ИНСТИТУТ ЗА КАРДИОВАСКУЛАРНЕ БОЛЕСТИ ВОЈВОДИНЕ, СРЕМСКА КАМЕНИЦА
Пут доктора Голдмана 4, 21204 Сремска Каменица
РЕПУБЛИКА СРБИЈА
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Ред.бр.JH-MB-07/19
Бр. 3742 - 7
Датум: 26.12.2019.

ПРЕДМЕТ: Додатно појашњење у вези са припремањем понуда за јавну набавку бр. JH-MB-07/19 – Батерије и акумулатори

Дана 25.12.2019. године електронским путем нам је достављен допис заинтересованог лица којим се тражи додатно појашњење у вези са припремањем понуде за јавну набавку **JH-MB-07/19 – Батерије и акумулатори**, у оквиру којег је тражено следеће појашњење:

“ С обзиром да је батерија AAA LR03 намењена за свакодневни рад холтер апарата, молимо Вас за информацију о минималним техничким карактеристикама у погледу унутрашњег отпора и животног века батерије.”

На основу члана 63. став 3. Закона о јавним набавкама („Службени гласник РС“ бр. 124/2012, бр. 14/15 и 68/15), достављамо појашњење:

У упуству произвођача за холтер апарат Lifecard CF се не захтевају минималне техничке карактеристике у погледу унутрашњег отпора и животног века батерије.
У упуству произвођача за холтер апарат Lifecard CF се за батерију захтева alkalna baterija **Duracell MN2400 или одговарајућа**.

На страни 3-6 тачка 3.3.3 упуства произвођача за холтер апарат Lifecard CF детаљно се наводи захтевани батеријски капацитет или еквивалент. Такође под тачком 3.3.4 се наводи упозорење произвођача, ако корисник холтер уређаја користи батерије које нису препорука произвођача може доћи до оштећења уређаја Lifecard CF тј. батеријских контаката или може угрозити дужину снимања података пацијента.

Сходно наведеном, потребно је да понуђено добро буде одговарајуће алкалној батерији **Duracell MN2400.**

Наручилац прилаже уз додатно појашњење упуство за употребу произвођача за холтер апарат Lifecard CF.

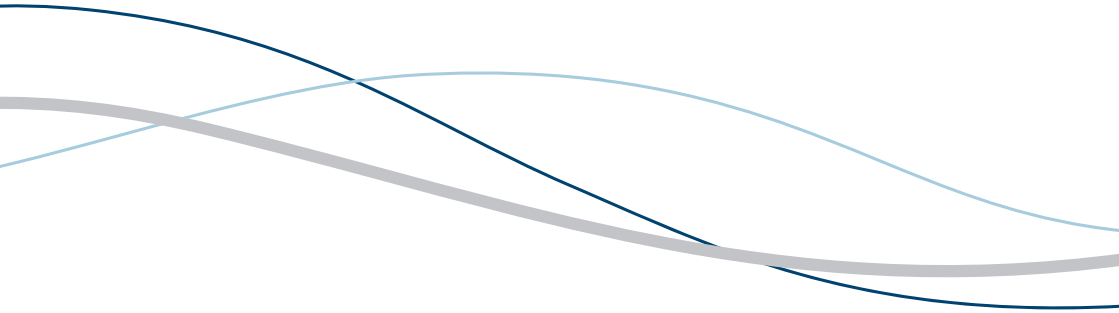
Ова информација, сходно члану 63. став 3. Закона о јавним набавкама, се објављује на Порталу јавних набавки и интернет страници Наручиоца.

Комисија за јавну набавку

SPACELABS HEALTHCARE

Lifecard CF & Lifecard 12

Firmware Rev7



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OPERATIONS MANUAL

Consult Documents

THIS SYMBOL MEANS YOU MUST READ THE ACCOMPANYING DOCUMENTS

(Note: All further instances of this symbol will be represented in black & white)

Spacelabs Healthcare considers itself responsible for the effects on safety, reliability and performance of the equipment only if:

- assembly operations, re-adjustments, modifications or repairs are carried out by persons authorized by Spacelabs Healthcare, and
- the electrical installation of the relevant room complies with the requirements of the standard in force, and
- the equipment is used in accordance with the operations manual.

Spacelabs Healthcare will make available, on request, such circuit diagrams, component part lists, descriptions, calibration instructions or other information which will assist appropriately qualified technical personnel to repair those parts of the equipment which are classified by Spacelabs Healthcare as field repairable.

Spacelabs Healthcare is committed to providing comprehensive customer support beginning with your initial inquiry through purchase, training, and service for the life of your Spacelabs Healthcare equipment.

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Caution:

℞ only — Federal (USA) law restricts this device to sale by or on the order of a medical practitioner licensed by the law of the state in which he practices to use or order the use of the device.

CE 0123 — CE marked in accordance with the Medical Device Directive, 93/42/EEC

Security-related information is indicated in the following manner in this manual:.

⚠ **"WARNING"** - Actions or circumstances that may result in personal injury or death.

"ATTENTION" - Actions or circumstances that could damage the equipment, produce inaccurate data, or invalidate a procedure.

"NOTE" - Useful information to a product feature, function, or procedure.

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Table of Contents

6. REFERENCE

1. Introduction

1.1 About This Manual

This manual contains detailed operating instructions for the Lifecard CF recorder and the 12-lead Lifecard 12 option. It is one of two manuals for this recorder.

- Lifecard CF / Lifecard 12 Instruction and Technical Manual.
- Lifecard CF Quick Guide

1.2 Disclaimer

Every effort has been taken to ensure the accuracy of this manual but Spacelabs Healthcare cannot accept liability for consequences caused by errors or omissions. You are advised to check with Spacelabs Healthcare on any point on which you are unsure or need confirmation.

All images within this manual are intended for illustration purposes only and may differ slightly from the actual product.

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2. SAFETY AND REGULATORY

The Lifecard CF is a compact Holter Ambulatory ECG Recorder utilizing a digital storage technique to store the ECG recording onto a Compact Flash (CF) card.

- The Lifecard CF provides continuous recording of 2 or 3 leads of ECG for up to 48 hours in standard mode and up to 7 days in extended mode.
- The Lifecard 12 option provides continuous recording of 12 leads of ECG for a period of 24 hours.

The recorder has a built in display for you to monitor the ECG and pacing detection during hook-up. This enables you to verify the ECG quality before starting the recording. Menu options are selected using the two buttons on the front of the recorder unit.

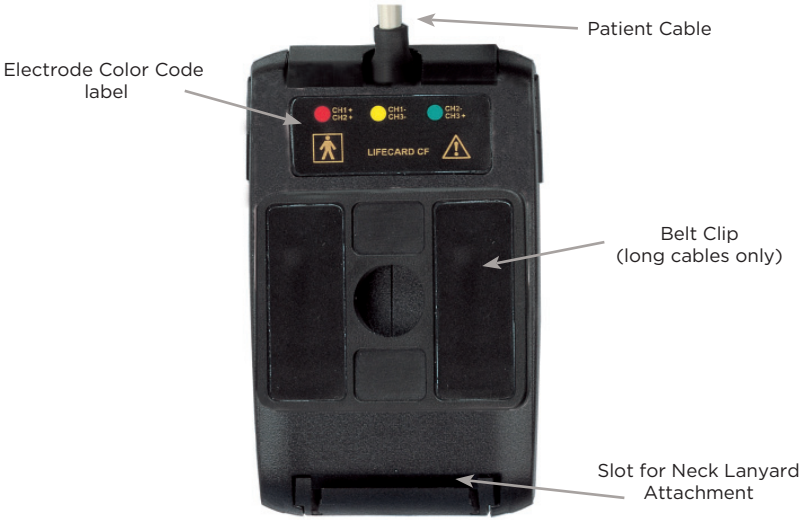
The Lifecard CF recorder requires one AAA (LR03) battery. The patient cables for the Lifecard CF are designed to prevent accidental disconnection from the recorder by the patient.

The Patient Event button on the front of the recorder unit enables the patient to indicate symptomatic episodes in the recording for correlation with the patient diary. Pacemaker pulse detection may be enabled and disabled by the physician or cardiac technician.

Recordings may be analyzed using a Spacelabs Healthcare Pathfinder, Pathfinder SL Impresario, or Lifescreen Holter analysis system, if they have compatible hardware and software. (Lifescreen is incompatible with 12-lead recordings.)

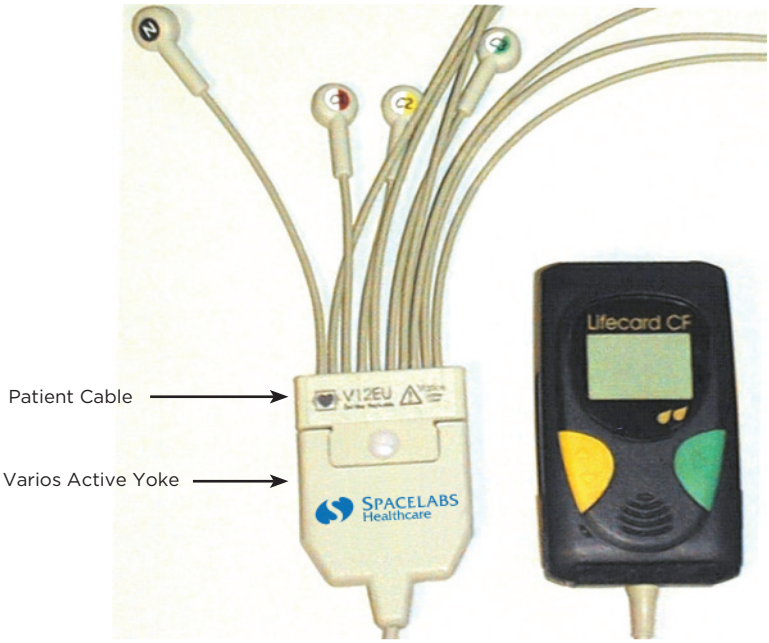
Recorder Unit

Patient Cable Unit



The Lifecard CF comprises two sections; the 'Recorder Unit' and the 'Patient Cable Unit'.

The 12-lead option has a two-part cable unit comprising the 'Varios' Active Yoke unit and the 10 electrode patient cable. The Lifecard CF recorder remains as shown on the previous page.



Note ***Do not attempt to remove the patient cable from the yoke, unless replacing a broken cable***

2.2 Indications and Intended Use

The Lifecard CF Holter recorder is to be used for the non-invasive ambulatory recording of two or three channel electrocardiograms on an approved compact flash card.

The Lifecard 12 option is to be used for the non-invasive ambulatory recording of 12-lead electrocardiograms on an approved compact flash card.

The recorder allows data to be collected over a continuous period of up to 7 days whilst allowing the subject to perform most of their normal daily activities.

The recordings can be analyzed on compatible analysis systems from Spacelabs Healthcare.

This device has been designed and supplied specifically for the long term recording of electrocardiograms in ambulatory patients using standard Holter monitoring techniques. It shall not be used for any other purposes.

The device shall be operated only be suitably competent personnel trained in the use and procedures of Holter electrocardiography for diagnostic purposes.

2.3 Contraindications

Not intended for use with infants weighing less than 10kg.

2.4 Precautions

Follow the cleaning instructions for reasons of basic hygiene and to reduce the risk of cross-infection.

Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC). The Lifecard CF should be used in accordance with the EMC guidance given in section 5.5 of this manual.

2.5 Warnings

This device must not be used for direct cardiac application.

Never attempt to connect any other device or instrument to the internal connections or circuitry of the Lifecard CF while it is connected to a patient. Electrodes and their associated connectors should not be allowed to contact other conductive parts even if they are at ground potential.

This device is not suitable for use in wet environments.

2.6 Adverse Reactions

Patients may suffer allergic skin reactions from the adhesive electrodes, causing reddening, soreness or irritation. Ask the patient if they suffer from these allergies. Contact the electrode manufacturer for further specific information.

2.7 Conformance to Standards

This device has been designed in accordance with EN60601 -1, “Medical electrical equipment, Part 1: General requirements for safety”, as follows:

1. EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE. The equipment is designed to be battery operated only. Under NO circumstances shall a mains powered battery eliminator or any other external power source be used with the equipment.
2. EQUIPMENT having a TYPE BF APPLIED PART.

or

3. EQUIPMENT having a TYPE CF APPLIED PART if so marked.
4. Not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide, or flammable cleaning agents.
5. Rated for CONTINUOUS OPERATION.
6. EQUIPMENT with an APPLIED PART, specifically designed for application where a CONDUCTIVE CONNECTION is made to the PATIENT, but not directly to the heart.

According to ANSI/AAMI EC38:1998.Lifecard CF is Type 1 ambulatory ECG device.

2.8 Adjustment, Replacement of Parts, Maintenance and Repair

The device requires no routine adjustments to maintain its operation.

The device contains no user serviceable parts. It shall be serviced only by Spacelabs Healthcare or by an agent accredited by them to service device of this type. Unauthorized repairs or dismantling of the device will invalidate the guarantee.

Spacelabs Healthcare will make available, on request, such circuit diagrams, component part lists, descriptions, calibration instructions or other information which will assist appropriately qualified technical personnel to repair those parts of the equipment which are classified by Spacelabs Healthcare as field repairable.

2.9 Defects and Abnormal Stresses

For continued safety the device must not be maltreated, used outside its specified operation conditions, or stored outside its specified storage conditions.

Lifecard CF contains protection against electrostatic discharge, but there is no protection against defibrillators. To avoid damage the device should be removed before defibrillating. (The 10-electrode patient cable has defibrillator protection).

Whenever it is likely that protection has been impaired, the device shall be made inoperative and secured against any unintended operation. The protection is likely to be impaired if, for example, the device :-

a) Shows visible damage
b) Fails to perform the intended measurements
c) Has been subjected to prolonged storage under unfavorable conditions
d) Has been subjected to severe transport stresses
e) The device has been connected to a patient during defibrillation.

2.10 Modifications

For continued safety, the device shall not be subjected to any unauthorized modifications and must be used only for the purpose for which it was originally supplied.

2.11 Declaration of Conformity

CE 0123

This product is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC concerning medical devices.

2.12 Warranty

Subject to the conditions set out below, Spacelabs Healthcare ("The Company") warrants that its Products will be free from defects in material and workmanship for a period of 12 months from delivery.

This warranty is given by The Company subject to the following conditions:

1. The Company shall be under no liability in respect of any defect arising from fair wear and tear, willful damage, negligence, abnormal working conditions, failure to follow instructions (whether oral or in writing), misuse, improper installation or alteration or repair of the Products without The Company's approval.
2. The above warranty does not extend to parts, materials or devices not manufactured by The Company, in respect of which the Customer shall only be entitled to the benefit of any such warranty or guarantee as is given by the manufacturer to The Company.
3. Subject as expressly provided here, all warranties, conditions or other terms implied by statute or common law are excluded to the fullest extent permitted by law.
4. Any claim by the Customer which is based on any defect in material or workmanship of the Products shall be notified to The Company immediately after discovery of the defect. If the Customer does not notify The Company accordingly, the Customer shall not be entitled to reject the Products and The Company shall have no liability for such defect.
5. Where any valid claim in respect of any of the Products which is based on any defect in the material or workmanship of the Products is notified to The Company, The Company shall be entitled to replace or repair (at The Company's sole discretion, either at the Customer's premises or at The Company's premises in the United Kingdom) the Products (or part in question) but The Company shall have no further liability to the Customer.

6. The Company shall not be liable to the Customer by reason of any representation, or implied warranty, condition or other term, or any duty at common law, or for any consequential loss or damage (whether for loss of profit or otherwise), costs, expenses or other claims for consequential compensation whatsoever arising out of or in connection with any act or omission of The Company relating to the manufacture or supply of the Products or use by the Customer.

7. Spacelabs Healthcare recommends the use only of approved accessories and parts. The use of third party accessories may result in damage to recordings or equipment, and may invalidate your warranty.

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3. LIFECARD CF OPERATING INSTRUCTIONS

This chapter of the manual provides detailed operating instructions for the Lifecard CF recorder. To help you get started, refer to the separate Quick Guide.

3.1 Recording Procedure Flow Diagram

Prepare the flashcard with patient details

↓

Prepare the recorder

↓

Prepare the patient

↓

Apply electrodes and hook-up

↓

Attach the recorder

↓

Start the recording

↓

Check the ECG quality

↓

Instruct the patient

↓

After recording, remove and clean the recorder

↓

Download the recording

3.2 Recording Patient Details

There are three ways to set up the patient details. For highest security, use methods '1 and '2':

1. **Initialize the Flashcard** using the utility supplied in the Pathfinder, CardioNavigator or Impresario program, and save the patient details if known.
2. **Make a speech recording** on the flashcard using the microphone on the front of the Lifecard CF, identifying the patient.
3. **Write the patient's name** or ID on the flashcard using a felt-tip marker. For best security, don't use this method alone, but combine it with '1' or '2'.

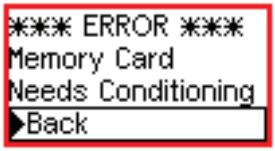
3.2.1. Initializing a Flashcard

Initializing the flashcard erases the previous recording and checks the file structure. Patient details, if known, can be stored on the card at this time.

Conditioning a Flashcard

Compact flashcards from Spacelabs Healthcare are supplied with the required file structure in place (conditioned), but occasionally a card may need reconditioning.

If a card needs to be conditioned before use, the recorder will display this message:



The following instructions will condition the card if required, and will delete any files that are on the card.

1. Insert the flashcard into the flashcard reader, ensuring the correct orientation of the card.

   The next step will depend upon which type of analyzer you are using.

   Select 2a, b, c, d, or e as appropriate.

You may be using:

- Pathfinder or Lifescreen with the CardioNavigator database (*see 2a*)
- Pathfinder or Lifescreen with the **Report Manager** (Archive Maintenance) database (*see 2b/2c*)
- Impresario (*see 2d*).
- Sentinel (*see 2e*)

Follow the appropriate instructions below, according to the system you have.

2a. Using CardioNavigator

1. Click on the Patient menu and select the **New Patient** option or click on the **New Patient** icon
2. Enter the details in the **New Patient** dialog box and when complete, click on **OK**.
3. Highlight the patient in the Patient List and with the flashcard inserted into the reader, click on the Lifecard CF Configure icon.The patient details will then be transferred to the card.

2b. Using Pathfinder with Report Manager

1. In the Pathfinder Utilities menu, select the Initialize Compact Flash option.
2. In the dialogue box displayed, you can enter the patient's name and ID. Click the **Initialize CF** button to store the details on the card and to prepare the card for a new recording.

2c. Using Lifescreen

If your Lifescreen program is using the CardioNavigator database, click on the File menu and then select CardioNavigator and follow the above procedure "2a".

If your Lifescreen program is using the **Report Manager** database, use the "**Initialize Lifecard CF**" desktop shortcut. This displays the same entry dialog as shown in "2b".

2d. Using Impresario

1. Open the Impresario application by double clicking on the desktop icon.

   The **Acquire** tab should be highlighted.
2. Enter the patient details or if the details are already in the database, select the patient from the patient list that appears upon selecting the **Browse** button [...]
3. Click on the **Initialize Lifecard** button.
4. A message will show when initialization is complete.

2e Using Sentinel

1. From the **Sentinel Home Page** click **Holter**.
2. The **Holter Worklist** page opens. Click **Configure**.

   Sentinel will now scan for all connected Holter recorders or Compact Flash cards and will display these in a list to the left of the screen.
3. Select the Lifecard CF.
4. Click the **Configure** button.
5. Enter the patients name or ID that is to be associated with the test in the **Find** text box.

6. If the correct record is shown in the search results, double click on the required record or click once on the record and then click on the **Select Patient** button.
7. If the desired record is not shown, click on **Add New Patient** and input the patients details.
8. You may at this time edit the test details by clicking on the **Edit Test** button and making the desired changes. (See Sentinel user manual for further details).
9. Click Save when finished.
10. To configure the recorder or Compact Flash card click on **Start Configure**.
11. Click **OK** in the successful configuration box.
12. You will now be presented with the **Holter Worklist Screen**.

3.2.2. Making a Speech Recording

A Speech Recording is made by the user, following the normal procedure to prepare the recorder and start the recording. (*See section 3.7.4 for further details.*)

The speech recording can be any message that will identify the patient later when the recording is downloaded. The recording can be replayed on the speaker of the analyzer PC.

There is no facility to record messages at any other time.

Note: ***Speech recording can be enabled or disabled in the Set Up Menu.***

3.2.3. Writing Details on the CF Card Label

1. Using a felt-tip marker, write the patient's name or ID onto the flashcard label.
2. Always check that the recording date and time displayed in the Pathfinder Patient Details match your appointment records.

For highest security, don't use this as the only method of identifying the recording. Initialize the card or make a speech recording.

Note:

- ***On starting the recording, if you haven't initialized the card with a patient name or made a speech recording, the recorder will prompt you to confirm that the correct name has been written on the card.***
- ***Ink may stain if not wiped off within a couple of days with alcohol. Indelible markers CAN be erased with an alcohol swab!***

3.3 Preparing the Recorder

3.3.1 Open the Recorder

1. Insert the opening card tool into the release catch.

2. Pull the release catch down in the direction of the arrows.

3. Grip the two halves of the recorder and pull to separate them.

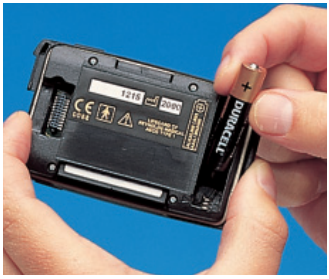
4. Remove the patient cable unit to expose the flashcard and battery compartments in the recorder unit.

Note: ***Keep the inside of the recorder clean and dry!***

3.3.2 Insert the Battery

Insert a single alkaline or NiMH AAA battery into the battery compartment of the recorder, 'negative' end first.

Ensure the battery is inserted the correct way round, as shown on the battery compartment label.



3.3.3 Battery Capacity

Battery Type	Standard Mode	Extended Mode
Alkaline (Duracell MN2400 or equivalent)	48 hours*	7 days
NiMH (Ansmann 600mAh or equivalent (Not suitable for 12-lead procedures.)	24 hous	3 days

Note:

- ***An alkaline battery may be used for two consecutive 24 hour recordings, if it is withdrawn promptly at the end of the first 24 hour period. Mark the battery after first use.***
- ***If the battery level is low when you start the recording, the Lifecard CF will display a warning message and you must change the battery.***
- ***If the monitor is going to be stored for an extended period of time, remove the batteries to prevent the possibility of leakage or discharge.***

3.3.4 ⚠ Warning!

Battery : Using batteries other than those specified can damage the Lifecard CF battery contacts or compromise the length of recording.

Power Source : Do not attempt to power the Lifecard from any external source such as a mains powered battery eliminator. This would be a safety hazard.

3.3.5 Insert the Flashcard

1. Insert the flashcard into the card slot of the Lifecard, with the label facing upwards and inserting in the direction of the arrows.

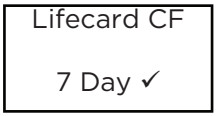
2. Push until it clicks into position.

3. Reassemble the recorder by 'hooking' the patient cable unit over the top of the hinge. Close the two halves then push in the hinged catch at the bottom until it clicks shut.

IMPORTANT:	***If a CF card with a recording marked as analyzed or stored is put in the recorder, the recording will be deleted as soon as the battery and patient cable are fitted.***

4. You should hear a 'boing' and the Lifecard will display 'Spacelabs Healthcare'.

Using 3, 4 or 6 electrode cables, this is followed by the '7 Day' logo.



If using the 10-electrode cable with the Varios active yoke, a '12-Lead✓ logo is displayed.

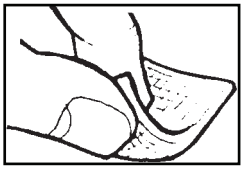
These are followed by the **Main Menu**.

Lifecard CF
Pacing Det. ON
▶Start
Start Week
ID. Cardio A
Set Up
English
About

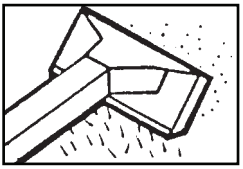
3.4 Preparing the Patient

3.4.1 Prepare the Skin

Clean Site
With alcohol swab



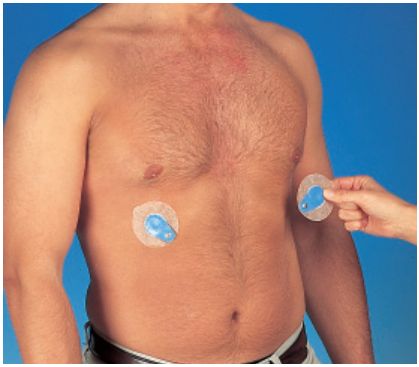
Shave Hair



Abrade The Skin
lightly redden the skin with dry cotton swab

Note: ***Use good quality electrodes for the final hook-up. We recommend Ambu Blue Sensor electrodes.***

Apply the electrodes

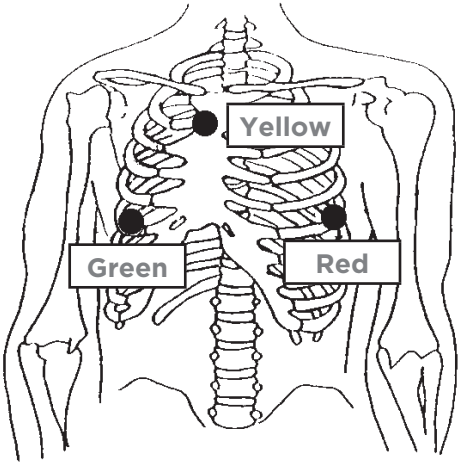


The electrode positions shown on the following pages are suggested but not mandatory. Alternative positions may be more suitable on individual patients.

Always check the quality on the ECG monitor display!

3.5 Procedures Using 3, 4 and 6 Electrode Patient Cables

3.5.1 Three Electrode Patient Cable



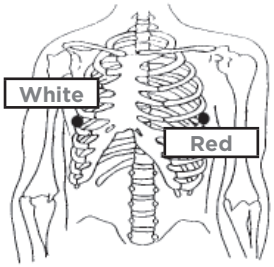
Yellow CH1 - CH3 -	On the right sternal border at the level of the 2nd rib.
Red CH1 + CH2 +	In the left anterior axillary line and on the 6th rib.
Green CH2 - CH3 +	In the right anterior axillary line and on the 6th rib.

Red/Yellow = CH1 = CM5 **Red/Green**=CH2 = CC5
Green/Yellow = CH3 = CM5R

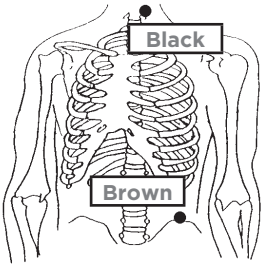
Procedures using 3 electrodes	90Mb CF Card	ECG Channels
Standard Mode (Start)	48 hours	1, 2 and 3
Extended Mode (Start Week)	7 days	1 and 2

Note:

- ***For paced patients- see hints in section 3.7.7***
- ***Use good quality electrodes for the final hook-up.***
- ***To minimize muscle artifact, place electrodes over bone rather than in the intercostal spaces.***

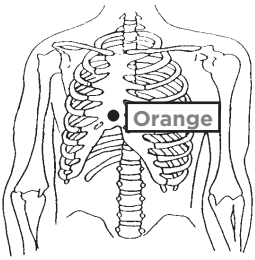


CH1 - V6, V6R

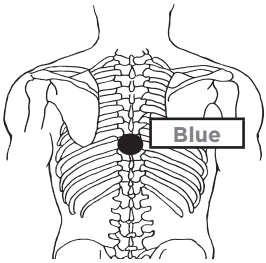


CH2 - H, F

Red CH1 +	Left mid axiliary line on the 6th rib.
White CH1 -	Right mid axiliary line on the 6th rib.
Brown CH2 +	Midclavicular line, on the illiac crest.
Black CH2 -	Neck



CH3 ANTERIOR - E



CH3 POSTERIOR - M

Orange CH3 +	Anterior centrally at the base of the sternum.
Blue CH3 -	Posterior centrally opposite orange.

Red/White = CH1 = X **Brown/Black =** CH2 = Y **Orange/Blue =** CH3 = Z

Procedures using 6 electrodes	90Mb CF Card	ECG Channels
Standard Mode (Start)	48 hours	1, 2 and 3
Extended Mode (Start Week)	Not Available	Not Available

Note:
- ***A harness is available to support the yoke.***
- ***Use good quality electrodes for the final hook-up.***

3.5.4 Attach to the Patient

There are four options for the patient to wear the Lifecard CF:

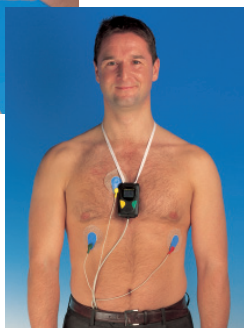
1. Neck Lanyard
2. Shoulder Pouch
3. Belt Clip
4. Single Use Pouch

The neck lanyard and shoulder pouch enable the patient to wear the recorder under their clothing. This means that undressing and changing are greatly simplified and are less likely to cause recording artifact or electrode detachment.

It also makes the recorder less visible.

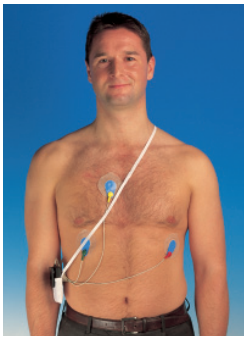
1. Neck Lanyard

Attach the lanyard cord around the hooked section at the back of the Lifecard and pull the cord tight to fasten it.



2. Shoulder Pouch

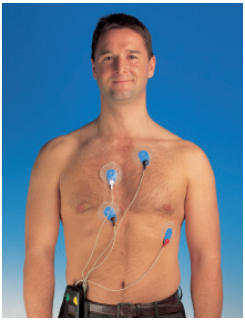
Put the Lifecard into the pouch and attach to the patient as shown here.



Note: ***The short patient cables are optimized for use with the lanyard or pouch and do not include a belt clip***

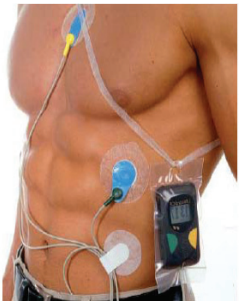
3. **Belt Clip**

The belt clip option is very convenient for patients preferring to wear the recorder on the outside of their clothes.



4. **Single Use Pouch**

The plastic pouch is attached with tape cut to the length required. It is discarded after each recording.



3.5.5 Securing the Patient Cable

Use Ambu SkinFix or tape to secure the individual lead wires and the thicker "trunk cable" to the patient's torso. Stabilizing the patient cable will reduce motion artifact and give a higher quality recording.

Leave a little slack wire ("stress loop") between the electrode and the securing tape, so the electrode connection is not stressed when the patient moves or stretches.

Do not tape across Ambu Blue Sensor electrodes and the snap connector, they are designed to tolerate movement.

3.5.6 Standard Recording Mode - The "Start" Menu Option

This mode enables the recording of up to 48 hours of 2 or 3 channel ECG (with 2.5 µV resolution).

The recording length depends upon the choice of patient cable and the memory card capacity.

Start...	90Mb card
3 electrode cables	48 hours 3 ch
4 electrode cables	48 hours 2 ch
6 electrode cables	48 hours 3 ch

3.5.7 Extended Recording Mode - The “Start Week” Menu Option

In this recording mode, you can record up to 7 days of 2 channel ECG. It is intended for patients who have infrequent symptoms.

The recording length depends upon the choice of patient cable and the memory card capacity.

Start...	90Mb card
3 electrode cables	48 hours 3 ch
4 electrode cables	48 hours 2 ch

Note: ***The 6 and 10 electrode cables cannot be used in Extended Recording Mode.***

Compression is used in the Extended Recording Mode. The signal quality exceeds the requirements of the ANSI/AAMI EC38:1998 Ambulatory Electrographs standard.

Note: ***To analyze Extended Mode recordings, you must have a Pathfinder Holter system with software Version 8.253 (or higher), Pathfinder SL or Lifescreen Holter software (all versions). Please contact your supplier if you require a software upgrade***

3.5.8 Lead Off Alarm in Extended Mode

In the hook-up screen, each channel number will ‘flash’ if a lead-off condition is detected in that channel.

During a recording, if a lead becomes detached, the Lifecard will generate an alarm to warn the patient.

Note: ***See section 3.7.6 for further details***

3.5.9 Battery Requirements in Extended Mode

The 7-day operation requires Alkaline AAA batteries. Rechargeable NiMH batteries may be used for shorter recordings.

3.5.10 Electrodes for Extended Recordings

Spacelabs Healthcare recommends Ambu VLC electrodes, which can stay on the patient for up to 7 days without replacement.

3.5.11 Additional Patient Instructions for Extended Recordings

When bathing/showering, the patient should disconnect the recorder from the electrodes.

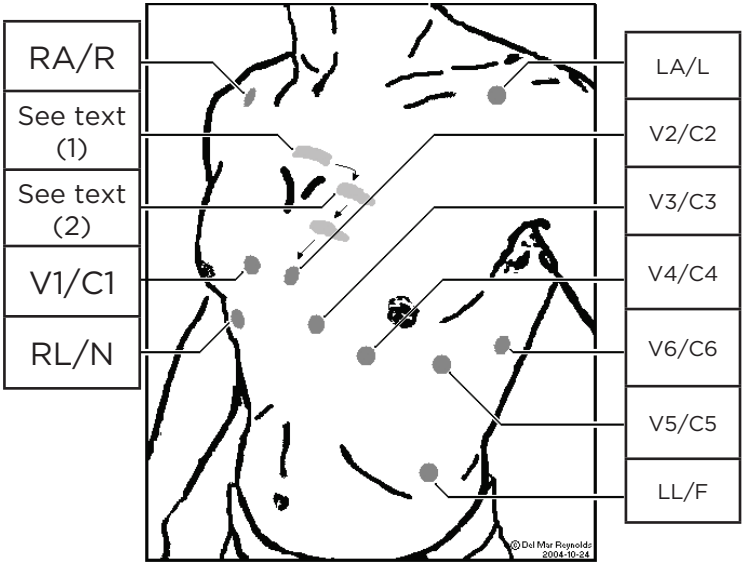
Note: ***Follow the instructions given in your patient diary.***

3.5.12 Start the Recording

See section 3.7

3.6 12-Lead Procedure Using the 10 Electrode Patient Cable

For 12-lead recording you need the Lifecard 12 option, comprising Lifecard CF firmware V7, the Varios Active Yoke and the 10-electrode patient cable. You need a 256Mbyte flashcard for a 24 hour recording.



Note:

- ***Do not use short-term resting/stress ECG electrodes for this procedure.***
- ***Ask female patients to wear a skirt or pants (trousers) for this procedure, to facilitate attaching the recorder by the belt clip.***

3.6.1 Apply the Electrodes

Use the following procedure for finding the precordial (chest) electrode positions:

- Locate the bony projection (1) at the base of the manubrium (Angle of Louis)
- The second intercostal space (2) is found by sliding to the side and down.
- Find the third and fourth intercostal spaces and locate V1(C1) and V2(C2).
- Next locate V4(C4), and then V6(C6) in the mid-axillary line.
- Finally, place V3(C3) and V5(C5)

3.6.2 Electrode Location and Labeling When Using the 10 Electrode Patient Cable

Location	AHA Label	AHA Color	IEC Label	IEC Color
On the clavicle, above the infraclavicular fossa medial to the border of the right deltoid muscle.	RA	White	**R**	Red
On the clavicle, above the infraclavicular fossa medial to the border of the left deltoid muscle	LA	Black	**L**	Yellow
Not critical: any convenient location on the right chest, in the vicinity of V3R or V4R	RL	Green	**N**	Black
In the anterior axillary line at the costal margin, over bone.	LL	Red	**F**	Green
In the fourth intercostal space at the right sternal border.	V1	Brown/Red	**C1**	White/Red
In the fourth intercostal space at the left sternal border.	V2	Brown/ Yellow	**C2**	White/ Yellow
Mid-way between V2 and V4.	V3	Brown/ Green	**C3**	White/ Green
In the fifth intercostal space in the left mid-clavicular line.	V4	Brown/Blue	**C4**	White/ Brown
In the left anterior axillary line at the level of V4.	V5	Brown/ Orange	**C5**	White/ Black
In the left mid-axillary line at the level of V4.	V6	Brown/ Purple	**C6**	White/ Violet

Procedures using 10 electrodes	256Mb CF Card	ECG Channels
Standard Mode (Start)	24 hours	12 Leads
Extended Mode (Start Week)	Not Available	Not Available

3.6.3 Assemble the Recorder

1. Insert a new alkaline AAA battery into the Lifecard CF.
2. Insert the 256Mbyte compact flashcard.
3. Attach the back to the recorder and close the catch.

3.6.4 Connect the Patient Cable

Start with the N lead, which is at the left-hand side as you look at the yoke. Connect the lead-wires from left to right to minimize tangling.

The sequence is:

RL - RA - V1 - V2 - LA - V3 - V4 - V5 - V6 - LL (*AHA labeling*)

N - R - C1 - C2 - L - C3 - C4 - C5 - C6 - F (*IEC labeling*)

3.6.5 ECG Variation Using the Mason-Likar System

The limb lead amplitudes may vary significantly compared with standard resting ECG. Other reported differences include a rightward shift of the mean QRS axis and a consequent reduction in R wave amplitude in leads I and aVL, together with an increase in R wave amplitude in leads II, III and aVF. Precordial (chest) leads are also modified due to the altered potential of the central terminal.

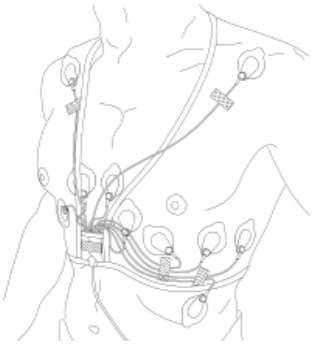
Note: ***See Section 6 - References***

3.6.6 Fit the Yoke Harness

Fit the Yoke Harness as shown in this diagram.

Put the yoke in the pouch and secure to the patient with the straps. Do not fit too tightly, or the straps may detach when the patient moves or stretches.

Attach the recorder by the belt clip to the patient's belt or waistband.



3.6.7 Secure the Lead-Wires

It is important to secure the longer lead-wires, or the patient's movements will pull at the electrodes, creating artifact that makes the recording difficult to interpret.

Tape where shown in the diagram. In particular, secure the RA (R), LA (L) and LL (F) lead-wires, and consider securing C5 (V5) and C6 (V6), around the same point as LL (F). The best arrangement depends on the shape and size of the patient.

Use an Ambu 'SkinFix' or surgical tape to fix the lead-wire near to the electrode. Arrange the slack between the tape and the electrode into a loop or curve (stress loop).

If you cannot use the harness on a particular patient, tape the yoke to the patient. (for example by using a large Ambu SkinFix or thick tape holding the larger cable at the base of the yoke). Ensure that none of the lead-wires are pulled tight.

3.6.8 12-Lead Recording Behavior with Lead Off

- If a precordial lead (C or V lead) is detached, a flat-line tracing will be recorded in that lead.
- If a limb lead (R/RA, LA/L or LL/F) is detached, a flat-line tracing will be recorded for all frontal leads (I, II, III, aVR, aVL, aVF). The amplitude and morphology of the precordial leads may be affected and should be reviewed with caution.
- If the reference lead (RL/N) is detached, the recording noise level may increase but the amplitude and morphology of the ECG will be unaffected.

Note: ***A broken wire in the 10-electrode patient cable will give the same indication.***

3.7 All Procedures- Start the Recording

3.7.1 Set the Pacing detection option

To set Pacing detection, highlight the option **Pacing Det**. by pressing the yellow ▲ Up or ▼ Down button, then press the green ► Select button until 'ON' or 'OFF' is displayed.

Note: ***Careful electrode placement is required for reliable pacing detection.***

3.7.2 Select Start... or Start Week...

Select Standard Mode (24 or 48 hour) or Extended Mode (up to 7 days).

For Standard Mode, highlight the **Start** . . . option and press the green ► Select button.

For Extended Mode, select the **Start Week** . . . option.

3.7.3 Confirm the Patient ID

If you have initialized the flashcard, you can now confirm that the patient name is correct. If the wrong name is shown, you can delete the stored details, but ensure that you then identify the patient by making a speech recording. Alternatively, you can open the recorder and re-Initialize the card using your analyzer system.

Note: ***Confirm Patient will only be displayed if patient data exists on the flashcard.***

3.7.4 Make a Speech Recording

If the recorder is set up for speech recording, you will now be prompted to make a recording.

(If you do not want to make a speech recording, select **Continue**.)

When you are ready to speak, select the **Record** option by pressing the green ► Select button, then hold the Lifecard CF close to your mouth, and speak into the microphone.

Lifecard CF will record for 8 seconds and then play back the recording. You can listen to it again by selecting the **Playback** option.

To confirm your recording, select the **Confirm** option, or **Delete** if you want to re-record it.

If no patient details have been stored and no voice recording is made, you are prompted to confirm that you have written the patient's name on the flashcard.

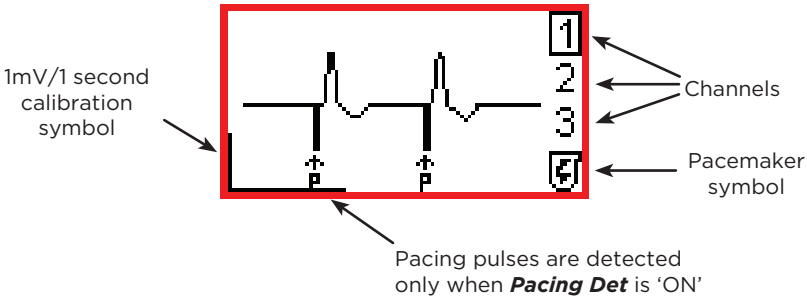
3.7.5 Monitor the ECG - Check the ECG Quality

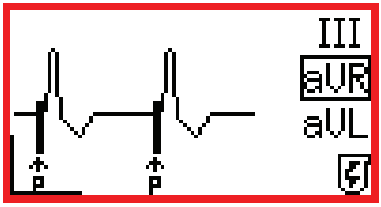
The monitor displays the ECG during hookup. The current channel being displayed is highlighted on the right of the screen.

To review a different channel, press on the yellow ▲ Up or ▼ Down button.

Push the green ► Select button when you have finished reviewing the ECG.

(You can return to the monitor by selecting Back in the next menu)





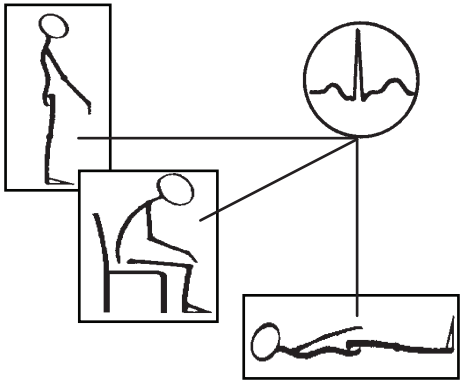
12-Lead mode

Note:

- ***If left uninterrupted for 10 minutes in the hook-up display, the recorder will start recording automatically***
- ***The number of channels visible depends on the patient cable and recording mode.***

Check the ECG is stable with positional change. Avoid changing axis/biphasic morphology and varying ST segment deviation.

If the morphology or ST segment change significantly with position, try relocating the electrodes.



3.7.6 High Impedance or Lead-off Warning

This check is only made in the Extended Recording Mode (Start week...).

If one of the channel numbers is flashing, this indicates a high-impedance or lead-off condition in that channel.

Ensure correct skin preparation and that the electrodes for that channel are firmly attached.

Pacing detection is inhibited whilst a lead-off condition exists.

Once the recording has started, there is an audible alarm if a lead is off.

3.7.7 Hints for Paced Patients

Check that the P symbol appears on the display whenever the pacemaker fires (practicable if the patient is dependent on the pacemaker).

It is easier to detect unipolar pacing than bipolar pacing, as the pacing artifact amplitude is much greater.

With dual-chamber pacemakers, optimize detection of the ventricular pulse.

If pacing is not detected, try moving one of the electrodes to a different position:

- **3 electrode cables**
  Try moving the green electrode towards position C3 (V3). This may improve detection of pacing artifact, although the ECG morphology in channels 2 and 3 may deteriorate.
- **4 electrode cables**
  Try moving the brown electrode towards position C3 (V3). In addition try moving the black electrode above the white electrode (on the manubrium).

  This may improve detection of pacing artifact. Channel 2 will become lead CM3, using the suggested position.
- **6 electrode cables**
  Try relocating the black electrode to the right sternal border and the brown electrode to C3 (V3).

  This may improve detection of pacing artifact. Channel 2 will become lead CM3, using the suggested position.
- **10 electrode cables**

  Pacing is detected in all leads with this cable, and generally the electrodes should not be repositioned for a 12-lead recording as the locations are rigorously defined.

Note: ***Pacing will not be detected during a lead-off condition.***

3.7.8 Check the Clock

When you are satisfied with the hook-up, press the green ► Select button.

Check the time and the date on the display. If they are incorrect, you can change them by moving the highlight and pressing the green ► Select button. Adjust as appropriate using the yellow ▲ Up or ▼ Down buttons and confirm with the green ► Select button.

Note: ***To change the time and date from the Set Up menu, see section 3.12.2.***

3.7.9 Start the Recording

Select '**Start Now**' by pressing the green ► Select button. The Lifecard CF will enter 'recording mode' which displays the current time in large digits for easy reading by the patient.

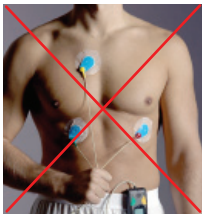
Selecting **Back** returns to the **Monitor Screen** without starting a recording.

3.8 Patient's Instructions

1. Carry out your normal daily routine. Do not open the recorder.

2. Do not pull on the electrodes or leads, or scratch the electrodes

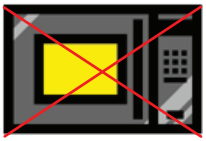
   For extended recordings: if you need to replace an electrode or if one becomes detached (the recorder will sound an alarm), follow the instructions given in your patient diary.

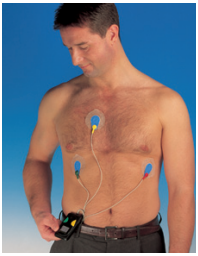


3. Do not bathe or shower whilst wearing the recorder.

   For extended recordings: if you need to disconnect the recorder, follow the instructions given in your patient diary.

4. Avoid electric blankets, microwave ovens, industrial machinery.





5. Use the Lifecard clock time to record your activity/ symptom diary.

6. If you experience symptoms, press either the green or yellow

   "Patient Event" button on the front of the recorder, and make a note in your patient diary.

3.9 During the Recording

3.9.1 Patient Event

Pressing either button during the recording records a Patient Event marker.

During analysis, you can go immediately to these events and review the ECG.

Ask the patient to note the time, date and symptoms of the event in their diary. (The date is displayed at the bottom right of the recorder screen in extended recording mode.)

3.9.2 Lead Off Alarm

In Extended recording mode only this alerts the patient if an electrode becomes detached, dried out or disconnected. The alarm is a two-tone chime lasting 15 seconds, and the clock display is replaced by a **lead off** message, indicating which channel is affected. When the electrode is reconnected, there is a "ding-ding" sound and the normal clock display is restored.

IMPORTANT:	• ***This feature should be demonstrated and explained before the patient leaves the clinic.***
	• ***The analyzer will blank the channel affected during the lead off period***

3.9.3 Checking the ECG

You can check the ECG at any time during the recording by pushing the yellow and green buttons simultaneously. This starts the ECG monitor display without interrupting the recording. After a 30 second interval or by pressing the green ► Select button, the clock display is restored.

Note:

- ***This feature is intended for checking satisfactory hook-up in hospitalized patients or when the patient is in the clinic.***

  IT IS NOT INTENDED FOR PATIENT USE
- ***This feature is not available during 12-lead recordings.***

3.9.4 Interrupting and Re-Starting the Recording

The Lifecard will stop recording if it is opened and resume recording when closed again (if there is space remaining on the flashcard). There is a short 'countdown' message before resuming. Select the **Enter Menu** option if you want to delete the recording and start again.

The battery may be changed, but do not change the flashcard unless you want to start a new recording.

3.9.5 End of Recording

Lifecard stops automatically at the end of the recording and switches to a low power state, displaying "**Recording completed**".

The patient should not open or interfere with the recorder.

3.10 On the Patient's return

1. Disconnect and Clean the Recorder

On the patient's return, remove the recorder.

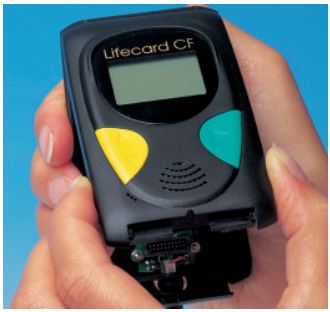
Before opening the recorder, clean the outer casing with a soft damp cloth. A mild detergent solution may be used, provided that it is wiped off with a damp cloth and the recorder is dried afterwards. We can supply a wipe that is applicable to cleansing the patient's skin and to cleaning the recorder.

Note: ***See section 4.2 for further details***

2. Open the Lifecard

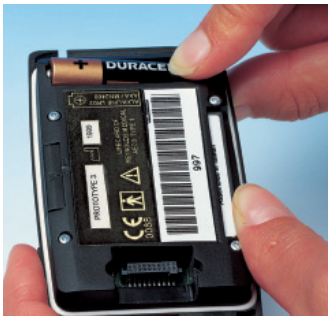
Use the card opener to open the catch.

Grip both halves of the recorder to separate the patient cable unit from the recorder unit.



3. Remove the Battery

Remove the battery from the Lifecard by pressing down on the 'negative' end of the battery.



Warning: ⚠	Discharge from an aged battery can damage the recorder. Dispose of used batteries carefully and in accordance with local regulations.

3.10.1 Downloading the Recording

Your Holter analyzer may be using:

- The CardioNavigator database- (*see 3.10.1.1*)
- The Report Manager (Archive Maintenance) database- (*see 3.10.1.2*)
- The Impresario database- (*see 3.10.1.3*)
- Sentinel - (*see 3.10.1.4*)

You can:

- Store the unanalyzed recording in the database, then load it later into

the analyzer. This uses 90Mbytes of disk space (48h/3CH recordings, 256Mbyte for 12-lead), but provides a copy of the raw data.

- Load the recording immediately into a Pathfinder or Lifescreen analyzer.
- Sebd the compressed ECG files via email For Holter

Follow the appropriate instructions below, according to the system you have.

3.10.1.1 Using CardioNavigator

a) Downloading the Recording into CardioNavigator

1. The patient details should already have been entered into the CardioNavigator database. If not, enter the appropriate patient details now.
2. With the correct patient details highlighted in the patient list, click on the Lifecard CF Download toolbar icon A message 'Reading data' will appear on the screen. When the download is complete, this recording will be highlighted in the recording list.
3. Double-click on the recording in the list to load the recording into the analyzer.

b) Loading the Recording Immediately from the CF Card

Insert the card into the flashcard reader, highlight the correct patient in the CardioNavigator patient list, then click the analyzer's button on the toolbar.

Pathfinder

Lifescreen

3.10.1.2 Using Report Manager

a) Downloading the Recording into Report Manager

1. Click on the menu Recording / Lifecard CF/ Store in archive
2. Enter the patient details in the next box that appears and click OK.
3. Choose the destination archive and click OK. A message on screen indicates that the recording is being transferred to the selected location.

   When the download is complete, this message box closes.
4. Double-click on the recording in the list to load the recording into the Pathfinder or Lifescreen analyzer.

b) Loading the Recording Immediately from the CF Card

1. Insert the card into the flashcard reader
2. In the Pathfinder program select Start Analysis, choose the Lifecard CF recorder type, then click Analyze.
3. In the Lifescreen program, select File - Load Recording.

Note: ***Lifescreen cannot load 12-lead recordings.***

3.10.1.3 Using Impresario V2.8 or later

Download recording into Impresario

1. Launch the Impresario application by double clicking on the desktop icon. Click on **Acquire 1** near the top of the Impresario window.
2. Check that the Lifecard CF is the selected recorder. If it is not, switch to the Recorder Configuration tab and select Lifecard CF from the drop down list.
3. Either enter the details for a new patient, or if the patient already exists in the database, select the correct patient.
4. Click on the large **Acquire** button (which should now be green) and confirm that you wish to begin the acquire process by clicking on **Yes** in the next 'confirm window' that follows.
5. The Analyzer set up window will open at the Lead selection Tab, so that you may select the leads that you wish to assign to Impresario channels 1, 2 and 3. Click **OK** when you have made your selection.
6. From the Lifecard CF window, choose the Impresario Patient details (the card may not have been initialized) and then select the recording details from the Lifecard CF. Then Click **OK** to load the recording. This will take several minutes.

3.10.1.4 Using Sentinel

This section describes the steps for checking the correct patient identity for a Holter recording, and downloading the recording into the database.

1. On the patients return with a completed recording, unhook the recorder and connect it, or the card, to the PC.
2. Log into Sentinel and from the **Sentinel Home Page** click **Holter**. The **Holter Worklist** screen is displayed.
3. Click the **Download** button.
4. Sentinel will read and display the **Patient Information** from the recorder or card.

To continue with the download click the **Download button** to the left of the recording. If the patient is located within Sentinel's database the patient name will be displayed and the recording automatically assigned. Click on Select Patient to confirm. Once the download is complete, a test summary will appear together with on-screen buttons allowing immediate test analysis.

Go to step 5.

OR

If Sentinel cannot locate the patient within the database or there is no **Patient Information** on the recorder or card, continue with the download by clicking the **Download** button.

Enter one of the patients demographics in the **Find** box. Select the required patient by double clicking on the record or by using the **Select Patient** button. The recording will now be assigned to that patient.

If no matching record can be found, click on the **Add New Patient** button.

OR

Click the **Identify Later** button to assign a patient later.

The test summary is displayed.

5. At this time the test details may be edited if required and **Diary** details can be entered. These steps are optional and you may proceed directly to analysis by clicking on the desired Holter analysis option (Impresario, **Lifescreen, Pathfinder SL or Pathfinder**) or the **Send Test Data** option to continue.

Analyze the recording

Please see the Instruction Manual for your Spacelabs Healthcare Holter analyzer.

3.11 Lifecard CF Menu

The Lifecard display is controlled by two buttons:

- The yellow ▲ Up and ▼ Down button is used to move up and down the menus, to highlight the menu option. You also use it to choose which channel is displayed on the monitor.
- The green ► Select button is used to select the highlighted option.

3.11.1 Main Menu

Displays options for starting and setting up the recorder.

3.11.2 Set Up Menu

Displays the options for setting the time and date on the recorder, and the contrast on the screen.

3.11.3 Monitor Mode

Display for checking the electrode attachment and signal quality.

3.11.4 Recording Mode

Displays the current time and also the 'patient event' indication.

3.11.5 Recorder Sleep Mode

The recorder will switch to a low power mode when the recording is complete.

3.12 Lifecard CF Menu Options

3.12.1 Main Menu Options

Displays options for starting and setting up the recorder.

1. Lifecard CF Option

   If alternative operating modes are available on your recorder and you wish to use them, contact Spacelabs Healthcare for the appropriate user manual.
2. Pacing Option

   Use this option to select or deselect pacing detection.
3. Start... Option

   Select Start when you want to make a recording in Standard Recording Mode, up to 48 hours of 2 or 3 channel ECG, or 24 hours of 12-lead ECG.
4. Start Week ...Option

   Select Start Week when you want to make a recording in Extended Recording Mode, to record up to 7 days of continuous 2 channel ECG.
5. Recorder ID

   This is a name or number you have chosen for the recorder using an option in the Set Up menu. Your chosen ID will appear in the Main Menu and on Pathfinder reports.

Note: ***There is a space inside the recorder unit for you to affix a bar code or similar***

6. Set Up Option

   Select this option to configure the recorder. (*See details below*).

7. Language Option

   Select this to change the language displayed on the monitor. Keep pressing the green ► Select button to switch between the languages until the correct one is displayed.

8. About Option

   This option displays the Software Version number and Hardware Serial number. Pressing the green ► Select button returns you to the Main Menu.

3.12.2 Set Up Menu Options

1. Contrast Option

   Displays a bar indicating the current setting of the contrast.

   The display can be darkened or lightened by pressing the yellow ▲ Up or ▼ Down button. Press the green ► Select button to return to the Set Up Menu.

2. Time Adjustment Option

   This option enables you to select a 12 or 24 hour clock display. Use the yellow ▲ Up or ▼ Down button to change the selection and then press the green ► Select button to select it.

   Adjust the hours by pressing the yellow ▲ Up or ▼ Down button until the correct one is displayed, then press the green ► Select button. This moves the highlight onto the minutes which you then adjust in the same way.

   Pressing the green ► Select button again returns you to the Set Up Menu.

3. Date Adjustment Option

   This option enables you to select a European or American date format. Use the yellow ▲ Up or ▼ Down button to change the selection and then press the green ► Select button to select it.

   Adjust the date in the same way as you have adjusted the time.

4. Speech Recording On/Off

   Press the green ► Select button to switch between the Speech Recording option being on or off.

5. ID:Enabled/Disabled

   This option enables you to give the recorder a personalized name or number ID. Your chosen ID will appear in the Main Menu and on reports.

To use this option, highlight the ID: Disabled line in the Set Up menu and press on the green ► Select button.

Press either of the yellow ▲ ▼ buttons until 'ID: enabled' is displayed.

Then press the green ► Select button to enter your recorder ID.

The first character of the ID will be highlighted. Use the yellow ▲ ▼ buttons to change the character as required and then press the green ▼ Select to move the highlight onto the next character.

You can enter a name or number up to 10 characters long.

6. Sounds On/Off

   Use the green ► Select button to select or deselect the Lifecard sounds.

7. Service

   The recorder will remind you when the annual service is due.

3.13 Lifecard CF Sounds

The Lifecard CF generates sounds to confirm your actions, or to inform you about the status of the recorder.

1. Click

   The 'click' sound is emitted whenever you press the yellow ▲ Up or ▼ Down button.

2. OK 'boing'

   The 'OK' boing tells you that the recorder is functioning properly and also sounds whenever you press the green ► Select button.

   The tone is a higher note than the 'error' tone.

3. Error tone

   The Error tone tells you that the recorder has identified an error or warning condition. The tone is a lower note than the 'OK' boing.

4. High Impedance or Lead Off Alarm

   During an extended recording, if a lead becomes detached, the Lifecard will generate an alarm to warn the patient. The alarm is a 'ding-dong' tone lasting 15 seconds, and the clock display will be replaced by the LEAD OFF message, indicating which channel has been affected.

   Once the patient has replaced the lead, the clock display resumes.

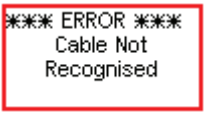
Note: ***You can turn the sound off by selecting Sound Off in the set up menu. This does not affect the 'Lead Off' alarm.***

3.14 Error and Warning Displays

1. You will see this error message if you are trying to use Extended Recording Mode with a six electrode cable. Either select Start. . . for Standard Recording Mode or change the patient cable.

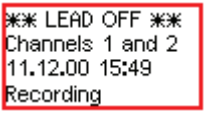
2. You are trying to use Standard Recording Mode with a two electrode cable. Either select Start Week for Extended Recording Mode or change the patient cable.

3. There may be a fault in the cable, or you may require a firmware upgrade to use this cable type.



4. If ***Error 0007*** message is displayed, contact the Service Department at Spacelabs Healthcare.

5. This message is displayed if a patient loses a lead during an Extended Recording. The Lifecard will also generate an alarm which will consist of a series of 'ding-dong' tones lasting 15 seconds. Once the patient has replaced the lead, the clock display resumes.

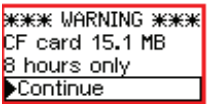


6. This warning is generated if you have selected Start Week... and the battery is partially discharged.

Note: ***7 day recording needs a new alkaline battery.***

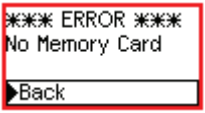
7. You will see a warning of this format if you have selected Start Week.... and the capacity is too small to record 7 days. Select Continue only if the recording description meets or exceeds your requirements

8. This message appears if the card capacity and patient cable are not appropriate to provide a 24 hour recording.

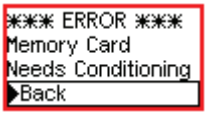


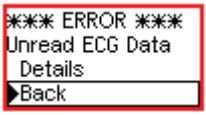
9. The Lifecard has been closed without a Flashcard inserted. Reopen the recorder and insert the card.

10. The Flashcard has been inserted before being correctly
Remove the card and follow the instructions to conditi
cards.

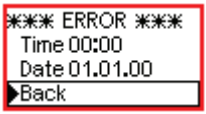


11. If the Flashcard contains a recording that has not previously been analyzed, you have the option to delete it. Select the 'Details' option - if the patient information is available, then the Patient screen is displayed. Otherwise the screen will display just the time that the recording was started.

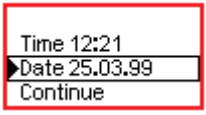


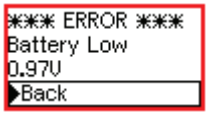


12. If the recorder detects that the rechargeable clock battery has discharged since the last use, you must enter the time and date.



13. If this message is displayed before you start a recordin insert a new battery immediately.





4. MAINTENANCE

There are no user-serviceable parts inside the Lifecard CF recorder and the Varios yoke so do not attempt to dismantle them.

- If you suspect that the recorder is not functioning correctly or any assistance is required, contact your supplier or the Service Department at Spacelabs Healthcare. The Lifecard CF recorder performs its own self-check before starting a recording.
- The patient electrodes are single-use-disposable - do not attempt to clean or reuse them.

4.1 Care of Flashcards

4.1.1 Reliability

To ensure reliability, observe the following:-

1. Use the flashcards only for recording and analyzing ECG using the equipment supplied. If you move, edit or overwrite files on the card using other software you will damage the data structure and the card will become unusable.
2. Only the Compact Flash cards supplied by Spacelabs Healthcare are proven to be compatible. Other types of card are not guaranteed to function correctly with Lifecard CF. CF cards supplied by Spacelabs Healthcare are individually tested and guaranteed, and fully labeled and serialized.

3. When inserting a card into the recorder, ensure the label is facing up.

4. Insert a card into the reader with the card capacity label facing up. If insertion is at all difficult, make sure the card is the correct way up and presented squarely to the reader. Also check that the connector pins in the card reader are straight - a defective reader must be replaced.

4.1.2 Difficulty in Reading Flashcards

If you find that you cannot read a recording, it may be that your card reader has stopped responding. Try listing the flashcard files in Windows Explorer by selecting the icon for the card reader in the left-hand panel. If you cannot list the files, save your work and switch the analyzer PC off. Switch the analyzer PC on again and re-try.

The card reader may be damaged. Periodically check that the connector pins in the card reader are straight - a defective reader must be replaced or the bent pins will damage your flashcards.

If a flashcard is misused it may develop problems which generate error messages on the recorder or analyzer. If this happens, follow the instructions in this manual to initialize the card. Remember that this will erase any ECG recording on the card. The analyzer software will usually re-condition the card if necessary, which will correct most problems.

4.2 Cleaning and Disinfecting Lifecard CF Recorders

The plastic parts of the recorder are strong and generally very durable, but some chemicals can attack them. Such chemicals may be found in specialist cleaning products, disinfectants, and skin-care products (e.g. sunscreens).

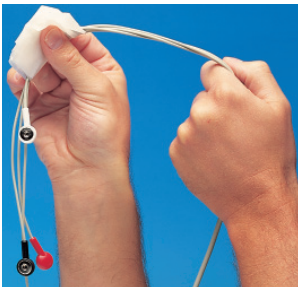
Due to the enormous range of chemical products, and the fact that some are corrosive in very small quantities, it is often impossible to find out what has caused damage. To ensure trouble-free service from your recorders, use only the cleaners and disinfectants recommended here.

4.2.1 Cleaning Lifecard CF

Clean the patient cable and recorder while they are fitted together, using a soft damp cloth. A mild detergent solution may be used, provided that it is wiped off with a damp cloth and the recorder is dried afterwards. Alternately,a wipe can be supplied that is applicable to cleansing the patient's skin and to cleaning the recorder. Please request our Alcohol Free Cleansing Wipe. DO NOT allow moisture inside the case or permanent damage may result.

4.2.2 Removing Adhesive Residues

It can be difficult to remove adhesive residues from the patient cable. Spacelabs Healthcare recommends isopropyl alcohol swabs (see below), ensure the wipe is used gently to avoid damaging the cables.



4.2.3 Cleaning Pouches and Lanyards

The pouches, lanyard and harness can all be washed in hot soapy water.

4.2.4 Disinfecting the Lifecard CF

If low-level surface disinfection is necessary, wipe the recorder and cable thoroughly with isopropyl alcohol, 70% (such as isopropyl alcohol prep pads). To avoid damage to the display window, wipe the alcohol off with a soft damp cloth and then dry the window.

4.2.5 Contamination by Body Fluids

If you suspect that the Lifecard CF has been contaminated by body fluids:-

- Wear protective gloves before handling the recorder
- Seal the recorder and patient cable in a hospital bag clearly marked for contaminated material
- Contact Spacelabs Healthcare Limited for advice
- Do NOT return the recorder or cable to your supplier or Spacelabs Healthcare before taking these precautions

4.3 Lifecard CF Accessories

Lifecard CF	
Lifecard CF Recorder	LCF
Lifecard 12 Recorder kit	LC12
12-Lead accessory kit	LC12KIT
Firmware V7 upgrade for 12-Lead	LC12UP
Flash cards	
90Mbyte Flashcard	CFC90MB
256Mbyte Flashcard	CFC256MB
Patient Cables for Lifecard CF	
3 electrode screened tinsel	46-0418
4 electrode screened tinsel	46-0556
6 electrode tinsel	46-0031 (also requires 19-7509)
3 electrode short screened tinsel	46-0480
4 electrode short screened tinsel	46-0557
10 electrode Patient Cable for Varios Active Yoke	
AHA color code (leads only)	46-1127
IEC color code (leads only)	46-1123
AHA color code (Yoke and Lead assembly)	46-1153
IEC color code (Yoke and Lead assembly)	46-1152
LCF back & Varios Active Yoke only	46-1125
Guides & Manuals	
Lifecard 12 Hook-Up Guide (Multilingual)	073-0259-00
Lifecard CF Hook-Up Guide (English)	46-0414
Instruction & Technical Manual (English)	070-2256-00
Lifecard CF CD manual	084-1420-01
Lifecard CF Service Manual	070-2263-00
Patient Diary (multilingual)	46-0573
Patient Instruction and Diary card (English)	073-0267-00

Accessories	
Shoulder fabric pouch/Neck lanyard set (pk of 2)	46-0408
Disposable pouches (100) for Lifecard CF	46-0512
Disposable cord (50m) for Lifecard CF	46-0005
Recorder Opening Card	46-0413
Marking pen (for Flashcards)	46-0411
Lifecard 12 hook-up kit	23189-114
Lifecard 12 hook-up kit (pack 20)	23189-114-401

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5. LIFECARD CF TECHNICAL MANUAL

5.1 Technical Specifications Lifecard CF

Standard Recording Mode - ECG Inputs	
Channels	3, type BF applied part patient isolation
Cable types	2 or 3 channel 3 electrode, 2 channel 4 electrode, 3 channel 6 electrode with detachable leadwires
Input impedance	> 5MOhms
Input DC offset	± 300mV, with saturation recovery circuit (3 seconds max)
CMRR	> 60dB at 10Hz, > 80dB at 50Hz and above, 2Vpp signal
Dynamic range	10mV
Resolution	2.5µV
Calibration	± 5%
Bandwidth	0.05 - 40Hz (-3 dB)
Sampling rate	1024 samples per second per channel
Noise filter	Linear phase filter effective from 60Hz to > 1MHz, 128 samples per second output rate
Standard Recording Mode - Pacemaker Pulse Detection	
Sensitivity	7mV nominal, channels 1 and 2 only
Noise rejection	> 50mVpp for sinusoids up to 200Hz
CMRR	2V common mode spikes are rejected
Refractory period	40ms

Standard Recording Mode - Data Storage	
Media type	Removable card, CompactFlash Association standard (Type 1)
Data types	Full disclosure ECG, with pacing and patient event markers. Recording Time and Date. Patient name and record number 8 second voice recording. Recorder serial number
Capacity required	15Mbytes per channel per 24 hours eg. a 48 hour three channel recording occupies 90Mbytes
User Interface	
Type	Text menus with audio cues and keys for up, down and select
Languages	English, German, French, Italian Spanish, Danish and Polish languages also Hebrew patient ID support
Clock	Clock and calendar (to 2098), selectable 12/24 hour and US/ European date formats. 13mm digit height for patient use.
Basic features	Pacing detection on/off, hook-up display, voice recording for patient identification
Ancillary features	Identify and delete unread recordings, warning/error screens for battery and memory card conditions
Hook-up display	Real time display of each channel, with 60µV/30ms resolution and pacing annotation
Set-up options	Time and date, language, display contrast, recorder identification.
Power Requirements	
Disposable cell	Single AAA alkaline (Duracell MN2400 or equivalent), two 24 hour recordings or one 48 hour recording
Rechargeable cell	Single AAA nickel metal hydride (Ansmann 600mAh or equivalent), one 24 hour recording per charge
Battery check	User is warned of poor battery condition before recording
Clock battery	Internal Rechargeable cell, charged during recording. The clock is maintained for > 3 months between recordings
Extended Recording Mode	
Channels	2 channel recording, with pacing detection
Cable Types	2 channel 3 electrode or 2 channel 4 electrode
Resolution	10µV
Sampling Rate	256 samples per second per channel

Compression	10µV maximum compression error when tested with MIT-BIH Arrhythmia and Compression databases
Disposable Cell	AAA alkaline (Duracell MN2400 or equivalent) for 1 week recording (1 or 2 channels).
User Interface	Includes an audible alarm to alert the patient if an electrode becomes detached. Sense current is < 10nA.
Note: other specifications are the same as Standard Recording Mode.	
Additional Specifications in 12-Lead Mode	
Channels	Standard 12-lead, one neutral and nine active electrodes
Cable types	10 electrode, defibrillation protected, IEC or AHA code
Isolation	DEFIBRILLATION-PROOF TYPE CF APPLIED PART
Input impedance	10MOhm
Sampling rate	4096 samples per second per channel
CMRR	> 80dB per IEC and ANSI/AAMI methods
Suppression	Active neutral system ('right leg drive')
Resolution	0.6µV
Noise	< 0.6µV RMS
Pacing detection	>2mV, 200µs to 5ms pulse in any electrode
Capacity required	256MByte card for 24 hour recording
Battery	An alkaline AAA (LR03) cell is required for 24 hour recording
Fault tolerance	In the event of electrode detachment noise is suppressed, and the available leads are recorded (differential V leads only if R, L or F is detached)
Note: ***other specifications are the same as Standard Recording Mode***	
Physical and Environmental Characteristics	
Dimensions	96 x 57 x 17.5mm with patient cable fitted
Weight	Recorder body 55g: patient load 130g including battery, card and typical patient cable
User labeling	Area provided is 52 x 15mm
Temperature	0 to 45°C operation, -20 to 65°C storage
Waterproofing	IPx4 with patient cable fitted (protected against splashing water)
Humidity	Operation or storage 5% to 95%, non-condensing
Pressure	Operation or storage air pressure 700 - 1060mbar
Shock	1m drop

5.2 Decontamination

Before commencing any service or maintenance procedures, ensure the Lifecard CF recorder has been suitably decontaminated.

Unless contamination with body fluids is known or suspected, Spacelabs Healthcare recommends low-level disinfection.

Note: ***See the user instructions for further details on cleaning and disinfecting the recorder.***

In the case of severe contamination, the recorder may be beyond repair. Please contact Spacelabs Healthcare for further advice.

5.3 Overview of the Lifecard CF Recorder

Lifecard CF is a solid-state ambulatory ECG recorder, operating from a single AAA battery. It comprises a microprocessor, ECG amplifiers, LCD display and power management functions, and stores digitized ECG onto a compact Flashcard . The Lifecard CF recorder can detect pacing artifact (spikes) on the skin surface from artificial pacemakers.

The recorder consists of two main parts:

1. The electronic unit, comprising all the electronic parts and the battery compartment.
2. The patient cable unit, comprising the patient cable and the back cover of the recorder.

For 12-lead recording, the patient cable unit includes the Varios Active Yoke, which contains amplifiers and A/D conversion.

5.3.1 Patient Cable

Lifecard CF patient cables use screened lead-wires with tinsel conductors and an anti-microphonic barrier to provide strength, flexibility and low noise. There is a choice of 7 patient cable units:

- 4 electrode cable with belt clip
- 4 electrode cable, short, no belt clip
- 3 electrode cable with belt clip
- 3 electrode cable, short, no belt clip
- 6 electrode cable with belt clip and renewable lead wires (unscreened)
- 10 electrode cable for connection to Varios Active Yoke

Cables with 4 electrodes provide two channels of ECG. The popper colour code, which is detailed on the cable, conforms to AHA (1985) recommendations. The short cable without a belt clip is designed to maximize patient comfort when the recorder

is worn under clothes.

The 3 electrode scheme and popper colour code, as detailed on the cable label, is proprietary to Spacelabs Healthcare.

The 6 electrode cable provides three channels of ECG from 6 electrodes. The individual lead wires are detachable and can be replaced with any DIN42802 connector lead wire,

useful in situations requiring unusual hook-up or electrode terminations. The yoke is colour coded to AHA (1985) recommendations.

The cable yoke/back unit forms a complete assembly and is not serviceable. In the case of failure, the complete assembly must be replaced.

In the case of the 6 electrode cable, the individual lead wires may be replaced if broken.

The 10 electrode cable is replaceable as a complete assembly by releasing the screw securing it to the Varios active yoke.

The Active Yoke itself it not serviceable and must be returned to Spacelabs Healthcare for repair.

5.3.1.1 Checking the Patient Cable

Use the built-in ECG monitoring feature to check the patient cable for breaks.

Using a calibrator or ECG simulator, follow the instructions in this manual to make a recording, and check each channel at the monitoring stage. Flex the lead wires gently to reveal any intermittent cable faults.

5.3.2 Battery

Lifecard CF requires one AAA cell, either:

Disposable cell	Single AAA alkaline (Duracell MN2400 or equivalent), two 24 hour recordings,one 48 hour recording or in Extended Recording Mode up to 7 days, or in 12-lead mode 24 hours.
Rechargeable cell	Single AAA Nickel Metal Hydride (Ansmann 600mAh or equivalent), one 24 hour recording per charge, or in Extended Recording Mode up to 3 days. Not suitable for 12-lead recording.

5.3.2.1 Battery Check

The user is warned of poor battery condition before recording, when starting the recorder. Please refer to the detailed instructions, in this user manual.

The real-time clock is maintained by an internal rechargeable lithium cell, charged during recording from the main battery. With a full charge, the clock is maintained for at least 3 months after the main battery is removed or exhausted.

The clock cell is not replaceable by the user, and in the case of suspected failure the Lifecard CF should be returned to Spacelabs Healthcare for service.

Dispose of used batteries carefully, using environmentally friendly methods wherever possible.

5.3.3 Compact Flashcard

The recorder uses a CF card (type 1) Compact Flashcard, non-volatile memory card meeting the Compact Flash Association type 1 standard.

A new flashcard must be conditioned before first-time use, which may be done by the user from a menu option in the Spacelabs Healthcare Holter analyzer. However, cards supplied by Spacelabs Healthcare are already conditioned.

Full details are in this manual.

Cards not supplied by Spacelabs Healthcare may give short or unreadable recordings.

5.4 Functional Confidence Check

Because Lifecard CF is a fully digital recorder, it requires no alignment or calibration.

To test the recorder, make a recording using either a calibrator or an ECG simulator, then replay it on a Spacelabs Healthcare Holter analyzer. Full details of how to make a recording are in the user instructions within this manual.

5.4.1 Checking the Hardware and Software Revision

1. Insert a battery and close the back cover.
2. Press the Yellow (DOWN) key to highlight the About menu option, then press the Green (SELECT) key.
3. The revision numbers are displayed on the LCD.

5.4.2 Annual Service Reminder

The Lifecard CF recorder will remind you when the annual service is due.

If you do not wish to take up a Spacelabs Healthcare service contract (where available), Spacelabs Healthcare recommends that you carry out basic preventative checks at least once a year.

Note: ***For further details refer to the Maintenance section***

5.4.3 How do I find out when the next service is due?

1. In the Main menu, select the Set Up option, then the Service option.
2. The display will then show the recommended date for your recorder's next service.

5.4.4 What happens when the service is due?

The Lifecard CF continues to work normally but a 'reminder screen' is displayed whenever the patient cable is fitted. Spacelabs Healthcare will reset the recommended service date when the recorder is serviced.

5.4.5 How do I clear the Reminder Screen?

1. Select **Set Up** from the main menu
2. Select **Service**
3. Select **Cancel Warning**

The Reminder Screen will reappear next year.

5.5 Electromagnetic Compatibility

5.5.1 General Notes

In testing the immunity of the Lifecard CF and Lifecard 12, the following were regarded as ESSENTIAL PERFORMANCE per EN60601-1-2:

- Recording of ECG with no noise sufficient to interfere with diagnosis
- Maintenance of stored ECG and patient data
- Maintenance of correct time and date
- No changes of operating mode or set-up selections
- No damage, failure, or safety hazard

Technical testing used simulated ECG with QRS amplitudes between 0.5 and 1.5mV. If the patient's QRS amplitude is below this range the immunity may be impaired and analysis of the recording will in general be more difficult due to artefacts from various sources.

The following were regarded as acceptable responses to electrostatic discharges (ESD) only:

- False positive pacing markers
- False positive R waves in automated analysis
- Brief blanking of the display with no interruption of the recording
- Reset followed by automatic recovery within 10 seconds

Analysis software will display resets during recording as blank sections in the ECG trace. Electrostatic discharges of sufficient size to induce these effects are infrequent in normal ambulatory recording.

Portable and mobile communications equipment can affect medical electrical equipment. In particular, emergency service radios and walkie-talkies can generate very strong interference signals.

Trials of Lifecard CF have shown no interference from mobile phones (cellphones) carried or used by the patient and no incidents of interference have been reported. However, phone technology is continuously evolving and standards vary from country to country, please be aware of the possibility of interference when analysing ECG recordings.

The Lifecard CF should be worn close to the patient's body as directed in section 3 above. It should not be placed adjacent to other equipment.

The patient cables listed in section 4.3 Lifecard CF Accessories provide compliance with the emissions and immunity requirements of EMC standard EN60601-1-2:2007 as detailed below. The use of other cables may result in increased emissions or decreased immunity.

5.5.2 Guidance and Manufacturer's declaration – electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Lifecard CF 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 Lifecard CF is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-2	Not applicable	

This equipment has been tested and found to comply with the limits for a class B computing device in accordance with the specifications in Subpart J of Part 15 of FCC Rules, which are designed to provide reasonable protection against interference to radio and television reception. This equipment generates and uses radio frequency energy and if not installed and used in accordance with the instructions it may cause interference. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause interference to radio or television

reception, which can be determined by turning the equipment off or on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient the receiving antenna
- Relocate the equipment with respect to the receiver
- Move the equipment away from the receiver

If necessary, the user should consult Spacelabs Healthcare or an experienced radio/television technician for additional suggestions. The user may find the following booklet prepared by the Federal Communications Commission helpful:

“How to Identify and Resolve Radio-TV Interference Problems”

This booklet is available from the U.S. Government Printing Office, Washington, DC 20402, Stock No. 004-000-00345-4

5.5.3 Guidance and manufacturer's declaration – electromagnetic immunity

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

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	Not applicable		
Surge IEC61000-4-5	Not applicable		
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	EN 60601-1-2 3A/m at 50 and 60Hz EN 60601-2-47 3A/m at 150 and 180Hz		Power frequency magnetic fields should be at levels caracteristic of a typical location in a typical commercial or hospital environment.

5.5.4 Guidance and manufacturer's declaration – electromagnetic immunity

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

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 Lifecard CF, including patient cables, than the recommended separation distance calculated from the equation applicable at the frequency of the transmitter: Recommended separation distance
Conducted RF IEC 61000-4-6	3V/m 150kHz to 80MHz	3V/m	d = 1.2 √ P 150kHz to 80MHz
Radiated RF IEC 61000-4-3	3V/m 80MHz to 2.5GHz	3V/m	d = 1.2 √ P 80MHz to 800MHz d = 2.3 √ P 800MHz to 2.5Hz
			where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey *, should be less than the compliance level in each frequency range. ** Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1. At 80MHz 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

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

5.5.5 Recommended separation distances between portable and mobile RF communications equipment and the Lifecard CF

The Lifecard CF is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Lifecard CF can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Lifecard CF 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 **m**		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	80MHz to 800MHz $d = 1.2\sqrt{P}$	800MHz to 2.5GHz $d = 2.3\sqrt{P}$
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 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 80MHz and 800MHz, 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.

6. REFERENCE

6.1 Reference Publications

6.1.1 General

ACC/AHA Guidelines for Ambulatory Electrocardiography: Executive Summary and Recommendations (Circulation. 1999;100:886-893).

6.1.2 12-Lead

Mason RE, Likar I. A new system of multiple-lead exercise electrocardiography. (Am. Heart J. 1996;71:196-205).

Papouchado M, Walker PR, James MA, Clarke LM. Fundamental differences between the standard 12-lead electrocardiograph and the modified (Mason-Likar) exercise lead system. (Eur. Heart J. 1987;8:725-733).

6.1.3 Ischemia

Jiang W et al, Relative importance of electrode placement over number of chanels in transient myocardial ischemia detection by Holter monitoring. (Am. J Cardiol 1995;76:350-354).

6.1.4 Pacing

Barold S, Usefulness of Holter Recordings in the Evaluation of Pacemaker Function. (A.N.E. 1998;3(4):345-379)

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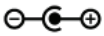
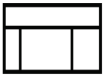
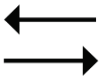
Appendix - Signs and Symbols

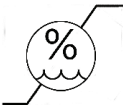
The following list of international and safety symbols describes all symbols used on Spacelabs Healthcare products. No one product contains every symbol.

General Safety			
	Consult instructions for use available on accompanying CD or via the Spacelabs Healthcare website		Consult Documents THIS SYMBOL MEANS YOU MUST READ THE ACCOMPANYING DOCUMENTS
	Caution		Caution - hazardous voltages. To reduce risk of electric shock, do not remove the cover or back. Refer servicing to a qualified field service engineer (U.S.A.). DANGER - High Voltage (International)
	Risk of Explosion if Used in the Presence of Flammable Anesthetics		Protective Earth Ground
	Fuse		Replace Fuse Only as Marked
	Functional Earth		Equipotentiality Terminal

General Safety cont.			
AECG TYPE 1	TYPE 1 AMBULATORY ECG DEVICE ACCORDING TO ANSI/ AAMI EC3B:1998		Low Battery
	Power supply jack polarity. (+ / - signs may be reversed)		Use only specified battery type.
	Battery Status		Replace only with the appropriate battery. (+ / - signs may be reversed)
	IEC 60601-1 Type B equipment. The unit displaying this symbol contains an adequate degree of protection against electric shock.		IEC 60601-1 Class II equipment, double-isolated. The unit displaying this symbol does not require a grounded outlet.
	IEC 60601-1 Type BF equipment which is defibrillator-proof. The unit displaying this symbol is an F-type isolated (floating) patient-applied part which contains and adequate degree of protection against electric shock, and is defibrillator-proof.		IEC 60601-1 Type BF equipment. The unit displaying this symbol is an F-Type isolated (floating) patient-applied part providing an adequate degree of protection against electric shock.
	EC 60601-1 Type CF equipment. The unit displaying this symbol is an F-Type isolated (floating) patient-applied part providing a high degree of protection against electric shock and is defibrillator-proof.		IEC 60601-1 Type CF equipment.,The unit displaying this symbol is an F-Type isolated (floating) patient-applied part providing a high degree of protection against electric shock.

General Use			
	ON — Power Connection to Mains		OFF — Power Disconnection from Mains
	ON/OFF		OFF Position for Push Button Power Switch
	START (NIBP) Key		STANDBY Key Power ON/ OFF Key
	START/STOP		STOP or CANCEL Key

Frequently Used Functions			
	Video Output		Infra Red Communications Port
	PRINT REPORT Key		Universal Serial Bus (USB)
	Network Connection		Power Indicator LED
	Audio Output, Speaker		HELP (Explain Prior Screen) Key
	Data Input/Output		Keypad
	Arterial Pulse		PCMCIA Card
	Keyboard Connection		Mouse Connection
	Serial Port		

Packaging			
	Non Sterile		PVC-Free
	Federal (USA) law restricts this dev1ce to sale by or on the order of a medical practitioner licensed by the law of the state in which he practices to use or order the use of the device.		Do Not Reuse; Single Use Only
IP N_1 N_2	IEC 60529 N_1 = 0 Non Protected 1 Protected against solid foreign objects of 50mm Ø and greater 2 Protected against solid foreign objects of 12,5mm Ø and greater 3 Protected against solid foreign objects of 2,5mm Ø and greater 4 Protected against solid foreign objects of 1,5mm Ø and greater N_2 = 0 Non Protected 1 Protection against vertically falling water drops 2 Protection against vertically falling water drops when ENCLOSURE tilted up to 15° 3 Protection against spraying water 4 Protection against splashing water		
	Environmental Shipping/ Storage Temperature imitations		Environmental Shipping/ Storage Humidity Limitations
	This Way Up		Fragile; Handle with Care
	Environmental Shipping/ Storage Altitude Limitations		Recycle
	All batteries should be disposed of properly to protect the environment. Lithium batteries should be fully discharged before disposal. Batteries such as lead-acid (Pb) and nickel-cadmium (Ni-Cd) must be recycled. Please follow your internal procedures and or local (provincial) laws regarding disposal or recycling.		This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.
	Keep Dry		Latex Free

Certification and Compliance

	ETL Laboratory Approved		Canadian Standards Association Approved
	CE marked in accordance with the Medical Device Directive, 93/42/EEC		Radio transmission device. High levels of ionizing radiation

Manufacturer Information and Traceability

	Manufacturer		Date of Manufacture
LOT	Catalog Number	SN	Serial Number The letters 'SN' stand for 'Serial Number' Each device has its own unique serial number

Notations and Abbreviations

Abbreviations used as symbols are shown below.

CH **ch**	ECG Channel ECG Channels – CH1, CH2, CH3, CH4	**C.O.** **CO** **co**	Cardiac Output
DIA **dia**	Diastolic	**ECG** **Ecg**	Electreocardiogram
ESIS	Electrosurgical Interface Suppression	**GND** **gnd**	Ground
HLO **hlo**	High Level Output	**NIBP** **nibp**	Noninvasive Blood Pressure
RESP **resp**	Respiration	**SPO2** **SpO2** **SpO_2** **SaO_2**	Arterial Oxygen Saturation as Measured by Pulse Oximetry
SYS **Sys**	Systolic		

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