

OXFORD

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510k SUMMARY



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510(k) Summary

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Name of device : Medilog FD4
Classification name : Monitor - Electrocardiograph

Name of predicate : Medilog MR63
K943862

Description

The Medilog FD4 uses the same case, mechanics, electrodes and input circuitry as the Medilog MR63. Visually, it looks like an MR63. The difference being the analogue cassette mechanism has been replaced with a digital acquisition module containing a slot for a PCMCIA Flash ATA card.

The patient is connected to the FD4 via disposable electrodes attached to the chest. These detect the electrical signals generated by the heart, which are then transferred to the recorder via the electrode leads and patient cable. In the recorder, these signals are amplified, filtered, digitised and compressed without loss before being stored on a removable PCMCIA Flash ATA card. At the completion of recording the flash memory card is removed and the recorded ECG data is replayed and analysed on the Oxford Instruments ECG Analysis System.

Intended use

The Medilog FD4 Holter monitor is intended to be used in the diagnosis of various cardiac disorders by the recording of ECG in an ambulatory mode. These disorders principally include cardiac arrhythmia's and myocardial ischaemia.

The ECG data is used by the physician as an aid in the diagnosis of the patients condition. In some circumstances the patient may be hospitalised as part of the medical evaluation and Holter monitoring may be performed in conjunction with other non-invasive or invasive procedures. In such cases there is no interaction between the FD4 and other equipment.

FD4 performance testing.

Performance bench tests have been carried out on FD4 in accordance with American National Standard EC38 "Ambulatory electrocardiographs" and draft British Standard BS5724- Medical Electrical Equipment- part 2: Particular requirements for safety- section 2.47: specification for ambulatory electrocardiographic monitors. The performance parameters tested were; input dynamic range, gain accuracy, system noise, multichannel crosstalk, frequency response, and minimum feature size. The FD4 was found to meet all requirements.

Summary of FD4 trial results

A total of 29 recordings, 17 of which were performed in tandem with an MR63, were carried out from a variety of sources, with a view to establishing that the FD4 recorder was equivalent to its predicate device, the Medilog MR63. The recording sources were; a programmable simulator (giving repeatable and recognisable EKGs); an EKG generator (providing real patient data from a database of recordings); and human volunteers. The recordings were checked for signal quality, reliability of recording and download, detection of patient events and recording duration. In addition the heart rate variability was monitored and logged for comparison with the predicate device. All recordings were archived to optical disk.

All recordings met the criteria for a successful recording as defined below.

- Recording lasted for its intended duration
- Patient events detected
- Signal quality and gain comparable with the predicate device, where applicable
- No problems with either the recording or the replay
- Successful review by Oxford Instruments clinical specialist

Comparison table of FD4/MR63 features & specification

	MR63	FD4	Impact on effectiveness	Impact on safety
Type of device	Holter ECG recorder	Holter ECG recorder	N/A	N/A
Device class	non-critical Regulatory Class II	non-critical Regulatory Class II	no change	no change
designed to comply with.....	IEC 601-1, UL 544, 93/42/EEC (MDD)	IEC 601-1, UL 2601-1, AAMI EC38, 93/42/EEC (MDD)	Improved, updated standards including EC38 performance.	none
EMC	IEC 601-1-2	IEC 601-1-2	no change	no change
Environmental	5 °C to 40 °C 10 to 95% RH	0 °C to 45 °C 10 to 95% RH	Improved operating range.	none
Recording duration	24 hours	24 hours	no change	no change
Mounting method	Belt-mounted pouch	Belt-mounted pouch	no change	no change
Case	Polycarbonate / ABS	Polycarbonate / ABS	no change	no change
Power source	2xAA 1.5v primary alkaline or 1.2v NiMH rechargeable	2xAA 1.5v primary alkaline or 1.2v NiMH rechargeable	no change	no change
Electrode system	3/5/7 lead configurations using yoke cable and individual electrode leads	3/5/7 lead configurations using yoke cable and individual electrode leads	no change	no change
Recording medium	C-60 cassette	20Mb flash ATA card	improved frequency response (no tape variations)	none
Recording method	Direct	Digitised and compressed without loss.	Improved (no replay variations)	none
Display	4 digit + colon 7 segment LCD displays time	4 digit + colon 7 segment LCD displays time and additional error codes	More effective use of display to show useful information	none
Audible sounder	4kHz bleeper used to provide feedback during time/date setting and patient events	Frequency of bleeping variable	Provide more effective feedback and to distinguish between various sounds	none
Patient event marking	encoded onto data track of cassette. Resolution 1 second	Stored in file header. Resolution 1/128 th sec	Higher resolution patient event timing an advantage	none
External controls	Patient event button (also used for time/date setting). Head arm switch	Patient event button (also used for time/date setting) plus ON/OFF slide switch under recorder lid	Need ON/OFF switch to replace head arm switch of tape mechanism.	none
Signals recorded	3 x analogue ECG	3 x digitised ECG	improved	none
Setting up	Analogue monitor socket (not isolated) for all 3 ECG channels	Fibre optic output producing ECG signals in digital format at real-time	Attaches directly to existing OXFORD replay systems. No need for separate write-out unit.	Provides patient isolation by virtue of plastic optical fibre.
Method of isolation during monitoring	XE-45 write-coupler	Automatically provided by plastic fibre optic cable	none	Plastic fibre optic inherently safer than relying on use of safe writer coupler.
Data recorded	Time/Date & patient events	Time/date & patient events	no change	no change
Data format	Pulse width modulated	Digital format in file header.	Better reliability-not sensitive to tape variations	none
Channel gain adjustment	Hardware gain adjustment using digital potentiometers.	Software gain adjustment to give optimum signal amplitude	Ensures high fidelity reproduction of small & large ECG signals	none
Dynamic range	50 µV to 10 mV	10 µV to 10 mV	Improved. Allows accurate recording of larger range of ECG amplitudes.	none

	MR63	FD4	Impact on effectiveness	Impact on safety
Overall recorder/replay bandwidth	0.5Hz - 25Hz	0.05Hz - 40 Hz	No frequency response limitation due to tape recording/replay. Frequency response only due to hardware filters.	none
Typical pk-pk noise over input bandwidth	<50 μ V	<12 μ V	Lack of tape eliminates tape noise from overall system noise	none
Data compression	analogue- none	Lossless compression. No data is lost - just packed more efficiently onto disk	Ensures 24 hours of data fit onto 20Mb flash card. No degradation of signal.	none
Replay & analysis system	Medilog Optima & Excel 2	Medilog Optima & Excel 2	none	none
Analysis features in recorder	none	none	N/A	N/A
Alarms, warnings	none	none	N/A	N/A
control over other equipment	none	none	N/A	N/A