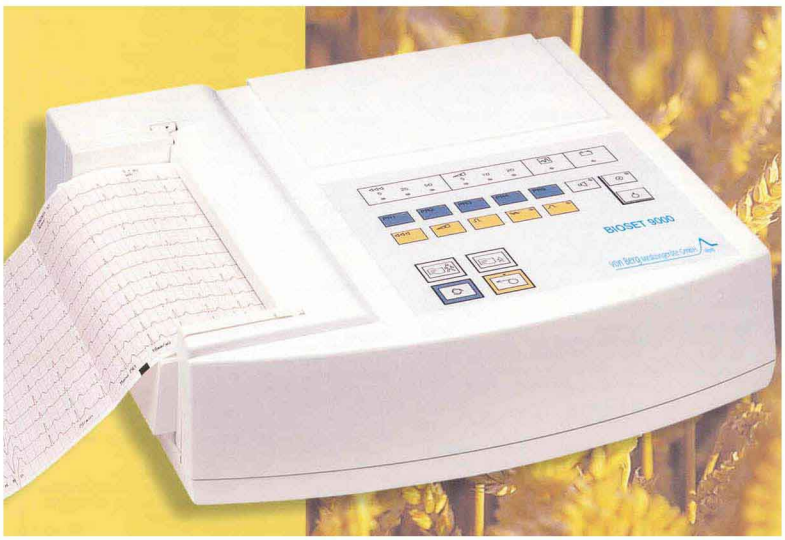
OPERATING MANUAL

6/12 Channel-Electrocardiograph

BIOSET 9000E



CE 0123

von Berg
Medizingeräte GmbH

vbm

E-0802

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Unit No.

Manufacturer’s Liability

The manufacturer can only be made liable for possible effects concerning safety, reliability, and performance of the unit, if

- installation works, extensions, resettings, changes, or repair works are executed by persons authorised by the manufacturer;
- the electric installation of the room meets the requirements of the applicable regulations;
- the unit is applied in accordance with this operating manual.

This unit may only be operated with accessories and other parts supplied from us. Otherwise, it may come to defects or false information.

1 General

1.1 Application

BIOSET 9000E is a 6/12-channel electrocardiograph.
As a variant, the unit can be supplied with automatic ECG measurement function or automatic measurement/ interpretation using the HES analysis program by the Medizinische Hochschule Hanover.
If desired, it is also possible to unlock the ECG measurement/interpretation function in the client's house.

BIOSET 9000E is foreseen for ECG recording in the ambulant practice and clinical routine.
Owing to its small dimensions, low weight, and possible battery operation it is suitable for home visits and emergency medicine.

1.2 Unit Design

BIOSET 9000E is a compact unit with horizontal upper side.
The casing consists of two plastic shells with easy-to-clean surface. The lower part is the chassis which includes the most significant components.

The main components of BIOSET 9000E are:

Lower casing part with
- circuit board with the entire electronic system
- recording unit as a separate module

Upper casing part with
- keypad including LEDs

The power pack is inside the unit; it is a plug-in type and can easily be exchanged.

The software is installed in a flash ROM memory. Through the RS 232 interface, it can easily be updated.

2 Patient's and Unit's Safety

BIOSET 9000 is in accordance with the Medical Products Act (MPG) and the "Directive 93/42/EEC on Medical Devices (MDD)" and meets thus the safety requirements as per EN 60 601-1 (IEC 601-1) and the anti-interference requirements as per EN 60 601-1-2 (EMC act).
According to the above guideline, the unit falls under the risk class IIa.

In order to protect both patient and personal, the unit must be grounded.
The unit complies with the protection class I. This way, it will be grounded through the protective conductor. Any usage of mains-connecting facilities which can cause the protective conductor to be interrupted is forbidden.

The unit is defibrillation- proof, provided, the patient's cable supplied with the accessories is used. During defibrillation, one must not touch the patient, the equipment or the bed.

In case that the unit is used for ECG acquisition from patients with heat pacemakers, or if a further electrical simulator is used simultaneously, the is no kind of endangering. Naturally, simulator should be used in a reasonable distance from the electrodes. In case of doubt, the patient should be disconnected from the electrocardiograph.

The unit should be operated inside rooms protected against vibrations and corrosive gases, and should not be exposed to direct sun radiation or heat from other sources. The unit works at ambient temperatures of 10° C ... 40° C.

For the safe operation to obtain, keep the unit free from condensation water. In order to prevent that, make the unit acclimate after relevant temperature alterations.
Once temperature and atmospheric humidity have compensated, the unit can be operated.

The unit is not intended to be run inside explosion-hazardous locations. If inflammable gas mixtures (e.g. ether) are present, explosion hazard cannot be excluded.

Connection of a PC to the RS232 interface requires the fulfilment of the standards by both PC and peripheral units. As per the IEC 601-1-1 (compound operation of electrical, medical equipment and electrical, non-medical equipment), the PC set must be located in a distance of ³ 1.5 m to the patient.

In case that the unit's instruction manual does not indicate whether a certain compound operation or coupling with other equipment is possible any kind of danger, a relevant information must be obtained from the manufacturer/supplier, or from an expert, in order to ensure that the total safety of all included units is not affected.
A situation of danger might arise, if more than one unit are connected to the patient, or at the electrocardiograph, and the sum of all discharge currents would be beyond the permissible limits.

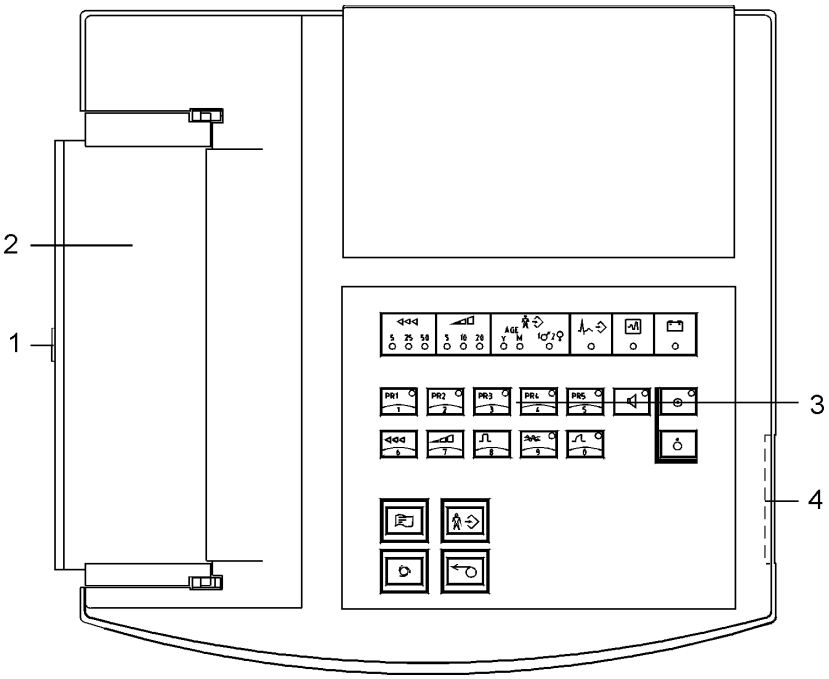
The units are allowed to be used only by persons, who due to their education, knowledge, and practical experience can guarantee proper handling and who have been made familiar with the unit in consideration of the operating manual.
Only those persons who due to their knowledge and practical experience are fit for briefing people on the handling of the device are allowed to instruct them.

☞ This operating manual is part of the electrocardiograph and must always be on hand. Strict observation of it is precondition for proper use, on which both patient's and operating personnel's safety are depending.

3 Operating Elements

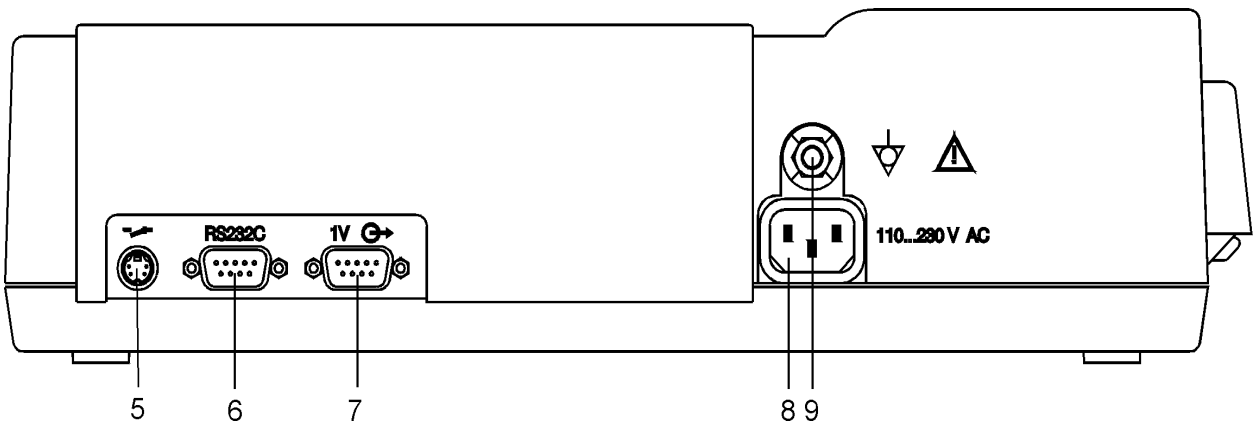
3.1 View

Upper Side:



1 cover opening button
2 cover of paper chamber
3 keypad
4 ECG inlet

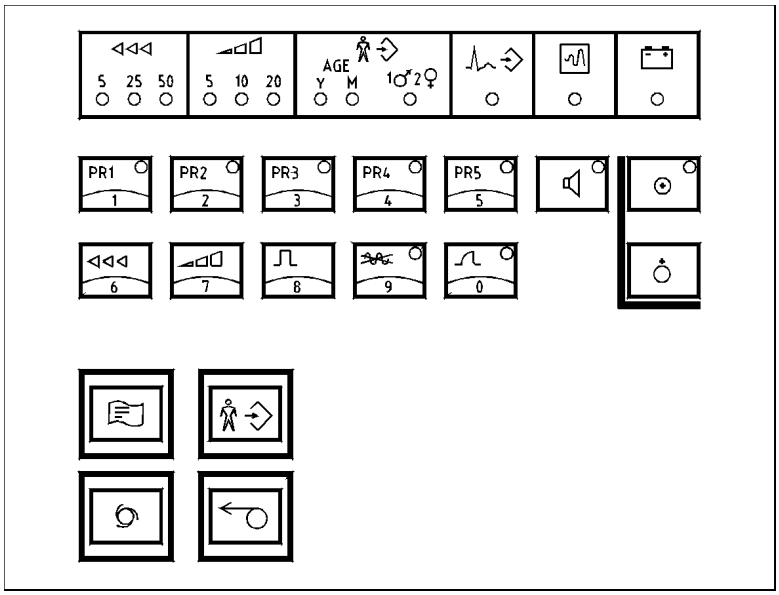
Rear side:



5 remote start inlet
6 RS 232C interface
7 1V-outlet
8 mains cable socket
9 potential equalisation connection

3.2 Keypad and Key Funktions

Keypad



unit on

unit off

PR1 ...lead programmes

QRS-sound on/off

speed selector

sensitivity selector

1mV-test pulse

AC filter on/off

muscle filter on/off

Automatic recording programme

Manual recording proramme START / STOP

Start analysisorbereitung)

Enter patient's data(i

4 Putting into Operation

4.1 Insertion of Recording Paper

The unit requires *thermoreactive recording paper as a block of continuous stationary of 400 sheets, with a width of 210mm and a total length of 60 m.*
To ensure good recording quality and proper paper run, it is recommended to use only original recording paper; it can be ordered from company von Berg Medizingeräte GmbH, order No. 2700-000-021.

New recording paper should be loaded when a red marking strip appears at the lower paper margin. If all paper is out, recording is stopped and

the indicating lamp  lights.

Recording paper must be inserted as follows:

- press the cover opening button to release the cover
- bring the cover into upright position and put it aside
- insert the paper block into the chamber, place properly, press it slightly inward and pull some paper out (*before reinserting the cover!*)

☞ Insert the block in such a manner, that the imprint side gets visible if the paper and is pulled to the left . The black paper marks must be downside (towards the operator).

- reinsert cover
- bring the recording paper into a symmetric position toward the cover
- close the cover by slightly pressing its left verge

For advice on handling thermoreactive recording paper, refer to annex 2.

4.2 Application of Electrodes

4.2.1 Resting ECG

Connect the delivered patient cable to the inlet marked as ECG INLET (ref. to p. 3-1) and fix it using the two screws.

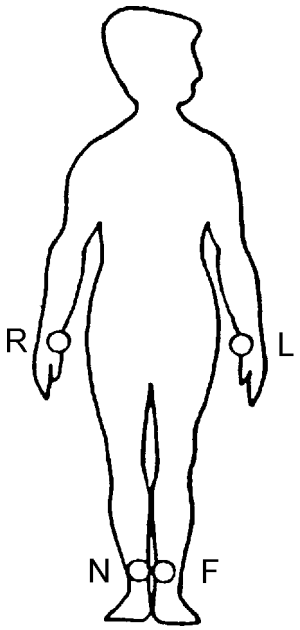
☞ Defibrillation protection of unit will only be effective, if that patient cable specified in accessories is used!

The accessories include 4 clamp electrodes for limb leads, and 6 chest wall suction electrodes.
Depending on the patient, prepare the application points, i.e. remove hairs and clean with alcohol. For application at the chest wall, slightly apply electrode gel to the skin areas.
For the limb electrodes, the their clamps should be prepared with electrode gel, as well.

In case of use of an ECG suction electrode system, please refer to the advice given in chapter 4.2.2.

In the following, there is an overview on the standard arrangement of electrodes.

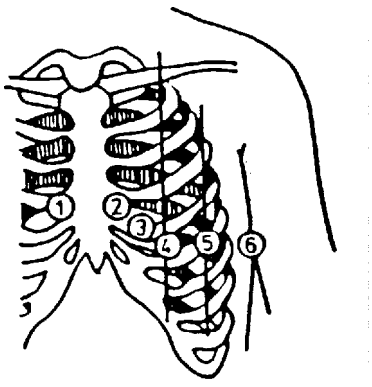
Einthoven and Goldberger Limb Leads



Electrode	Code Colour	Electrode Position
R	red	RH arm
L	yellow	LH arm
F	green	LH leg
N	black	RH leg

Lead	Linkage of Electrodes	
I	L-R	
II	F-R	
III	F-L	
aVR	R-LF	LF=(L+F)/2
aVL	L-RF	RF=(R+F)/2
aVF	F-RL	RL=(R+L)/2

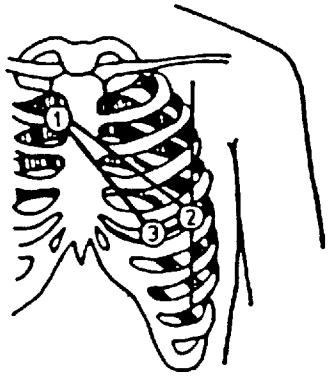
Wilson Chest Wall Leads



Electrode	Code Colour	Electrode Position
C1	white & red	4th interspace, RH sternal border
C2	white & yellow	4th interspace,LH sternal border
C3	white & green	between C2 and C4
C4	white & brown	5th interspace, LH midclavicular line
C5	white & black	LH anterior axillary line, on altitude of C4
C6	white & violet	LH central axillary line, on altitude of C4

Lead		Linkage of Electrodes	
V1,	V7	C1-CT	
V2,	V8	C2-CT	
V3,	V9, V3R	C3-CT	$CT=\frac{(R+L+F)}{3}$
V4,	V4R	C4-CT	
V5,	V5R	C5-CT	
V6,	V6R	C6-CT	

Nehb Leads



Electrode	Code Colour	Electrode Position
CN1/C1	white & red	2nd rib, RH sternal border
CN2/C2	white & yellow	LH posterior axillary line on altitude of apex beat
CN3/C3	white & green	above apex beat

Lead	Linkage of Electrodes
D	C2-C1
A	C3-C1
J	C3-C2

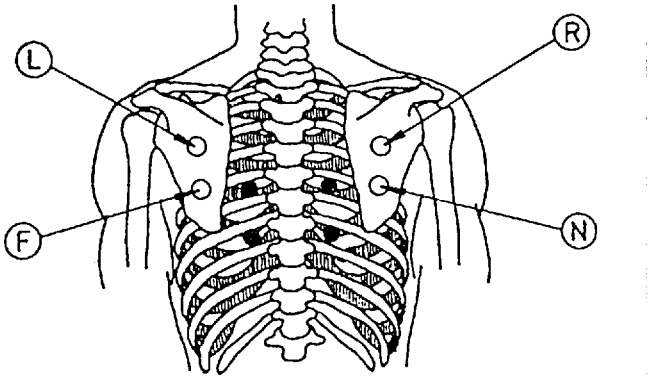
4.2.2 Exercise ECG

The exercise ECG is acquired using either a suitable ECG suction-type electrode system or adhesive electrodes and connected patient cables.

☞ Defibrillation protection of unit will only be effective, if that patient cable specified in accessories is used! For use of an ECG suction-type electrode system, consider possible pieces of advice of the instructions.

Apply the electrodes to the skin areas specially prepared in advance.
Compared with the resting ECG, a modified positioning of the extremity electrodes will be required due to muscle exercises.

Ergometry Leads acc. to Rosenkranz and Drews:
(position further electrodes on the thorax acc. to Wilson)



- ○ classic application points in the scapula area
- ● change paravertebral

4.3 Switching the Unit on and off

The unit can be energised using either the included, rechargeable power pack or the main supply.

4.3.1 Mains Operation

Connect the mains inlet (chapter 3-1, item 8) and the grounded mains socket of the room using the mains cable; the charge indicator  (green LED) glows.

Depending on its charge, the power pack is automatically and permanently recharged. The unit can be permanently plugged in without damages occurring to it or its power pack.
Recharging of a completely discharged power pack would take approx. 2 h.

4.3.2 Battery Operation

The mains inlet of the unit is not connected to the mains socket - the charge indicator (green LED) does not glow.

In case that the battery is to be used not so much, battery operation should be selected only when an electrocardiogram must be registered very quickly, and a mains socket is not available. A completely charged battery provides a minimum of 1 h of 6-channel recording at 25mm/s.

Discharge of the power pack is indicated by both acoustic and optical warning. Once the charge is low (20 %), the indication  will change into permanent light, and a warning sound comes in certain intervals. After these signals have come, there is only a few time left for recording.
Once the power pack is discharged, a short, permanent sound comes, and the indicator blinks. After that, the unit goes automatically off.

In order to get a maximum operation time per power pack charge, the unit has a **sleep mode**. That means that after an acoustic warning the unit will always get off automatically after no key was pressed for 4 minutes. If the recording process lasts longer, the unit, of course, remains on.

4.3.3 Switching ON and OFF

Use the key  to switch the unit on.

After completion of a switch-on routine, the selected programme (usually PR1) is activated, provided that the electrodes have been properly arranged. (For information on electrode faults, refer to chapter 5.1).

Use the key  to switch the unit off.

5 ECG Recording

ECGs can be recorded under MANUAL with PR1 … PR5 and AUTOMATIC.
After switching-on - with electrodes applied - the programme selected in the setup (usually PR1) is indicated by permanent light of the relevant green LED.

5.1 Recording in Manual Mode

The following parameters can be changed prior to or during recording. The active selection is indicated by the relevant LED.

Use the keys [PR1] ... [PR5] to select **the lead programmes**.

The following standard 12 or 6-channel programmes can be selected:
PR 1: I, II, III, aVR, aVL, aVF, V1...6 (12 standard leads)
PR 2: I, II, III, aVR, aVL, aVF (limb leads)
PR 3: V1...V6 (chest wall leads)
PR 4: aVL, I, -aVR, II, aVF, III (Cabrera)
PR 5: I, II, III, D, A, J (limb and NEHB leads)

Change the **recording speeds** of 5, 25, 50 mm/s using the key [◁◁◁].

Change the **sensitivities** of 5, 10, 20 mm/mV using the key [⊿⊿].

Use the key [⎍] to switch the **muscle filter** ON and OFF.

Use the key [≈] to switch the **AC filter** ON and OFF.

The **drift filter** for reduction of the zero line variation is usually ON, however, it can be switched OFF in the unit setup.
Muscle, AC and drift filters act simultaneously for all channels.

☞ **Since the task of filters is it to ‚filter out' certain frequency ranges, this will result in a change of the ECG curve. Therefore, one should always try to eliminate the source of fault before switching muscle or AC filter ON.**

Use the key [🔊] to switch the **QRS sound**, i.e. the acoustic signal per QRS complex , ON and OFF.

Recording can be started, once the indicator [🔊] blinks in rhythm with the heart rate, or – if the QRS sound is on – the heart rhythm can be heard.
After electrode application, there are polarisation voltages. They have first to stabilise before a properly centred recording can be made.

Start recording by pressing [⟲].

During registration, the **1 mV test pulse** can be indicated at any time [⎍].

Stop recording by pressing once more [⟲].

If sheet or time control according to chapter 7 is selected, recording stops automatically.

Electrode Faults:
Every ECG acquisition includes a permanent test of all electrodes.
In case that electrode fault occur, those LEDs start blinking, the programmes of which include faulty electrodes. That means in particular:
If the electrodes R, L, F or N are faulty, LEDs PR1...PR5 start blinking.
If the electrodes C1, C2 and C3 are faulty, the LEDs of the programmes with chest wall leads and/or NEHB leads, i.e. PR1, PR3 and PR5 start blinking.
If the electrodes C4, C5 and C6 are faulty, the LEDs of the programmes with chest wall leads, i.e. PR1 and PR3 start blinking.

The selected programme lights again after the sources of electrode faults were eliminated.
In case that electrodes drop off in the course of further ECG acquisition, the above mentioned fault indication will take place.

☞ In case that the ECG is recorded despite of indication of electrode faults, only those leads, the electrodes of which are in proper condition, are recorded.

Intermediate settlement:
Dropped-off electrodes, distinct artefacts or insufficient waiting time after electrode application may be the reason of zero line fluctuations during ECG acquisition.
An ‚intermediate settlement' can be initiated **by pressing the same key once more.**
The **ECG curve** - caused by the time constant switched over - shows a **changed signal form** being marked additional by a 1 mm marking at the lower paper margin.

Defibrillation during ECG recording will lead to overload of the ECG inlet. To eliminate this overload, there is an automatic settlement without time limitation after defibrillation. The ECG curve being now visible again shows, owing to the switched-over time constant, a different signal form which is marked additionally by marks at the lower and upper margin of the paper strip.

After completion of the intermediate settlement, the ECG is again recorded with normal time constant. Once defibrillation was made, this can be done approx. 30s after the defibrillation, depending on the defibrillation energy.

☞ This mode can activate itself automatically in case of loose electrodes or other significant artefacts.

☞ In case of heavy artefacts or electrode drop, the heart rate found may not be correct in every case. For pacemaker patients, it cannot be fully excluded that the SM pulses for heart rate measurement are taken for ventricular complexes, or ventricular complexes are suppressed. In any case, additional ECG testing is required.

5.2 Recording in Automatic Mode

In AUTOMATIC MODE, 12 standard leads (limb leads PR2 and chest wall leads) are registered with the registration length (1 to 4 sheets per programme) selected in the Setup.

Recording can be started, once the indicator  blinks in rhythm with the heart rate, or – if the QRS sound is on – the heart rhythm can be heard.

Use key  to start **automatic registration**.

The AUTOMATIC programme runs with filter setting, speed and sensitivity, as selected before starting it. After completion of the automatic registration, the system returns to that programme which has been selected before starting it.

Recording of both programmes runs time-synchronously.
Time-synchronous means that 12 leads are acquired simultaneously, and a maximum of 10 seconds of an electrocardiogram are saved. Hence, programme 2 is registered directly, and programme 3 - time-synchronous to PR 2 from the memory.
All settings with regard to speed, sensitivity, Muscle and AC filter, as well as QRS sound are made according to chapter 5.1.

Using the  key, the programme can be cancelled at any time.

5.3 Recording with Ergometry (Remote Start)

The remote start facilitates **automatic ECG recording on change of load stage**.
The start of recording is induced by the ergometer. Recording is made for the currently selected lead program. Recording stops automatically when the selected recording time is up.
The duration of recording can be sheet- or time-controlled and is made in the Setup (chapter 7).
Also in the setup, the interface is set for the ergometer to be used.
If one of the ergometers mentioned below is used, the control of ECG recording and data exchange by means of the appropriate cable is accomplished through the RS 232 interface (p. 3-1, connector 6).
(Data exchange is the recording of the concerned load (for Ergometrics 900 additionally the last measured blood pressure).

The following ergometers can be connected:

Unit	Cable	Item No.
Ergometer SECA 100 (from YOM 99)	starter cable SM	2700-050-000
Ergometer Ergometrics 900	connecting cable EL	2100-068-000
Ergometer Variobike 550	connecting cable BO	2100-062-000

Connection of a Monitor
Additionally it is possible to connect a monitor, using a monitor cable, to the 1 V outlet (p. 3-1, connector 7).

unit	designation	item No.
EMC 1000 monitor, elmed	monitor cable EM	2500-072-000

The 1 V outlets are allocated to the following recording channels (standard):

	outlet 1	outlet 2	outlet 3
PR 1 channel	8	10	12
PR 2 channel	1	2	3
PR 3 channel	2	4	6
PR 4 channel	2	4	6
PR 5 channel	1	2	3

5.4 Recording a Test ECG

For demonstration purposes, the unit includes an ECG simulator.

The simulator can be opened at any time by simultaneous pressing  and  .

Now it is possible to record manually or automatically and to easily demonstrate setup variants, particularly the effect of filters.
For safety purposes, the recording strip includes the marking ‘Test ECG’.

The simulator can be closed by simultaneous pressing  and  .

If a test ECG is desired to demonstrate measurement/interpretation, proceed as described in chapter 6.1.
Input of patient’s data: 30 years old, male.

6 ECG Measurement and interpretation

The ECG measurement and interpretation is executed by means of ht HES analysis program. By the buyer's desire, it can be unlocked either in his premises or before despatch.

ECG evaluation requires the I, II and V1 to V6 leads were acquired over a period of 10 seconds (the III, aVR, aVL and aVF leads are calculated).

To obtain reliable analysis results, take care that ECG recording is performed without interference. Furthermore, analysis is not possible with leads according to Nehb, and in case of electrode faults or intermediate settlements.

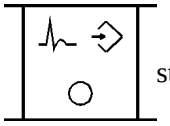
☞ Inclusion of filters is, as a rule, the worst way of elimination of disturbances, because this is most likely to falsify the ECG.
Only the unfiltered signal is analysed. With muscle and mains filter on, there would be differences between the representative cycles (unfiltered) and the ECG (filtered).

The analysis program considers the patient's age and sex.

6.1 Measurement and interpretation

Before starting the analysis, the patient's age and sex must be entered as **patient's data** (use the keys 1 ...0). Therefore, press key  . On blinking of the left-hand LED below 'Y' enter the age (in years) and confirm by repeated pressing this key  . For children under 4 years, the LED below 'M' will now start blinking, and the months of life of the unfinished year must be entered. Confirm this input by pressing key  as well.

The measurement can be started after 10 seconds of trouble-free ECG recording.

This is the case if after the indicator's blinking  in rhythm with the heart rate one waits another 10 sec before starting the mesurement, or until the LED in the indication field  stops blinking.

As long as a 10-sec-ECG which can be evaluated has not been recorded, the analysis cannot be started, i.e. the analysis key is locked (acoustic signal on pressing within the rejection time.)

Subsequently the right-hand LED will blink, and the patient's sex must be entered (1=male, 2=female).

Pressing the key  starts the automatic analysis.

The progress of the automatic analysis is indicated by the PR1 LED, later by PR2 and PR3.
The analysis takes 4 to 5 seconds.

After completion of the measurement, the results are printed out automatically. Depending on the unit setup (chapter 7), the measured-value table and the analysed ECG can be printed out in various formats.

6.2 Analysis results

The following information is given out after the patient's data:

- Heart frequency in beats per min.
  In case of adults, for a heart rates of more than 100 beats per min., a hint on TACHYCARDIA will be inserted, and for rates of less than 60 beats per min., a hint on BRADYCARDIA.
  For children:
  a hart rate <60 beats per min. gives a hint on BRADYCARDIA;
  a hart rate 60 to 70 beats per min. gives a hint on AGE-CONDITIONED BRADYCARDIA;
  a hart rate >120 beats per min. gives a hint on TACHYCARDIA;
- Global measured values
  P-duration, P-Q interval, QRS duration, Q-T interval, QTc as the Q-T interval corrected acc. to BAZETT, as well as this relative Q-T interval in percent (normalised to a Q-T duration of 0.39 s at a heart frequency of 60 beats per minute acc. to HOLZMANN).

Intervals marked by a star (*) differ from the normal values.

- Frontal vectors
  in the frontal plain, longest vectors for P wave, QRS complex and T wave in the Cabrera circle;
  indication of the position type for the QRS vector
- Rhythm
  Indication of rhythm with hints , e.g., for sinus rhythm, sinus arrhythmia, ventricular extrasystoles, arterial fibrillation.
  The rhythm analysis considers R-R distances, P- and T-wave forms, morphology of QRS complex, and coupling relations.
- Rhythm diagram
  * brief survey on the beat sequence of ECG cycles with a statement on how many beats have been in cluded by the 10 s recording into the evaluation
  * meaning of the characters/letters
    ”+” ”normal beats” included in the mean-taking process for the representative cycle
    Not included in the message:
    ”2,3,4” the respective beat is an extrasystole or an aberrant complex
    (each figure stands for a different type)
    ”B” base-line fluctuation
    ”P, T” aberrations of P- or T-contours
    ”O” aberrations of P- and T-contours
    ”R” too short intervals towards the preceding and following cycle
    “X” other variations
    “V” position at the beginning or end of the 10-sec-ECG
    “U” aberrant complex, complex with spikes
    “!” pacemaker-triggered beat

* The distance between characters represents, in the roughened grid, the R-R distance

- Findings
  * found disturbance in the raw data ECG including qualification: slight, medium or heavy

  * Indication of QRS waves occurred
    in limb (EX) leads: I, II, III, aVR, aVL, aVF
    and chest wall (BW) leads: V1 - V6

  * interpretation of significant ECG measured values for morphologic individualities, e.g. Q wave in certain leads, R losses, Delta waves, ST changes

  * repolarisation disturbances by inner and outer layer type as well as graduation

- QT Dispersion
  In the HES ECG, the QT dispersion is indicated as the dispersion of earlier repolarisation, measured from the QRS beginning up to the extrema of the T wave (QT-peak dispersion).
  The QT dispersion shows the standard deviation of the moments of T extrema together with the absolute value of the maximum time difference of these values as well as the number of the leads used for calculation, applied to the 8 measuring leads.
- QRS-T Evalation
  Interpretation of the representative cycle after diagnosis of infarction, hypetrophy/bundle branch block etc.

ECGs of children (under 14) are not subjected to QRS-T evaluation in order to avoid misunderstandings.

- Finally the ECG is subjected to an overall evaluation.

In addition to the analysis results, lead II of the analysed ECG is shown *in unfiltered condition* at 10 mm/sec.

Representative Cycles (optionally selectable)
- shows the mean value of the ”normal beats” with markings for P beginning, P end, QRS beginning, QRS end, and T-end (50 mm/s - *unfiltered*)
- additional recording of the measured ECG lead II at 10mm/sec *(unfiltered)*

Measurement Results (optionally selectable)
Out of the 12 standard leads, it will be put out:
- measured values of QRS range
  Q-, R-, S-duration; Q-, R-, S-amplitude; ratio of Q/R and R/S amplitudes as well as the integral of the QRS range
- measured values of ST-T range
  ST amplitudes; positive and negative T-amplitudes, as well as the integral of the T-wave
- measured values of P-range
  positive and negative amplitudes of P-wave, as well as the integral of the range.

☞**Any computer-aided evaluation or interpretation must be checked (and be given remarks, if need be) and signed by a physician.**

More detailed explanations about the analysis results and the algorithm of the ECG analysis are given in the HES MWZ ECG manual for the Hanover ECG program.

7 Unit Setup

The unit Setup allows customisation according to the user's desire.
Unit setup means that the unit start with changed parameters.
All parameters to be selected by function keys (marked with *) can of course be changed during operation.

Can following parameters can be customised:
- the lead programme made default *
- recording speed of all programmes *
- sensitivity of all programmes *
- number of sheets for AUTOMATIC programme (every individual lead sequence)
- in MANUAL mode, start/stop operation, or selectable number of sheets or recording time
- muscle filter ON / OFF *
- AC filter ON / OFF *
- QRS sound ON / OFF *
- drift filter ON / OFF *
- language for paper margin imprint (and measurement results)
- RS232 mode: OFF, remote control, data transfer from ergometer, PC linkage (PC Link is an online data transfer format "0002" of HOERMANN)
- ECG recording at change of load stage (remote start ergometry)
- date and time
- setup of optional measurement and interpretation

Operation

The Setup is opened by simultaneous pressing of  +  .
(Apply these setting only in ready-to-work condition, i.e. with loaded paper)

☞ As soon as  is blinking, the unit is in SETUP mode.

The individual parameters are set up as follows:

parameter	key	blinking LEDs	variant	selection	change accepted
programme		programme	PR1		
			PR2		
			PR3		permanent light of sel. programme
			PR4		
			PR5		
speed		speed	5mm/s		
			25mm/s		permanent light of selected speed
			50mm/s		
sensitivity		sensitivity	5mm/mV		
			10mm/mV		permanent light of sel. sensitivity
			20mm/mV		

parameter	key	blinking LEDs	variant	selection	change accepted
no. of sheets (AUT.)		speed 25	1sheet *)	PR1	
			2sheets *)	PR2	-
			3sheets *)	PR3	
			4sheets *)	PR4	

*) Since the ECG memory accepts a maximum of 10 seconds, it is recommended to select only 1 or 2 sheets for a recording speed of 25 mm/s, or 1 sheet for 5 mm/s.

MAN. recording		speed 5	- **)	PR1	
			1sheet **)	PR2	
			2sheets **)	PR3	-
			5s **)	PR4	
			10s **)	PR5	

**) selectable recording speed:

-	without sheet control, i.e. recording must be stopped manually
1, 2 sheets	sheet control, i.e. recording stops automatically after selected number of sheets
5, 10 s	time control, i.e. recording stops automatically after selected recording time

muscle filter		muscle filter	on	PR1	permanent light if ON
			off	PR2	
AC filter		AC filter	on	PR1	permanent light if ON
			off	PR2	
QRS sound		QRS sound	on	PR1	permanent light if ON
			off	PR2	
drift filter		speed 50	on	PR1	-
			off	PR2	
language	PR3	sensitivity 5	1 (German)	PR1	
			2 (English)	PR2	-
			3 (Russian)	PR3	-
			4 (French)*	PR4	
			5 (Czech)	PR5	

Instead of 3 (Russian), the unit having the unit No. includes according to page 0-1
Slovak ( ), Romanian ( ), ( )
Instead of 4 (French), the unit having the unit No. includes according to page 0-1
, Slovak ( ), Romanian ( ), ( )
Instead of 5 (Czech), the unit having the unit No. includes according to page 0-1
Slovak ( ), Romanian ( ), ( )

* with interpretation texts in English

parameter	key	blinking LEDs	variant	selection	change accepted
RS 232 mode	PR5	sensitiv. 20	off	PR1	
			remote contr.	PR2	
			SECA100	PR3	-
			Ergometrics	PR4	
			PC-Link	PR5	
Erg-y recording	← + ↻	speed 5/25	0	PR1	
			1sheet	PR2	
			2sheets	PR3	-
			5s	PR4	
			10s	PR5	
date and time	PR1 + PR2	PR1 + PR2			

Date and time (day, month, year, hour, minute, second) have to be entered in the following way:
ddmmyyhhmmss
Use the following keys to enter the digits:
PR1 for 1, PR2 for 2, PR3 for 3, PR4 for 4, PR5 for 5, ◁◁◁ for 6, ◿ for 7, ⎍ for 8, ∿ for 9, ⎍ for 0.

Every input is confirmed by a beep. In any case, it must be **12 digits**.
Changes and corrections require complete reinput of the digits.

Optional print-outs of measurement and interpretation:
Settings for print-outs in addition to the measurement/interpretation results:

rep. cycles	sbsqntly. PR1	**+PR1	yes	PR1	permanent light of active condition
			no	PR2	
meas. val. table	sbsqntly. PR2	**+PR2	yes	PR1	permanent light of active condition
			no	PR2	

Programming of the also printed ECG acc. to measurement/interpretation results:

print ECG	sbsqntly. PR3	**+PR3	yes	PR1	permanent light if ON
			no	PR2	
number of chann.*)	sbsqntly. PR4	**+PR4	PR1=12ch.	PR1	permanent light if ON
			PR2+3=6ch.	PR2	

*) ECG recording using the PR1 (12 channels), or successively using PR2 and PR3.
**) blinking LEDs: speed, sensitivity

parameter	key	blinking LEDs	variant	selection	change accepted
number of sheets	sbsqntly. PR5	**+PR5	1 sh. each*)	PR1	
			2 sh. each*)	PR2	
			3 sh. each*)	PR3	permanent light if ON
			4 sh. each*)	PR4	

*) Since the ECG memory can store max. 10 seconds, it is advisable to select only 1 or 2 sheets for recording at 25 mm/sec, and only 1 sheet for 5 mm/sec.

speed	sbsqntly.	**+PR1+PR5	curr. speed.*)	PR1	
			5 mm/sec*)	PR2	
			25 mm/sec*)	PR3	permanent light if ON
			50 mm/sec*)	PR4	
sensitivity	sbsqntly.	**+PR2+PR5	curr.sty. *)	PR1	
			5 mm/mV*)	PR2	
			10 mm/mV*)	PR3	permanent light if ON
			20 mm/mV*)	PR4	

**) blinking LEDs: speed, sensitivity

As long as the system is in SETUP mode, any changes can be made.

Setup is closed by simultaneous pressing of + .
Closing saves all parameters settings.
After that, all settings are automatically printed out.

The indication stops blinking.

☞ The printout of the unit setup gives a detailed overview of all settings and, if existing, special variants. Preferably, it should be kept with the operating manual.

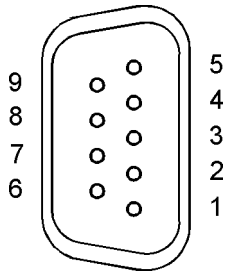
8 Interfaces

⚠

It must be provable that any additional equipment to be connected to the unit's analogue and digital interfaces are in accordance with the relevant EN specifications (i.e. EN 60950 for data-processing equipment and EN 60601-1 for electro-medical equipment). Furthermore, all combinations must be in accordance with the system standard EN 60601-1-1.
All non-medical units must be connected to the same circuit.
In case of questions, please contact your local dealer or the technical service.

8.1 Analogous (1V) Outlets

Connection scheme (seen onto socket)

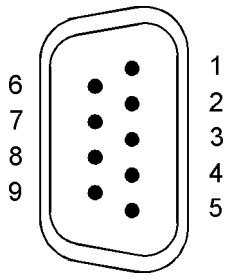


1 —
2 GND
3 outlet 2
4 QRS trigger outlet
5 —
6 —
7 outlet 1
8 outlet 3
9 —

Allocation of outlets of programmes 1 ... 5 is desribed in chapter 5.3

8.2 Serial Interface RS 232

Connection scheme (seen onto plug)



1 —
2 RxD (Received Data)
3 TxD (Transmitted Data)
4 —
5 GND (Ground)
6 —
7 —
8 —
9 —

9 Technical Characteristics BIOSET 9000E

9.1 General Data

operation	mains and battery
mains voltage range	230 V ± 10%, AC
power drain	22 W
mains frequency range	50 Hz / 60 Hz
mains connection	mains lead, plug-in type
battery	power pack, nickel-metal hybride 12 V; 2.1 Ah
safety degree	IP 20 acc. to DIN 40050
electrical safety	protective class I / unit with internal power supply
application class	CF type
potential equalisation connection	at the ECG unit
classification acc. to “Directive 93/42/EEC”MDD	class IIa

Design according to the anti-interference requirements as per EN 60601-1-2 (EMC act) including radio anti-interference filter.

dimensions (w x d x h)	358 x 340 x 98 mm^3
weight with battery	approx. 5.5 kg
modes of operation	
mains operation	permanent operation
battery operation	short-time operation
operating time with battery	min. 1 h for 6-channel recording at 25 mm/s

Application conditions acc. to DIN IEC 721

ambient temperature	+10 °C to +40 °C
max. permissible humidity	95%, without condensation

Transportation:

temperature range	-25 °C to +70 °C
relative humidity	max. 95 % at +40 °C

Long-term storage:

temperature range	-25 °C to +55 °C
relative humidity	10 % to 100 %

9.2 Recording Unit

writing method	thermoreactive
writing element	thermoline 210 mm wide, 8 dots per mm,
writing width	> 40 mm / channel
resolution of registration in Y direction	8 dots per mm
resolution of registration in X direction	20 dots per mm at 50 mm/s
	40 dots per mm at 25 mm/s
	200 dots per mm at 5 mm/s
zero adjustment	automatic write centring
frequency range	0,05...120 Hz +5 % -30 %

recording paper	continuous stationary, 400 sheets, 210 mm wide, 60 m long, with grid imprint, red side logo, sheet control marks
paper type	thermoreactive, order No. 2700-000-021
recording speeds	5, 25, 50 mm/s ± 5%

9.3 ECG Section

electrode inlets:	
Einthoven	R, L, F, N,
Wilson	C1, C2, C3, C4, C5, C6,
Nehb	C1=CN1, C2=CN2, C3=CN3,
electrode test	monitoring before and during ECG acquisition
number of channels	12, 6
lead programmes	
PR 1	I, II, III, aVR, aVL, aVF, V1 ... V6 (12 standard leads)
PR2	I, II, III, aVR, aVL, aVF (limb leads)
PR 3	V1 ... V6 (chest wall leads)
PR 4:	aVL, I, -aVR, II, aVF, III (Cabrera)
PR 5:	I, II, III, D, A, J (limb and NEHB leads)
progr. sequence for AUTOMATIC Mode	PR2 and PR 3; time-synchronous
recording duration per lead programme	optional 1 - 4 sheets, to be selected in the unit Setup
application unit	F insulated
input resistance	≥2 x 50 MOhms
time constant	3,2s
overload protection	for voltage pulses from defibrillators and cautery apparatuses; automatic intermediate settlement
rejection factor (IMMR)	≥ 100 dB
equivalent interference voltage (p-p)	≤ 20 µV
superposed DC voltage	≤ ± 0,3 V
transmission range	0,05 ...150 Hz
sensitivities	5, 10, 20 mm/mV ± 5 %
muscle filter	fg = 35 Hz (slope: 4 ...6 dB/Okt.)
mains frequency filter	adaptive digital filter; 50/60 Hz ± 2 %, (damping: ≥ 20 dB)
drift filter (ADS)	high-pass; limit frequency (3dB): 0.6 Hz ± 0.1 Hz signal delay <1.1s; enabled (default); can be disabled in the unit Setup
AD conversion	scanning frequency 1000 Hz, resolution: 13 bit
pacemaker	recognition, marking (pacemaker voltage on body surface ≤ 700 mV, pacemaker pulse width ≤2 ms; also double-chamber pacemakers)

heart frequency indication	
measuring range	30 - 240/min
recording paper	print-out of average
QRS sound	can be switched off

9.4 Operation Section

keyboard	plastic-foil keypad; wipe-resistant LED indicators

9.5 Standard Interfaces

signal inlet	TTL level
registration mode	mode 1: L registration start, H registration stop mode 2: L registration start, automatic registration acc. to time or number of sheet selected

9.6 Optional Interfaces

Analogous signal outlets:

number of outlets	3
outlets	short-circuit resistant, asymmetric, frequency range: 0.05 … 250 Hz sensitivity: 1.00 V / 1 mV 0.50 V / 1 mV 0.25 V / 1 mV sensitivity change synchronous to inlet sensitivity channels time synchronous; DA converter: 8 bits, modulation range: ± 4V
QRS trigger:	digital outlet signal 5 V, 150 ms; time-synchronous to ECG inlet

Computer interfaces:

type	RS 232 C, 9-pole
function	PC-Link for PC coupling data communication with SECA 100, Ergometrics 900, (Variobike550, Variotrainer500) update programming

9.6 Measurement Software

HES MWZ EKG Evaluation program for analysis of resting ECGs

- time-synchronous acquisition of the 12 standard leads
- ECG measurement
- analysis of rhythm and form
- rhythm analysis based on leads II, V1, V6,
- output of complete, analog curves or representative cycles with measurement marks
- output of the measure-value report
- output of the ECG interpretation

10 Cleaning, Disinfection

Only clean and disinfect the instrument in switched-off condition and disconnected from the mains.

☞ Make sure that cleaning and disinfectant agents are only used in compliance with the manufacturers' provisions, e.g. in due dilution.

Electrodes, patient cable, and accessories

- to be cleaned after use acc. to in-house specifications.

General rules
- clean electrodes with running hot water after use.
- disinfect electrodes and cables by means of a disinfectant-soaked cloth (e.g. Cidex, Gigasept).

Note:
- do not dip plug connectors of cables into fluids.
- the use of acetone, alcohol, chloroform, or strong solvents results in flexibility loss of and damage to cable.
- gas sterilisation is possible, sterilisation by hot air and steam is inadmissible.

Unit

- regularly clean it by means of a soft and non-fuzzy cloth, using a mild soap solution.
- for a necessary disinfection, use Gigasept or the like. Sterilisation by steam, hot water or air is inadmissible.

Note:
- do not use ether, petrol, propyl alcohol, or acetone.
- prevent fluids from getting into instrument or connecting sockets.

11 Maintenance, Checks

In the interest of the instrument's permanent availability and in order to guarantee the required safety for both patient and operating personnel in handling the BIOSET9000, inspections and checks are specified.

If deficiencies concerning safety and serviceability are thereby detected, inform your service partner. In case of defects or function deficiencies of the unit, which may impair the safety of both patient and operator, the unit may be used only after elimination of these faults. Service partners can get a service manual from von Berg Medizingeräte GmbH.

Checking when Putting into Operation

- new instruments are installed, checked, and handed over in a functional and safe condition by the manufacturer or his service partner.

Daily Checks

- prior to using the unit, make a visual check of unit, cables and electrodes for damages and other defects.

Periodic Checks

- a close functional test should be accomplished every 12 months;
- perform a safety check as per IEC 601-1 and IEC 601-2-25;
- for a function test, advantageously use an ECG simulator; (if using the internal simulator, patient cables and ECG input section must be connected before starting the check)

Check the following:

- patient cable and electrodes (visual inspection);
- all printed curves and parameters;
- simulate the external "start" function and monitor signals;
- full functionality of the patient cable. Therefore, remove each electrode one after the other from the simulator. An electrode fault must be indicated in every case.
- Evaluate the recording test (see below);
- it is also possible to check recording quality. Therefore, open and close the unit Setup as described in chapter 7. This will record the settings plus three parallel, oblique test lines which allow assessment of the printing quality.

In case that national regulations require more extensive checks, these must be performed.

Thermoline

- in case of contamination of the thermoline, the printing edge may be cleaned with utmost care, using an alcohol-soaked cotton swap. Make sure that the unit is unplugged, and no patient is connected.

Power Pack

- the power pack is service-free. If with battery operation a reasonable recording time is not longer achieved, contact a service partner.

12 Environmental Protection / Waste Removal

Neither the use of the units nor of its accessories causes harmful emissions of waste substances.
The following information applies to all equipment manufactured by us so that parts of it may not apply to this unit.

Used Units

Classification: electronic waste / waste for recycling

If the customer desires, von Berg Medizingeräte GmbH takes used units back for removal. Reasonably, individual assemblies are regenerated to be used as spare parts. All other components – separated by types of materials – are transferred to authorised enterprises for removal.
In case that the customer wants to remove the unit by himself, he may obtain a list of authorised, German waste removers.

Computers and Components of It

Classification: electronic waste / waste for recycling of waste for recycling being subject to control

Computer and components of it (boards etc.) do, for power supply, often include batteries of power packs which are either replaceable or fixed. Since, in the course of technical development, it happens that suppliers of computer components change from power packs to batteries and vice-versa, from soldered to replaceable types, or change the types to be used, the appropriate way of removal may only be selected after having seen the components. Also refer to the USED UNITS section.

NiMH Power Packs

Classification: batteries / waste for recycling

Exhausted NiMH power packs must not be removed as normal waste. They include nickel-II-hydroxide (classified as hazardous waste) and have to be recycled considering the local regulations, or to be removed in an environmentally friendly way by
- von Berg Medizingeräte GmbH
- local collecting centres
- authorised removers.

NiCd Power Packs

Classification: batteries / waste for recycling being subject to control

Exhausted NiCd power packs must not be removed as normal waste. They include highly poisonous cadmium and have to be recycled considering the local regulations, or to be removed in an environmentally friendly way by
- manufacturer
- von Berg Medizingeräte GmbH
- local collecting centres
- authorised removers.

Lithium Batteries

Classification: dry batteries / hazardous waste

Exhausted lithium batteries must not be removed as normal waste. They have to be removed in an environmentally friendly way by
- von Berg Medizingeräte GmbH
- local collecting centres
- authorised removers.

Timer Modules

Classification: electronic waste / waste for recycling

If the customer desires, von Berg Medizingeräte GmbH takes electronic waste back for removal. In case that the customer wants to remove the unit by himself, he may obtain a list of authorised, German waste removers.

Accessories, Cables, Electrodes, Patient's Cables

Classification: electronic waste / waste for recycling

As far as possible, these components are repaired by our service. Removal can be accomplished in the same way as of used units.

Electrode Cream

Classification: normal waste

Depending on local regulations, it can be removed through normal waste bins or as industrial waste.

Annex 1

Unit symbols

	ECG inlet, type CF
	IMPORTANT: see accompanying documents (operating manual)
	connection of potential equalisation
	1V outlet
RS 232C	RS 232C interface
	remote start inlet
CE 0123	acc. 93/42/EEC (MDD) Notified Body: TÜV Produktservice München

Keypad is described in chapter 3.2.

Annex 2

Advice on Handling Thermoreactive Recording Paper

In order to achieve best recording quality, and to fulfil the requirements for long-term storage of ECG records, make sure that following is guaranteed:

- storage of both fresh paper and records at an ambient temperature of <30 ^{O}C and humidity < 65 %;
- do not expose it to direct sunlight or neon light for longer time; preferably, store the paper in a dark room;
- avoid longer contact of it with plastics, like PVC (e.g. PVC envelops) or self-adhesive foils (for filling, we recommend paper envelops);
- do not use glues which contain alcohol or ether;
- do not rub or scratch the paper (friction heat will cause colour changes)

In order to achieve best recording quality and exact paper run, we strongly recommend to use only company´s von Berg Medizingeräte GmbH original recording paper.
Company von Berg Medizingeräte GmbH shall not be held responsible for malfunctions and defects which may arise from the use of recording paper other than from us. Malfunctions and defects of this type might be:

- essential deterioration of the writing quality,
- improper paper run
- contamination, or even destruction of the thermoline.

von Berg
Medizingeräte GmbH
Bahnhofstraße 62
D-08297 Zwönitz

☎: (03 77 54) 3 13 33
Fax: (03 77 54) 3 13 01
e-mail: info@von-berg-medizingeraete.de
internet: www.von-berg-medizingeraete.de