	User Documentation	Document 40228
	Audicor CiPH With AM (Holter) Quick Reference Guide, Addendum For Demonstration/Evaluation Only, Exclusively for Clinical Investigations	Revision 1
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1 Intended Use - This system is for evaluation and demonstration purposes only. The product will be labeled “Exclusively for Clinical Investigations”

- a. **Rx Only** Federal law restricts the sale of the device identified in this manual to, or on the order of, a licensed medical practitioner.
- b. This documentation is intended for use by medical practitioners who perform computer-aided phonocardiography, Holter monitoring, electrocardiography (ECG) and similar tests. It is also intended for physicians who interpret heart sounds and ECG data.
- c. 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 ElectroMechanical Activation Time (EMAT), Left Ventricular Systolic Time (LVST), third heart sound (S3) strength, fourth heart sound (S4) strength, and the Systolic Dysfunction Index (SDI).
- d. Selected parameters are typically reported in a trended report format where multiple data points are trended over time. The Audicor system accepts and analyzes downloads of up to 48 hours of patient data from the ambulatory ECG/heart sounds collection device.
- e. AUDICOR’s 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 consideration of patient symptoms, history and other relevant factors and diagnostic tests.
- f. AUDICOR testing is indicated for patients 18 years of age and older who present with cardiac symptoms, including shortness of breath, and for patients who are at risk for heart disease.
- g. Contraindications: AUDICOR CiPH analyses are not valid for patients under 18 years of age.
- h. Precautions: AUDICOR CiPH 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 CiPH may not be appropriate for patients that have skin allergies or are otherwise sensitive to the disposable electrodes and or the AUDICOR sensor 2.0 used with the system. See warnings and cautions for additional important precautions.

2 Notations in This Addendum



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.



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

3 AUDICOR CiPH+AM 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, ECG electrodes and patient cable 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 data and/or reports.
- 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 CiPH 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, abuse or mishandling of this device could result in electrical shorts and 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** 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** The AUDICOR AM meets requirements for "recording ECG signals in the presence of implanted pacemaker pulses". It does NOT meet requirements for "being capable of recording the activity of an implanted pacemaker". Note: Failure to detect the pacemaker could result in incorrect ElectroMechanical Activation Time (EMAT) measurements.
- Warning** During preview, insure the AUDICOR CiPH preview data is from the patient you are working with and not a second or third patient in the waiting room. First check that you have entered the correct Sensor I.D and RF Channel information (See back of AM device) in the Patient Setup- Select Holter

Device screen. Once you are receiving patient waveform data from a particular AUDICOR AM, use a pencil to tap on the back of the Audicor sensor being displayed. You should observe artifact on the preview display that corresponds with each tap to verify that the preview waveforms are from the recording device currently being set up.



- Caution** Simultaneously attaching patient leads for another device to the same patient could cause the ECG signals to be corrupted.
- Caution** Attach only AUDICOR adapters to AUDICOR sensors. AUDICOR sensors will not function with other adapters.
- Caution** Do not allow an AUDICOR sensor to touch an electrode or another sensor. Allowing contact causes recording of incorrect signals.
- Caution** To ensure proper patient isolation and signal quality, securely and properly connect all cables to the AUDICOR Holter device before you attach lead wires to the patient.
- Caution** To avoid damaging AUDICOR components, take the following precautions:
- Do not shower, bathe, swim or engage in other activity that may immerse the Audicor AM device or lead set or get them wet.
 - Do not use organic solvents on any parts of the patient cable or on the AUDICOR AM/Holter device.
 - Do not immerse AUDICOR AM components in any type of liquid, including water
 - Do not perform any type of sterilization procedure on AUDICOR AM components
 - Do not drop the AUDICOR AM device
- Caution** To avoid damaging the AUDICOR AM/Holter device, be extremely careful not to allow fluid into the seams of the AM device, especially at any point around the battery door/ compartment. The AUDICOR CiPH+AM warranty does not cover damage from fluids applied to the AM device.
- Caution** Except for the battery and storage card, there are no serviceable parts inside the AUDICOR AM/Holter device. Do not attempt to open the AUDICOR Holter device other than to remove the battery cover to access and replace the battery and or the memory/storage card. Doing so voids the warranty.
- Caution** When handling the battery, be careful not to touch or contaminate the metal battery terminals. This is especially true after handling ECG electrodes or Audicor Sensors. These devices contain hydrogel that can be very corrosive and may damage both the battery terminals and the Audicor AM battery contacts.
- Caution** Be careful to first release the storage card from the Audicor AM storage card slot before attempting to remove the card. To release the card, gently push in with your thumbnail until you feel and or hear a slight click. If the card is released it will protrude enough from the storage card slot to allow capturing it between your thumbnail and index finger for removal.
- Caution** When inserting the storage card into the Audicor AM storage card slot expect to feel a spring like action, insure the card slides evenly and symmetrically into the storage card slot. Do not force the

card into the slot, if the card catches because it is misaligned pull the card out and realign so that it is square and even in the card slot, forcing the card in at an angle may irreparably damage the card latching mechanism.

- Caution** Be careful to match the battery to the correct charging device before applying AC/Mains power. 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 for both the battery and the charger.
- Caution** The battery used in this device may present a risk of fire or chemical burn if mistreated. Do not disassemble, heat above 60°C (140°F), or incinerate. Replace battery with (Inovise Medical, Inc., Part # 20213) only. Use of another battery may present a risk of fire or explosion.
- Caution** For AUDICOR AM battery, charging temperature range must be maintained between (+10 and +45) degrees C or (50-113) degrees F. Maintain discharge temperature within 0 to +45) degrees C or (32-113) degrees F.
- Caution** DO NOT remove the battery from the AUDICOR AM device while the recording session is underway, doing so may corrupt the data file. Turn off the AUDICOR AM device by pressing and holding the On/Standby button until the LED stops flashing. Opening the battery door for a few seconds will also terminate the recording session.
- Caution** Dispose of used batteries properly and according to local standards for Lithium-polymer batteries. Keep away from children. Do not disassemble and do not dispose of in fire.
- Caution** The AUDICOR CiPH+AM System is equipped with wireless telecommunication features. If it appears AUDICOR CiPH + AM 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)
- Caution** The AUDICOR CIPH+AM System is not equipped to detect the presence of a pacemaker and/or mark the presence of a pacemaker spike.
- Caution** The AUDICOR CiPH + AM System is not equipped with antivirus software. This medical system should not be network or Internet connected for this reason. Adding antivirus software may compromise the performance of this medical application and therefore void any remaining warranty.
- Caution** There will be no indication on the AUDICOR AM device that leads are off or data is noisy.
- Caution** The battery charger is not a medical device and therefore keep at least 1.5 meters from patient care areas.

4 User Capabilities

The medical personnel performing the Audicor AM test (User) need to have the ability to follow the instructions and guidelines in the User Documentation set which include the Quick Reference guide and associated Addendum. Users also need to have sufficient dexterity to hold and manipulate small objects such as the Audicor AM memory card. The User should first read in their entirety, the Quick Reference Guide (part #40227) and the Quick Reference Guide Addendum (part #40228) before applying Audicor to the patient.

5 Patient Instructions

While setting up Audicor and applying the recording device to the patient, it is important to orient and inform the patient about the operation and use of the device. The User should at a minimum train the patient how to:

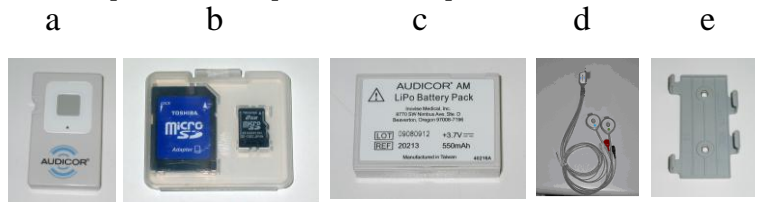
- Locate the Audicor AM Event button and describe the proper use.
- How to reconnect the patient lead wires, sensors, electrodes, overpatch and the Holter device itself should they detach.
- How to interpret the flashing LED color code. For example orange is expected and does not indicate a problem with the Audicor AM.
- The patient should be instructed not to shower, bathe, swim or engage in other activity that may immerse the AM recording device, the patient cable, sensors or electrodes.

6 Getting Started

Getting Started: Preparing the Audicor AM Recording Device with Accessories for Use

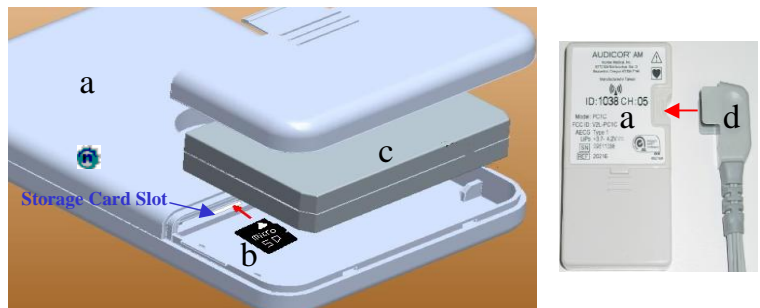
Step 1 – Locate the parts that make up the Audicor AM Device

1. Locate the following items
 - a. Audicor AM recording device
 - b. 2Gb Storage Card
 - c. Fully Charged 3.7 Volt Lipoly battery
 - d. 5-Wire Audicor Patient Cable
 - e. Audicor AM Holster
 - f. Battery Charger & Power Supply

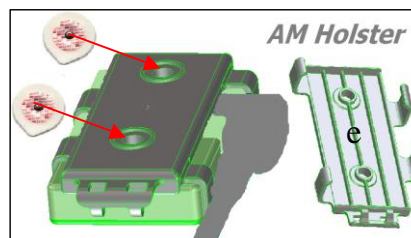


2. Place the Audicor AM recording device face down to expose the battery cover. Use your thumb to slide the battery cover off.
3. Locate the storage card slot and insert the 2Gb storage card. Use your thumbnail to carefully push the card into the slot until it locks into place. Note: Do not force the card should it catch due to misalignment, carefully realign and insert until latched into place.
4. Place the fully charged battery in the battery compartment. The battery contacts should align with the gold contacts.
5. Slide the battery cover into place. Ensure the cover is firmly seated and flush with the AM housing.
6. Affix the 5-Wire Patient Cable to the AM device.
7. Slide the assembled Audicor AM into the Holster. Affix snap electrodes only when ready to mount on patients abdomen.
8. Charging the Lipoly 3.7 Volt battery. Charge for approximately 4 hours.

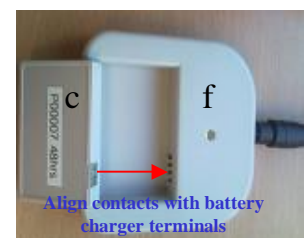
Steps 2-6 Assembling the Audicor AM recording device



Steps 7 - Applying the AM Holster



Steps 8 - Charging the Battery



7 Troubleshooting the Wireless Preview Mode

The wireless preview mode is used to verify the signal quality and patient connection. If you are having difficulty follow these steps.

- Is the antenna connected/powering? If the USB antenna is properly connected and installed on the PC via the USB extension cable, the antenna LED light should be on or flashing while in the wireless preview mode. To view traces in preview the Audicor AM device must also be powered and connected to the patient via the patient cable and appropriate electrodes/sensors. If the antenna LED is not on or flashing, exit the preview mode and close the CiPH application then remove the antenna for ten seconds and reconnect to allow the PC to establish a new hardware connection. Launch the CiPH application and re-enter I.D. and channel information as required to preview the data.
- If the problem persists shut down the CiPH application, remove the USB antenna from the PC, slide the Audicor AM battery cover open and remove the battery for 60 seconds then reinstall the battery and close the battery cover. Now reconnect the USB antenna. This procedure will reset the AM device, the USB antenna and the CiPH application. Start the CiPH application, Re-enter the ID and Channel information and proceed with the preview mode.
- Does the preview display indicate “Waiting for Data” or “Buffering ...” but no data appears? Position the USB antenna to obtain line of sight with the Audicor AM recording device? It’s best to mount the antenna approximately 5-6 feet above the floor to allow for line of site with the AM device (within 10 feet) of the patient preparation area. See antenna wall mounting instructions in AUDICOR CiPH with AM Quick Reference Guide, step 1 of “Prepare the AM System for Use”.
- Audicor AM is a low power device therefore some local wireless systems may interfere with the Audicor AM wireless preview feature. In this case you will need to start the AM recorder manually. Follow the instructions in the AUDICOR CiPH with AM Quick Reference Guide entitled “Starting and Stopping the AM recording session without AUDICOR CiPH.”

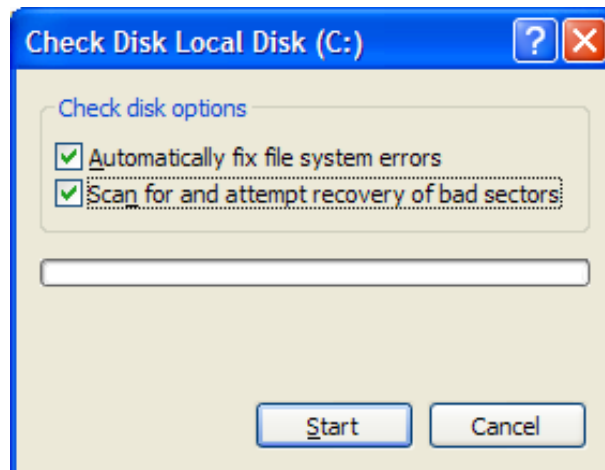
8 Troubleshooting Signal Quality – Adjust Leads, Patient and Environment if Necessary

If you need to improve the signal quality, check the following:

- Ensure good contact between the patient’s skin, ECG electrodes and snap adapters, and the AUDICOR sensors and sensor connectors. If the ECG or sound quality is still poor disconnect and reconnect ECG snap and Sensor leads. Check that the sensors are secure by running your fingers around the edge of the sensor. If problems continue replace any suspect sensor or ECG electrode.
- Request that the patient maintain a quiet, calm and relaxed demeanor while the recording session is underway. The patient should refrain from strenuous or vigorous exercising while recording to avoid excessive motion artifact. The patient should also avoid loud noisy settings that could compromise heart sound data for extended periods (hours).
- Verify the AUDICOR AM patient cable is well seated with the AUDICOR AM/Holter device.

9 Troubleshooting Data Management:

- What if there are multiple files on the Audicor AM memory card? Multiple files are usually the result of patient restart. If the patient cannot provide the start time, analyze the files, one at a time. In order to determine the start time of the next file, use the end time of the previous file. The order of the files is determined by the file extension: RAW, 001,002, etc.
- What if I see the message 'Possible Memory Card Problem - One or more files on the memory card are invalid. This may be correctable by following the directions in the "Troubleshooting" section of the AUDICOR CiPH + AM " Quick Reference Guide, Addendum, " which is available on your Desktop.' This message is generally a result of the recorded file having a file size of zero bytes. In windows explorer, right click on the SD drive (with Vista, probably "Removable Disk") and select properties. Choose the tools tab, and click the check Now ...button. Select both check boxes and click start.



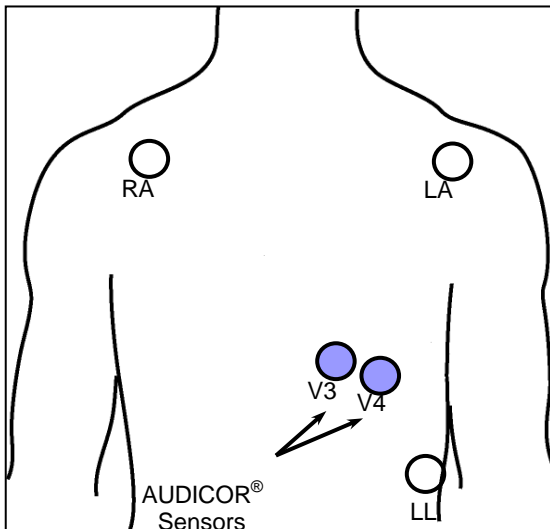
- What if there is a "No Disk" error & unhandled exception after clicking " Analyze New Holter"? This is typically due to a printer or other PC peripheral device that has an empty memory card slot. Printers and other accessory devices that have been added to your PC may have these slots for flash cards (photo accessories etc.). If there is no memory card or memory card adapter inserted in the slots this error may appear. You can work around this problem by clicking any of the three options presented. [Cancel] [Try Again] [Continue] to resume analysis of the data files. Note: Installing a memory card or a memory card adapter will prevent this error from reoccurring when clicking "Analyze New Holter".

10 AUDICOR CiPH+AM components suitable for use within the patient environment:

AUDICOR AM recording device with battery, memory card, patient cable and holster
AUDICOR Sensor LC

11 Prepare ECG Electrode and AUDICOR Sensor Sites

Prepare the ECG sites for a 5-lead recording session.



5-Lead Lead Placement Diagram

Place V3 between fourth intercostal space at left sternal border and V4

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

- RA – Right arm at clavicle
- LA – Left arm at clavicle
- LL – Left leg at hip
- V3 – Midway between V2 and V4. Use an AUDICOR sensor here
- V4 – Fifth intercostal space left of midclavicular line. Use an AUDICOR sensor here



Tip - When applying the Audicor AM recording device to the patient, PREVIEW the waveform/signal quality before adding additional adhesive fasteners to secure the lead wires, Audicor AM and Sensors for extended recording periods (hours). Removing the extra adhesive dressings from the patient due to a poor or defective electrode or patient cable is uncomfortable and can be avoided if you check the signal quality via preview first.



Tip - The ideal mounting location for the Audicor AM device is vertically on the abdomen above the waste line so as not to interfere with clothing. The Audicor AM device is mounted using two standard snap ECG electrodes. To avoid uncomfortable pushing and probing to engage the snaps on the patients abdomen, install the Audicor AM mounting snap electrodes on the holster prior to affixing to the patient. For patients with oily skin consider using extra adhesive fasteners (Tegaderm®) to secure the AM in place. The snap electrodes may not be enough for extended recording sessions.

Tip – Consider taping the ECG lead wires to the body near the electrode. This will reduce the risk something will hook the wire and pull it off the snap electrode.

Tip – When the sensor position for V3 and V4 are directly in-line with or adjacent to the female bra line, consider lowering the sensor position slightly to reduce interference and discomfort.

12 Contact Information



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

13 Data Analysis Methods:

Methods for HR and ST Measurement: Heart rate is calculated by computing the average R-R interval in the 12-second interval being analyzed. That quantity is then divided into 60000 to convert to beats/minute, so: Heart Rate = 60000 / (average R-R interval) ST segments are measured for each ECG lead by computing a median beat and determining the J point and measuring its value from the isoelectric. Only measurements are calculated and no determination of “depression” or “elevation” is made. Measurements are provided for each 12-second interval in the analysis period.

Symbols

The following symbols may appear on the AUDICOR CiPH, the AUDICOR AM and on the AUDICOR accessories.



Part number/catalog item



Serial number



Lot number

Rx Only

For use by, or on the order of, a physician



Date of manufacture (yymmdd)



Manufacturer



Authorized Representative for the CE Mark



Not Defibrillator-proof type of CS equipment



Cardiac Protected Equipment, (Type CF - Not a defibrillator protected device)



Consult accompanying documents



Reset



External Power



Serial Port



USB port



Headphones



Do Not Re-use – “Use Only Once”



Contains no Latex



Use by YYYY-MM-DD



Audicor Sensor



Sensor Pouch



Sensor Box

14 Federal Communications Commission (FCC) Statement

Clause 15.21 You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

Clause 15.105(b)-This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of the FCC Rules-Operation is subject to the following two conditions:

- 1) this device may not cause harmful interference and
- 2) this device must accept any interference received, including interference that may cause undesired operation of the device.

FCC RF Radiation Exposure Statement:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

15 Field Replaceable Units:

Other than the battery and memory/storage card, there are no serviceable parts associated with AUDICOR AM. Should your product fail to operate in the manner described in the accompanying documentation contact Inovise Service and Support.

http://www.audicor.com/Forms/Support_Req.html

See Specification Table at the end of this document for a list of Field Replaceable Units. These parts may be replaced or exchanged per the terms of the then current product warranty and/or as part of a fee for service contract after the warranty terms have expired.

16 Customer Acceptance/Verification Procedure:**Verify that all AUDICOR CiPH with AM system components are present:**

- P/N - Audicor PC with AUDICOR CiPH+AM SW installed
 - PC Power Supply
 - PC Power Supply AC Power Cord
 - PC Rechargeable Battery
- P/N 20214 - USB Wireless Adapter (antenna)
- Cable USB data, Extension 6 Ft. (For mounting antenna)
- P/N - Audicor Ambulatory Monitor (AM), with accessories
 - Audicor Ambulatory Monitory (Includes battery cover)
 - 3.7 Volt 550 mAh Lithium-Polymer Rechargeable Battery (2-Each)
 - 2Gb Micro SD, storage card, w/adaptor
 - Holster, Audicor AM
 - Battery Charger with power supply
 - 5-Wire Audicor AM Patient Cable
- P/N 40227 - AUDICOR CiPH+AM Quick Reference Guide
- P/N 40228 - AUDICOR CiPH+AM Quick Reference Guide Addendum

Customer acceptance criteria:

Acceptance Criteria	Pass/Fail
1. Install the battery in the AUDICOR CiPH+AM PC, connect the power supply and AC power cord to AC mains power. Does the AC LED light?	
2. Power on the HP Notebook PC and wait until the desktop is fully loaded. Double click the AUDICOR CiPH ICON to launch the application. Is the AUDICOR CiPH+AM application screen displayed? (See AUDICOR CiPH+AM Quick Ref. Guide 40227 Fig. 1)	
3. Follow Quick Reference Guide P/N 40227 instructions steps 2-4 under "Preparing the Audicor AM device for Use". Does the AM LED light when the Event Mark button is pressed?	

The AUDICOR CiPH application software runs on a notebook PC manufactured in China.

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