TECHNICAL INFORMATION

CORTRIUM C3+ HOLTER MONITOR

Technical specification

Technical	
Type of ECG Recorder	Holter, ambulatory ECG
No. of Channels	3
Wear Time	Up to 7 days
Recording Format	Continuous
Power Requirement	Lithium Polymer, 3.7V, 520 mAh
Dimensions	85 x 80 x 15 mm
Weight	32 grams
Sampling Rate	256 Hz
Input Impedance	10 Mohm
Resolution	24 bit
Performance Standard	Design verification IEC 60601-2-47

Safety	
Safety Standard	IEC 60601-1 Basic Safety & Essential Performance IEC 60601-2-47

Biological	
Medicinal Substances	N/A
Tissue	N/A
Body fluids contacted by device	N/A
Type of contact to intact skin	Non-invasive
Duration of skin contact	Up to 7 days continued contact
Mucosal membrane contact	N/A
Sterile or non-sterile	Non-sterile
Biological compatibility	ISO 10993-5 ISO 10993-10

Clinical	
Medical purpose	Ambulatory ECG
Single use / reusable	Reusable/Rechargeable Monitor
Recording standard	Holter
Recording format	Continuous
Intended placement	Midsternal line
Recording period	Up to 7 days on a single charge

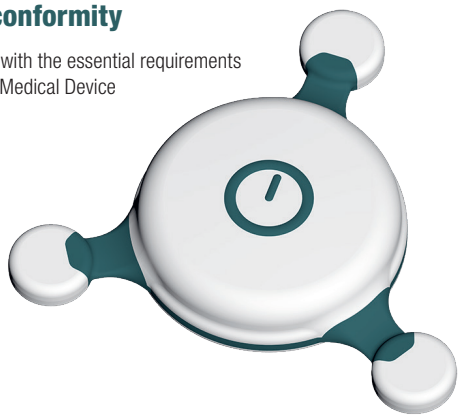
Regulatory information

The C3+ is a class IIa medical device according to 93/42/EEC. The C3+ complies with the following product standards:

DS/EN 60601-1-1	Safety Requirements for Medical Electrical Systems
DS/EN 60601-1-2	Electromagnetic Disturbances
DS/EN 60601-1-6	Medical Electrical Usability
DS/EN 60601-1-11	Home Healthcare Environment
DS/EN 60601-2-47	Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
DS/EN 62366-1	Application of usability engineering to medical devices
DS/EN ISO 10993-1	Biological evaluation of medical devices
DS/EN ISO 15223-1	Symbols to be used with medical devices labels, labeling and information supplied
DS/EN 1041	Information supplied by the manufacturer of medical devices
DS/EN 62304	Medical device software – software life cycle processes
DS/EN ISO 14971	Application of risk management to medical devices
EN 301 489-17 V3.1.1	Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 17
EN 300 328 V2.1.1	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band

Declaration of conformity

The C3+ is in conformity with the essential requirements and provisions of the EU Medical Device Directive (MDD).[1]



1 COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices.