-1.

**Warning** Do not connect any devices other than the AUDICOR TS power supply and the printer power supply to the power strip that is provided with the AUDICOR TS system. Connecting other devices may result in current leakage in excess limits permitted by IEC-60601-1.



**Caution** Use only your fingers, the stylus or the top of a pen to touch the display screen. The ink-end of a pen may cause damage.

**Caution** Align connector and port markers before you plug in connectors. Forcing misaligned connectors can damage connector pins.

**Caution** Attach only AUDICOR adapters to AUDICOR sensors. AUDICOR sensors will not function with other adapters.

**Caution** Ensure system remains plugged into AC/Mains at all times when not in use. NOTE: The AUDICOR console date and time must be reset if the main battery is depleted or replaced.

**Caution** To ensure proper patient isolation and signal quality, securely and properly connect all cables to the AUDICOR TS console before you attach lead wires to the patient.

**Caution** Do not allow cables to dangle into the printer area; they can jam the printer at the paper input tray and in the wire paper catcher area.

**Caution** The Multiple portable socket outlet that is provided with the AUDICOR TS system should not be placed on the floor.



- Caution** Simultaneously attaching patient leads for another device to the same patient could cause the ECG signals to be corrupted.
- Caution** Only use Inovise supplied AC cords and country specific AC/Mains adapters. Look for Inovise Medical and or the AUDICOR brand as an initial measure of compatibility.
- Caution** Dispose of used batteries properly and according to local standards for Lithium-ion batteries. Keep away from children. Do not disassemble and do not dispose of in fire.
- Caution** The AUDICOR System is equipped with wireless “Bluetooth” communication features for printing. If it appears that AUDICOR interferes with the use or operation of other business or medical equipment within the immediate proximity of the device, discontinue use immediately and notify Inovise Medical, Inc. ([productsupport@inovise.com](mailto:productsupport@inovise.com))
- Caution** The AUDICOR System is not equipped with antivirus software. This medical system should not be network or internet connected for this reason. Adding antivirus/software or any unauthorized software may compromise the clinical results analysis and printing performance of this medical application and therefore void any remaining warranty.
- Caution** To avoid damaging AUDICOR TS components, take the following precautions:
- Do not use organic solvents on any parts of the patient cable or on the AUDICOR TS console.
  - Do not immerse AUDICOR TS components in any type of liquid, including water.
  - Do not perform any type of sterilization procedure on AUDICOR TS components
- Caution** To avoid damaging the console, be extremely careful not to allow fluid into the seams of the console housing, especially at any point where the console screen meets the housing. The AUDICOR TS warranty does not cover damage from fluids applied to the console.
- Caution** To prevent damage to the printer, install (or replace) ink cartridges only when the carriage is in the “ink cartridge change” position. To prevent clogs, ink failure and bad electrical connections, do not touch the ink nozzles or the copper contacts on the cartridges.
- Caution** There are no serviceable parts in the AUDICOR console. Do not open the AUDICOR console except to replace the battery. Doing so voids the warranty.






















**Caution** User Capabilities: The medical personnel performing the AUDICOR test need to have the ability to follow the instructions and guidelines in the User Documentation set which include the Quick Reference Guide, Operating Summary and the AUDICOR sensor insert. Users also need to have sufficient dexterity to hold and manipulate the small objects and connectors associated with the electrode system including the patient cable. The user should first read all accompanying documents before applying AUDICOR to the patient.

**Caution** For those systems equipped with a roll stand, to prevent damage or injury, ensure that the wheels are locked after the system is oriented adjacent to the test subject and also locked when charging and not in use.

# Symbols

The following symbols may appear on the AUDICOR TS and on the AUDICOR accessories.

	Part number/catalog item
	Serial number
	Lot number
	For use by, or on the order of, a physician
	Date of manufacture (yymmdd)
	Manufacturer
	Authorized Representative for the CE Mark
	Defibrillator-proof type of CS equipment
	Consult accompanying documents
	Reset
	External Power
	Serial Port
	USB port
	Headphones
	Contains no Latex
	Use by YYYY-MM-DD
	Audicor Sensor
	Sensor Pouch
	Sensor Box



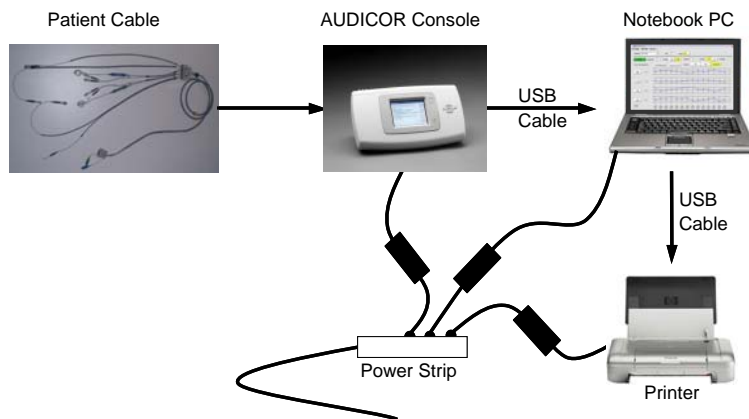
# 2

## PREPARE THE SYSTEM FOR USE

AUDICOR TS consists of an AUDICOR console, patient cable, AUDICOR sensors, printer, and a notebook PC that displays and trends AUDICOR data.

The steps required to set up the AUDICOR Trending System are as follows:

1. Prepare the Patient cable and Connect to AUDICOR Console
2. Connect AUDICOR Console to Notebook PC with a USB cable
3. Connect Notebook PC to Printer with a second USB cable
4. Connect AUDICOR Console to Power Strip
5. Connect Notebook PC to Power Strip
6. Connect Printer to Power Strip
7. Load paper



### Note

While the Notebook PC requires a USB cable to communicate with the printer, the AUDICOR Console interacts with the printer by wireless (Bluetooth) communications. No physical connection is necessary

## Prepare the Patient Cable

### Attach the Tab Adapters to ECG Lead Wires

Connect snap/tab adapters to cardiograph lead wires (all except the V3 and V4 wires).



### Connect the Sound Connectors to the V3 and V4 Lead Wires

1. Align the markers on the connectors, and gently push the AUDICOR SV3 adapter connector into the V3 lead wires connector.



2. Turn the connectors in the direction of the arrows until the connectors lock into place.
3. Repeat with the SV4 adapter and V4 lead wire.

## Connect the Patient Cable to the AUDICOR Console



1. Insert the green SV3 input connector into the green SV3 port on the AUDICOR console.
2. Insert the blue SV4 input connector into the blue SV4 port on the AUDICOR console.
3. Insert the ECG input connector into the ECG IN port on the AUDICOR console.



on Align connector and port markers before you plug in connectors. Forcing misaligned connectors can damage connector pins.

## Connect AUDICOR Console to Notebook PC



1. Insert the USB Communications cable into the AUDICOR console.
2. Insert the USB Communications cable into Notebook PC.

## Connect Notebook PC to Printer



1. Insert the USB Communications cable into the Notebook PC.
2. Insert the USB Communications cable into the Printer.



**Caution** To ensure proper operation, do not install other software applications on Notebook PC.



**Note** Please refer to HP Deskjet 460 Printer documentation for detailed setup instructions. The necessary printer software is already installed on the Console and Notebook PC.

## Connect AUDICOR Console to Power Strip



Connect the appropriate AC power adapter to the AUDICOR console.

Connect the appropriate power cord to the power adapter.

Connect the same power cord to the power strip.

## Connect Notebook PC to Power Strip



Connect the appropriate AC power adapter to the Notebook PC.

Connect the appropriate power cord to the power adapter.

Connect the same power cord to the power strip.

## Connect Printer to Power Strip



Connect the appropriate AC power adapter to the Printer.

Connect the appropriate power cord to the power adapter.

Connect the same power cord to the power strip.

## Connect Power Strip to Outlet



Plug the power strip into a nearby outlet.

Install protector plug into unused outlet

Secure power cords and protector plug to power strip with tie-wraps



**Caution** Do not plug any other devices into power strip.

## Load Paper

Insert up to 50 sheets of plain paper into the tray.

Slide the paper guide snugly against the edge of the paper.



**Note** Please consult your Inovise representative for assistance in configuring test settings and institution name.



**Note** Please refer to instructions provided with optional roll-stand for assembly.


# 3

## START THE SYSTEM

---

1. Turn on the AUDICOR Console.
2. Turn on the Notebook PC.
3. Turn on the Printer.




The AUDICOR TS application should launch automatically when the Notebook PC is powered on. Otherwise, double-click the AUDICOR icon  on the Notebook PC to launch AUDICOR TS.

Data communication between the AUDICOR Console and Notebook PC should begin automatically when they are connected and powered on. Otherwise disconnect the USB communications cable, turn off the console, turn on the console, and reconnect the USB communications cable. A chime and a brief pop-up message on the console will indicate that communication is being successfully established.



**Note** If a “Set Up a Partnership” popup box appears on the display, select the ACQUIRE tab to continue.



**Note** If not in the Verify Trace screen, select the  button in the Patient Information screen on the AUDICOR Console to advance.

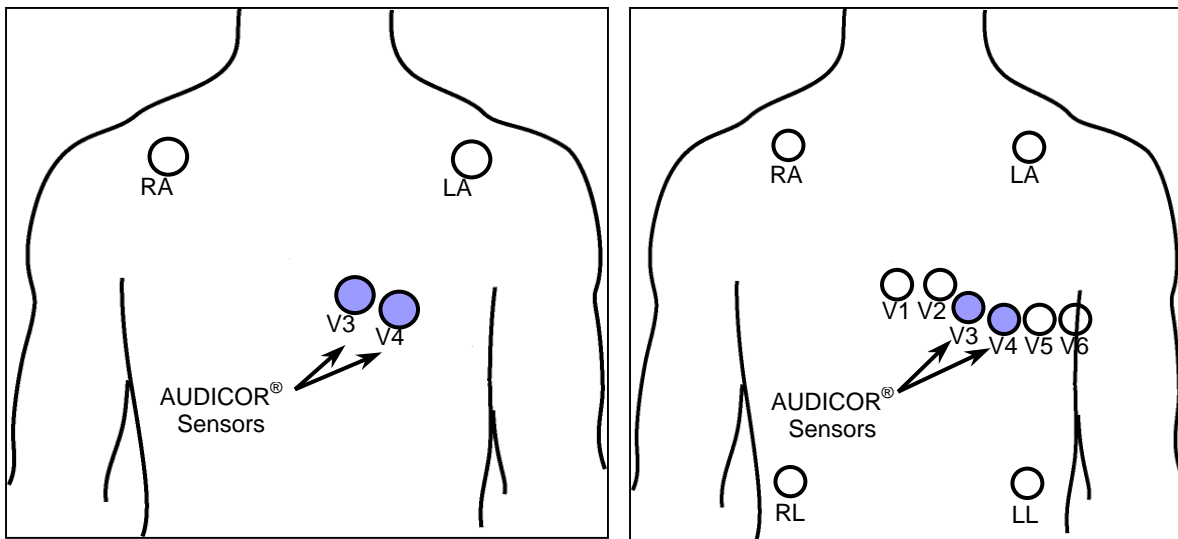
You are now ready to connect the patient.

# 4

## PREPARE THE PATIENT

### Prepare ECG Electrode and AUDICOR Sensor Sites

1 Prepare the ECG sites as usual for a standard 12-lead resting ECG.



**4-Lead Solution Lead Placement**  
Place V3 between fourth intercostal space at left sternal border and V4

**10-Lead Solution Lead Placement**

2 Place tab electrodes and AUDICOR Sensors in these traditional lead positions.

- \*RA – Right arm at clavicle or inner wrist
- \*LA – Left arm at clavicle or inner wrist
- \*V3 – Midway between V2 and V4. Use an AUDICOR sensor here
- \*V4 – Fifth intercostal space left of midclavicular line. Use an AUDICOR sensor here
- RL – Right leg at hip or ankle
- LL – Left leg at hip or ankle
- V1 – Fourth intercostal space at right sternal border
- V2 – Fourth intercostal space at left sternal border
- V5 – Anterior axillary line at same level as V4
- V6 – Midaxillary line at same level as V4

\*Only leads V3, V4, RA and LA are required for the 4-lead solution.

## Apply AUDICOR Sensors and attach Adapters

1. Before applying the AUDICOR Sensors, prepare the patient as you would for a resting 12-lead ECG. Next, press the V3 and V4 adapters securely into the sensor collar until it snaps into place.



2. Remove the release liner from each sensor and apply AUDICOR Sensors to lead positions V3 & V4 with moderate pressure and then smooth the entire pad to ensure good adhesion to the skin. The AUDICOR Sensor blue tab and adapter lead wires should point towards the patients abdomen.



### Application hints:

- For optimal results, position the patient's torso at an angle between 15°-30°.
- Ensure the patient is relaxed and comfortable.
- If the patient has obvious ankle edema (swelling), move the lower-limb electrodes to the upper leg or trunk to get the best ECG signal acquisition
- If chest hair is thick or coarse, shave the sites.
- Using a dry gauze, clean away dirt, perspiration, excessive oils and lotions.
- It is essential for the V3 and V4 positions be properly prepared for good contact between the patient's skin and the AUDICOR sensors.



**Tip** If you experience difficulty achieving clear sound signals at lead positions V3 and V4, reposition the sound sensors to the immediate left and right of the point of maximum impulse (the apex of the heart).



**Caution** Attach only AUDICOR adapters to AUDICOR sensors. AUDICOR sensors will not function with other adapters.

**Caution** Simultaneously attaching patient leads for another device could cause the ECG signals to be corrupted.



**Warning** Once the AUDICOR sensors or one or more ECG electrodes are connected to the patient, do not allow the patient cable connectors or the AUDICOR adapter connectors to meet any grounded or live parts. Contact could cause unacceptable levels of electrical current to flow to the patient.

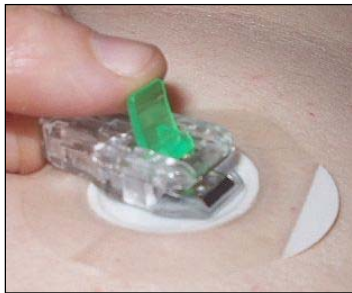
**Warning** Before performing defibrillation or applying any high frequency surgical equipment to a patient, remove AUDICOR sensors, AUDICOR adapter connector and ECG electrodes from the chest area. Sensors or electrodes trapped under defibrillator pads or paddles during defibrillation or sensors or electrodes in contact with high frequency electrosurgical equipment can cause patient burns.

## Attach the Snap/Tab Adapters to ECG Electrodes

- 1a. For tab-style electrodes, lift the green latch on top of the adapter, slip the opening at the front of the adapter onto the free end of the tab electrode and push down the green latch.



- 1b. For snap-style electrodes, lift the green latch on top of the adapter, slip the opening on the underside of the adapter over the top of the snap and push down the green latch.



**Warning** Use only Ag/AgCL-type ECG electrodes with AUDICOR sensors. Other types of electrodes might result in a leads off condition and incomplete AUDICOR or ECG reports.

# Prepare the Area and Calm the Patient

## Minimize Environmental Noise

It is especially important to eliminate as much electrical and acoustic noise from the environment as is reasonably possible before recording. The following situations or conditions can degrade signal quality:

- Touching the patient or the bed
- Electrostatic discharge
- Noise caused by equipment, such as air conditioners and bed motors
- Tangled lead-wires across chest
- Drapes or sheets that move and rub on lead wires, electrodes and sensors

## Calm the Patient

Patient movement affects the acquisition of both electrical and acoustic signals. It is very important to keep the patient as relaxed, quiet and still as possible. Pay particular attention to tension in the neck shoulders and arms. Ensuring the patient is warm, comfortable and these areas are properly supported and relaxed will significantly improve the quality of the recordings. Some patient conditions that can adversely affect the recording are as follows:

- Talking
- Tension
- Body motion
- Coughing
- Twitching
- Muscle tremor
- Obesity
- Swallowing
- Shivering
- Gastro-esophageal noises
- Restricted/Labored breathing
- Clearing nose & throat
- Asthma / bronchitis
- Snoring
- Colds / stuffy nose
- Draping the patient

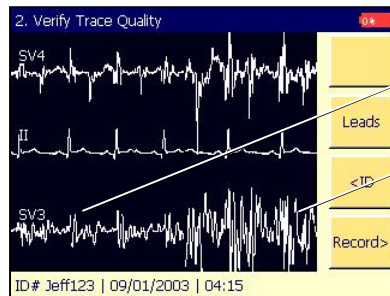
## Verify Clean Sound Traces on AUDICOR Console



Clean Traces



Noisy Traces



A better-quality trace

A poor quality trace

1. Preview the sound trace signal quality.

Acceptable *sound* traces (SV4 and SV3) have clear, well-defined peaks and troughs. Poor-quality sound traces often have many bursts and spikes of significant amplitude and duration.

## Adjust Leads, Patient and Environment if Necessary

If you need to improve the signal quality, check these things.

- Ensure good contact between the patient's skin, ECG electrodes and snap/tab adapters, and the AUDICOR sensors and sensor connectors.
- Verify good contact between all of the patient cable connectors and between the patient cable plugs and their corresponding AUDICOR TS console ports.
- Ensure the patient is quiet, breathing normally and relaxed, especially in the neck and shoulder areas.
- Reposition AUDICOR electrodes and sensors away from other sources of electrical interference such as monitors, patient cables, pacemaker wands, bed motors, etc. Limb leads may be repositioned from shoulders and hips to wrists and ankles.
- If possible, temporarily turn off or disconnect other sources of electrical interference such as monitors, patient cables, pacemaker wands, bed motors, etc.
- Minimize equipment noise in the room and refrain from touching the patient or patient's bed.



**Tip** For optimal results, elevate the patient's torso at a 15-30 degree angle.

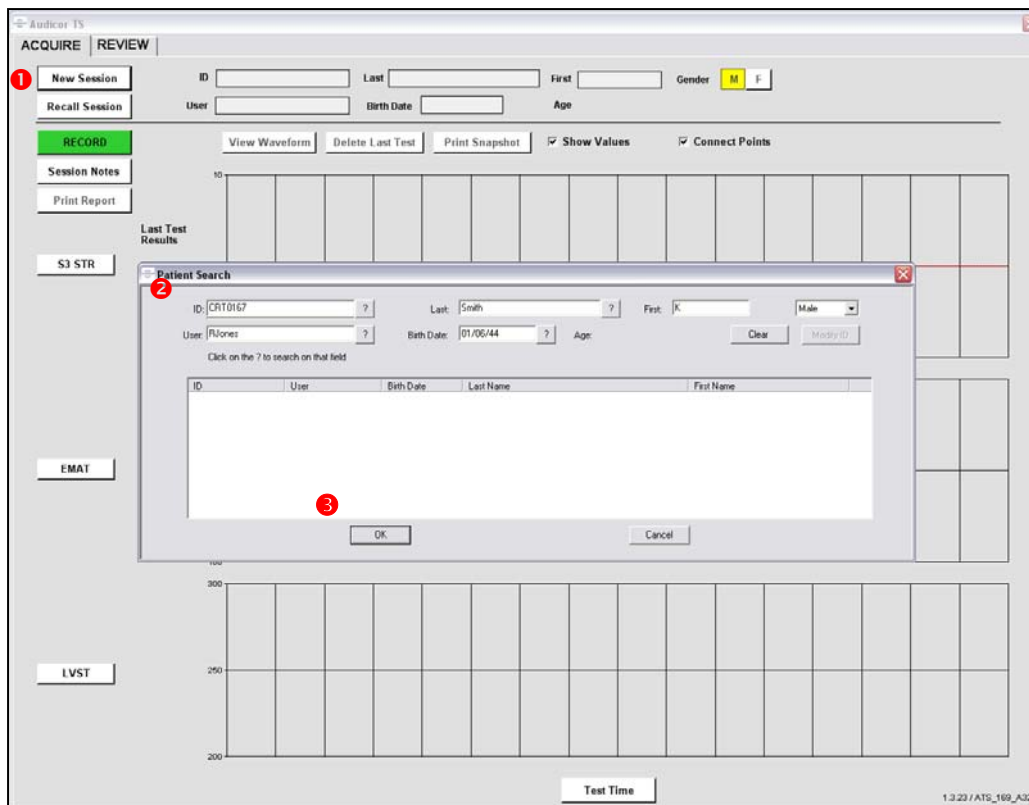


**Tip** Draping the patient may create waveform noise and artifact as the drape moves across the sensor or sensor patient cables. If it is necessary to drape for warmth or privacy in the area of the AUDICOR sensors, create a space (tent) between the sensors, the cables and the drape to keep them from rubbing together and generating noise and artifact.

# 5

## RECORD A TEST

### Enter Patient ID



- 1 In the ACQUIRE tab, select **New Session**.
- 2 For existing patients, enter any piece of identifying information, then select "?" to activate the search. The available matches found will appear below the pane. If the patient search is successful, select the correct entry in the pane (the entry will be highlighted in dark blue).

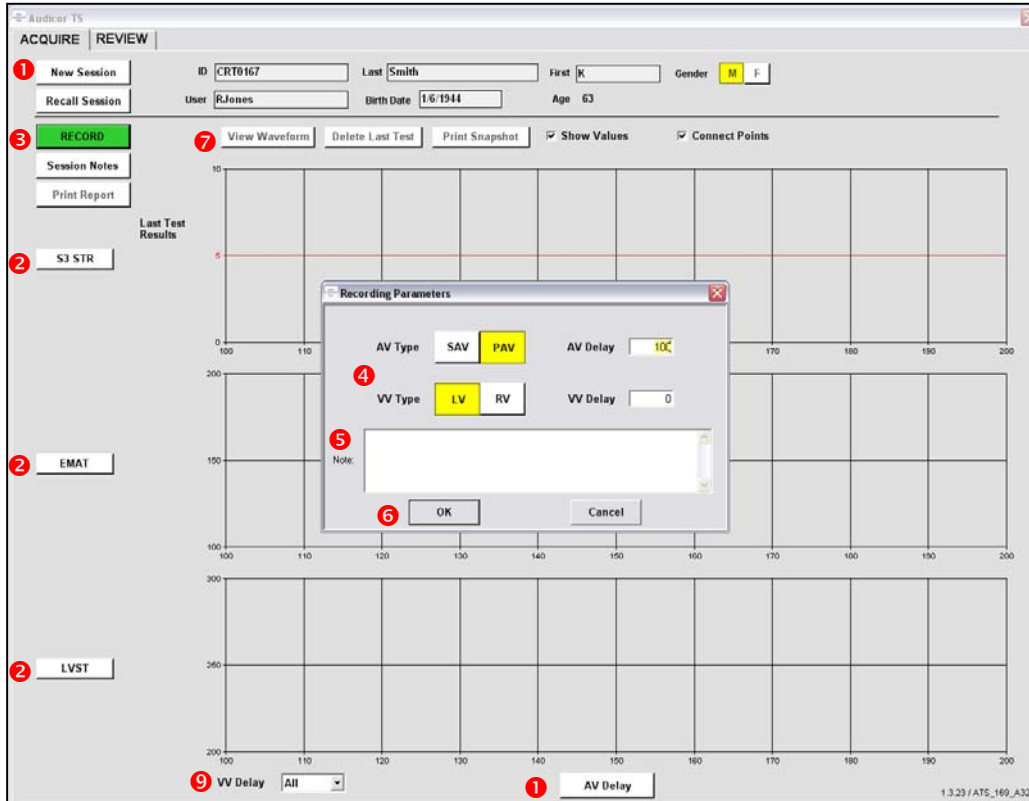
For new patients or if patient is not found, enter ID. You may also enter last and first name, gender, and birth date if desired

- 3 Select **OK**.



**Caution** The Patient ID is used as an identifier for data storage; ensure that a unique one is assigned for each patient.

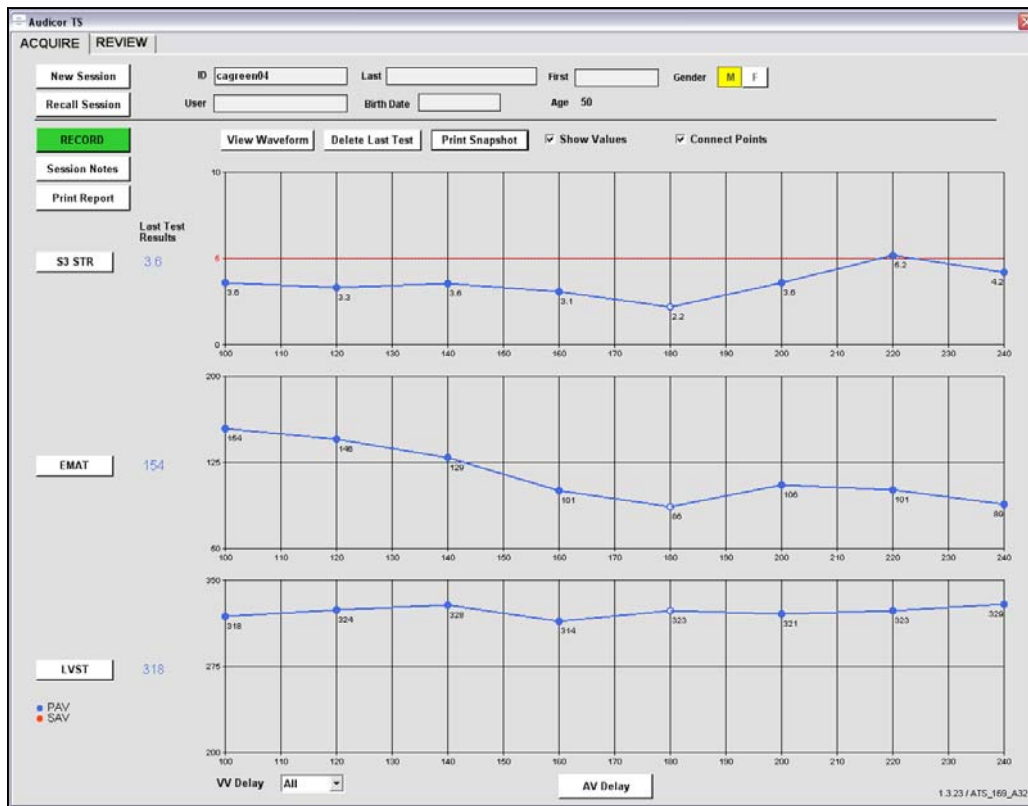
## Record AUDICOR Measurements



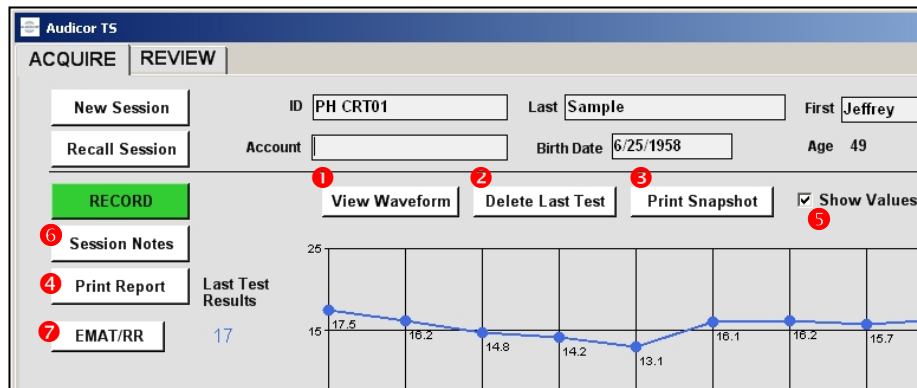
- 1 Select the scale (X axis) you wish to trend during this session. Order data points on X-axis by choosing delay setting (AV, VV) or time of recording. Choices include AV Delay, VV Delay, Test Time, and Heart Rate.
- 2 In the ACQUIRE tab, select the AUDICOR measurements (Y axis) you wish to trend during this session. Choices include EMAT, S3 Strength, LVST, QRS Duration, S4 Strength, Heart Rate, EMAT/RR, LVST/RR, and Signal Quality.
- 3 Select **RECORD**.
- 4 This will cause the "Recording Parameters" window to appear. Select the test settings for this recording (e.g. PAV or SAV, RV or LV). Enter the AV or VV delay values at which you will record with settings.
- 5 Enter comments, if desired, for this specific data point.
- 6 Select **OK** to acquire and analyze a 10-second data sample, then plot the resulting values for the selected parameters on the trend graph.
- 7 Select **View Waveform** to verify that you have a good quality sound tracing on AUDICOR Console.
  - Make sure the patient is relaxed and comfortable.
  - Ask the patient not to move or speak during the optimization.
- 8 Repeat steps 3-6 until all desired settings have been recorded for this session.
- 9 To display data points that were acquired at only a specific VV or AV delay setting, select the desired value.

## Examine Recorded Trend

During each recording session, the analyzed values for each parameter are plotted in the Y-axis, and the scale setting in which they were acquired along the X-axis.




## Other Functions In Acquire Screen

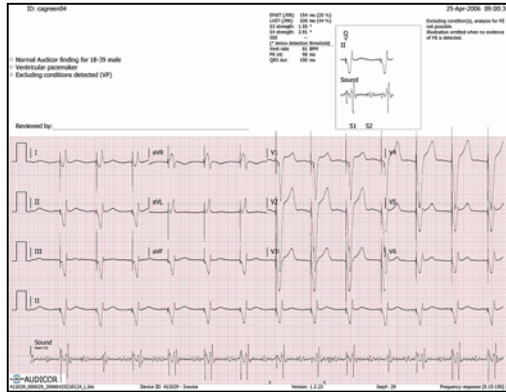


- 1 **VIEW WAVEFORM** – Select to review the quality of ECG and Sound traces for the most recently recorded data. Use the scroll bar on the view window to ensure all waveform data is visible.

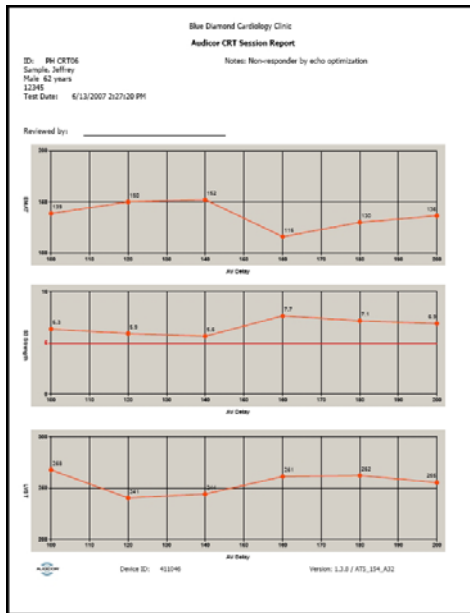


- Scroll down to view sound trace from V4 sensor position
  - Print copy of Sound & ECG Traces, if desired.
  - Click on  to close the View Waveform window and return to the ACQUIRE screen.
- 2 **DELETE LAST TEST** – If the Sound and ECG Traces or other test settings are considered unsatisfactory for most recent recording, select Delete Last Test to erase this data from the trend, then re-record.

- 3 **PRINT SNAPSHOT** – Select to print AUDICOR waveforms, measurement parameters and interpretive statements for heart sounds and ECG for the most recent data point



- 4 **PRINT REPORT** –To print a paper copy of the parameters displayed in the “ACQUIRE” Screen trended against the scale selected for the X-axis, select Print Report.

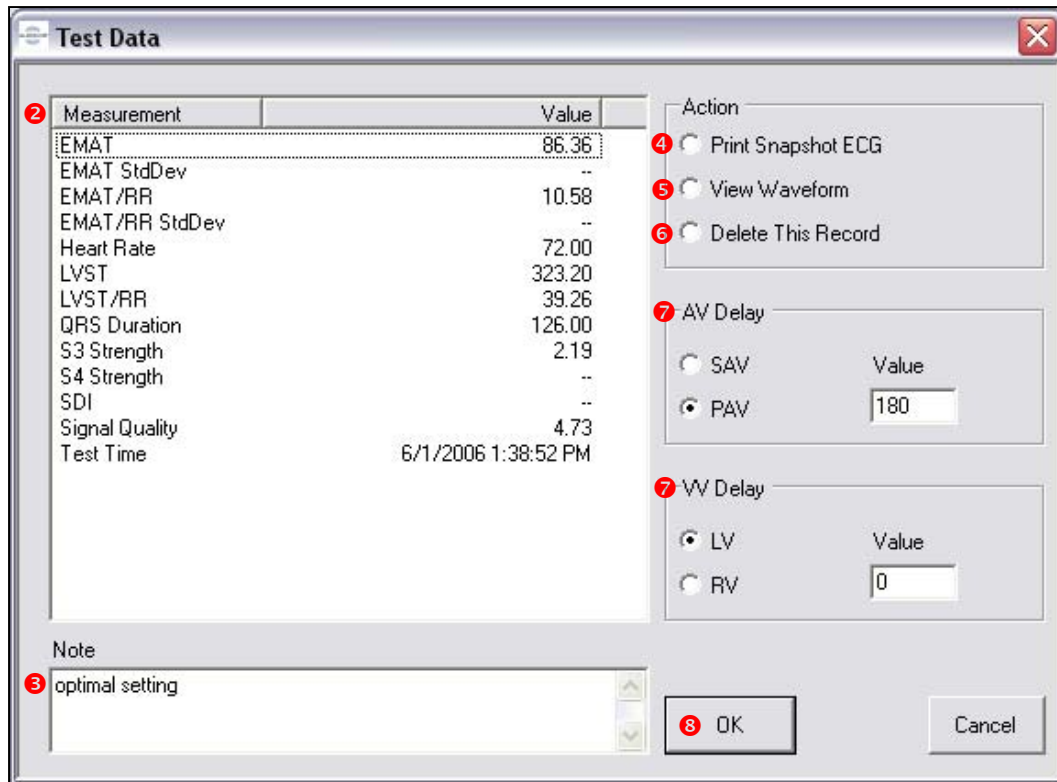


- 5 **SHOW VALUES** – To show values of measured parameters select the “Show Values” option. Trended values will be shown on the “ACQUIRE” Screen and on the printed report
- 6 **SESSION NOTES** – Select “Session Notes” to save comments, or select data point and capture notes for each recording. Data points with notes will appear with white center. Notes will be saved with the session and printed on the trend report.

## Review and Interact with a Single Data Point

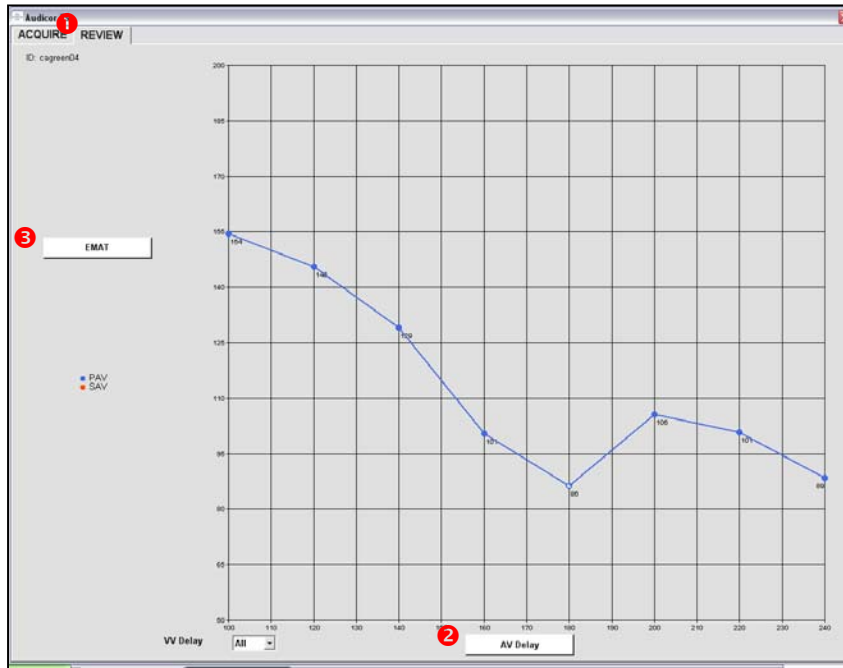
You may review or interact with any data point in the acquire or review tab

- 1 Place the cursor directly over the point. When a  appears, click on it to display the following popup window.



- 2 Review all available measurements for the selected data point
- 3 Enter a comment for the selected data point. These will be printed as a second page of footnotes with the trend report.
- 4 Print an ACG snapshot for the selected data point.
- 5 View the On-screen waveform for the selected data point.
- 6 Permanently delete the selected data point from the trend.
- 7 Edit AV and VV delay settings for selected data point.
- 8 Select  to continue.

## Review Trend for a Single Measurement



- 1 For closer review of the trend for a single parameter, click on the "Review" tab.
  - 2 Select the button for the X-axis and select the AUDICOR parameter from the dropdown list that you wish to trend.
  - 3 Select the button for the y-axis and select the AUDICOR parameter from the dropdown list that you wish to trend.
- The plotted data for the selected parameters will be displayed automatically



**Note** If a ToolTip at the bottom of the display alerts you that the printer is out of paper, load more paper, then select the ACQUIRE tab to continue.



**Note** There is no need to explicitly save the recording or optimization session. All data is automatically stored and accessible through the RECALL Screen.

## To Recall a Previous Test Session

The Patient ID is used as an identifier for data storage. There is no need to explicitly save the recording or optimization session. All data entered and recorded tests will be automatically stored on the notebook PC.

In Acquire Screen, select Recall Session

The screenshot shows a 'Patient Search' window with the following fields and data:

- ID: PH CRT06 (with a red circle 1 next to the ID field and a red circle 2 next to the search icon)
- Last: Sample (with a search icon)
- First: Jeffrey (with a dropdown menu set to 'Male')
- Account: 12345 (with a search icon)
- Birth Date: 5/1/1945 (with a search icon)
- Age: 62
- Buttons: 'Click on the ? to search on that field' and 'Clear'

Results are displayed in two tables:

ID	Account	Birth Date	Last Name	First Name
CRT13				
CRT21				
PH CRT01				
PH CRT06	12345	5/1/1945	Sample	Jeffrey

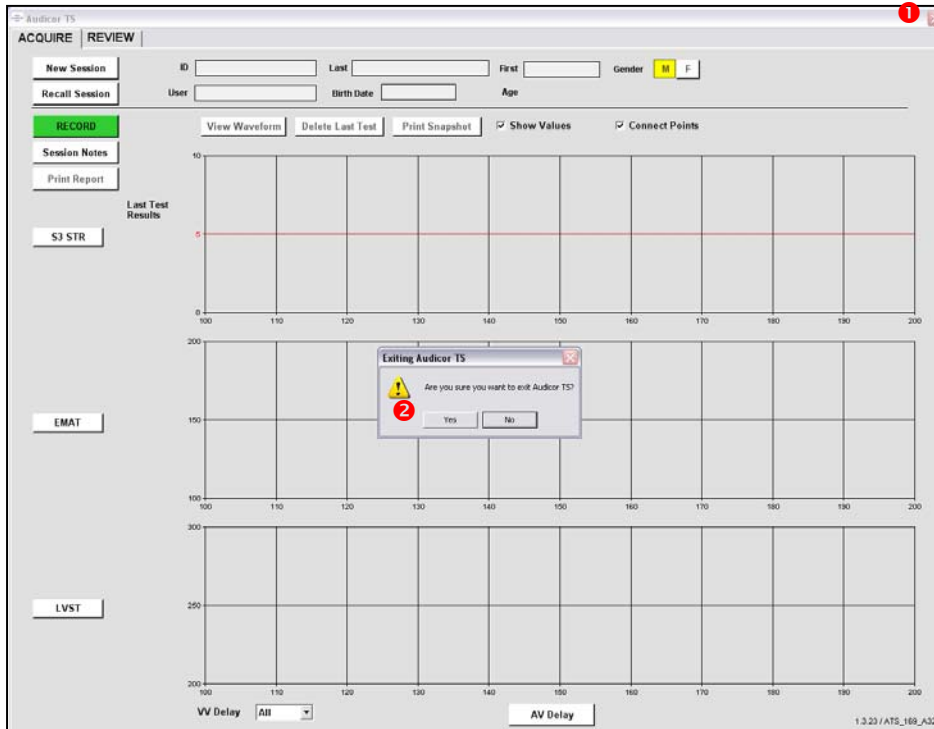
Session List			
Time	ID	Last Name	Notes
6/13/2007 2:22:20 PM	PH CRT06	Sample	Nonresponse by echo optimization


Search by Time options: Last 10 Days, Prior 3 Months, Between (12/15/2006 to 6/15/2007). Bottom buttons: '1 Records', 'OK', 'Cancel', 'Print'.

- 1 Enter ID, or other patient identifier for searching
- 2 Select "?" to immediate right of this window to activate search
- 3 Matches for the patient are shown in the upper results pane. Recorded sessions for the patient will appear in the lower results pane
- 4 Select the session to be recalled. It will be highlighted in dark blue. Select "OK" to complete steps for session recall.
- 5 Corrections to the ID field can be done by selecting Modify ID. Other patient identifiers can be edited directly within the fields where they appear. Select "Ok" to accept edit changes.

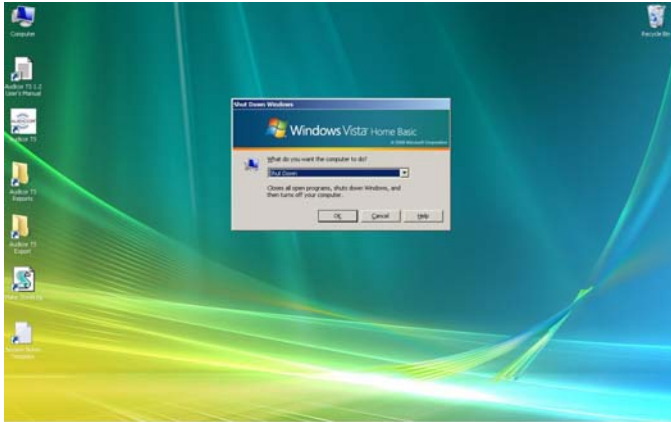
# Exit AUDICOR TS and Shut Down Notebook PC

## Exit AUDICOR TS



1. To exit AUDICOR TS, click on  in upper right corner.
2. A popup window will ask "Are you sure you want to exit AUDICOR TS?" Select  to exit.

## Shut Down Notebook PC

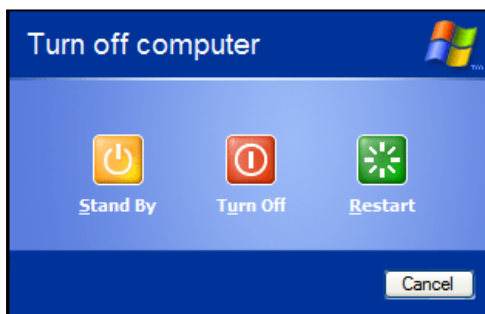


3. To shut down Windows and turn off the Notebook PC, hold down the **Alt** key (next to space bar) while simultaneously pressing the **F4** key (at top of keyboard).  
NOTE: You may first need to click an open space on the Windows Desktop.
4. Windows Vista will display the following Popup



Select "Shut Down", then **OK** to exit.

5. Windows XP will display the following Popup

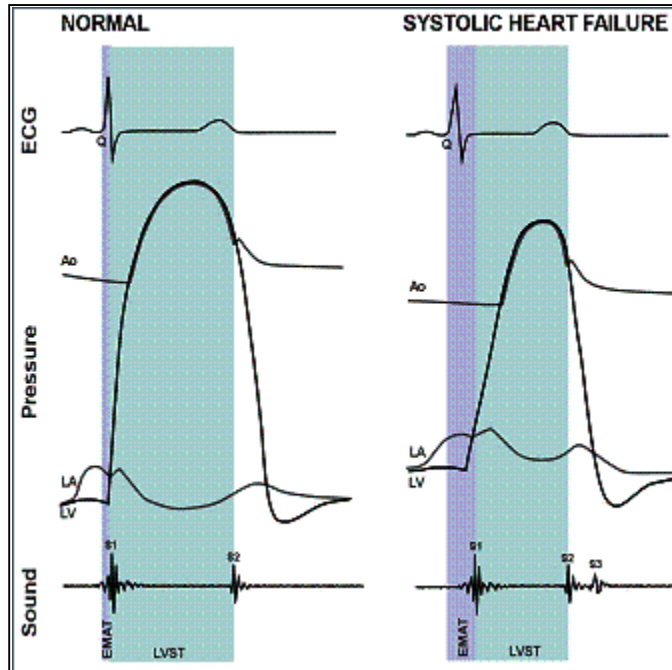


Select "Turn Off" to exit.

# 6

## PHYSICIAN INFORMATION

AUDICOR TS allows the user to select and display one or more of the several ECG/heart sound extended measurements. These Advanced parameters may be useful in evaluating baseline cardiac health or in monitoring to evaluate effects of treatment. The measurements are discussed in detail here:



Parameter	Definition	Correlation
Electromechanical Activation Time (EMAT)	Q-S1 Interval Q-wave to S1 Mitral closure	PCWP, (dP/dt)
S3 Strength	Continuous S3 Parameter (based on probability for presence and intensity of S3)	LVEDP
Left Ventricular Systolic Time (LVST)	S1-S2 S1 Mitral to S2 Aortic closure (Hemodynamic systole)	dP/dt, Afterload

## Q onset to S1 (EMAT, electromechanical activation time)

This measurement is affected by conduction abnormalities such as left bundle branch block (LBBB) and disease. It represents both the delay for electrical activation of the ventricle as well as mechanical delay to close the mitral and tricuspid valves, including a portion of isovolumic contraction.

**Summary:** The interval from Q onset to S1 has been studied previously through the use of manual measurements made on phonocardiographic traces. This interval is believed to be related to myocardial contractility, and is affected by abnormal conduction, such as LBBB. Although heart rate correction was used in the past literature, there has been no gender adjustment recommended. No change in QS1 has been found with acute MI. Shortening of QS1 in patients with mitral stenosis and hypertensive valvular disease has been shown. Long QS1 implies impairment of myocardial contractility and has been documented as a finding in elderly subjects with and without heart disease. The mechanical delay will be driven by the left atrial pressure at onset of systole as well as dP/dt.

**Measurement Description:** EMAT is the time interval from Q onset to the S1 dominant high-frequency peak. Q onset on a beat-by-beat basis is determined on lead V4. Ectopic beats are flagged, and rhythm abnormalities are detected so that the QS1 interval is considered in the context of conduction abnormalities if they are present.

## Left Ventricular Systolic Time (LVST)

Defined as the time interval between the S1 and the S2 heart sound, it is the systolic portion of the cardiac cycle.

**Summary:** In the most basic terms the cardiac cycle is divided into 2 phases, systole (contraction/ejection) and diastole (relaxation/filling). The systolic portion of the cardiac cycle can be approximated as the time between the S1 and S2 heart sounds. The S1 heart sound contains the acoustic vibrations due to the closure of the mitral and tricuspid valves that mark the end of LV filling inflow, and the beginning of isovolumic contraction. Between the S1 and S2, ejection of blood out of the ventricles into the major arteries occurs. The S2 heart sound contains the acoustic vibrations due to the closure of the aortic and pulmonic valves that indicate the end of ejection. LVST has some heart rate dependence, and tends to be approximately 40% (range 30-50%) of the cardiac cycle but is affected by disease that produces poor contractility and/or low ejection fraction.

**Measurement Description:** Left Ventricular Systolic Time is defined as the time between the dominant high-frequency peaks of the S1 and the S2. Thus, LVST closely approximates the time between mitral valve closure and aortic valve closure. The Percentage LV Systolic Time is the time from S1 to S2 divided by the R-to-R interval. Although measurements are made on all beats, ectopic beats are not included in the average measurement.

## S3 Strength

A continuous measure of the evidence or probability that an S3 is present in the time segment being analyzed.

**Measurement Description:** Third heart sounds are detected on a beat-by-beat basis, and each detected sound has a real-valued score associated with it that reflects the log likelihood of detection. Typically, sounds with higher intensity will have a higher score, provided that the timing, morphology, and frequency content are appropriate to the detected sound. On beats without a detection, the score is taken as the probability of the sound occurring during the beat-relative time-interval taken as the median of the beat-relative times of the same sound on beats with detections. Typically, S3 scores from beats with no detections will be negative or small positive numbers. To arrive at the S3 strength, the scores from all beats are summed, and mapped to the range 0 to 10 by mapping values less than -170 to zero, and values greater than 300 to ten. Values between those limits follow a linear mapping to values between zero and ten. In the absence of any S3 detection on any beat, no scores can be computed, and the S3 strength is reported as zero.

# 7

## MAINTENANCE & TROUBLESHOOTING

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### Maintain AUDICOR Sensors

To keep AUDICOR sensors clean and protected, keep them in their sealed pouches until use. Prolonged exposure to air can damage the gel-coated underside.

Expiration dates for individual sensors are printed on the pouch in which they are packaged. To ensure maximum shelf life, store the sensors in a cool, dry place. . The estimated shelf life of an AUDICOR sensor is based on the storage temperature of 23°C (73.4°F). If the storage temperature is higher, the actual shelf life may be less.

### Replace the Console Battery

If sustained operation is no longer available following recharging, take the following steps to insert a fresh battery.



1. Slide the battery door open.
2. Unplug the battery cable.
3. Remove the battery from the console.
4. Replace with a fresh battery.
5. Plug in the battery cable.

Close the battery door.

# Maintain the Printer

## Change Printer Ink Cartridges

The printer uses two types of ink cartridges: a black cartridge and a color cartridge. Always keep a set of extra ink cartridges handy, along with extra paper for the printer.

The inside of the front printer cover includes graphics to remind you how to replace an ink cartridge. You can also follow these steps:

1. Turn on the printer.
2. Remove each ink cartridge from its package, and then pull the colored tab to remove the protective film from each cartridge.
3. Open the front cover of the printer and wait for the carriage to go to the "ink cartridge change" position. This should take only a few seconds.



**Caution** To prevent damage to the printer, install (or replace) ink cartridges only when the carriage is in the "ink cartridge change" position. To prevent clogs, ink failure and bad electrical connections; do not touch the ink nozzles or the copper contacts on the cartridges.

4. Lift the ink cartridge latches.



5. Pop out the empty ink cartridge(s).
6. Remove protective tape from nozzle and insert the new ink cartridge in the correct socket. A black cartridge (No. 94) goes in the right socket. A color cartridge (No. 95) goes in the left socket. Make sure you insert the ink cartridges at a slightly tilted-back angle.
7. Close the ink cartridge latches. If you have installed the cartridges correctly, closing the latches gently pushes the cartridges into their sockets. Press the latches to ensure they are seated flat on the cartridges.
8. Close the front access cover. Wait for the carriage to return to the Enter Patient Information position at the right side of the printer.

## Clean and Inspect the Patient Cable

Regularly inspect the cables and wires for signs of damage or excessive wear, such as surface splits or cracks, or breaks in connectors. Over time, monitor patient cable performance for signs of malfunction or failure, such as consistently poor signal acquisition or inoperable sensor connectors and snap/tab adapters.

Discard and replace the patient cable when performance is compromised.

## Clean the Sensor Connectors

Clean the AUDICOR sensor connectors on a regular basis to keep the connectors clean and assure good connections to the sensors.

1. Use a dry, small soft bristle brush to remove dust, particles, and other buildup from the round opening on the underside of the sensor connectors (do not use a cotton swab).
2. Use a soft cloth dampened with mild detergent to wipe dirt and residue from external surfaces.
3. Allow the connectors to air-dry.



**Caution** Do not immerse the V3 and V4 sensor adapters in bleach or other disinfectants. Doing so will damage the connectors.

## Disinfect External Surfaces of the Patient Cable

1. Use a soft cloth dampened with a 10% bleach solution (or an FDA-cleared disinfectant) to remove contaminants from the external surfaces of the patient cable.
2. Wipe the components clean with another soft, dampened cloth.
3. Allow the components to air-dry.








**Caution** To avoid damaging AUDICOR components, take the following precautions:

Do not use organic solvents on any parts of the patient cable or on the AUDICOR console.

Do not immerse AUDICOR components in any type of liquid, including water.

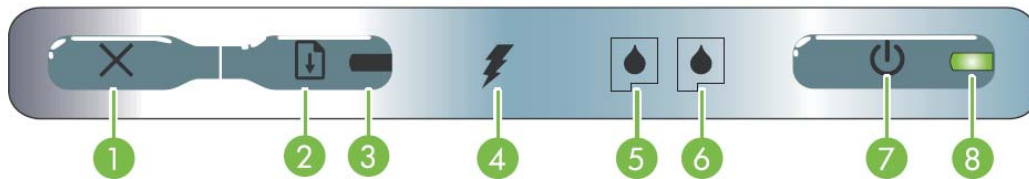
Do not perform any type of sterilization procedure on AUDICOR components.

## Respond to Noisy Sound Traces

TRACE DESCRIPTION	SUGGESTED RESPONSE
<p>Good Signal</p> 	<p>Acceptable traces have clear, well-defined first and second heart sounds and relatively clean baselines.</p>
<p>Excessive Baseline Artifact</p> 	<ul style="list-style-type: none"> <li>• Use a gauze pad to remove oils &amp; perspiration for dry, pink skin</li> <li>• Shave as necessary</li> <li>• Place limb electrodes on torso near hips and clavicles.</li> <li>• Check all electrodes for good contact</li> <li>• Ensure patient is still and relaxed</li> </ul>
<p>Sporadic Noise</p> 	<ul style="list-style-type: none"> <li>• Ensure patient is not talking and surrounding environment is as quiet as possible</li> <li>• Do not touch or rub sensors and wires when recording</li> <li>• Ensure sensors are properly positioned</li> </ul>
<p>Weak Signal</p> 	<ul style="list-style-type: none"> <li>• Ensure sensor firmly adheres to skin.</li> <li>• Shave chest hair</li> <li>• Place sensor underneath breast</li> <li>• Properly position (move closer to PMI)</li> <li>• Replace sensor as necessary</li> </ul>
<p>Leads Off</p> 	<p>Ensure firm connections:</p> <ul style="list-style-type: none"> <li>• Adapters to Sensors</li> <li>• Adapters to lead wires</li> <li>• Patient cables to console.</li> </ul>

# Troubleshoot the Printer

## Printer Indicators and Keys



Indicator / Button	Description
1. Cancel button	Press this button only once to cancel a queued print job
2. Resume button	Resumes a print job that is waiting or after temporary interruption (for example, when adding print media to the printer)
3. Resume light	Lights up in amber when a print job is waiting, and blinks or turns on to relay status or a need for intervention
4. Battery charging light	Lights up in green when the battery is charging
5. Left print cartridge light	Blinks when the left print cartridge is absent or improperly functioning. Turns on solid when the ink is low or empty
6. Right print cartridge light	Blinks when the right print cartridge is absent or improperly functioning. Turns on solid when the ink is low or empty
7. Power button	Turns the printer off or on
8. Power light	Lights up in green when the printer is turned on using the AC adapter or a 41-100% charged battery. When powered by battery, lights up in amber when battery is 10-40% charged, and red when battery is below 10% charged. Blinks during printing

## Respond to Alert Messages on Notebook PC

Message	Suggested Response
Error loading the application settings. The system may not function properly"	Contact Inovise Technical Support if problem persists.
Error: Audicor TS has to exit due to a fatal system error."	Restart devices and reconnect if necessary. Contact Inovise Technical Support if problem persists
Error: Cannot analyze due to signal quality. Would you like to view waveform?	View the waveform to understand cause of trace quality problems (see p. 42). Correct and re-record.
Error: Only numeric values are accepted for this field.	Enter correct <u>numeric</u> information before proceeding
Error: Record failed, Cannot analyze heart sounds - defective data. Identify cause, correct and re-record if possible.	View the waveform to understand cause of trace quality problems (see p. 42). Correct and re-record.
Error: Record failed. Cannot communicate with console. Restart console, reconnect USB cable, select OK> on console.	AUDICOR Console cannot communicate with Notebook PC. Ensure USB cable is securely connected to both devices and communications link is properly established. Restart devices and reconnect if necessary.
Error: Record failed. Could not acquire file.	Reset all devices, reconnect if necessary, and restart recording session.
Error: Record failed. Error acquiring file. acquire: 3: The waveform screen is not active.	The AUDICOR Console must be in "Verify Trace" screen. Select the <input type="button" value="OK&gt;"/> button (see p. 19) in the initial (Patient Information) screen to activate this mode.
Error: Record failed. Error storing the last test results to database	Attempt to re-record at current settings. Reset all devices and restart recording session. Contact Inovise Technical Support if problem persists.
Error: Record failed. File acquisition did not complete.	Reset all devices, reconnect if necessary, and restart recording session.
Error: Sound quality (in lead Vx) may affect analysis. View waveform, delete and re-record if necessary.	View the waveform for lead V3 or V4 to understand cause of trace quality problems (see p. 42). Correct and re-record. If not successful, consider repositioning V3 & V4 leads immediately to the right and left of the PMI (Point of Maximal Impulse – Apex of Heart) to improve signal quality.
Error: Invalid age entered. The age cannot be less than 18	AUDICOR analysis is not valid for patients under 18 years of age. Enter correct age or discontinue test.
Error: There is no current file to view. Click Record to acquire a new recording.	A first recording must be acquired for each test session before any traces can be displayed or trends reviewed.
Error: This field cannot be blank	Enter correct information before proceeding
Warning: Are you sure you want to delete the last test? The data cannot be recovered once it is deleted	User must confirm that testing is completed for this session.

Message	Suggested Response
Warning: Exiting AUDICOR TS. Are you sure you want to exit AUDICOR TS?	User must confirm that testing is completed for this session.
Warning: New Patient ID Entered. Clear all results before starting a new patient?	To avoid associating test results with incorrect patient, user must confirm when switching from one Patient ID to another.
Warning: The patient ID has changed:	To avoid associating test results with incorrect patient, user must confirm when switching from one Patient ID to another.
Warning: Data displayed for previous session. Would you like to clear the display and begin a new session for this Patient ID?	Select <input type="checkbox"/> <b>Yes</b> to clear the currently displayed data and begin a new session with the same ID, gender, and age. Select <input type="checkbox"/> <b>No</b> to continue reviewing the currently displayed session.

## Contact Inovise Customer Support



**Note** Please locate your AUDICOR TS serial number before you call.



**Caution** There are no serviceable parts in the AUDICOR console. Do not open the AUDICOR console except to replace the battery. Doing so voids the warranty.

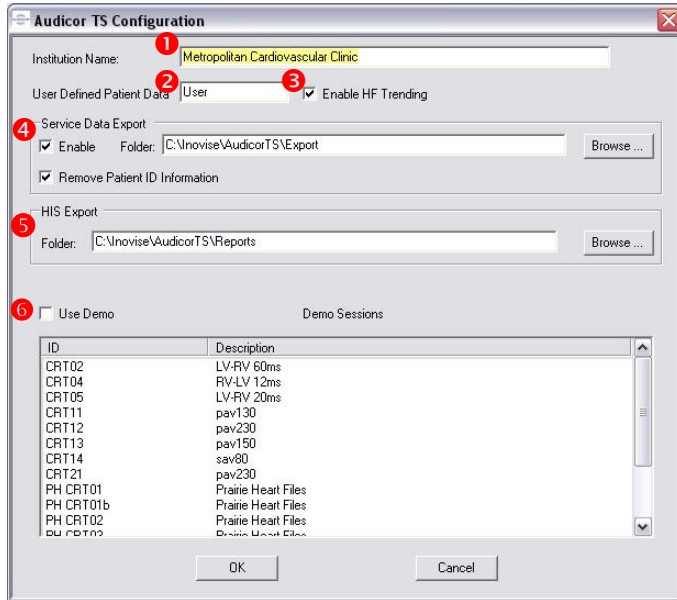
Online support	Telephone support	Fax and email support
<p><a href="http://www.audicor.com">http://www.audicor.com</a></p> <p>Useful AUDICOR TS information, product updates, frequently-asked questions (FAQS) and e-mail support</p>	<p>Telephone: 1-503-431-3800</p> <p>Toll-Free USA: 1-877-466-8473 (1-877-INOVISE)</p> <p>Customer support in English is available regarding installation and operation of the AUDICOR TS.</p>	<p>FAX: 1-503-431-3801</p> <p>Email: <a href="mailto:productsupport@inovise.com">productsupport@inovise.com</a></p>

# 8

## ADVANCED TOPICS

### Adjusting Configuration Settings

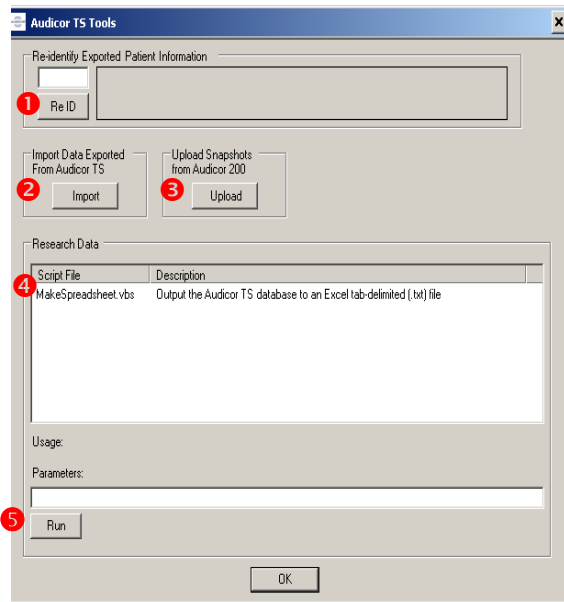
Enter Alt+c to invoke the Audicor TS configuration screen



- 1 Enter Institution Name
- 2 Set name for user-defined patient identifier. Examples include account number (shown), physician name, or study name
- 3 Enable HF Trending allows new data to be added to a recalled HF trending session (does not apply to optimization sessions).
- 4 Data can be exported for field support purposes. Exporting allows database records and waveform files to be moved between laptops. Used with the "import" function, export can be used to share case studies. The tools and export provide further explanation. Note: It may be convenient to set the export folder to a thumbdrive. "Remove Patient ID Information" sanitizes patient ID.
- 5 As trends are printed, electronic copies (PDF format) are also created. These electronic copies can be re-printed later, or can be copied off the laptop and transferred into an HIS or CMS. The default archival folder for these reports is setup here.
- 6 Pre-recorded files can be chosen as demonstration recordings. Enable "Use Demo", then select the demonstration file of interest.

## Using Advanced Tools

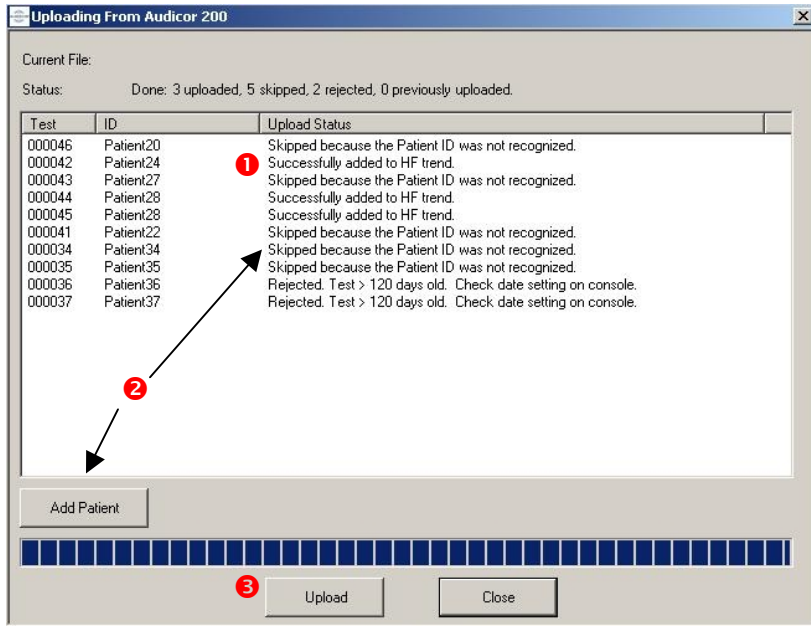
Enter Alt+t to invoke the Audicor TS Tools screen



- 1** "ReID" is used for internal, research purposes only.
- 2** The Import function is the companion to the export function enabled in the configuration screen. Select "Import" to browse to the location where exported records have been placed. Imported records are then accessible through the "Recall Session" function on the "Acquire" screen.
- 3** The Upload function is used to transfer data to ATS that has been acquired on the AUDICOR 200S. An ActiveSync connection between ATS and the 200S is established following the usual procedure. See the following section for further details.
- 4** The Research Data window shows a list of scripts available to support research activities. The one script shown in this window allows for extracting database records into an Excel-compatible format for further study and analysis..
- 5** To activate, select the desired script from those available. Once highlighted, the script command will appear within the Parameters field below. Select "Run" to execute the command.

## Uploading Records from AUDICOR 200S

Selecting "Upload" on the Tools Menu (previous page) will initiate a transfer of records to ATS. Records will be transferred if the ID for the record has been established on ATS and if the recording on the 200S occurred within the last 120 days.



- 1 Records successfully transferred will be appended to HF trending sessions.
- 2 Select "Add Patient" to add patient ID of records not already existing on ATS.
- 3 Select "Upload" to re-initiate transfer of records from the 200S. Perform this step after using the "Add Patient" function.



**Note** The console date and time must be correct to successfully upload ACG "snapshot" files to the notebook PC.

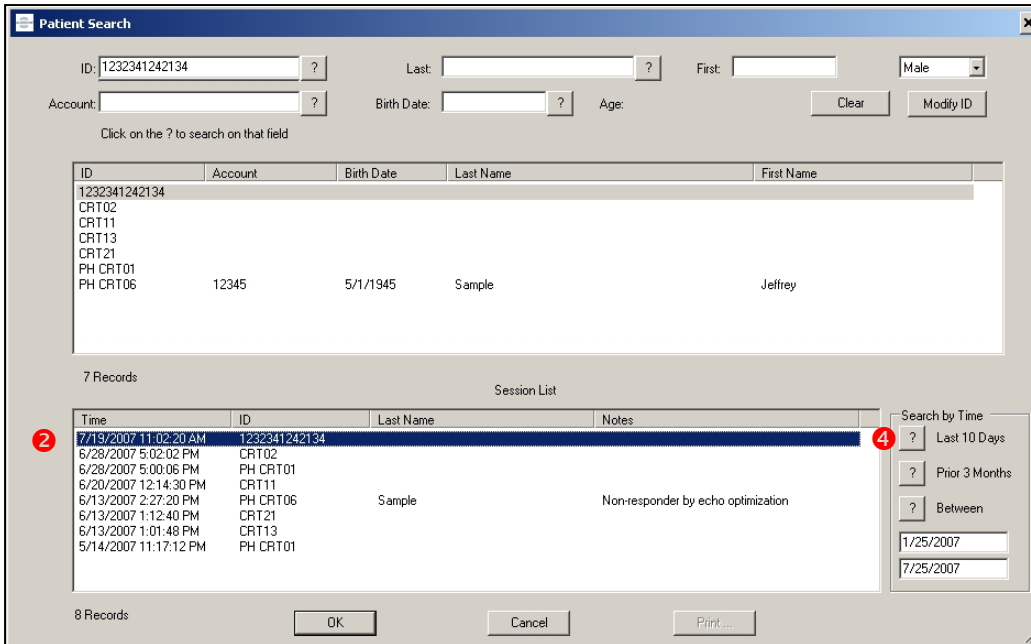


**Note** If the AUDICOR 200 battery completely discharges, you must re-enter the date and time.

# Exporting Records

Enter Alt+t to invoke the Audicor TS Export screen

1. A single session will be exported while a new or recalled session is active.
2. With the "Recall Session" window open, those record(s) shown in the lower, session list window will be exported.
3. To export all sessions for a patient, find the patient in the search window first. Once their sessions are shown press Alt+x
4. If all sessions on the system are to be exported, enter search dates wide enough to include all recordings, then press the "?" labeled "Between". All recorded sessions will appear in the session list. Press Alt+x to export the records.



# SPECIFICATIONS

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Feature	Specification
Console dimensions	(H) 133.4mm (5.25in), (W) 237.5mm (9.35in), (D) 69.3mm (2.73in)
Battery in console	Lithium-ion Replace after ~12 months Up to 50 report copies on a single charge Recharge after ~4 hours continuous use
Power strip	Medical grade, for all device components Rated at 15 amps
Environmental operating conditions	10 to 40 degrees C (32 to 104 degrees F) 20 to 80% relative humidity (non-condensing)
Storage and Transport	-20 to 60 degrees C (-40 to 140 degrees F) 10 to 95% relative humidity (non-condensing)
Safety	Complies with IEC 601-1 CSA certified
Performance standards	IEC 60601-2-25
Notebook PC	Intel® Notebook PC Microsoft® Windows® Vista or XP Professional
Printer	HP Deskjet 460 color inkjet USB communication to Notebook PC
AUDICOR TS replaceable parts and supplies	20185 Laptop, Software Configured 20224 AUDICOR 200S Console, (for use with Sensor 4.0) 20132 Console Battery 20119 AUDICOR 200S 4-Wire Patient Cable (AHA) 30112 AUDICOR 200 Adapter 4.0 for V3-Green 30113 AUDICOR 200 Adapter 4.0 for V4-Blue 30076 AUDICOR Patient Cable, 12 Lead+, AHA 12124 Printer, HP DeskJet 460wbt Mobile Printer 11095 Cartridge, Inkjet, Black # 94, HP 11096 Cartridge, Inkjet, Color # 95, HP 12213 Multi-Clip Adapter, Snap and Tab, Each 30104 AUDICOR Sensor 4.0, Pouch of 10 Each 30105 AUDICOR Sensor 4.0, Box of 100 Each 12151 USB Cable, A->B, 6'

Inovise Medical, Inc.  
8770 SW Nimbus Avenue, Suite D  
Beaverton, Oregon 97008-7196 USA

