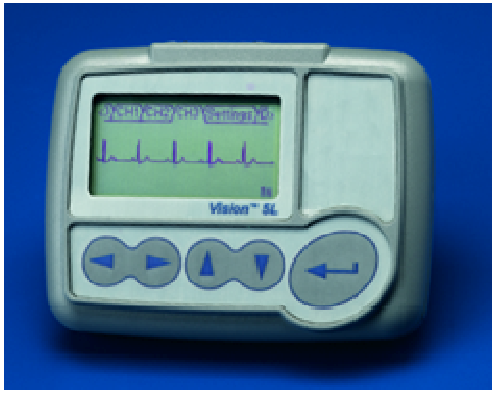
Operating Instructions



Vision 5L Digital Holter Recorder

Document Number: 010-1646-00
Revision: H

CARDIAC SCIENCE

Bothell, Washington 98021-8969 (608)-764-1919

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

Manufactured for
Cardiac Science Corp.
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CE
0297

Authorized Representative
per MDD 93/42/EEC

MDSS
Burckhardtstrasse 1
D-30163 Hannover, Germany

Recommended Separation Distances

Refer to the following table for recommended separation distances between the Vision 5L and portable and mobile RF communications equipment.

The Vision 5L is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Vision 5L can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Vision 5L as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.

NOTE1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

NOTE 1: At 80 MHz and 800MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
* Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Vision 5L is used exceeds the applicable RF compliance level above, then the Vision 5L should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Vision 5L. † Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

PC Card Compatibility
Vision Series Holter Analysis Systems
92500, 92501, 92502, 92503

The Vision™ 5L CompactFlash card is only compatible with the following Vision Series Holter Analysis Systems:

- Windows 98 2nd Edition
- Windows 2000 Professional
- Windows XP Professional

The CompactFlash card is guaranteed for use only in the above systems, and is not appropriate for use with any other system or computer.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Vision 5L, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 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 metres (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 Vision 5L 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 Vision 5L 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.

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.

Table of Contents

Overview

Description

The Vision 5L Holter recorder is a battery operated solid state recorder designed for 24 to 48 hour continuous recording of ambulatory ECG data and the ability to detect and record pacemaker pulses in accordance with appropriate AAMI pacer detection criteria.

The Vision 5L is an AAMI Type I device, which is part of a conventional AECG monitoring system where the ECG is recorded on a CompactFlash memory card installed in the Vision 5L. After the recording is complete, the CompactFlash card is removed and placed in a Card Reader connected to the Vision Series Holter Analysis system. Follow the instructions provided with your Vision Series system to down load and analyze the recorded ECG data. The Vision 5L is compatible with Windows 98SE or higher and only computers complying with EN60950 should be used.

Indications for Use

The Vision 5L Holter recorder is intended for patients requiring ambulatory (Holter) monitoring from 1 to 48 hours. Such monitoring is most frequently used for the indications below:

1. Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.
2. Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients.
3. Evaluation of patients for ST segment changes.
4. Evaluation of a patient's response after resuming occupational or recreational activities (e.g., after M.I. or cardiac surgery.)
5. Clinical and epidemiological research studies.
6. Evaluation of patients with pacemakers.
7. Reporting of time and frequency domain heart rate variability.
8. Reporting of QT Interval.

EMC Declaration Tables

WARNING: Use of accessories or cables other than those specified, with the exception of Burdick accessories and cables sold by Cardiac Science Corp. as replacement parts for internal components, may result in increased emissions or decreased immunity of the Vision 5L.

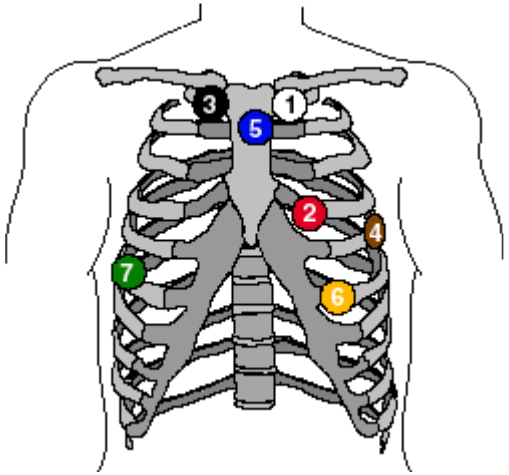
CAUTION: The Vision 5L requires special precautions regarding EMC. Install and use the Vision 5L according to the guidelines of the EMC declaration tables.

CAUTION: Portable and RF communications equipment may affect the Vision 5L. Always observe the recommended separation distances as defined in the EMC declaration tables.

The Vision 5L is intended for use in the electromagnetic environment specified below. The customer or the user of the Vision 5L should assure that it is used in such an environment.

3 Channel (7 lead) Electrode Placement

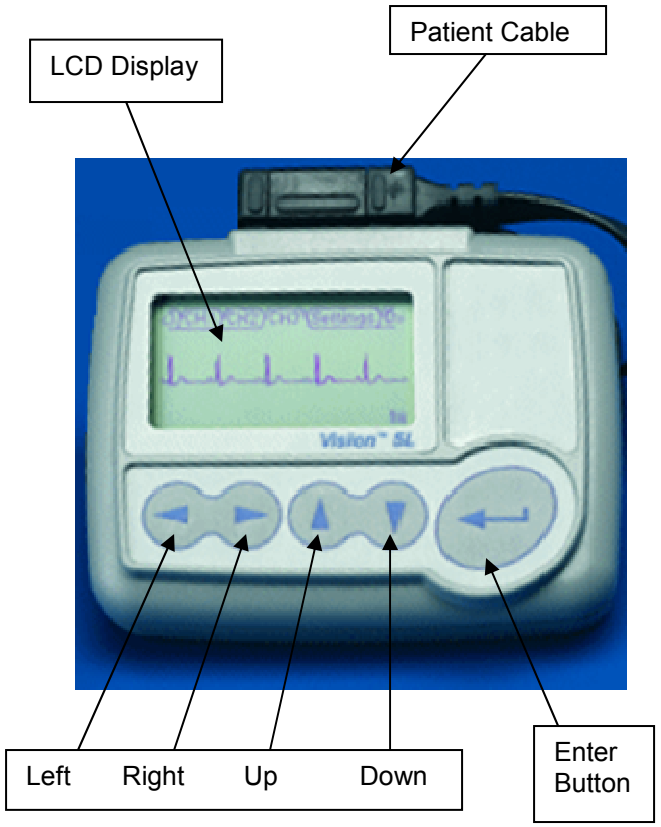
Seven color-coded leadwires are utilized to create a 3 channel ECG recording.



7 Lead Electrode Placement

#	Channel	Color	Placement
1	1-	White	Below left clavicle, just lateral to the midclavicular line
2	1+	Red	At the fourth rib to the left of the sternal border
3	2-	Black	Below right clavicle, just lateral to the midclavicular line
4	2+	Brown	Fifth rib at the left anterior axillary line
5	3-	Blue	At manubrium sterni
6	3+	Orange	Sixth rib at the left midclavicular line
7	Reference	Green	Lower right chest wall, rib

Recorder Components



Equipment Symbols

Symbol	Description
	Type B equipment.
	Consult manual.
CE 0086	Complies with the Medical Device Directive of the European Union.
20XX	Year of Manufacture
SN	Serial Number
REF	Catalog/reorder number
	Complies with the North American ETL safety standards

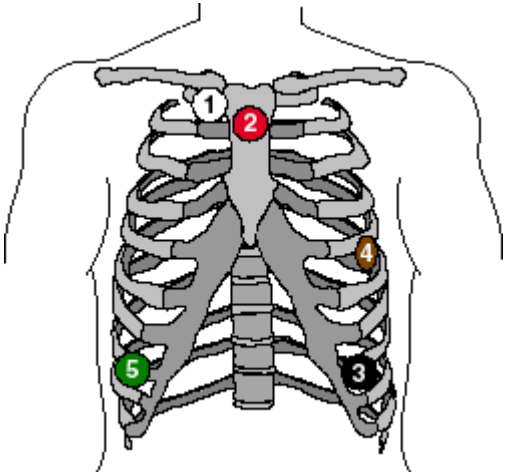
Precautions

- Patient leads must be removed from electrodes before defibrillation.
- When using Pacer Detect, the physician should be aware that false positive and false negative pacer detects 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.
- When reviewing ECG data the presence of pacemaker signals in the ECG trace should not be considered true representations of the actual pacemaker stimulus amplitude.
- Observe local laws for disposal of alkaline batteries.
- Do not leave the batteries in the recorder when it is not in use. Damage from corrosion could result.
- 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.

Electrode Placement

3 Channel (5 lead) Electrode Placement

Five color-coded leadwires are utilized to create a 3 channel ECG recording.



5 Lead Electrode Placement

#	Channel	Color	Placement
1	3-	White	Below right clavicle, just lateral to the midclavicular line
2	1-, 2-	Red	Top of the sternum
3	2+, 3+	Black	Eighth rib at the left midclavicular line
4	1+	Brown	Fifth rib at the left anterior axillary line
5	Reference	Green	Eighth rib at the right midclavicular line

NOTE:

BROWN – RED = Channel 1
BLACK – RED = Channel 2
BLACK – WHITE = Channel 3

Specifications

Functional	
Channels	3
Resolution	8-10 bit sampling, 4X Oversampling Programmable
Recording	Full disclosure
Download interface	Removable CompactFlash (Non-volatile)
Sample rate	200/sec
Frequency response	0.05Hz to 60Hz, @ -3dB
Signal verification	LCD display
Pacemaker Detection	
Memory	
Recording time	24 or 48 hours
Type	Non-volatile Flash Memory
Capacity	128MB (Removable)
Physical	
Dimensions	3.75” x 3.00” x 0.90” (95 x 76 x 23mm)
Weight with batteries	4 oz. (114 grams)
Enclosure	Molded plastic (UL 94V-0)
Operating position	Any orientation
Electrical	
Gain settings	1X
Connector	20 pin
Patient cable	5 or 7 lead
Environmental	
Operating temperature	0° C (32° F) to 45° C (113° F)
Non-operating temperature	-20° C (-4° F) to 65°C (149° F)
Operating humidity	10% to 95% (non-condensing)
Non-Operating humidity	5% to 95% (non-condensing)
Battery	
Type	(1) AA Alkaline IEC-LR6
Life	48 hours

Electrode Application

- It is recommended that trained medical personnel handle the application of electrodes.
- Use only electrodes designed for longer term Holter monitoring.
- Proper preparation of the patient's skin is absolutely essential for obtaining a quality ECG recording. Refer to your electrode provider for instructions on skin preparation techniques.
- Apply electrodes per Electrode Placement diagrams on page 13 in this manual, or as instructed by the physician.

Operation

Initialize the CompactFlash Card

Refer to the Operating Instructions of your Vision™ Series system for the initialization procedure.

NOTE: The Vision 5L Holter Recorder is only compatible with the CompactFlash card provided, part number 010-1640-00. The CompactFlash card is exclusively for use with the Vision 5L Holter Recorder, and is not compatible with other Holter recorders.

CAUTION: CompactFlash card must be initialized prior to recording. Otherwise, ECG data from previous recording is retained.

How to Record

1. Install initialized CompactFlash card observing correct insertion direction and method.

   It is recommended that the CompactFlash card be installed first before installing the battery.

2. Install fresh AA alkaline battery in the Vision 5L.

   Be sure to observe the correct battery polarity.

3. Hook up the patient to the device via the patient cable.

CAUTION: Insert the patient cable in the orientation as shown in the picture on page 2. The patient cable will require a very firm squeeze on the locking clip of the cable plug in order to install or remove it from the Vision 5L. However, it only needs to be removed in the event of damage.

Service Items & Accessories

Description	Part Number
128 MB CompactFlash Card	010-1640-00
3 Channel Recorder Prep Kit, with 5 electrodes	043250
3 Channel Recorder Prep Kit, with 7 electrodes	043272
5 Lead Patient Cable	010-1642-00
7 Lead Patient Cable	010-1643-00
Pouch with Strap	010-1644-00
Belt Clip	010-1645-00
Operating Instructions	010-1646-00

NOTE: The Vision 5L Holter Recorder is only compatible with the CompactFlash card listed above. The CompactFlash card is exclusively for use with the Vision 5L Holter Recorder, and is not compatible with other Holter recorders.

Troubleshooting

Symptom	Recommended Solution
No display	Ensure patient cable is connected.
	Ensure battery is inserted with correct polarity.
	Install new alkaline battery
Low battery	Inspect battery compartment, clean contacts if necessary.
	Install new alkaline battery.
Battery does not last 24 or 48 hours	Ensure new alkaline battery is being used.
Noise artifacts on ECG signal	Ensure all electrodes are securely attached to the patient.
	Replace the patient cable.

To turn on the recorder push any one of the keypad buttons. A splash screen will be displayed for a couple seconds, then the trace screen will be displayed.

The device will not turn on unless a cable is plugged in.

4. Push the "◄" and "►" keypad buttons to change the active screen.
5. To input Patient ID choose “Input Patient ID” from the proper screen. Scroll Numerical line for Patient ID using ◄, ►, ▲, and ▼ buttons. “ENTER” button selects each entry of Patient ID.
6. ***It is recommended that, after the patient hook up is complete, the device be inserted in the Vision 5L pouch to be worn by the patient either on the belt or with the shoulder strap.***

Screen	Description
Trace	Displays the signal trace in real time, pacer pulse marks | if selected. There is one screen for each ECG channel. • *The gain setting is the same for all channels.* • *Pacer pulse marks | are displayed below the trace to indicate each pacer pulse detection.*
Settings	For setting the record time, user language, LCD contrast. To change settings, press the “ENTER” button for set mode. To change fields, push the ▲ and ▼ buttons. To change values push the ◄ and ► buttons. Push “ENTER” again to save and exit. • *The default for pacer detect is OFF. It must be turned ON for each procedure in which it will be used.*
Date/Time	For setting the date and clock. To set the clock, press “ENTER” for set mode. To change fields, push the ▲ and ▼ buttons. To change values push the ◄ and ► buttons. Push “ENTER” again to save and exit.
About	Unit information and Copyright notice
Start	After configuring or reviewing all the settings, select the start screen and push the “ENTER” button. This will start the recording.

Recording Display
The Vision 5L displays the current time and the remaining recording time.

Patient Event Marker
To register an event, push the “ENTER” button.

Early Out and Real Time ECG Display
Hold the◄ arrow button and the “ENTER” button simultaneously to access the menus for Early Out and Real Time Display. The Early-Out feature allows a trained individual to stop a recording before the selected recording time has elapsed. When viewing the Real Time Display, the user can return to the recording screen manually, or the Vision 5L will automatically return after five minutes have elapsed. Real Time mode does not interrupt recording.

Caution: Do not remove CompactFlash card or battery until session is complete or Early Out procedure is finished.

Session Complete
Remove the CompactFlash card, disconnect the patient leads from the electrodes, and dispose of the electrodes. The patient cable connector can remain connected to the Vision 5L for the next procedure. Remove and properly dispose of the alkaline battery according to local laws.

Analyzing the ECG Data
Insert the CompactFlash card into the card reader of the Vision Series system on which the ECG analysis is to be performed.

Once the data transfer is complete, the previous patient’s name and any other information written on the CompactFlash card’s label should be removed. Be sure to initialize the CompactFlash card prior to next use.

Service & Maintenance

Maintenance

Cleaning
Dampen a soft cloth with mild detergent and water to clean the recorder, lead wires, and belt clip. Remove the battery before cleaning the recorder.

Service
If there is a problem with the recorder, review the problem descriptions and solutions listed below. If additional assistance is required contact Cardiac Science Technical Support. (Contact Technical Support before returning a recorder to make shipping arrangements.)

Phone: (800) 777-1777
(608) 764-1919
E-mail: techsupport@cardiacscience.com