User Manual

CardioScout

Multi-ECG

Recorder

INNOVATIVE MEDICAL SOLUTIONS

SR-Medizinelektronik
Haussmannstrasse 66
D - 70188 Stuttgart
Germany
Fon: +49 (0)711 9144650
Fax: +49 (0)711 9144651
info@sr-med.de
www.sr-med.de

Haussmannstr. 66
70188 Stuttgart
Germany

Tel: +49 711 9144650
Fax: +49 711 9144651
Mail: info@sr-med.de

CardioScout Multi-ECG

Software and these instructions are written with special diligence focused on users and intend to enable the user to make full use of all technical features of the CardioScout Multi-ECG Recorder. They are tested for their state of the art and for correctness.

SR-Medizinelektronik doesn't assume responsibility for quality, capability and merchantability of the CardioScout Multi-ECG in modified use as described in the product description and included in delivery.

SR-Medizinelektronik only assumes responsibility for any harm that is directly or indirectly due to the usage of the documentation and the corresponding software and any consequential damage, in case of on purpose source or negligent acts.

Exempted from liability are all hardware and software losses or damages and all consequential losses of data following as direct or indirect errors and damages, and all expenses that are due to wrong installation of the software, that is not processed by SR-Medizinelektronik.

All information's included in this documentation an the corresponding software can be changed without any specific announcement for technical progress.

The **CardioScout Multi ECG** Recorder is compatible to the following software products:

- **CardioExplorer Multi-ECG Analysis software (SR-Medizinelektronik)**
- **VMX00 Rest ECG Software (SR-Medizinelektronik)**
- **Multi-ECG Android Software (SR-Medizinelektronik)**
- **Multi-ECG iOS Software (SR-Medizinelektronik)**
- **HRV-Scanner (Biosign GmbH)**

RELEASED: APRIL 2015

Table of Contents

Haussmannstr. 66
70188 Stuttgart
Germany

Tel: +49 711 9144650
Fax: +49 711 9144651
Mail: info@sr-med.de

1. Introduction

With the purchase of the new CardioScout Multi-ECG Recorder of SR-Medizinektronik you receive one of the smallest and most innovative ECG system. Together with one of our software packages you are the owner of a compact and trend setting unit.

Intended use

The CardioScout Multi-ECG Recorder is a highly integrated Holter-ECG-System to record patients heart activities fixed to the patient with the Fixation Pads and using standard ECG electrodes. With the help of the included USB and Flash controller, the recorded data are transmitted very fast to a PC. There the data sets are managed, analyzed and archived by the Analysis-Software. While having a Bluetooth interface and the possibility to send out all channel high resolution ECG data the system can be used for rest and stress testing also. Software solutions for Apple and Android devices offers a very flexible and mobile use of the system.

The system may only be operated by specialists in medical staff.

General

The CardioScout Multi-ECG Recorder is certified by CE and meets the requirements of the 93/42/EWG. Before using accessories produced by another manufacturer make sure that all safety standards are proved by a authorized examining board. (conformity certification). All accessories connected to the units of CardioScout Multi-ECG Recorder shall comply with appropriate IEC/UL/CAN standards.

Additional equipment used with analog and digital interfaces of the system need to veritably meet the requirements for the according EN specifications, (e.g. EN 60950 about Safety of information technology equipment and EN 60601 Medical electrical equipment). All configurations must suffice the current release of the system norm EN 60601-1-1. The user of additional equipment in input and output interfaces is configurating the system and becomes responsible for the compliance with regulations of the current version of the the systemnorm EN 60601-1-1. For further inquiry contact your local specialist dealer or your technical support.

Haussmannstr. 66
70188 Stuttgart
Germany
Tel: +49 711 9144650
Fax: +49 711 9144651
Mail: info@sr-med.de

Classification

Classification according to EN 60601-1:

- Type of protection against electric shock:
  Device of safety class II
- Grade of protection against electric shock:
  Device of type BF
- Grade of protection when using the devices while anesthetics are present:
  Device must not be used in explosive atmospheres or in explosive mixtures of anesthetics with oxygen or laughing gas.
- Approved methods of usage:
  Devices are suitable for continuous operation.

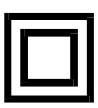
Classification according to MPG:

- Device of class IIa

Used Symbols

CE 0483 CE-Certification

 Typ BF

 safety class II

Notice

- Together with this CardioScout Multi-ECG Recorder device use only accessories and devices recommended by SR-Medizinelektronik.
- Never pull at the cable, always use the plug!
- The device should only be opened, maintained and repaired by technicians authorized by SR-Medizinelektronik.
- Dispose of the device and all accessories according to national laws and guidelines.
- Technical Safety controls should be performed every 1 to 2 years. Technical documentation equipment can be required on demand.
- Conductive parts of the electrodes and connected plugs of the ECG, including the neutral electrode, may not come in contact with other conductive parts including ground.
- The system is not suitable for the operation together with a defilibrator.

Conditions for operation

The following operation conditions must be met:

temperature:	+10 to +50°C
ambient pressure:	600 to 1200 hPa
relative humidity:	0 to 95%

Conditions for transport and storage

The following transportation and storage conditions must be met:

temperature:	-20°C to 60°C
ambient pressure:	500 hPa to 1060 hPa
relative humidity:	5% to 90%

Notice

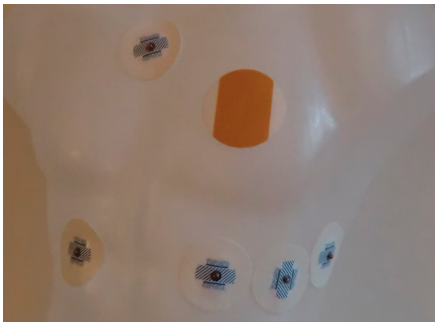
- During transport and storage the devices must be kept dry.
- Don't turn them upside down or place them on side during transport and storage.
- The devices are fragile.
- Don't use hand hooks for transport.

2. Putting into Operation

Mounting the recorder

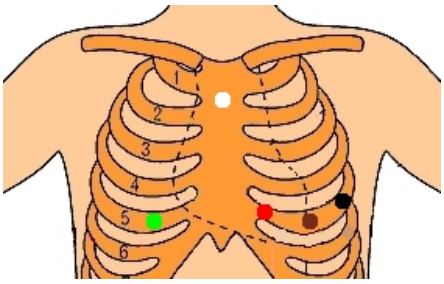
Clean the skin at the positions of the electrodes and the Pad for the recorder very properly and mount the electrodes and the recorder pad.

Please note, that the quality of your recognition belongs directly to the quality of your skin preparation. The skin should be lean and hairless.



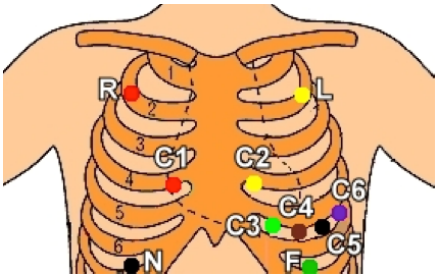
3-ch ECG and 3D Accelerometer (4/5 pol. Cabel)

Electrode	Connector color
Channel 1	red
Channel 2	brown
Channel 3	black
Referece	white
com. Ground	green (option)



12-Channel ECG (10 pol. Cabel)

Electrode	AHA	Electrode	AHA
right arm	(R) Red	***V2***	(C2) Yellow
left arm	(L) Yellow	***V3***	(C3) Green
left leg	(F) Green	***V4***	(C4) Brown
right leg	(N) Black	***V5***	(C5) Black
V1	(C1) Red	***V6***	(C6) Violet



SRM Innovative Medical Solutions
Haussmannstr. 66
70188 Stuttgart
Germany
Tel: +49 711 9144650
Fax: +49 711 9144651
Mail: info@sr-med.de

Connect all electrode cables with the electrodes and check the rightness of the colours.

After mounting the system you can plug the electrode connector into the recorder for switching on. The seal should not be seen after plugging inn.

If Autostart function is activated, the recorder will beep 2 times and the recording will start automatically.

If Bluetooth startup is activated, the recorder will beep only one time and then he will wait until a Bluetooth connection is established. Please refer you software manual to see how to start the recorder.

When having problems with the signal quality you shoud remove the electrodes and clean the skin again, or choose other positions for the electrodes.

As we use such short electrode cables, there is no need for additional fixations. The systemk is now ready to work.

The recorder pads are produced of bio compatible materials that makes them eudermic. It is possible that the skin of sensitive patients may be irritated. The patients should be clarifyed about this.

The electrodes and pads are designed for single use only. Do not use them for more than one recording and dispose all accessories according to national laws and guidelines.

The recharchable batteries should be loaded after every holter use. Please connect the recorder to the charger or USB interface until you can see the green light indication.

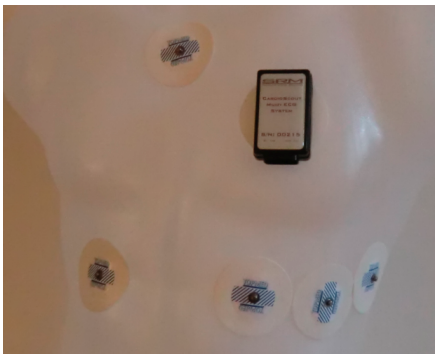
Dismounting the recorder

Unplug the electrode connector

Remove all electrodes and take off the recorder together with the adhesive pad.

Remove the electrodes and the adhesive pad from the recorder.

Clean the patients skin.



Connect the recorder with the USB cable to your computer for charging and downloasing the data.

Important: When using the CardioScout Multi-ECG recorder with Autostart modus please note that recorder will delete the ECG data file each time when plugging inn the electrode cable. Please ensure that you have downloaded the data before restarting the recorder!

3. Internal Flash Memory

If your CardioScout Multi-ECG recorder has internal flash memory, please ensure not to delete or to modify the data on it.

The Flash memory needs to have some special preparations to ensure that the recorders will work correctly:

- The Flash Memory must be formatted in the format ***FAT*** or ***FAT16*** (not FAT32)
- The Flash Memory must contain a ***cscout.sys*** file
- The Flash Memory must contain the ***rec.inf*** file
- The Flash Memory must contain the ***patient.0*** file
- The Flash Memory must contain the ***ecg.dat*** file (this file must be copied last and separate)

Please contact the manufacturer or your distributor if you don't have them.

Please ensure not to delete or modify these files while this can damage the recorder.

4. Splashproof housing

The CardioScout Recorder has a splshproof housing so that your patients can have a shower during recognition. This is a great benefit for the patient and increase the comfort during holter investigation.

But while having an interface connector you have to ensure that

- the sealing ring is in a good condition with no cracks or flaws
- the connector is fully plugged inn, so that the seal can't be seen
- the patient does not pull on the electrode cords
- the patient does not unplug the connector during shower
- the patient dry the area of the recorder and electrodes carefully

Also it is not advisable to unplug the electrode connector as long as the recorder is wet or moist. Please dry the recorder and the cable first.

Check that the sealing ring is completely faultless before allowing the patient to have a shower, and plug the connector as far as possible into the recorder!

Ask the patient to be carefully during shower and not to pull on the electrode cables!

The sealing ring is available as a spare part. Please exchange damaged sealing rings.

5. Technical Data

Dynamic Range	+/- 6 mV
Sampling Rate	500 Hz (optional 1000 Hz)
Frequency Response	0.05 – 150 Hz (- 3 dB)
Accuracy	10 uV (digital resolution)
Max. Electrode potential	+/- 300 mVdc
Time Constant	<=3.2 s
CMRR	> 100 dB
Dimensions	37x62x16 mm (WxLxH)
Weight	42 g (incl. Battery)
Data Acquisition	Simultaneously, max. 12 Channel, 24h
Power Consumption	42 mW
Power Supply	Input: 100 - 240V~/50Hz Output: 5V=/1000mA
Memory	integrated Flash (max. 32 GB)
Data Transfer	about 30 sec / 24 h
Standards	
Conformity	CE according to 93/42/EWG
Conditions for Operation	Temperature: +10°C bis +50°C Ambient pressure: 600-1200hPa Relative humidity: 0-95%
Conditions for Transport and Storage	Temperature: -20°C bis +60°C Ambient pressure: 500-1060 hPa Relative humidity: 5-90%
Classification	Safety Class II / Typ BF Device of class IIa

Technical changes reserved.

6. Accessories

Article	Number
Electrode cable – 10 poles	02 S 0100
Electrode cable, 5 poles, 30 cm	02 S 0105
Electrode cable, 4 poles, 30 cm	02 S 0108
Electrode cable, 3 poles, 30 cm	02 S 0110
Electrode cable, 2 poles, 30 cm	02 S 0112
Electrode cable, 2 poles, 60 cm	02 S 0115
Electrode connector, 0 poles (Accelerometer only)	02 S 0130
Suction Electrode Systen cable adapter (10 leads)	02 S 0150
USB Charger / data cable	02 S 0160
USB Power Supply (5V, 1000mA)	02 S 0170
Necklace, adjustable length, with safety lock	02 S 0200
Adhesive Pads (Package with 25 pieces)	02 S 0080
Sealing ring (Package with 5 rings)	02 S 0300

7. Care and Cleaning

When using the CardioScout Multi-ECGas a holter it is usually over a period of 24 hour in use of a patient, so that for reason of hygiene the system should be cleaned after each recording.

Through the adhesive pad, it is not a direct contact between the recorder and the patient's skin, so that is usually sufficient to clean the recorder and the electrode cable with a damp cloth. After that the recorder should be rubbed with a dry cloth to dry again.

If dirt it is recommended to moisten a cloth with some soap and thus to clean the plastic parts and the electrode cable and plugs. For stubborn stains repeat the cleaning process.

	Always make sure that the device is not saturated or that the cleaning cloth is not too moist. Moisture can damage the recorder if the electrode cable is not plugged inn.

8. Possible errors and correction

The CardioScout Multi-ECG Recorder is a highly integrated system for continuous recording or online transmission of ECG signals.

Due to the small size and the fact that patients will carry the system up to 24h we have decided not to incorporate control parts for the control or service of the equipment.

Each time you start the system performs a self test and also checks the internal memory (if exist).

Therefore the following validation options exist:

I) When inserting the electrode connector:

Event	Cause	Action
There is no beep	Battery is empty	Charge the battery
	Electrode connector is damaged	Try to use another electrode connector if available or contact the manufacturer / distributor
	Recorder is damaged	Please contact the manufacturer / distributor
	Flash Memory is damaged	Please contact the manufacturer / distributor

II) When charging the battery

Event	Cause	Action
Battery can't be charged, no light indication	Battery is damaged	Please contact the manufacturer / distributor
	Integrated charger is damaged	Please contact the manufacturer / distributor
	Power supply is damaged	Please contact the manufacturer / distributor
Light indication will not jump to green (Full)	Battery is damaged	Please contact the manufacturer / distributor
	Integrated charger is damaged	Please contact the manufacturer / distributor

9. Notes

SRM
INNOVATIVE MEDICAL SOLUTIONS

Haussmannstr. 66
70188 Stuttgart
Germany

Tel: +49 711 9144650
Fax: +49 711 9144651
Mail: info@sr-med.de

10. Declaration of Conformity

SR-Medizinelektronik
Haussmannstrasse 66
D-70188 Stuttgart
Germany

declares, that the following class IIa ECG systems

Holter System CardioScout Multi ECG
Holter System CardioScout
SRA+ Recorder
SRA-Recorder
Bodycom
ECGLink

meets all applicable requirements of Directive 93/42/EEC.

This statement applies to all products that are produced by 14.03.2020

Notified Body:

mdc, medical device certification GmbH, Kriegerstrasse 6, D-70191 Stuttgart

Conformity assessment procedures:

Directive 93/42/EWG – appendix VI

Stuttgart, 04.04.2015

Hartmut Richter (medical officer)

11. Training protocoll

Name of Trainer: _____

Date of Training: _____

Trained persons: _____

_____

_____

_____

_____

There was a briefing in the following topics:

Operation of the recorder / Hardware
Charging and operation of the battery / possible risks / storage conditions
Handling the internal Flash Memory
Patient preparation / pretreatment of the skin
Mounting the recorder / placing the electrodes
Data archiving and data security
Warranty and Service

_____

_____

_____, _____ _____

_____

_____

_____

_____ _____

Signature Trainer Signature trained persons

12. Customer questionnaire

We like to know your opinion

Please be so kind and use this questionnaire in case of problems, questions or incitation to our hard- and software system.

Your name: _____ Your address: _____

_____

Fon: _____ _____

Product: _____

I have the following Problem Question Incitation

Request _____

_____

_____

_____

_____

Please call me back Please arrange a date

Please confirm the reception of this message

_____,_____

_____

Customer sign

Please fax to: SR-Medizinelektronik – fax number +49 711 9144651

SRM Innovative Medical Solutions
Haussmannstr. 66
70188 Stuttgart
Germany
Tel: +49 711 9144650
Fax: +49 711 9144651
Mail: info@sr-med.de