

**AUSTRALIAN CARDIAC DIAGNOSTIC SERVICE
DR. MAURICE ROSENBAUM
M.D. (Melb) F.R.A.C.P.**

HOLTERNET

**HOLTER MONITOR AND SIGNAL
AVERAGED E.C.G SERVICE**

USER MANUAL

CARE AND MANAGEMENT OF THE PATIENT UNITS

Care of the Units

Under no circumstances must units be exposed to dust, physical trauma or water. It is therefore, most important that patients do not shower, submerge themselves in water or expose the units to sandy or dirty environments as this may cause complete unit failure.

Setting up the Unit

1. Insertion of the flash card: The card must be inserted before the battery, with the proper sense (that is with the arrow facing down and on the right hand side of the chip as you examine the chip (in the Datrix 512), or upwards, underneath and inside the unit (in the DMS300). **Under no circumstances should the chip be placed incorrectly and forced. If this is done, it will do irreparable damage to the chip holder and the repair is expensive.**
2. After the chip is inserted, a **new battery** should be inserted with the correct polarity.
3. The cover should be replaced
4. If the battery polarity is correct, the unit will beep and after up to four minutes will beep again three to four times, indicating that recording has started. The clock starts at that time.

Unit Sounds

The following sounds indicate faults:

- **No beep after the battery is installed:** This indicates a flat battery, incorrect polarity of the battery or the fact that the cellophane cover has been left on the battery.
- **Continuous tone:** This indicates that the flash card is not installed or not installed properly.
- **Two-tone continuous alarm:** This indicates a faulty or improperly installed flash card.

The battery must go in last. If an error signal occurs and you wish to re-try, the battery should be removed, the flash card changed or re-inserted and the battery then re-inserted

Always use a new battery otherwise the record may be short or inaccurate

Event Button

All DMS 300 series recorders have an event button at the top of the recorder next to the patient lead wire inputs. Instruct the patient to push this button any time he/she feels something. This signal is automatically put on the SANDISK compact flash card. When you analyze the patient data, the time of the event along with an 8-second ECG strip will be listed in the ECG strip category.

Belting and Placing the Unit

The unit is supplied with a belt and pouch. The belt may either be placed around the neck or around the waist and its length can be adjusted.

Care should be taken that the belt does not produce discomfort to the patient or pressure the neck.

Cleaning the Unit and Pouch

The unit and pouch may be cleaned as follows:

1. Alcohol may be used to clean the unit as often as desired
2. The pouch may be washed in cold water with a mild detergent and left to dry before use

CARE AND MAILING OF THE FLASH CARDS

The flash cards contain a dense data storage component and are relatively delicate.

At the conclusion of the monitoring session the card should be removed and sent with the patient notes and referral slip to:

Australian Cardiac Diagnostic Service (ACDS)
PO Box 8218
Camberwell North VIC 3124

Mailing should be in a padded mailbag with sufficient protection against the damage from rough handling, (a typical specification is Australia Post Padded Bag '0').

Extreme care should be taken that the bag is sealed.

**Transmission of the chip by mail will not be required when the Internet
Transmission system is completed**

ELECTRODES

Electrode type

Blue sensor type L-00-S is an appropriate electrode type, however other electrode types may be suitable.

In choosing electrodes it is important that a type with long-term adhesiveness be chosen, do not use routine electrocardiogram electrodes, as these will tend to fall off.

It is desirable, but not essential that the skin be cleaned with spirit before the application of the electrodes.

Shaving of hair is rarely required, and some variation in electrode placement is usually preferable.

Placement

Placement of electrodes varies, depending on whether a five or a seven lead unit is used.

Placement should be according to the electrode placement chart in Appendix II.

TERMINATION OF THE INVESTIGATION

Duration of monitoring

1. The Health Insurance Commission requires a minimum of 12 hours monitoring before a Holter monitor rebate can be claimed.
2. Optimal recording information is for 24 hours, after which the recorder will automatically terminate recording.
3. A minimum of 45 minutes of running time is required before the unit is processable. Anything less than 45 minutes will not produce a usable record.

Removal of the Unit

Removal of the unit and electrodes may be performed by the practitioner, his staff or the patient.

At the time of removal, the leads should be removed from the electrodes by disconnecting the press-studs from the electrodes by gently working the press-studs and without pulling on the leads. Electrodes may then be removed either at the time of removing the unit or at the time of showering and discarded.

Duration of data storage

Data storage on the flash cards is indefinite and the flash card memory will not deteriorate.

PATIENT ACTIVITIES, RECORD AND EVENT MARKER

Activities

Patients should be advised that all activities are permitted with the exception of those that may damage the unit.

Patient Record

The patient should be encouraged to fill out notes on any episode during the monitoring period, particularly transient episodes. Record notes should include the time of any event and for this to be accurately assessed the time needs to be measured from the beginning of the recording since the recorder clock will only commence running after the beeps registration.

Event may, therefore be indicated by either of the following means:

- a. The time after the beginning of recording
- b. The time of day, provided that the time of the commencement of the recording is recorded.

Patient should be advised to keep their notes brief and these notes should be mailed with the flash card.

Event marker

If the patient uses the event marker on the top of the unit, it will encode a signal that is eventually printed on the disclosure.

Appendix III is a Holter monitor patient instruction sheet and this may be photocopied and supplied to the patients.

Appendix IV is a patient record sheet and this may be photocopied and supplied to the patients.

DISPOSABLES, REPLACEMENTS AND SERVICE

Disposables

The following stock of disposables should be kept by the clinic.

| | |
|-------------------|--|
| <u>Electrodes</u> | Blue Sensor – type L00-S or equivalent |
| <u>Batteries</u> | 9 volt alkaline batteries for Datrix 512 or 1.5 volt (AA batteries) for DMS 300 |
| <u>Stationery</u> | Xerox copies of Holter monitor patient instruction sheets (see appendix III) and patient record sheets (see appendix IV) |

All disposables:

These may also be available from your preferred supplier.

Replacements and Service

In general, the units will last indefinitely if not mishandled (see notes on card insertion and reference to water etc).

The predominant cause of failure is lead failure and leads are relatively inexpensive to replace.

If possible, Australian Cardiac Diagnostic Service will loan a spare unit if unit failure occurs.

Service Enquiries

All enquires should be directed as follows:

Either:

| | |
|---------------------------|-------------------|
| ACDS (Victoria) | ph: 03 9819 0099 |
| PO Box 8218 | fax: 03 9819 4699 |
| NORTH CAMBERWELL VIC 3124 | |

OR

| | |
|-------------------------|-------------------|
| Ray Jarvis | ph: 0416 025 868 |
| PO Box 1234 | fax: 03 9841 7160 |
| EAST DONCASTER VIC 3109 | |

Unit Manufacturer

| | |
|------------------------|--------------------------|
| Datrix | ph: + (1) (760) 480 8874 |
| 316 State Place | |
| ESCONDIDO CA 92029 USA | |

REMOVING THE BATTERY

Upon completion of the Holter recording, disconnect the recorder from the patient.

To remove the battery door, lightly press on the middle of the door and slide the door out and over the recorder chassis. Place your index finger in the notched area next to the battery. Gently pop the battery out of its compartment.

NOTE: Do not move the battery up and down in its compartment. This may cause the recorder to turn off and on, starting the initialization of a new recording and erasing the flash card data.

HOLTER MONITOR PATIENT INSTRUCTIONS

The Unit

The unit you have been provided with is delicate and must not be handled roughly or exposed to water, dust or sand. Under no circumstances should you have a shower or bathe with the unit on and if it is raining, you should wear it under a coat.

The unit should not be subjected to physical stresses.

Activities

All routine activities can be performed with the unit on if they are not of the type that are likely to cause damage to the unit. (see above)

Diary and Events

Record any unusual events in the diary sheet but keep them brief. Do not forget to indicate the time of the event.

Activate the event marker button on the top of the unit if you wish to draw attention to an event.

Removal of the Unit

Removal of the unit will either be by you, your medical practitioner or his staff.

If you remove the unit, do not pull on the leads, but remove by working off the press studs from the electrodes.

When the unit is disconnected from the electrodes, you may remove the electrodes either at that time or in the shower and dispose of them.

Return of the Unit

The unit should be returned immediately after removal to your medical practitioner or by arrangement.

REMOVING THE SANDISK COMPACT FLASH CARD

There is a black slide bar adjacent to the SANDISK Compact Flash Card that extracts the SANDISK Compact Flash Card from the digital Holter recorder. Pushing down on the slide bar does not accomplish anything. To extract the SANDISK Compact Flash Card, push the slide bar into the recorder in the direction of the top of the recorder where the electrode lead wires are inserted.

DESCRIPTION OF UNIT

The DMS digital Holter recorders are 50% the size and weight of cassette Holter recorders, measuring 4.8" x 2.8" x 0.9" and weighing 5 ounces with the battery and flash card loaded. The recorder fits conveniently into a small pocket, or can be worn with its carrying case.

The DMS digital Holter recorders use SANDISK Compact Flash Cards as a recording medium. This technology allows the ECG recording to be substantially better than cassette recordings. The use of flash cards allows for exact sample location throughout the Holter recording. The R-wave peaks, P-waves and ST Segment are precise and the heart rate and HRV analysis are more accurate. Also, the time of day is precise throughout the Holter recording. The digital Holter recorder can generate 2-lead, 3-lead and 12-lead ECG strips.

The high maintenance cost of Holter cassette recorders is a thing of the past. There are no moving parts to wear out. Due to the long life of the SANDISK Compact Flash Cards, the cost is significantly lower in the long run when compared to cassette tapes. A powerful microprocessor chip contains much of the capability of the older cassette technology. This microprocessor chip is in a removable socket, so that updating in the future is simply a quick exchange of the chip.

CLOSING THE BATTERY DOOR

To close the battery door, place the door over most of the battery compartment, leaving a gap of only about ¼ inch. Push the battery door compartment until both sides are flush with the sides of the recorder. Slide the door the remaining ¼ inch until the battery door snaps closed.

DO NOT TRY TO SLIDE THE BATTERY DOOR FROM THE BOTTOM TO THE TOP

The recorder will beep after the SANDISK Compact Flash Card and the battery is inserted. For 60 seconds nothing will happen, allotting for any adjustments the technician may want to make. 2 ½ minutes after the beep, you will hear 3 beeps. This means the recorder has completed its initialization and erased the flash card. The recording of data starts after the 3 beeps

BATTERY INSTALLATION

The recorder is powered by a quantity of one AA 1.5v Alkaline battery. There is a minus and plus side for the battery insertion. Notice the plus and minus marking in the battery compartment. Insert the battery with the plus on the battery matching the plus in the battery compartment.

NOTE: Insertion of a non-alkaline or used alkaline battery will probably result in a blank or short recording.

The SANDISK Compact Flash Card can only be inserted in the correct position. All other incorrect positions are blocked from being inserted. The red label side of the SANDISK Compact Flash Card should face upward. Slide the SANDISK Compact Flash Card into the slot until you feel and hear complete insertion. Upon complete insertion, the black side bar next to the SANDISK Compact Flash Card will line up along its side.

FLASH CARD INSTALLATION

Remove the battery door from the back of the digital Holter recorder.

The compartment exposed after removing the battery door is for the SANDISK Compact Flash Card and the AA 1.5v Alkaline battery. Notice the CE label inside this compartment. Arrow #1 shows the direction for the placement of the flash card and Arrow #2 shows the direction of the battery location.

ADMINISTRATIVE STAFF

| Title | Name | Phone | Mobile |
|-------------------------|-------------------|--------------|---------------|
| Operation Manager | Giovanni | 9819 4202 | 0416 164 430 |
| ACDS Operations Manager | Heather Pannell | 9819 4202 | 0416 164 430 |
| Medical Director | Maurice Rosenbaum | 9419 9700 | 0417 056 094 |
| Technical Management | Ray Jarvis | 9841 8244 | 0416 025 868 |

ANCILLARY SERVICES

Australian Cardiac Diagnostic Service provides the following ancillary services:

Telephone hotline

If you wish to discuss any echocardiogram with the reporter, the hotline is available during working hours on 03 1800 003 224

Newsletters

Newsletters are provided from time to time on various cardiological topics of interest

Other services

Trans thoracic echocardiogram

Carotid arterial doppler echogram

Abdominal arterial doppler echogram

Peripheral arterial doppler echogram

Peripheral venous doppler echogram

These services are available by mutual arrangement either in the general practice or in one of Australian Cardiac Diagnostic Service's other locations

SLEEP APNOEA SCREENING

The ACDS Holter monitor system allows the measurement of ventilation rate (by assessment of the RR interval for sinus arrhythmia, which is presumed to correspond with ventilation).

This forms an indication for Holter monitoring in individuals in whom sleep apnea is suspected.

It is emphasized that this is a screening test only, a positive test may form the basis for further sleep investigation, and a negative test should be clinically reviewed.

SIGNAL AVERAGED ECG

By superimposing and averaging about 100 to 200 beats, it is possible to obtain high definition of the electrocardiogram. Subtle changes in this signal provide evidence of myocardial disease and proneness to arrhythmias

SPECIFIC CARDIAC CONDITIONS DETECTED BY HOLTER MONITORING

BRADYARRHYTHMIAS: Bradyarrhythmias should be suspected in individuals who suffer transient loss of consciousness, transient cerebral symptoms or consciousness of cessation of the heartbeat. In this situation, monitoring may reveal complete or partial heart block, sinus bradycardia, sinoatrial block or other suspicious distal blocks such as right bundle branch block with left anterior hemiblock. Holter monitoring is particularly effective in defining bradyarrhythmias and because of their potentially fatal nature, every effort should be made to diagnose these in the presence of the symptoms defined above.

TACHYARRHYTHMIAS: These are usually manifest by the symptom of palpitations with consciousness of the heartbeat, irregular heartbeat, fast heartbeat or transient loss of consciousness. Since tachyarrhythmias are usually intermittent and often not detected by the patient, monitoring may reveal short bursts of atrial fibrillation, atrial tachycardia, ventricular tachycardia or ventricular fibrillation without symptoms in individuals who also suffer symptomatic episodes.

TRANSIENT ISCHAEMIA: If there is a suspicion of coronary artery disease based on the presence of chest pain etc, this may be confirmed by Holter monitoring of the ST-T segments.

PACEMAKER MONITORING: Pacemaker capture and any major changes in pacemaker function can be defined by Holter monitoring if there is a clinical suspicion of partial or complete pacemaker failure.

Conditions definable are indicated under the heading 'sleep apnea screening' and 'signal averaged ECG'

FINANCIAL DETAILS AND CONDITIONS

The medical practice may choose any of the following methods of operation:

- 1. Outright ownership of the Holter monitor unit.** In this situation, the practice purchases a patient unit and two flash cards. The unit is applied within the practice and the flash cards are posted (later transmitted) for reporting. The practice charges the patient and ACDS charges the practice \$60 +GST for reporting the Holter monitor and an additional fee of \$20 if signal averaged ECG is reported.
- 2. The unit may be lent by ACDS on a trial basis.** In this situation, all billing is done by ACDS
- 3. ACDS offers Holter monitoring on request with application by our technician in the practice with billing by ACDS.**

Financial Details

| | | |
|---|-------------|-------------------|
| Disposable – Battery and disposable electrodes | (per study) | \$ 5.00 approx. |
| Electronic processing and reporting fee to ACDS | | |
| Holter monitor | (per study) | \$ 75.00 inc. GST |
| Fee to general practice | | |
| Holter monitor | Item: 11709 | |
| | Rebate | \$ 125.80 |
| | Schedule | \$ 149.50 |

Application and removal of the unit may be associated with practice visits attracting a further fee and rebate to the practitioner.

Conditions of operation

1. Australian Cardiac Diagnostic Service will make every effort to find a financial system that is most suitable for the practice. Within reasonable limits, practices may change their method of service as required.
2. Until fully paid for, the Holter monitor patient unit remains the property Australian Cardiac Diagnostic Service
3. The Australian Cardiac Diagnostic Service fees may alter from time to time.
4. Australian Cardiac Diagnostic Service takes no benefit on the sale of the units.

INDICATIONS FOR HOLTER MONITORING

Introduction

Because of the high incidence of sudden death and the potential seriousness of arrhythmias and strokes, Holter monitoring should be regarded as a critical test in all patients with a predisposition to, or a suspicion of arrhythmias or heart block. This is of particular importance, with the recognition of intermittent atrial fibrillation as a cause of stroke, the development of powerful anti-arrhythmics and the clearly demonstrable benefit of implantable defibrillators.

CLINICAL CONDITIONS SUGGESTING NEED FOR HOLTER MONITORS

High Blood Pressure

High blood pressure, particularly when associated with left ventricular hypertrophy, is associated with an increased incidence of serious arrhythmias and atrial fibrillation.

Cardiac Failure

Recent findings indicate that the mortality from cardiac failure can be reduced by approximately 30% by the use of an implantable defibrillator. This clearly reinforces the high incidence of serious arrhythmias in this group and its role as a preventable terminal event.

Myocardial Disease

Myocardial diseases including ischaemic heart disease and cardiomyopathy have a high incidence of arrhythmias which is presumed to form the basis of sudden death in these groups.

Valvular Disease and Atrial Dilatation

The incidence of undefined atrial fibrillation is high within the community, particularly in the elderly and in hypertensive individuals with some left atrial dilatation on the echocardiogram. While short runs of atrial fibrillation are not of haemodynamic significance, these are of clinical significance as a basis for stroke (many previously defined thrombotic strokes are now defined as due to atrial fibrillation with embolisation). Because of the easy reversibility of this situation with anti-arrhythmics, Aspirin or anti-coagulants, it is important that short runs of atrial fibrillation be defined in this situation.

Short runs Cardiac Irregularities

While the incidence of ventricular ectopics and atrial ectopics in the community is very high, in some individuals these are harbingers of more serious arrhythmias.

Blackouts & Episodes of dizziness

These may be the harbinger of short transient episodes of blackout or dizziness may be symptomatic of cessation of cardiac function due to SA block or AV block or arrhythmias.

DATA ACQUIRED BY THE UNIT

The reading unit is sophisticated and reads virtually every heartbeat recorded.

Reporting is predominantly in terms of abnormalities, but other variable as follows are routinely provided.

1. Complete heart rate record
2. Heart rate variability record
3. Ventricular and supra-ventricular ectopic rate per hour
4. Any abnormal beats or runs of beats
5. STT changes in each of the leads
6. Five minute interval heart rate average
7. RR interval variability, 5 minute interval average
8. Heartbeat power function
9. Ventilation rate
10. Signal averaged ECG
11. Automated report
12. Cardiologist report

This data is normally returned by mail, but may be returned by fax as the report or as the full disclosure.

DESCRIPTION OF THE PATIENT UNIT

Australian Cardiac Diagnostic Service (ACDS) uses Datrix 512 and DMS300 Digital recorder units.

These are small, state of art, solid state devices that record three channels of data on a removable data card (flash card, IDE-PCMCIA compact flash), through five leads (Datrix 512) or 7 leads (DMS300).

At the present time the chip is posted to Australian Cardiac Diagnostic Service and the reported full disclosure of the Holter monitor and if requested, the signal averaged ECG is either faxed or mailed to the practitioner. A development program is underway for the Internet transmission of the data and this data transmission should be available in 2002.

Physical aspects of the unit

| | |
|----------------------------|---|
| Weight | 4 oz |
| Size | 5" x 2 ³ / ₄ " x 1" |
| Operating temperature | 0 - 60° Centigrade |
| Operating humidity | up to 90% |
| Shock absorbing capability | up to 26' drop |

INTRODUCTION

Australian Cardiac Diagnostic Service operates the Holternet service on an Australian-wide basis.

In this service, the patient units are applied by the general practitioners and the Australian Cardiac Diagnostic Service provides an analysis and reporting service.

This document covers all aspect of the use of the system.

Units can only be used under the orders of a medical practitioner

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HOLTER MONITOR PATIENT RECORD

Patient name: _____

Date: _____ **Placement time:** _____

| Time of day | Activities | Events |
|--------------------|-------------------|---------------|
| | | |

