



Holter Recorder

 | Lifecard[®] CF

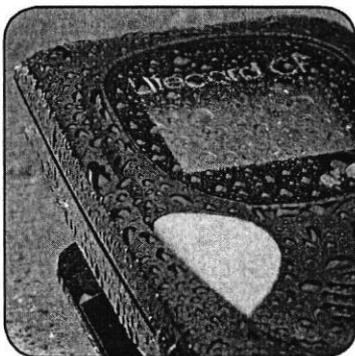
Lifecard CF



Lifecard CF

Lifecard CF has a number of features that makes for a flexible recorder to meet all of you diagnostic ECG needs. From patient compliant 3 lead cables with comfortable lanyard wearing solutions capable of recording ECG over 7 days, to a full 10-Lead cable offering 12-Lead ECG recordings.

1.1.5. 1.1.1.



Practical, modular Holter

Lifecard CF is quick to hook up to a patient and practical in use. Rugged and splash-proof rated to IP22*, Lifecard CF is designed to cope with the challenging environment of use with ambulatory patients.



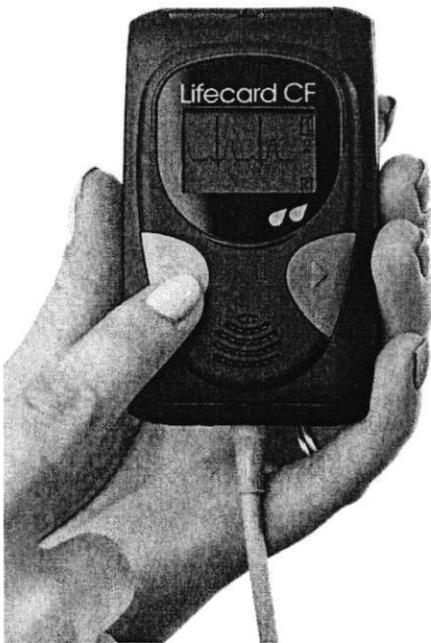
Comfortable patients = better recordings

Lifecard CF's patented 3-channel 3-electrode hook up improves patient comfort for 7 day recordings. The splash-proof design and disposable carrying pouch make it practical and convenient to wear the device under clothing, minimizing electrode disturbance and improving ECG quality. This gives the patient the freedom to carry out activities of normal daily living.

1.1.3.

*when new

Lifecard CF



Pacemaker Spike Detection

Lifecard CF has a sensitive pacemaker detection circuit with excellent noise rejection that operates continuously, with performance better than 10,000 Hz sampled pacemaker detection methods. *1.1.6.*

On-board ECG Display

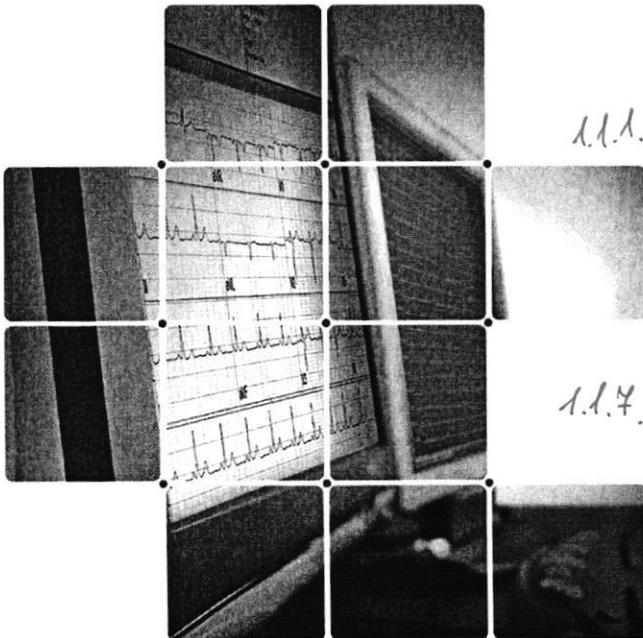
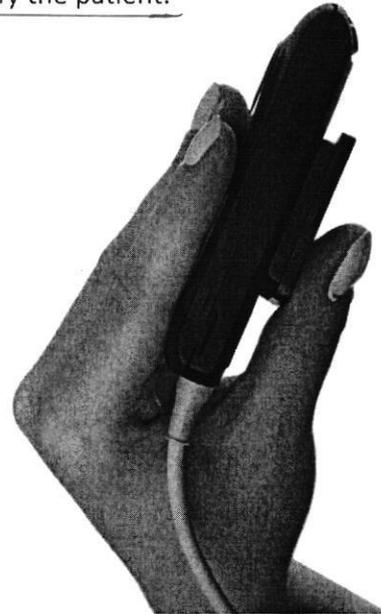
Lifecard CF has a built in ECG display that allows you to monitor the ECG during hook up. It even marks when it has detected each atrial and ventricular pacing spike so you can optimize lead placement.

Voice recording

Lifecard CF's built in voice recording capability can be used as a secondary means to identify the patient. *1.1.11.*

High resolution recordings

1.1.8. Lifecard CF uses 12-bit technology and digital oversampling, which enables subtle atrial arrhythmias and pacing to be clearly seen. P-waves are rounded, not squared off, and details like notched P-waves are precisely reproduced. 12-bit ECG can make the difference between confident diagnosis and an inconclusive Holter test.



1.1.1. 7-day continuous ECG capability

Diagnose arrhythmias before they become an everyday occurrence.

1.1.7. Lifecard CF can record up to 7 days of continuous ECG using one AAA battery and one memory card therefore requiring no patient interaction. Lifecard CF will even notify the patient if an electrode becomes displaced allowing this to be corrected. *1.1.4.*

The full 7 day recording can be analyzed rapidly in the Pathfinder SL for one complete report.

2. SAFETY AND REGULATORY

2.1 Device Description

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.

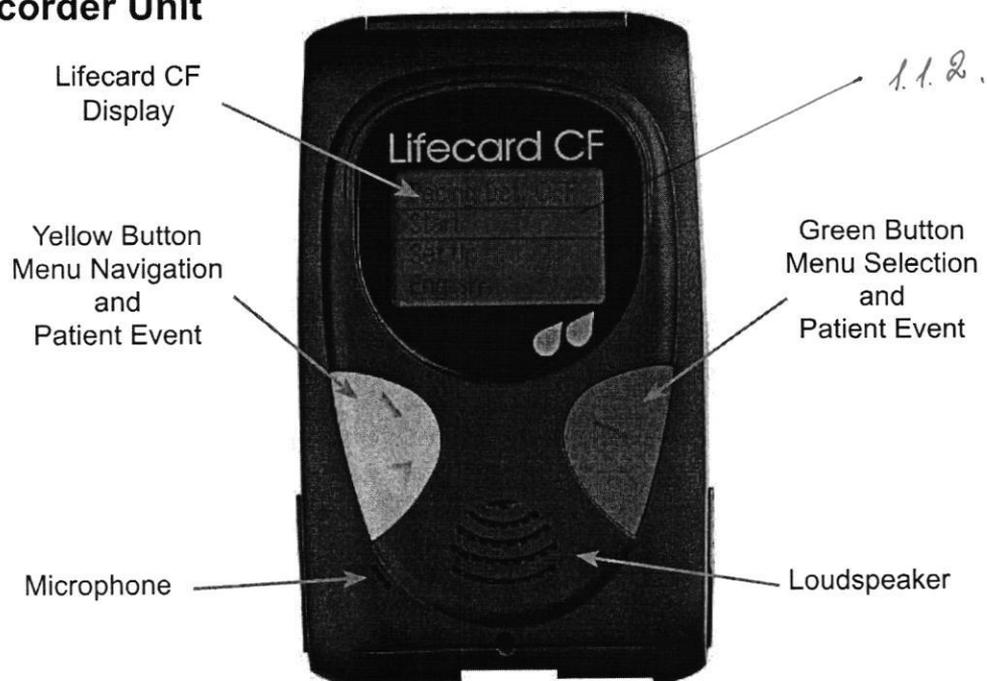
The recorder has a built in display for you to monitor the ECG and pacing detection during hook-up. This enables you to verify the ECG quality before starting the recording. Menu options are selected using the two buttons on the front of the recorder unit.

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, Impresario, or Lifescreen Holter analysis system, if they have compatible hardware and software. (Lifescreen is incompatible with 12-lead recordings.)

Recorder Unit



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.



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.

1.1.2.

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

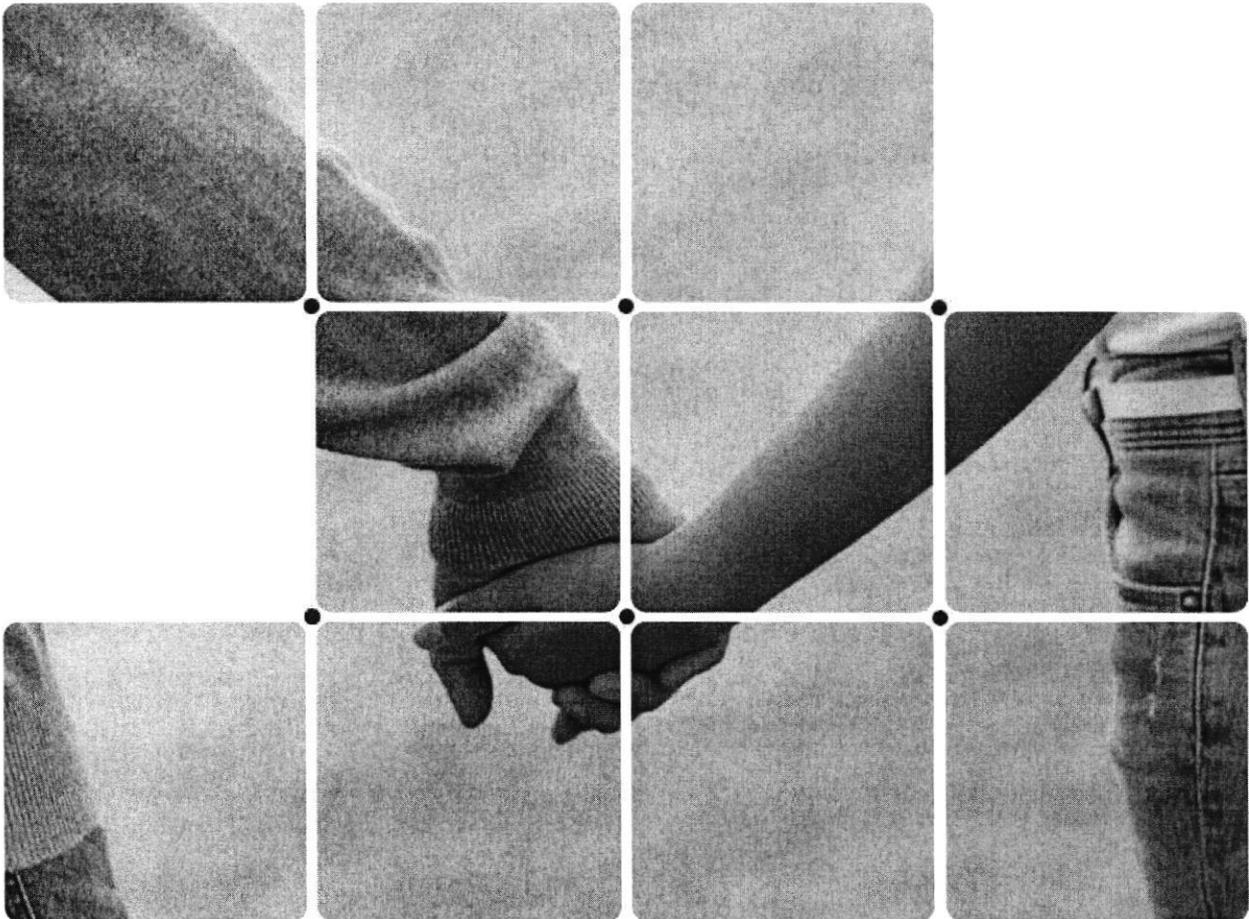
Lifecard CF patient cables use screened lead-wires with tinsel conductors and an anti-microphonic barrier to provide strength, flexibility and low noise. There is a choice of 7 patient cable units:

- 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

Lifecard CF provides a flexible and comprehensive solution to all your ambulatory ECG recording needs.

Flexible workflow, good patient compliance, 7 day recording and 12-Lead ECG in one device!

A.A. G.



Lifecard CF



12 Channel Holter

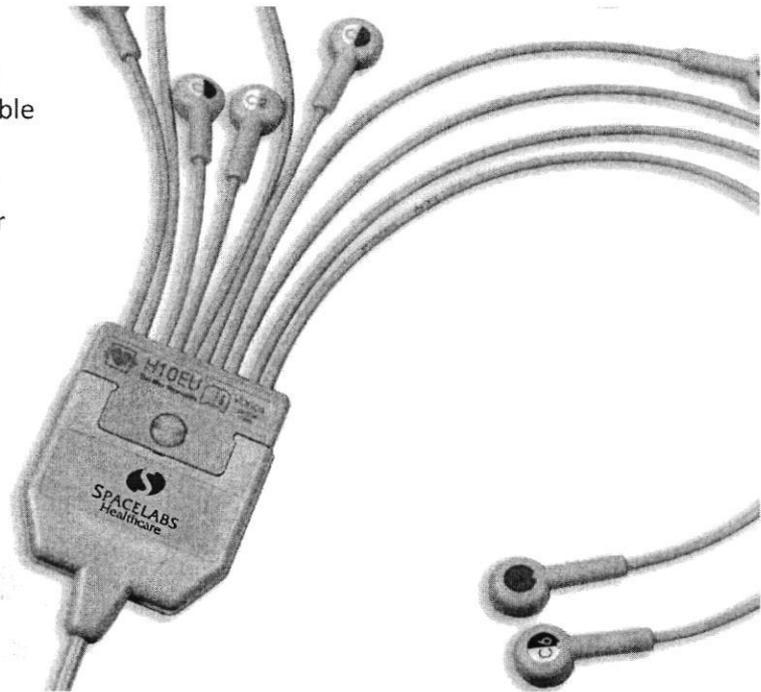
Using the Varios active 10 lead yoke and a 256MB card, Lifecard CF converts into a 12 channel recorder. This modular approach adds 24 hour 12-Lead ECG functionality to any Lifecard CF recorder. *1.1.5*

1.1.5. 12-Lead Holter provides a number of benefits to clinicians in helping to diagnose complex arrhythmias and ST changes over multiple leads.

Lifecard CF provides the optimal Holter bandwidth ECG by the use of advanced technology:

- 10 electrode patient cable to give true 12-Lead ECG results as opposed to derived results.
- 4096 Hz sampled ECG per lead
- 0.6 μ V digitization for maximum ECG fidelity
- No data compression

The lightweight 12-Lead yoke is worn on the patient's sternum, giving a comfortable hookup and reducing the need for long obtrusive lead wires. All 12 leads can be checked via the built-in hook-up monitor to ensure the highest quality signal is obtained.



Sentinel

Data Management & Networking

Lifecard CF recordings integrate with the Spacelabs Healthcare Cardiology Information Management System, Sentinel. This provides one central platform and core database for all ECG data and links to the Hospital Information Management System (HIS).

Upload patient details directly from the HIS via Sentinel into the Lifecard CF to save time and reduce transcription errors. Completed recordings can then be downloaded to any terminal on the Sentinel network for analysis using the Pathfinder SL Holter analyzer. All Holter data, including raw ECG and reports, are stored in the same central location as other integrated procedures.



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Comfortable patients - better recordings

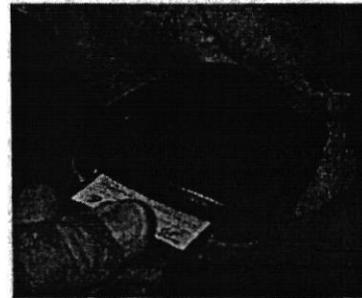
Lifecard CF's patented 3-channel 3-electrode hook-up improves patient comfort, which is very important for 7-day recordings. The splashproof design and disposable carrying pouch (see picture opposite) make it practical and convenient to wear the device under the clothing with short cables. This minimizes electrode disturbance and improves ECG quality, and it gives the patient the freedom to change clothes and perform their daily routine.

Never lose a recording again

Lifecard CF is designed to prevent tampering by the patient. Even if the battery or CF card is accidentally removed, when replaced the recording continues as normal, leaving a gap in the ECG and not a flat line. A back-up rechargeable battery maintains the clock and user settings for over three months when the recorder is not being used.



Voice recording stores patient name and ID



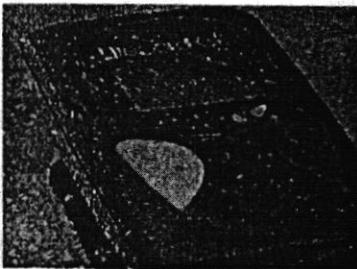
Inserting a CF card into the Holter analyzer's card reader for immediate analysis

Latest technology in a rugged, splashproof enclosure

Lifecard CF benefits from all the latest improvements in CompactFlash memory technology. Removable cards allow future memory upgrades for today's devices. Using multiple cards allows quick transition to the next patient, and ECGs recorded on cards can easily be sent to a remote location for analysis.

Rugged

Lifecard CF is tested to withstand a 3-foot drop onto concrete and still function perfectly.



Splashproof for added practicality

Splashproof

A new Lifecard CF is rated to IPX4 when the seals are new, so you can be confident that it will be splashproof for years to come.

Voice recording: No PC necessary at hook-up

If no PC is available during hook-up, a voice recording of the patient's name and ID can be stored on the card, so hook-ups can be done anywhere. With multiple cards, there is no need to access a PC before re-using the recorder – just insert a fresh card and make a voice recording.

Data Management & Networking

Lifecard CF recordings integrate with the Spacelabs Healthcare Cardiology Information Management System. CardioNavigator® (C-NAV)

provides one central platform and core database for all ECG data and links to the Hospital Information Management System (HIS).

Upload patient details directly from the HIS via C-NAV into the Lifecard CF to save time and reduce transcription errors. Completed recordings can then be downloaded to any terminal on the C-NAV network for analysis on any networked system. All Holter data, including raw ECG and reports, are stored in the same central location as these other C-NAV integrated procedures:

- Resting ECG
- Stress Testing
- ECG Event Recording
- Ambulatory BP

Additional Features

Pacemaker Spike Detection	Time and Date Recording
Single AAA alkaline cell required	Patient event button <i>1.1.13.</i>
Splash proof	Large Digit LCD Clock Display
Patient ID storage (voice recording)	On board ECG hook up monitor
Lightweight and comfortable to wear	Belt Clip standard on long length patient cables
7-Day Capability with Lifescreen screening system for increased diagnostic yield	

Technical Specification

Dimensions

96 x 57 x 18 mm (3.8 x 2.2 x 0.7 inches)

Weight 118 g (4.2 oz) weight includes battery, patient cable and compact flash card

Power Supply

One AAA alkaline or rechargeable battery (NiMH)

Memory

90 MB removable CF card

Procedure Options

3 or 6 electrode	3 channel 48 hr
4 electrode	2 channel 48 hr
2 electrode	1 channel 7-day
OR	
3 or 4 electrode	2 channel 7-day

Data Compression

None in 48 hour recording.

In 7 day mode: 10 m V max. error compressing MIT-BIH databases. Exceeds EC38 requirements.

Further Information

Dynamic Range	10 mV
Amplitude Resolution	2.5 microvolt (0.0025 mV)
Sampling Rate	1024 samples per second
Frequency Response	0.05 Hz to 40 Hz
Pacemaker Pulse Detection	Channels 1 and 2
Pacemaker Pulse Sensitivity	7 mV
Calibration	Automatic
Signal to Noise Ratio	70 dB
Common Mode Rejection	>80dB at 50/60 Hz
Input Impedance	>5 Mohm
Temperature Operating:	0° to +45° C
Storage	-20° to +65°C

R_x only **CE**
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Specifications subject to change without notice

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2 psl.

1.1.1. Elektrokardiogramos registracijos trukmė - 7 paros.

1.1.5. Galimybė registruoti 12 EKG derivacijų.

1.1.3. Pacientui pritvirtinamų elektrodų skaičius registruojant tris EKG derivacijas – 3.

3 psl.

1.1.6. Kardiostimulatoriaus impulsų registravimas.

1.1.11. Paciento identifikacijos duomenų įrašymas į registracijos įrenginį balsu;

1.1.8. Skaitmeninė rezoliucija - 12 bitų;

1.1.1. Elektrokardiogramos registracijos trukmė - 7 paros.

1.1.4. AAA baterijos – maitinimo šaltinis.

1.1.7. EKG įrašymas į išimamą atminties kortelę.

4 psl.

1.1.2. LCD ekranas.

5 psl.

1.1.2. LCD ekranas.

6 psl.

1.1.5. Galimybė registruoti 12 EKG derivacijų.

7 psl.

1.1.5. Galimybė registruoti 12 EKG derivacijų.

8 psl.

1.1.7. EKG įrašymas į išimamą atminties kortelę.

1.1.16. Atsparus vandeniui IPX4 klasė

9 psl.

1.1.13. Įmontuotas įvykių registracijos klavišas.

1.1.15. Svoris 118 g su baterija

1.1.12. Amplitudės skiriamoji geba 2,5 μ V

1.1.14. Diskretizavimo dažnis 1024 Hz/kanalui

1.1.10. Dažnio diapazonas (0,05 – 40) Hz.

1.1.9. Kalibracija – automatinė.