V300 Holter Monitor

Operator Manual

V300 Holter Monitor

Document Number: 600020 Revision: 00A

WARRANTY

VectraCor Inc. warrants the **V300 Holter Monitor**, when new, to be free of defects in material and workmanship and to perform according to manufacturer's specifications for a period of twenty-four (24) months from the date of retail purchase from VectraCor Inc. or its authorized distributors or agents. VectraCor Inc. will either repair or replace any components found to be defective or at variance from manufacturer's specifications within this time. It shall be the purchaser's responsibility to return the instrument directly to VectraCor Inc., post-paid. **This warranty does not include cables, batteries, and other accessories**. This warranty does not include breakage or failure due to tampering, misuse, neglect, accidents, modification, or shipping. This warranty is void if the instrument is not used in accordance with the manufacturer's recommendations. This warranty is void if unauthorized or unqualified persons attempt to make repairs. The warranty entitles the owner of the equipment to replacement or repair of the part(s) or unit at VectraCor Inc.'s discretion. Purchase date determines warranty requirements. **THE WARRANTY PROVIDED ABOVE AND THE LIABILITIES AND OBLIGATIONS OF VECTRACOR INC. PROVIDED FOR THEREIN ARE EXCLUSIVE AND IN LIEU OF ALL OTHER REMEDIES, WARRANTIES, GUARANTEES, OR LIABILITIES, EXPRESS OR IMPLIED, ARISING BY LAW OR OTHERWISE (INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE AND CONSEQUENTIAL DAMAGES) WHETHER OR NOT OCCASIONED BY VectraCor Inc. NEGLIGENCE.**

Please return the instrument registration card for warranty validation.

In case of a defect, or other warranty service, please call VectraCor Inc. for a Return Material Authorization (RMA) Number and return the unit post-paid directly to our facility. No returns will be accepted without an RMA number issued by VectraCor Inc. Mark the RMA number on the outside of the package and return to:

WARRANTY SERVICE
VectraCor Inc.
785 Totowa Road, Suite 100
Totowa, NJ 07512 USA

Tel: (973) 904-0444 Fax: (973) 904-0411

Any repairs made to the product that are not covered by the warranty shall be billed to the customer.

Outside the United States, please contact your local VectraCor Inc. authorized distributor for return instructions.

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Thank you for purchasing this VectraCor Inc., ***V300* Holter Monitor**. The operating and maintenance instructions that are found in this manual should be followed carefully to insure many years of reliable service. Please read these instructions thoroughly before using your ***V300* Holter Monitor.**

Published By

VectraCor Inc.
785 Totowa Road, Suite 100
Totowa, NJ 07512
USA

(973) 904-0444

Current Revision: 00A
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NOTE: *The abbreviations ECG and EKG, are used interchangeably throughout this manual for the terms electrocardiograph and/or electrocardiogram.*

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Overview

Description

The ***V300* Holter Monitor** is a small light weight solid state device, powered by a single AAA Alkaline battery designed to record 1, 2, or 3 channels of a patient's electrical heart activity (EKG) for 24 or more hours of continuous recording. This device will collect, store and transfer ECG data to a computer for analysis, review and interpretation by VectraCor Inc., line of VectraCor Holter Analysis Software It also has the ability to detect and record pacemaker pulses in accordance with appropriate AAMI/ANSI pacer detection criteria.

The ***V300* Holter Monitor** is an AAMI Type I device, which is part of a conventional AECG monitoring system where the ECG is recorded on a micro–Secure Digital (μSD) memory card installed in the ***V300 Holter Monitor.*** Data is downloaded via a USB Cable or the μSD card is removed from the monitor and placed in a Card Reader connected to a PC with Trillium Holter Analysis Software installed. Follow the instructions provided with your Trillium Holter Analysis Software to download and analyze the recorded ECG data.

The ***V300* Holter Monitor** is compatible with Windows XP SP2 or higher; and only computers complying with EN60950-1 and having properly functioning and configured hardware, software, and drivers that comply with Universal Serial Bus (USB) Specification rev. 2.0, and the USB Mass Storage Class specification ver. 1.0 should be used.

Indications for Use

The ***V300* Holter Monitor** is intended to record continuous EKG data up to 7 days for the detection of arrhythmias in ambulatory patients. Such monitoring is frequently used for patient symptoms such as: palpitations, shortness of breath, chest pain, and syncope. Also, for the evaluation of ECG documenting therapeutic interventions, a patient's response after resuming occupational or recreational activities (e.g., after M.I. or cardiac surgery), evaluating pacemaker dependency, heart rate variability, and in the course of clinical studies.

Precautions

1. **Warning: Device is unsafe to use near Magnetic Resonance (MR) Environment**

Do not expose the device to a magnetic resonance (MR) environment.

- The device may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnetic core.
- Thermal injury and burns may occur due to metal components of the device that can heat during MR scanning
- The device may generate artifacts in the MR image.
- The device may not function properly due to strong magnetic fields and radiofrequency fields generated by the MR scanner.

2. Consult accompanying documents before use. (Including these operator instructions).
3. Use only a certified memory card for recording.
4. It is very important that you observe the “Early Out” procedure if necessary to end the recording before its programmed time. Failure to do so may result in the loss of the recorded ECG data. See End Recording Early (Early Out) Section.
5. To prevent damage to the holter monitor, remove patient leads before defibrillating a patient.
6. Users must ensure that they configure the ***V300 Holter Monitor*** with settings compatible with their Trillium Holter Analysis software.
7. When using Pacer Detect, the physician should be aware that false positive and false negative pacer spike detections may occur.
   False positives - may result from poor electrode hook-up or high noise conditions.
   False negatives - may occur with bipolar pacers due to a weak pacer pulse signal at the patient's skin surface.
8. When viewing the ECG data, the presence of pacemaker signals in the ECG tracing should not be considered true representations of the actual pacemaker stimulus amplitude.
9. Use of rechargeable batteries is not recommended.
10. Observe local regulations for disposal of alkaline and lithium batteries.
11. Do not leave the batteries in the monitor when it is not in use. Damage from corrosion could result.

12. For the best recording results, the patient should be instructed to avoid close proximity to heavy electrical equipment or other sources of electromagnetic interference such as electric blankets, heating pads, etc.
13. This device should not be used for monitoring vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient.

Additional equipment classification information as required by EN 60601-1

A. EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE
B. IPX0-Ordinary Equipment (enclosed equipment without protection against ingress of water)
C. Internally Powered Equipment
D. Mode of Operation – Continuous Operation

Notice: U.S. Federal law restricts this device to sale by or on the order of a physician.

Operation

Monitor Components

The device has a simple human interface consisting of an LCD and a keypad containing ▲<up>, ▼<down>, ◀<left>, ▶<right> and ↵ <enter> keys. There is also an <EVENT> button for the patient to note significant times during the monitoring period as instructed.

Generally, navigation between screens is accomplished using the ◀ and ▶ keys and navigation between elements on a screen uses the ▲ and ▼ buttons.

To select an item for modification, first navigate to the appropriate screen, then move ▲ or ▼ to place the cursor on the item you wish to modify. Press ↵ to enable the spinner control that enables you to navigate within the control and change the selection to the desired content. The ◀ and ▶ behavior is modified to navigate within a control while the ▲ and ▼ scroll through the valid items selectable within a particular spin control. When the modifications are completed, press ↵ to accept your changes or <event> to cancel them and exit the modification state.

Any device settings made during setup are stored in non-volatile memory and are saved for the next session.
Patient specific information is not stored beyond the context of the current recording session to prevent cross-contamination of data, that is: mixing up the next patient's data with a prior patient's information.

NOTE:

Do not use sharp fingernails or other sharp objects to press the keypad buttons. Doing so can cause a crease in the overlay layer of the keypad which may cause a button to get 'stuck' or stop working. Use the pad of your fingertip or a pencil eraser – you will feel the button depress and see the change in the LCD screen.

Device Screens and Workflows

Display Menus

'About This Unit'

The first screen to appear is the About This Unit screen. This screen stays on for about 3 seconds after battery insertion and contains unit information including:

- *VectraCor Inc.*
- *V300* — *Model Number*
- *Rev Level (n.nn)* — *Firmware Revision Number*
- *S/N F0000000* — *Serial Number*
- *H/W Revision 00* — *Hardware Revision Number*
- *Update Software* — *Allows holter monitor software to be updated in the field.*

'Unit Settings'

The first time the unit is used, the screen will automatically advance to the Unit Settings screen so that some basic information and preferences can be entered. The modifiable information on this screen includes:

- *Date* — *Set Month, Day, and Year*
- *Time* — *Set the Time*
- *Contrast* — *LCD contrast for Viewing*
- *Factory Defaults* — *Returns all setting as they were 'out of the box'.*
- *Update Software* — *Select to upgrade Firmware in the holter monitor – Updates will be issued by VectraCor Inc., with detailed instructions,*

'Preferences'

The preferences screen has 5 modifiable fields.

- *ID Style: Numeric* — *Alpha-Numeric or Numeric can be selected*
- *Template : ************** — *The FORMAT of the ID can be set*
- *Auto Off : On* — *Toggle between **On** and Off*
- *Confirm Erase : Yes* — ***Yes** or No can be selected*

AUTO OFF is a battery saver. If a recording session isn't started within the allotted time, the unit powers down to save the battery. Good for when the user just tosses the unit in a drawer and doesn't turn it off or pull the battery.

CONFIRM ERASE happens when the holter monitor finds a file that has not been uploaded. There is an archive bit "A" set in the properties of the file. The code that uploads the file is supposed to clear this so the holter monitor knows the file has been uploaded. If the archive bit is set, then the holter monitor prompts to remind you that the file hasn't been uploaded and asks if you still want to erase the file.

'ECG Settings'

The ECG Settings screen has 4 modifiable fields.

- *Duration: 1 Day* — *Select **1**,2,3,4,5,6,7 Days*
- *Device Mode: 3-Channel* — *Shows which Patient Cable is installed – 2-Channel or 3-Channel*

AUTO START feature is for when the tech has performed a hookup review, but failed to actually start the recording session. After the specified time, the unit will transition into monitor mode on its own.

'Patient Info'

The ECG Settings screen has 4 modifiable fields.

- *Patient ID:* — *Input Patient ID for this recording*
- *D.O.B. **/**/**** * — *Input this patient's DOB*
- *Pacer Analysis: No* — *Select Yes or No whether Patient has implanted Pacemaker*
- *Erase All Files* — *Erase previous file and format the μSD card. See Above.*

'Review & Start'

The review and start screen enables the clinician to view the signal tracings on each channel and start the recording process. Upon first start the device navigates to the Unit Settings Screen, however on subsequent starts the device automatically advances to the Review and Start screen. The clinician is able to navigate back to other panels at any time if changes are desired to any of the existing settings.

- *Review Leads* — *Select to view each channel's tracing to preview the Hookup.*
- *Start Recording* — *Select to Start the Recording.*
- *Pt ID: ********** * — *Displays ID that was entered above.*

'Review Leads'

Select Review Leads from Review & Start Menu above.
Each Channel's real-time EKG tracing will be displayed 1 Channel at a time – use the Left and Right arrow keys (◀ and ▶) to toggle between channels. The Gain can be set using the Up and Down Arrow keys (▲ and ▼). Gain settings of 1/4x, 1/2x, 1x, 2x and 4x are selectable. The Default is 1x. The gain selected will apply to all channels.
When Review is complete, Press the Enter button (↵) to return to the Review & Start Menu.

Recording

Once the Setup is complete, Select Start Recording from the "Review & Start' Menu. Press ↵ <Enter> to start. The holter monitor will erase the microSD card, calibrate the incoming signal, then display the ECG Data screen.

This is the screen display for the duration of the monitoring period. The patient can register an event by pressing the Event Button after which another event cannot be registered for 30 seconds.

The holter monitor will operate continuously for up to 4 days on a single AAA alkaline battery, if the monitoring period is set for a longer time, the unit's LCD will then prompt the user (patient) to replace the battery. This message will be displayed for about 30 seconds, then the unit will power down awaiting a fresh battery. Once the battery is changed, the unit will power-on come out of sleep mode, then resume monitoring for the duration of the pre selected monitoring period.

If desired and available, for longer duration monitoring sessions, a 1.5-volt AAA lithium battery may be used (EverReady Ultimate Lithium or equivalent). This will allow a full monitoring session without the need to change batteries.

Shelf Life and Disposal of Electrodes, Batteries, and Device.

Electrodes: The device requires quality wet or gel type electrodes deigned for extended use. Always check the electrode's date code and do not use expired electrodes as electrical performance will deteriorate.

Battery: The device will operate according to specifications on either a new "AAA" Alkaline or Lithium 1.5v battery. The device is not rated for operation on rechargeable cells such as nickel metal-hydride, or nickel cadmium cells. Please consult local regulations for proper disposal of batteries.

Device: The ***V300* Holter Monitor** does not have a shelf-life per se, because it does not contain any components subject to wear or degradation. At the end of its useful life, please return the device and cable to VectraCor Inc. for proper disposal or dispose of with other electrical equipment per local regulations.

Patient Hook-Up

Introduction

As with all Holter systems and all Holter procedures, the patient hook-up procedure is a major factor in the quality of the report that will ultimately be created. While every effort has been made to produce the finest Holter Monitor and analysis software that today's technology can produce, ultimately the care that goes into the patient hook-up can either allow the system's capabilities to show through or defeat the best efforts of the system and the operator in creating an accurate, readable, report. Please review this section carefully and practice each of these suggestions diligently, the reward will be greater comfort

for the patient and less effort for the operator and physician in reviewing and interpreting the report that results.

Patient Preparation

Inform the patient that the procedure is painless and safe. Some minor irritation may result from the electrodes and tape. The patient can also expect some awkwardness in wearing the device for 24 hours and should be assured that the test is beneficial in helping the physician assess and evaluate the patient's cardiac condition.

Please use the lead placement diagrams on the following pages for correct electrode and wire color placement.

Skin Preparation

Shave all locations where tape and electrodes contact the skin.
Rub and clean electrode sites aggressively with alcohol to remove dead tissue cells, body oils, perspiration, dirt, skin creams, etc.
Abrade electrode sites using 2 X 2's or 4 X 4's. (Normal redness may result.)
Use the highest quality long term HOLTER electrodes possible.
Select flat areas (over bone) on the chest avoiding large muscle areas and breast tissue as much as possible.

NOTE:

Be sure to allow the alcohol sufficient time to evaporate as it may not be compatible with the wetting gel on the electrode.

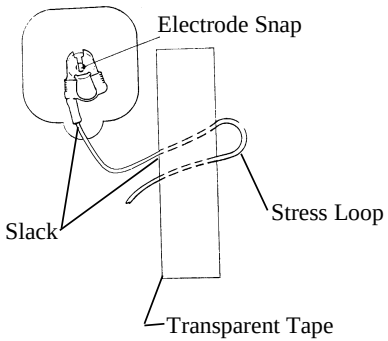
Attach Electrodes to Lead Wires

Attach the wires to the electrodes before securing to the patient. It is essential that the lead wires be firmly "snapped" and "set" onto the electrodes. A gentile tug should not result in lead-wire displacement.

Carefully apply electrodes ensuring the center gel is in solid contact with the skin. The electrodes' adhesive border should be pressed firmly for consistent adhesion without wrinkling or creasing the tape. Remove and replace any electrode not firmly adhering to the skin.

Stress Loops

Taping down the wire portion of the lead-wires will minimize artifact and noise in the recording. (See illustration.) (Remember to shave stress loop sites.) Leave enough slack in loop, allowing for normal patient movement without pulling on the electrodes, lead-wires.



Verify Signal Quality

Verify proper patient hookup of all channels/leads by using "Review Leads' feature from the Review & Start screen on the holter monitor. Verify the appropriate amplitude signal is being obtained from each channel/lead without noise or artifacts. Electrodes may be re-positioned at this time to obtain optimum signal integrity and holter monitor performance.

Patient Diary

Please take time to explain and consult the patient about the clinical value in correctly using the diary. A properly used diary is essential in the "time and event" relationship and is an integral part of the Holter procedure.

During a recording

During recording, the ***V300 Holter Monitor*** displays the date, current time, time remaining for the recording, and any lead errors or cable loss if they are present.

Patient Event Marker

Instruct the patient to press the Event Button at the end of the holter monitor to mark the time of a significant event during the recording. The patient should also make a Diary Entry describing the event at that time as well.

NOTE: *Once a manual event has been activated, the patient must wait one minute to activate another manual event.*

Normal Ending

When data acquisition time is completed, the device will automatically stop and power down. The screen with go blank – no data will be lost; it may then be returned to the office for transfer of the data.

"Early Out"

If the device has not turned itself off and is actively recording, the clinician can use a four key sequence to end the session immediately. To do this first press ↵ <enter>, then ► <right> then ↵ <enter>, then the Event Button. Do not press the keys at the same time but do press them one after the other. If you have done so appropriately the device will prompt you with "Press EVENT" to end the recording. If you do not do so within 3 seconds, the key sequence is dismissed and the device continues to operate. This particular key sequence was selected with this specific timing to ensure that a patient bumping a device, rolling over on it in their sleep, or someone pressing the keypad at random would be unlikely to cause a premature shutdown of the device.

NOTE: The holter monitor will automatically shut down and save the data if the battery level becomes too low. The recording is saved and is ready to be transferred to the Holter Analysis Software.

Removal of Monitor, Battery and Patient Cable

1. Remove the electrodes from the patient.
2. Leave the battery in the holter monitor if it will be connected to a USB cable for data transfer to VectraCor Holter Software. Remove the battery if it will not be used for an extended period. Properly dispose of the battery according to local laws.
3. Remove the patient cable by squeezing the two side latches on the head of the patient cable and pulling away from the monitor.

NOTE: *NEVER pull on the cable itself because this can break the wire inside the insulation. Pulling on the cable also can cause a noisy and intermittent ECG recording.*

Electrode Placement

See the following pages for the various typical hookup configurations. Variations on the suggested sites may be chosen by the physician depending on the type of arrhythmia the patient is suspected of having or other factors that could affect electrode placement.

NOTES:

- *Proper preparation of the patient's skin is essential for obtaining a good ECG recording.*
- *Use only quality electrodes designed for longer term recording with a Holter monitor.*
- *All the electrodes should come from the same manufacturer.*
- *Improper connection will cause inaccuracies in the ECG recording and difficulty in interpreting the data.*

General guidelines for electrode placement:
If Amplitude of complexes is less than 1mv:
In Channel 1: Position Black electrodes further from sternum.
DO NOT USE SAME ELECTRODE, then move wire to new electrode – if amplitude improves, remove first electrode.

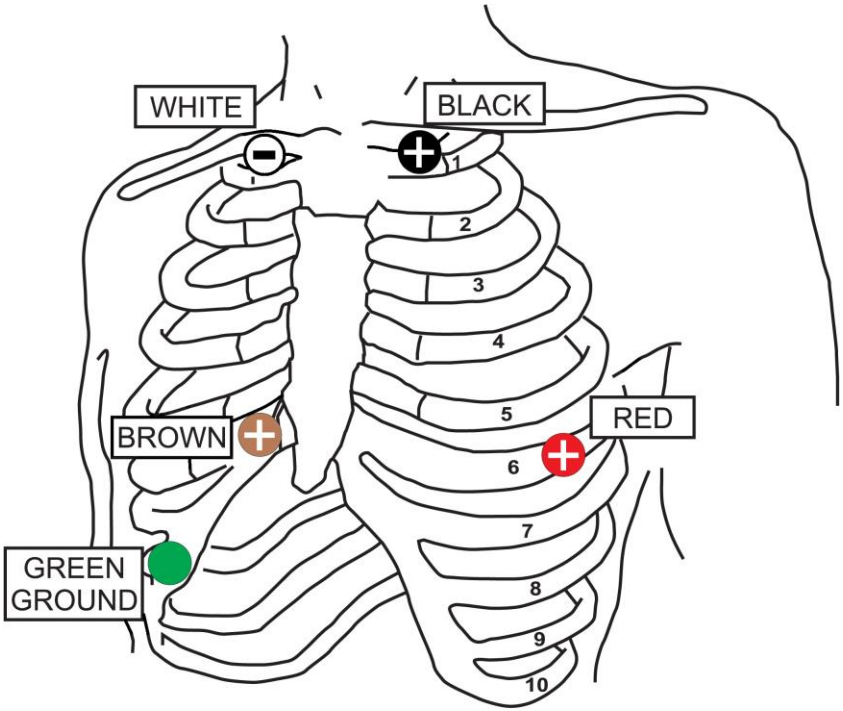
In Channel 2: Position new electrode closer to apex than current Red electrode (toward patient's Right – closer to V4 position). DO NOT USE SAME ELECTRODE, then move Red wire to new electrode –
if amplitude improves, remove first electrode.

In Channel 3: Position new electrode closer to apex than current Brown electrode (toward patient's Right – closer to V4 position). DO NOT USE SAME ELECTRODE, then move Brown wire to new electrode –
if amplitude improves, remove first electrode.

** Alternate Lead Placement Configurations may be used depending on specific aspects of EKG waveform being sought by the physician.

3-Channel, 5-Lead Electrode Placement

Five color-coded lead wires are utilized to create a 3-channel ECG recording. This is a typical electrode placement; refer to Analysis System software and the physician for recommended positioning.



Electrode	Channel	Position
White	1 -, 2 -	4cm Right of Manubrial Border of Sternum, below Clavicle.
Red	2 +	Left Anterior Axillary Line 6th Rib.
Black	1 +	4cm Left of Manubrial Border of Sternum, below Clavicle.
Brown	3 +	2 cm Right of Xiphoid Process. on the Rib Margin.
	3 -	Wilson Central Terminal (Combined from other leads)
Green	Reference	Lower Right Rib Margin Over Bone.

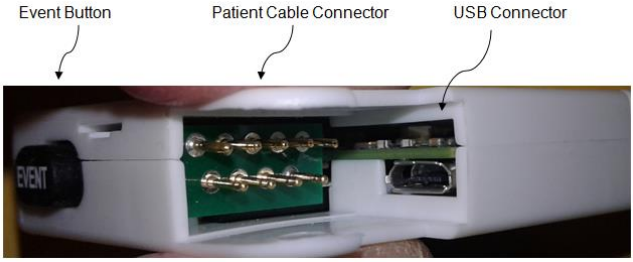
Check list for the Experienced Operator

Please thoroughly review the detailed steps after this section for all aspects of operating the holter monitor. The 'Short List;' is presented here as a primer and for review.

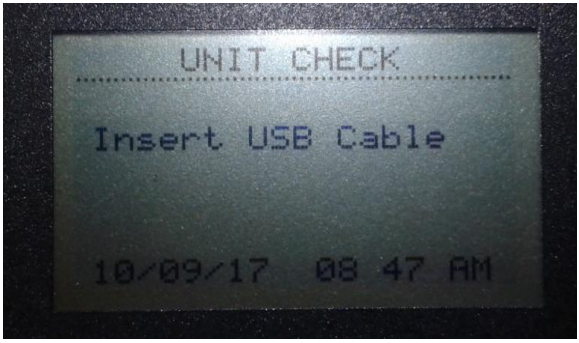
- Select electrode sites and prepare patient's skin.
- Connect electrodes to lead wires.
- Review unit with patient (event button, battery replacement (if necessary) lead wires, etc.).
- Connect Patient Cable to holter monitor.
- Install new "AAA" Alkaline or Lithium battery. Be sure to observe the correct battery polarity. The monitor will display a splash screen: Press any key to start.
- Enter Patient ID.
- Enter Date of Birth.
- Review patient EKG on LCD.
- Select Duration of Recording and if Pacer Detection is required.
- Log information in diary.
- Press "Start Recording"

Data Transfer

For transferring patient data at end the of session, please remove patient cable and insert a standard Micro USB cable into the device (see below) and connect to a computer workstation.



The USB cable is 'polarized' meaning that it can only be inserted one way – Do Not force the cable in, you may need to flip the connector over to insert it. The display on the monitor will change once inserted, and you may hear Windows beep indicating that it 'found' the holter monitor. Once inserted, you can turn your attention to the Trillium Holter Analysis software to complete the transfer.



Analyzing the ECG Data

The user has two options to download the captured ECG data:

1 USB connectivity: Confirm that the memory card is still in the monitor and is powered up with a sufficient battery (Low Battery message does not come on). Now remove the patient cable from the holter monitor, and replace it with the USB cable (P/N 59N-0454). Attach the other end of the USB cable to an available USB port on the computer. The monitor is now acting as a card reader and can be accessed similarly as any removable disk drive would be, the LCD on the Holter monitor should show “USB”.

2 Remove the memory card from the holter monitor and insert the memory card into a card reader at the Computer Analysis System and transfer the ECG data according to its requirements.

Troubleshooting

Lead-Quality Problems
"Artifact" on the screen
Artifact is any signal not of cardiac origin that makes it difficult to accurately discern the waveform morphology.
Causes
• The patient was moving.
• There was hair trapped in the electrode's adhesive.
• The electrode or lead wire was loose.
• The patient was shivering.
• There is electrical interference.
Actions
See actions for wandering baseline, muscle tremor, and AC interference.

Wandering Baseline
Wandering baseline is an upward and downward fluctuation of the tracing.
Causes
• Electrodes are dirty, corroded, loose, or positioned on bony areas.
• The electrode gel is insufficient or dried.
• The patient has oily skin or used body lotions.
• Rising and falling of chest during rapid or apprehensive breathing.
Actions
• Clean the patient's skin with alcohol or acetone.
• Reposition or replace the electrodes.
• Verify that the patient is comfortable, warm, and relaxed.
• If wandering baseline persists, turn the baseline filter on.

Muscle tremor
Causes
• The patient is uncomfortable, tense, or nervous.
• The patient is cold and shivering.
• The exam bed is too narrow or short to comfortably support arms and legs.
Actions
• Verify that the patient is comfortable, warm, and relaxed.
• Check all electrode contacts.
• If interference still persists, the problem is probably electrical in nature. See the suggestions for reducing AC interference (see below).

AC interference
AC interference superimposes even-peaked, regular voltage on the waveforms.
Causes
• The patient or technician was touching an electrode during recording.
• The patient was touching a metal part of an exam table or bed.
• A lead wire, patient cable, or power cord is broken.
• Electrical devices in the immediate area, or lighting, or wiring concealed in walls or floors are interfering.

• An electrical outlet is improperly grounded.

Actions
• Verify that the patient is not touching any metal.
• Verify that an AC power cable is not touching the patient cable.
• If interference still persists, the noise may be caused by other equipment in the room or by poorly grounded power lines. Try moving to another room.

Error Messages

The ***V300* Holter Monitor** series performs a power-on self-test when the battery is installed. If the test finds a problem with the monitor, it displays an error message on the LCD. The common error codes and action are as follows:

Error Message	**Solution or Recommendation**
Replace Battery	Install a fresh battery. Only Displays if monitoring session was set to over 4 days or weak battery was used.
No Cable Detected	Connect an appropriate cable
Insert USB Cable	Monitoring session is complete. Insert USB cable to transfer data.
No Display	Check battery direction
Crystal Failed Or Self Test Failed	Hardware failure - Return the unit for Repair
Battery does not last for the selected number of hours	Ensure new battery is being used. Check that the memory card is certified by VectraCor Inc..
Monitor does not run for the selected number of hours	Check that Settings screen is set for the desired number of hours.
Noise artifacts on ECG signal	Ensure all electrodes are securely attached to the patient. Ensure patient cable is inserted completely. Replace the patient cable.
Defective Card Message	If multiple cards are defective, call for service.
Any Other Errors	Contact VectraCor Inc.
ECG signal quality problems	Verify fresh electrodes & good connections. If the issue exists on more than 1 channel, check the reference electrode (Green) as that is used to generate signal that minimizes interference in the signal.

Maintenance

Only perform Maintenance when the device and patient cable are removed from patient.

After each use: Use a soft cloth dampened with germicidal solution to clean the holter monitor and pouch.

Prior to each patient use, inspect the patient cable and lead wires for damage. As necessary, clean the patient cable and lead wires using a soft cloth dampened with a germicidal solution.

DO NOT use alcohol or acetone on the lead wires since they could stiffen and crack the insulating plastic.

DO NOT leave a battery in the holter monitor if it is not to be used for an extended period of time. Damage from battery leakage and corrosion could result.

Service

Other than daily cleaning, service is only needed when the device does not perform as expected or an error message appears.

The device, patient cable and micro-SD card must be returned to VectraCor Inc. for repair.

Often a return can be avoided by contacting VectraCor Inc. with a detailed description of the problem and the circumstances that lead up to it.

THERE ARE NO SERVICEABLE PARTS INSIDE THE UNIT.

Please refer all enquiries to:

VectraCor Inc.
785 Totowa Road, Suite 100
Totowa, NJ 07512
973-904-0444
800-844-2037
info@vectracor.com
www.vectracor.com

Specifications

Please note some features may not be available on all ***V300 Holter Monitor*** models.

Functional	
Leads	4-Lead (2-Channel) or 5-Lead (3-Channel) Standard ECG Snap contacts
Resolution	12 bit
Sample Rate transmitted	250 SPS
Over Sampling	24,000 Hz over-sampling all channels
Frequency response	0.05 – 100 Hz (3dB)
Common mode rejection	60 db minimum, 60 Hz common mode signal
Gain settings	0.25x, 0.5x, 1x, 2x and 4x
Pacemaker detection	Concurrent pacemaker detection on all channels Programmable On/Off
Defibrillator Protection	NONE - Must be removed before Defibrillation
Data integrity	Unique device signature and CRC-16 on every frame sent; individual lead framing format ensures any wireless packet loss will not affect all leads simultaneously
Signal verification	Device LCD provides lead placement and signal quality verification during patient hook-up
Download interface	USB 2.0
Display	Monochrome 2.4” LCD
Physical	
Dimensions	2.5” L X 2.0” W X 0.5” D
Weight	1.4 oz. With battery
Case	Molded, high-impact, textured plastic enclosure
Operating position	Any orientation
Storage Media	µSD Card
Clock	Real-time clock with date and time
Power	
Power source	One "AAA" alkaline, or 1.5v Lithium battery with reverse polarity protection
Battery Life	Up to 4 days for Alkaline, 7 for Lithium.

Environmental Conditions

Operating

Temperature Range	+5°C to +45°C
Humidity	Operating: 10% to 95% non-condensing
Atmospheric Temp.	70.0Kpa to 106.0 Kpa

Storage & Transport

Temperature range	10°C to 70°C
Humidity	10% to 90% non-condensing
Atmospheric Temp.	7 Kpa to 106 Kpa

FCC Compliance Statement

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.

Note:

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.
- Contact VectraCor Inc., for additional troubleshooting techniques.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this device.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the ***V300* Holter Monitor**: for equipment and systems that are not life-supporting

The ***V300* Holter Monitor** is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the holter monitor can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the holter monitor as recommended, according to the maximum output power of the communications equipment.

Separation Distance According to Frequency

Rated Maximum Output Power of Transmitter Watts	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	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1.0	1.2	1.2	2.3
10.0	3.8	3.8	7.3
100.0	12.0	12.0	23.0

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 the 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 unit is used exceeds the applicable RF compliance level above, then the unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the unit.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±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%.
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
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 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[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The ***V300 Holter Monitor*** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The ***V300 Holter Monitor*** 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.

Equipment Symbols

Symbol	Description
	Type B Applied Part
	Consult manual.
R_x only	Caution: U.S. Federal law restricts this device to sale by or on the order of a Physician or other qualified Healthcare Provider
CE ####	Complies with the Medical Device Directive of the European Union.
	Waste Electrical and Electronic Equipment (WEEE) It is the responsibility of the end user to dispose of this equipment at a designated collection point for recycling.
20XX 	Year of Manufacture
SN	Serial Number
	Manufacturer
	Temperature range
	Humidity range
	Atmospheric Pressure
	Operator Manual must be read
	Magnetic Resonance Unsafe

Note Concerning Flash Cards

Not All Flash Memory Cards are created equal!

The objective of this Technical Note is focused on achieving optimal ECG recordings with the ***V300* Holter Monitor** AECG recorders. The key point is to understand the wide quality range of flash memory cards that are built and marketed by different manufacturers. Micro Secure Digital (μSD) Flash memory suppliers market several grades of memory from military and industrial grades to consumer grades (commonly used in cell phones, digital cameras and popular consumer electronics). It is generally unknown by most users how widely quality varies among various grades and brands regarding excessively high-power consumption and susceptibility to defective memory sectors on the card. It should be noted that flash card suppliers frequently change designs of chip sets, effectively changing performance of the card without notice and regard to performance implications (Often without a change to labeling or part numbers). VectraCor Inc., takes considerable time to test and specify only the highest quality, most reliable models and highest quality brands of flash memory cards to optimize ECG recording performance and reliability. It is impossible unfortunately, for VectraCor Inc., to test every variation of every manufacturer's card or keep an exhaustive list of all possible cards.

Recording performance will vary **significantly** from brand to brand.

Recommendations
Use only VectraCor Inc. certified flash memory cards in V300 Holter monitor to achieve optimized recording and quality performance. Certified flash memory cards are labeled and shipped with each monitor. They are also available from VectraCor as accessory items.

Use cards other than VectraCor Inc. certified cards at your own risk!

Should it become necessary to use other than flash memory cards supplied by VectraCor Inc., only the highest quality supplier and industrial or military grade cards are recommended for use in ***V300* Holter Monitor** for maximum recording quality. Fast write speed cards are generally not recommended as power consumption is usually significantly higher in these cards and may not allow a full recording period to take place. Capacities greater than 16 Gigabytes are not supported by the ***V300* Holter Monitor**. Some cards have better internal memory 'wear-leveling' and error correcting controllers and can be the source of longer or shorter life spans. If possible, use cards of the same memory capacity as those originally supplied with each ***V300* Holter Monitor**; if necessary, higher density cards may be used, but always less than the 16 Gigabyte maximum.

VectraCor Inc. recommends a minimum test run of 24 - 48 hours before use on a patient.

Please contact VectraCor Customer Service to purchase additional cards.

REMINDER! All ***V300*** **Holter Monitor** require that the Flash memory card be inserted with its front label toward the BACK of the holter monitor. The monitor will not power-up and may be damaged with the card inserted backwards.

Notes

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