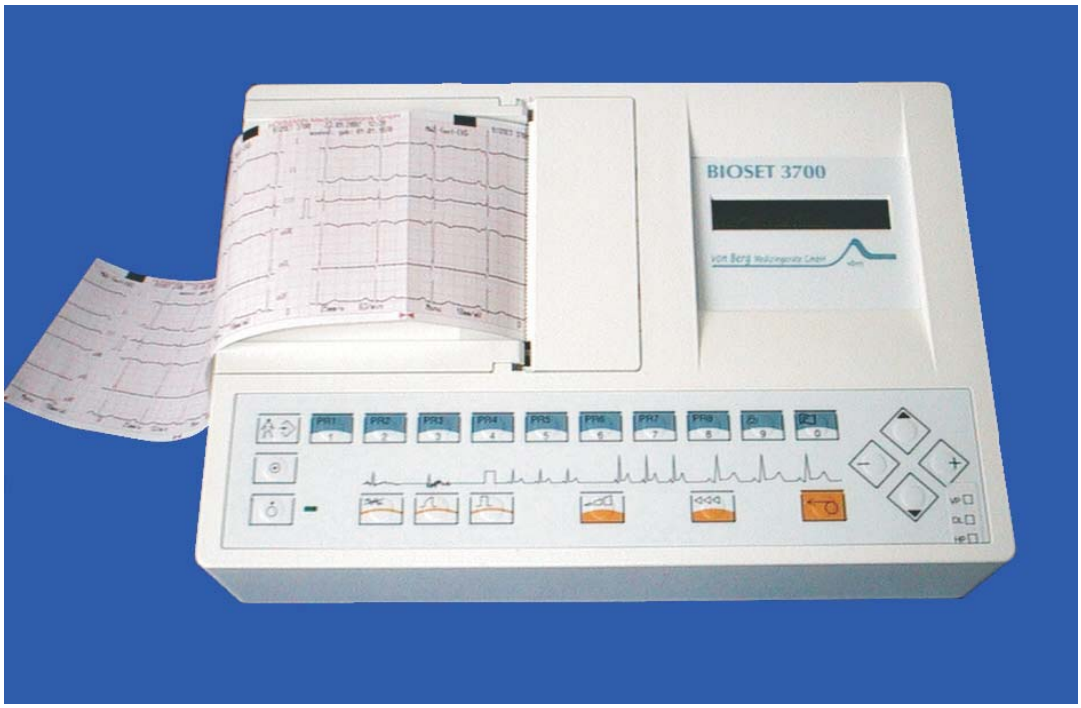
OPERATING MANUAL

3/6 Channel-Electrocardiograph

BIOSET 3700



CE 0494

von Berg
Medizingeräte GmbH

vbm

E-180106

Contents

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.

1 General Description

1.1 Purpose of Application

BIOSET 3700 is a 6-channel electrocardiograph.
The unit can be optionally equipped with accumulator, 1 V outlets and an additional computer interface.

BIOSET 3700 is intended for ECG recording under the conditions of ambulant practice and clinical routine. Owing to its small size, low weight and possibility of battery operation, it is suited for home visits and emergency medicine, too.

1.2 Unit Design

BIOSET 3700 is a compact unit with the upper side slightly inclined to the user.
The casing consists of two plastic shells with easy-to-clean surface.
A handle at the unit's left hand side permits convenient carrying.

Main components:

Upper casing part including
- signal board
- keyboard
- display
- recoding unit

Lower casing part including
- power supply

2 Patient's and Unit's Safety

The unit is in conformity with the Medical Products Act (MPG) and the "Guideline 93/42/EC on medical products" and the meets thus the safety requirements as per EN 60 601-1 (IEC 601-1) as well as the EMC requirements as per EN 60-601-1-2 (EMC act).
With reference to the above guideline, the unit is categorised as risk class IIa.

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

For establishing the connection to the room's central earth connection point, use the earth clamp. If this earth clamp is to be applied on thin-walled electric installation materials, proceed cautiously because of destruction hazard.

If that patient cable designed for due application is used, the unit will work as a defibrillation-proof one. Patient, unit, and bed must not be touched during defibrillation.

Conducting parts of electrodes and electrode connectors must neither touch different conducting parts nor have earth contact.

The unit should be operated inside rooms protected against vibrations and corrosive gases. The unit works at ambient temperatures of 10 °C ... 35 °C.

For a 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.

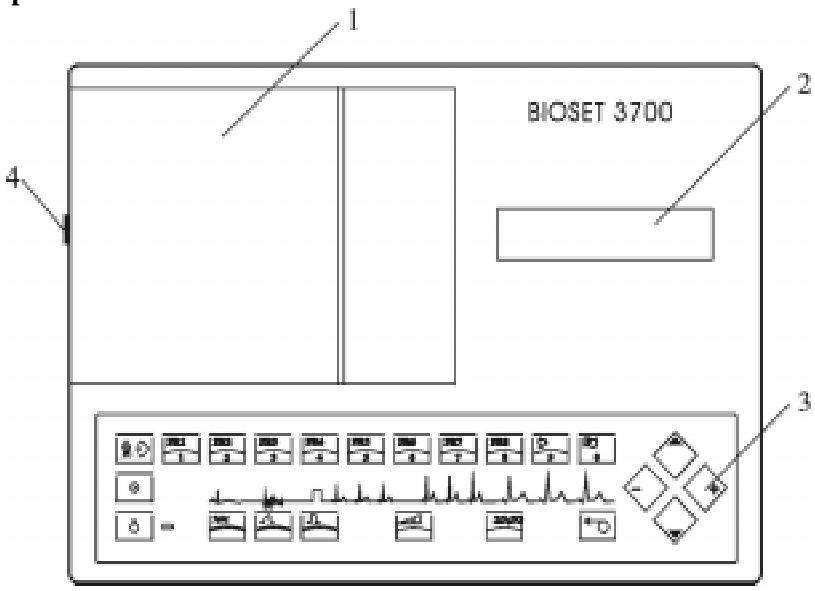
If the instrument documentation does not suggest, whether or not some combination or coupling of the unit with other devices is possible without hazards, the user has to make sure - by questioning the manufacturers/ suppliers concerned or by inquiring an expert - that the necessary safety of all included devices will not be impaired by the combination intended.
Such a case might arise, if several devices were connected to the patient or the electrocardiograph and the summarised lead current exceeded the admissible limits.

The devices are only allowed to be used 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 that due to their knowledge and practical experience are fit for briefing people on the handling of these devices are allowed to instruct them.

3 Operating Elements

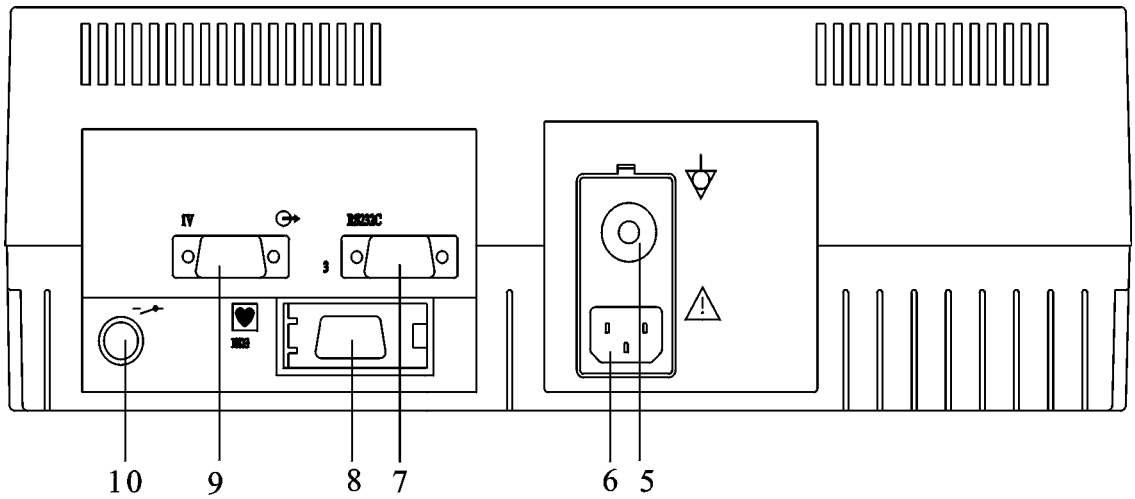
3.1 Top and Rear Sides

Top side



1 cover of paper chamber
2 display
3 keyboard
4 cover opening button

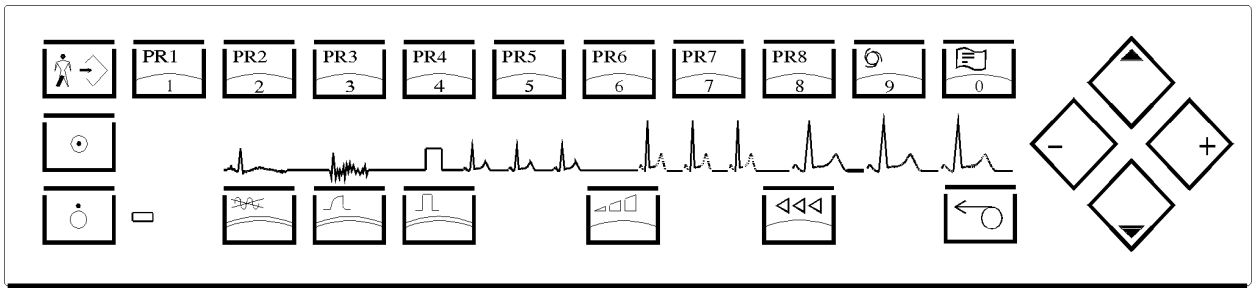
Rear side



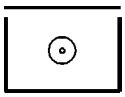
5 potential equalisation connection
6 mains socket
7 RS 232C interfaces (optional)
8 patient cable connection
9 1 V outlet (optional)
10 remote start inlet

3.2 Keyboard and Key Functions

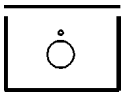
Keyboard



Basic Functions

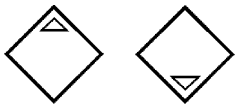


unit ON

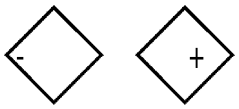


unit OFF

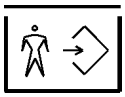
mains indicator



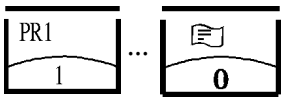
cursor keys



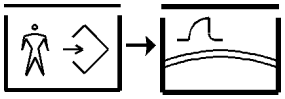
+/- keys for parameter setting



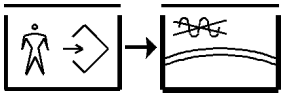
open/close the patient's data editor



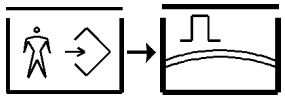
numeric patient's data inputs (1...0)



unit setup

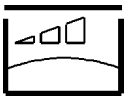


self-test

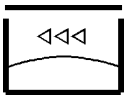


select test patient

ECG recording



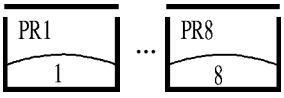
select sensitivity



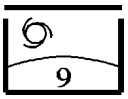
select recording speed

muscle filter ON/OFF

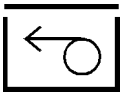
AC filter ON/OFF



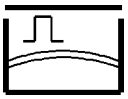
select MANUAL recording programmes



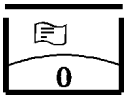
select AUTOMATIC recording programme



recording start/stop



1 mV test pulse



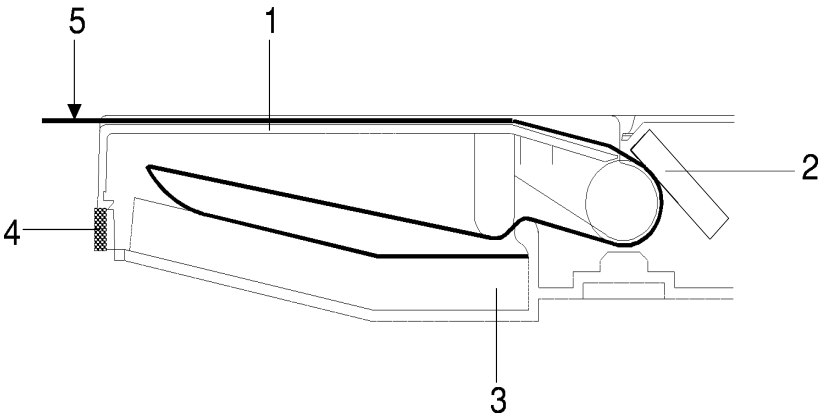
select ECG analysis - measurement (under preparation)

4 Putting into Operation

4.1 Insertion of Recording Paper

BIOSET 3700 requires thermoreactive recording paper as a block of continuous stationary of 180 sheets, with a width of 110mm and a total length of 18m.
To ensure good recording quality and proper paper run, it is recommended to use only original recording paper; it can be ordered from von Berg-Medizingeräte GmbH, order No. 2300-000-021.

Paper run



1 cover

2 thermal printing head

3 continuous stationary

4 cover opening button

5 imprint side

- press the cover opening button (4) to release the cover
- bring cover 1 into upright position and put it aside
- insert the paper block (3) into the chamber, place properly, and pull some paper out

> Insert the block in such a manner, that the imprint side gets visible if the paper and is pulled to the left (ref. to above illustration). The black paper marks are above (behind).

- reinsert cover 1
- bring the recording paper into a symmetric position toward the cover
- close the cover by slightly pressing its left verge

4.2 Application of electrodes

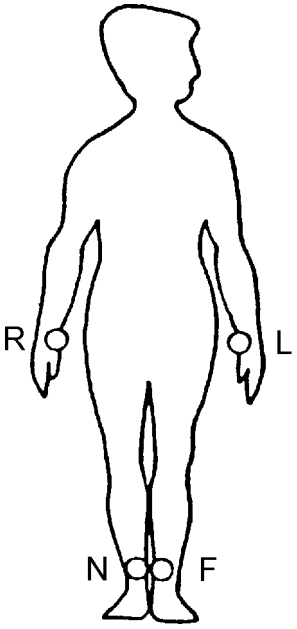
4.2.1 Resting ECG

Fix the supplied patient cable to the appropriate socket (item 8, ref. to p. 3-1).

> The unit's defibrillation protection is only effective with the patient cable supplied along with the unit!

The electrodes should be applied to the appropriate skin areas which had been prepared before in the usual manner.

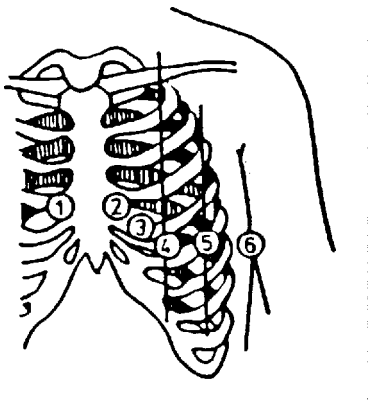
Einthoven and Goldberger Limb Leads



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
VR	R-CT	
VL	L-CT	$CT=\frac{(R+L+F)}{3}$
VF	F-CT	

Wilson Chest Wall Leads



Electrode	Code Colour	Electrode Position
C1	white & red	4thinterspace,RHsternalborder
C2	white & yellow	4tinterspace, LHsternalborder
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

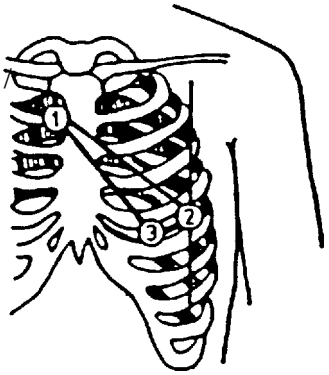
Lead	Linkage of Electrodes	
V1, V7	C1-CT	
V2, V8	C2-CT	
V3, V9, V3R	C3-CT	$CT=\frac{(R+L+F)}{3}$
V4, V4R	C4-CT	
V5, V5R	C5-CT	
V6, V6R	C6-CT	

Expanded Chest Wall Leads

For the expanded leads, the electrodes can be allocated freely to the leads In the basic setup (ref. to chapter 9.2). The typical allocation is preselected in the factory setup.

Lead	Electrode	Electrode Position
V7	C1	4th interspace, LH posterior axillary line
V8	C2	4th interspace, LH scapular line
V9	C3	4th interspace, LH paravertebral line
V3R	C3	between V1 and V4R
V4R	C4	4th interspace, RH midclavicular line
V5R	C5	between V4R and V6R
V6R	C6	height V4R LH midaxillary line

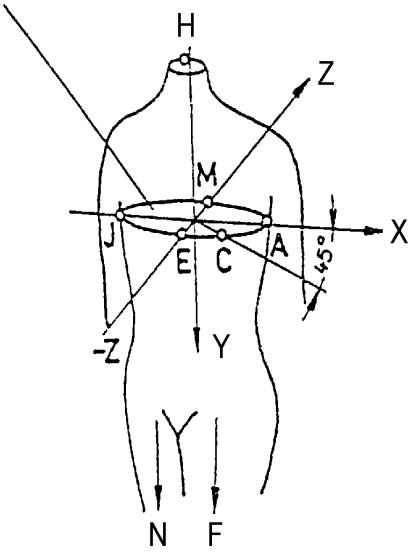
Nehb Leads



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

Frank Leads



Electrode	Code Colour	Electrode Position
J/C1	white & red	altitude of 4th interspace
E/C2	white & yellow	altitude of 4th interspace
C/C3	white & green	altitude of 4th interspace
A/C4	white & brown	altitude of 4th interspace
M/C5	white & black	altitude of 4th interspace
H/C6	white & violet	neck
F	green	LH leg
N	black	RH leg

Lead	Linkage of Electrodes
Vx	0,610xC4+0,171xC3-0,781xC1
Vy	0,655xF +0,345xC5-1,000xC6
Vz	0,133xC4+0,736xC5-0,264xC1 -0,373x C2-0,231x C3

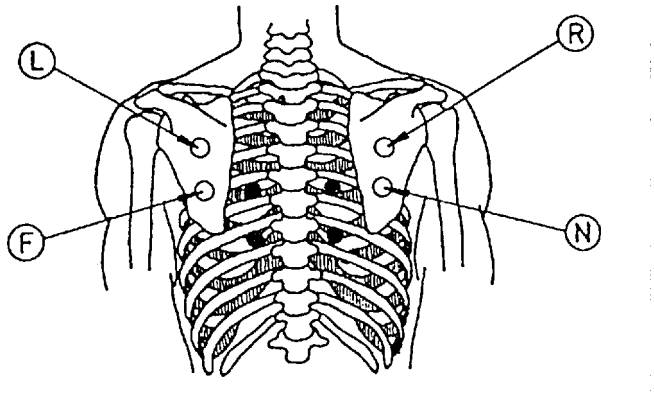
4.2.2 Exercise ECG

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

4.3.1 Mains Operation

Use the mains cable to connect the mains input socket (chapter 3.1, item 6) and the grounded socked of the room; the green LED must light.

Battery variant:
Depending on the battery charge and the unit's on/off condition, the unit will perform either a quick charging or a conservation charging. If the battery is discharged and the unit is off (green LED is lighting), there will be a quick charging. The time of quick charging of a discharged battery will be about 4 hours.
Preferably, the unit should be connected to the mains as often as possible; this will provide permanent recharging of the battery.

4.3.2 Battery Operation

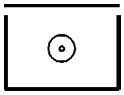
Do not connect the mains inlet of BIOSET 3700 with the mains socket; the charge indicator (green LED) must not light.

In case that the battery is intended not to be used so much, battery operation should be selected only in cases where instant ECG recording is required. A completely charged battery allows at least 1 hour of 5-channel recording with 25 mm/s.

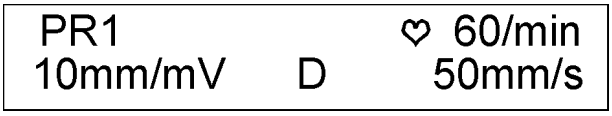
The battery charge is indicated under the unit setup (ref. to chapter 7).
The battery discharge is indicated by an acoustic signal. A low charge (20 %) is signalised by an interrupted noise. On appearing of this signal, recording is still possible.
If a permanent noise comes, recording with battery operation is not longer possible.

4.3.3 ON/OFF, Sleep Mode

switch the unit on



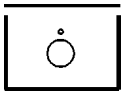
After running-off of a switch-on routine, programme 1 is enabled provided that there is no electrode fault. It is briefly indicated, and the dialogue box of the programme comes:



Sleep mode:

In order to attain the longest possible operation time per battery charge, BIOSET 3700 is provided with an automatic sleep mode.
On battery operation, the sleep mode ensures that - after an acoustic signal - the unit will be disconnected automatically in case that no key was pressed over a period of 4 min.
Taking the above into consideration, the patient cable should be applied prior to the switching-on of the unit with battery operation.

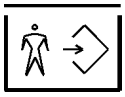
switch the unit off



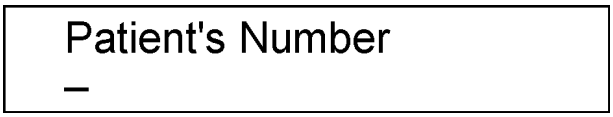
5 Patient's Data Input

5.1 Input

The patient's data can be entered before starting the registration of the ECG.

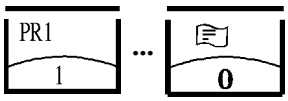
open patient's data editor 

The patient's data input box appears:



Inputs:

No. of patient: max. 20 characters
date of birth: dd-mm-yyyy
sex: <1> male, <2> female

enter data ***alphanumeric keys*** 

Having completed a line, change to the next input:

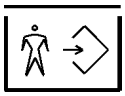
enable next input 

For necessary corrections, move the cursor to the line to be corrected:

enable previous input 

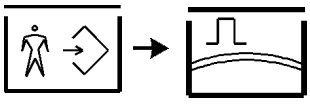
Now the data can be entered newly.

After having entered the patient's data, the menu is closed and the programme returns automatically to the previous function.

complete input 

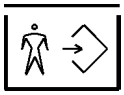
5.2 Test ECG

For the purpose of demonstration, the unit includes an ECG simulator.

enable test ECG 

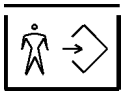
The remark TEST appears.

disable test ECG



Now one can enter new patient's data.
If intended to generate an ECG without patient's data, so

close patient's data editor



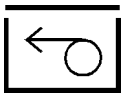
6 ECG Recording

ECG can be recorded under MANUAL with PR1... PR8 and AUTOMATIC.
After switching-on - with electrodes applied - the dialogue box of the programme appears:

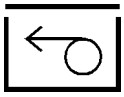
6.1 Instant ECG Recording

For instant recording in a case of emergency:

start recording



stop recording

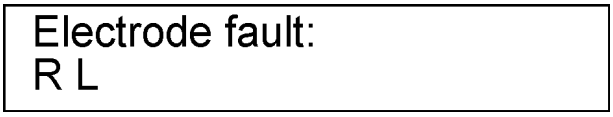


6.2 Messages

6.2.1 Electrode faults

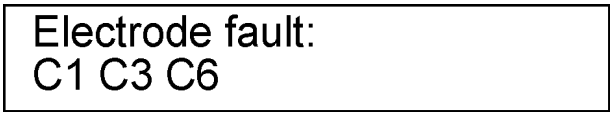
All electrodes are permanently tested during every ECG acquisition. Faulty electrodes are indicated in the display.

If any electrodes of the selected programme are faulty, a message box, like e.g. that of the electrode faults comes:



After elimination of the electrode faults, the above dialogue box of the programme comes.
If electrodes get off during the further ECG acquisition, the electrode fault message box comes instantly (provided that these electrodes belong to the selected programme.

If faulty electrodes do not belong to the selected programme, the following message box is displayed for about 2 seconds:



Then there comes the above programme menu.

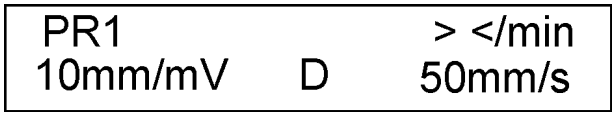
If the N electrode is faulty, the fault indication includes only ”N”.

Notice:
If the ECG is recorded despite of electrode fault warnings, only those leads are recorded the electrodes of which are correct.

6.2.2 Indication of the Heart Rate

The heart rate is determined from the lead with the largest amplitude.
The heart symbol blinks in rhythm with the patient's heart beats recognised.

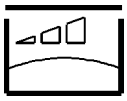
The hart rate determined is permanently updated (instantaneous value).
In case that the amplitude is smaller than 0.3 mV, or the heart rate attains > 240 beats/min or < 30 beats/ min, neither the heart symbol nor the heart rate will be indicated but



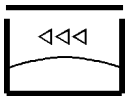
6.3 Selection of Speed, Sensitivity, Filters

BIOSET 3700 includes 3 selectable sensitivity stages of 5, 10 and 20 mm/mV and 4 speed stages of 2,5, 5, 25 and 50 mm/s.

change sensitivity stages



change speed stages



BIOSET 3700 includes each 1 in-and excludable muscle filter for suppression of muscle artefacts, AC filter for suppression of mains interference and drift filter for reduction of base line variations. The drift filter's default condition of ON, however, it can be disabled in the unit setup.
The muscle, AC and drift filters act simultaneously on all channels.

muscle filter on/off

AC filter on/off

Marking on the recording paper with active filters:

AC filter: N
muscle filter: M
drift filter: D

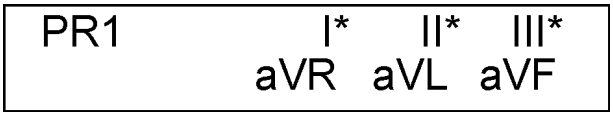
Notice:
Since filters are usually FILTERING certain frequency ranges OUT, this will lead to an alteration of the ECG curve. Hence, it is recommended to always try to eliminate the source of fault rather than include the filters.

The selected sensitivity, recording speed, as well as the muscle or AC filters included are indicated in the display.

Every lead programme can be customised in the unit setup (ref. to chapters 7.2 and 7.3).

6.4 Recording in MANUAL Mode

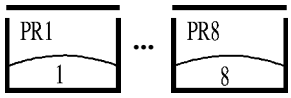
After switching-on, lead programme 1 appears briefly (2 s):



Then there comes the dialogue box of programme 1:

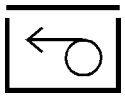
If a different programme is desired, so

select lead programme



Analogue to programme 1, for every lead programme there comes the lead programme, followed by the programme's dialogue box.

start recording



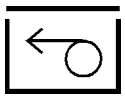
Depending on the mode of recording as selected in the unit setup (chapter 7.2), the recording is executed

sheet-controlled
The lead programme is recorded with recording speed and no. of sheets selected; recording is stopped automatically.

time-controlled
The lead programme is recorded with recording speed and recording time selected; recording is stopped automatically.

with start/stop operation
The lead programme is recorded with recording speed and can be stopped at any time.

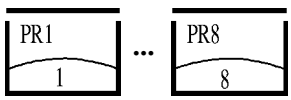
stop recording



<u>Intermediate Settlement</u>

Every ECG acquisition can include zero-line variations due to dropped electrodes or other distinct artefacts.
An "intermediate settlement" can be enabled by repeated pressing of the same programme key.

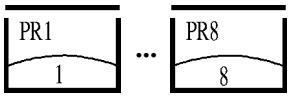
enable settl. by the same programme key



The ECG curve shows - due to the switched time constant - a **modified signal shape** which is highlighted additionally by a 1 mm mark at the lower margin of the paper strip.

If defibrillation is executed during the ECG acquisition, this will lead to overdriving of the ECG inlet. To eliminate this overdriving, after defibrillation there will be an automatic settlement without time limitation. The ECG curve, which is now visible again, shows again - due to the switched time constant - a modified signal shape which is highlighted additionally by a 1 mm mark at the lower margin of the paper strip.

disable settlement by the same programme key

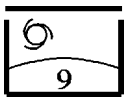


After completion of the intermediate settlement, the ECG recording is continued with normal time constant. If it was defibrillated, this would take place - depending on the defibrillation energy - about 30 s after the defibrillation.

Notice:
This mode can activate itself automatically due to dropped electrodes or other distinct artefacts.

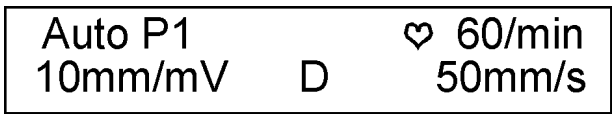
6.5 Recording in AUTOMATIC Mode

start automatic programme

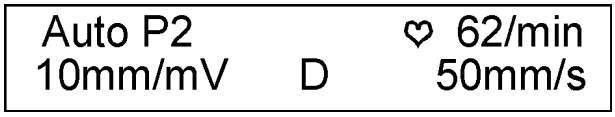


Analogous to manual recording, first the lead programme appears briefly, followed - if all electrodes are correct - by the programme dialogue box.

That means



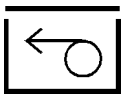
followed by



The automatic programme runs with the filter setting and sensitivity as selected before the start.
After running-off of automatic recording, that programme, which was active before automatic recording, is reactivated.

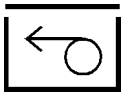
In case that there is an electrode fault, registration can started despite of that, if need be:

start registration



The automatic programme can be cancelled at any time:

stop registration



In the unit setup, automatic recording can be selected as not ”time-synchronous” and ”time-synchronous” (ref. to chapter 7.2).

NON-TIME-SYNCHRONOUS RECORDING
The lead programmes P1...P4 are recorded *one after the other* and registered at the moment of acquisition. All selected lead programmes are recorded with recording speed and no. of sheets or registration time selected; recording is stopped automatically.

TIME-SYNCHRONOUS RECORDING
The lead programmes P1...P4 are recorded, acquired and stored The 1st lead programme is registered with recording speed and no. of sheets or registration time selected, whereas all further lead programmes, from the memory time-synchronously to the 1st programme.
The 1st lead programme is recorded with recording speed and no. of sheets or registration time selected. The remaining lead programmes are registered over max. 10 s with the sensitivity, as selected for programme 1. The recording is stopped automatically.

6.6 Recording with Ergometry (Remote Start)

Remote Start without Data Transfer
Remote start allows **automatic ECG registration at the end of the load stages**.
The recording is started by the ergometer and the selected programme is registered. The recording is stopped automatically after run-off of the selected recording length.
The **time-controlled** or **sheet-controlled** recording length is described in chapter 7.2. It is recommended to configure one programme - preferably programme 4 - for the ergometry parameters and to use it for ergometry.
The interface of BIOSET 3700 can be set as desired (ref. to chapter 7.6)
The remote start interface of the ergometer is connected to the remote start inlet (ref. to page 3-1, connector 10) by means of a connecting cable.
The following ergometers can be connected by means of a connecting cable:

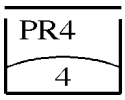
type	designation	item No.
ergometer MEDICOUNT/SECA 100	start cable SM	2500-050-000
ergometer ERGOMETRICS	start cable EL	2500-057-000
ergometer ERGO-FIT	start cable EF	2500-055-000

Remote Start with Data Transfer
On using one of the ergometers mentioned below, a data exchange cable to the RS 232 interface (ref. to page 3-1, connector 7) can be used additionally. Data exchange is recording of the concerned load and speed (with Ergometrics, additionally the last measured blood pressure).
The interface must be set for the particular ergometer (ref. to chapter 7.6).
The following ergometers can be connected by means of a connecting cable:

type	designation	item No.
ergometer MEDICOUNT/SECA 100	control cable SM	2300-062-000
ergometer ERGOMETRICS	control cable EL	2100-068-000

To enable the registration by the ergometer, it is necessary to create the readiness of the ECG by activating a manual programme. In case of appropriate setup, preferably the programme 4 should be selected.

create readiness



Monitor Connection

Using a monitor cable, a monitor can be connected additionally to the 1 V outlet (ref. to page 3-1, connector 9).
(RS 232 interface and 1 V outlet are optional).

The following monitor can be connected by means of a connecting cable:

type	designation	item No.	no. of contacts
monitor EMC 1000, elmed	monitor cable SM	2500-072-000	15/15

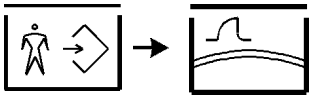
7 Unit Setup

The unit setup allows customisation to the user's individual objectives.
Without coding, it is possible to
- indicate the battery charge (battery-operated units only)
- set date
- set time.

With coding, the following can be changed:
- manual programmes
- automatic programmes
- language
- electrode allocation
- interfaces

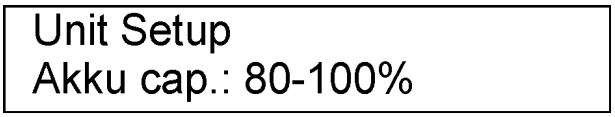
Printing-out of the unit setup is possible.

open unit setup menu

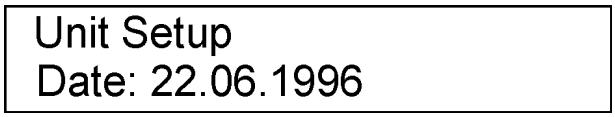


The following messages will appear:

battery variant:



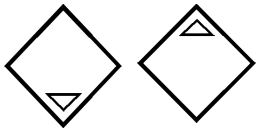
mains variant:



7.1 Date, Time, Code

The menus are used to enter date and time.

open next or previous menu



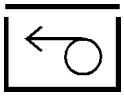
modify date and time

Further unit setup modifications require entering of the 4-digit code number.

enter code number

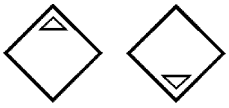
The code number is **8295**.

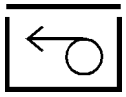
confirm input

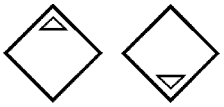


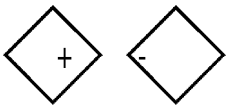
The input is hidden; a character is displayed as an X.
Once entered, a character cannot be corrected. On error, the unit setup must be reopened.

For further unit settings, proceed according to the following principle:

select setup menu 

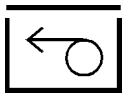
open setup menu 

select within the setup menu 

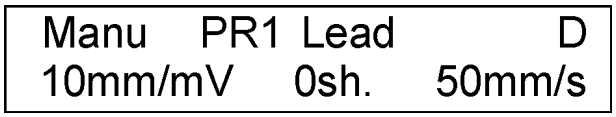
modify 

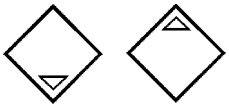
7.2 MANUAL

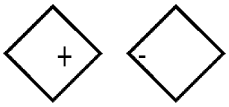
Once having entered and confirmed the code number, the MANUAL setup menu appears.

open MANUAL menu 

The MANUAL 1 dialogue box appears:



select parameter to be modified 

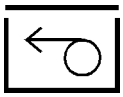
modify parameter 

Customisations:

- lead programmes:	PR1...PR8 with further settings
- filters:	muscle filter on/off AC filter on/off drift (ADS) filter on/off
- sensitivity:	5, 10, 20 mm/mV
- recording duration:	Osh. = without sheet control, i.e. manual stop of registration; 1...5 sheets = sheet-controlled, i.e. registration is stopped automatically after the selected number of sheets; 5, 10, 15, 20 s = time-controlled, i.e. registration is stopped automatically after the selected time.
- registration speed:	2,5, 5, 25, 50 mm/s

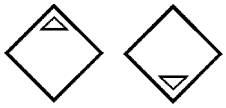
To modify individual lead programmes, select ”Lead”.

open setup of the lead programmes

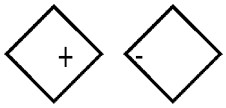


The MANUAL 2 dialogue box appears:

select parameter to be modified



modify parameter

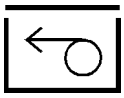


Customisations:

- leads of channels 1..6: I; II; III; aVR; aVL; aVF
  V1...V6; V3R; V4R; V5R; V6R; V7; V8; V9;
  D; A; J; Vx; Vy; Vz;
  zero = channel short-circuited
  (blank field) = channel faded out

Within every lead programme one can select which of the max. 3 leads is to be lead to the outlet. The selection is made for every lead programme.

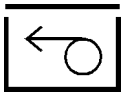
enable/disable selection



The enabled lead is marked by ”*” behind the channel No.. The marking applies to that lead programme in which the cursor is.

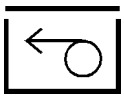
If desired to go back to the MANUAL 1 setup menu, use the cursor to select ”Manu 1”.

go back to MANUAL 1



If desired to go back to the MANUAL setup menu, use the cursor to select ”Manu”.

go back to MANUAL

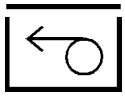


7.3 AUTOMATICS

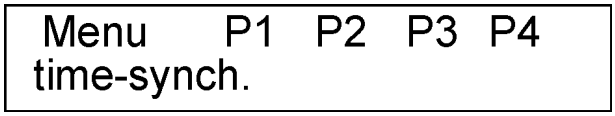
AUTOMATICS is opened after the MANUAL setup menu

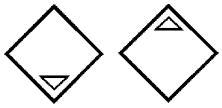
select automatics menu 

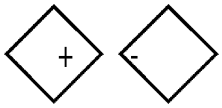
The AUTOMATICS dialogue box appears:

open AUTOMATICS menu 

The AUTOMATICS 1 dialogue box appears:



select parameter to be modified 

modify parameter 

Customisations:

- lead programmes: PR1...PR4 with individual settings
- registration mode: time-synchronous, non-time-synchronous

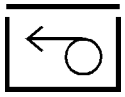
The automatic programme can be registered either in ”time-synchronous” or in ”non-time-synchronous” mode:

NON-TIME-SYNCHRONOUS RECORDING
The lead programmes P1...P4 are recorded *one after the other* and registered at the moment of acquisition.

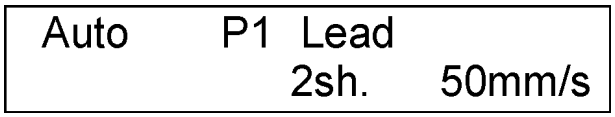
TIME-SYNCHRONOUS RECORDING
The lead programmes P1...P4 are recorded, acquired and stored The 1st lead programme is registered/ displayed with no. of sheets or registration time selected, whereas the remaining lead programmes, from the memory time-synchronously to and with the sensitivity of the 1st programme.
The synchronous running time is max. 10 s. If P1 runs less than 10s, so the synchronous running time is determined by P1. If P1 runs longer than 10 s, so only the last 10 s of P1 are time-synchronous to P2...P4.
For the programmes P1...P4, a total of 12 leads are permitted (repeatedly occurring leads are also counted repeatedly).

If further parameters are to be set, so ”P1” (”P2...P4”) has to be selected.

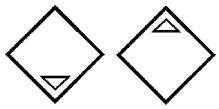
open parameter setup



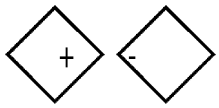
The AUTOMATICS 2 dialogue box appears:



select parameter to be modified



modify parameter

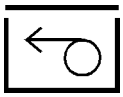


Customisations:

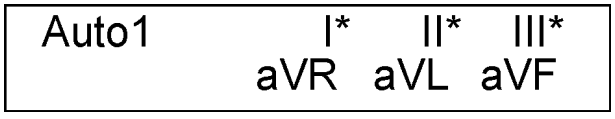
- lead programmes:	PR1...PR4 with further settings	
- recording duration:		
non-time-synchronous	1...5 sheets = sheet-controlled;	
	5, 10, 15, 20 s = time-controlled;	
time-synchronous:	1st lead programme:	1...5 sheets
		5, 10, 15, 20 s
	2nd...4th lead programme:	1...5 sheets at 50 mm/s
		1...3 sheets at 25 mm/s
		1 sheet at 2,5 and 5mm/s
		5, 10 s
- registration speed:	2,5, 5, 25, 50 mm/s	

To modify individual lead programmes, **select ”Lead”.**

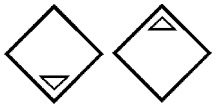
open setup of the lead programmes



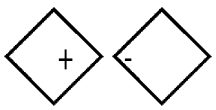
The AUTOMATIC 3 dialogue box appears:



select parameter to be modified

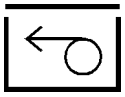


modify parameter



Customisations:
- leads of channels 1...6: I; II; III; aVR; aVL; aVF
  V1...V6; V3R; V4R; V5R; V6R; V7; V8; V9;
  D; A; J; Vx; Vy; Vz;
  zero = channel short-circuited
  (blank field) = channel faded out
- one may select max. 12 leads, out of that max. 9 leads for programmes 2...4;
- the setting sequence must be P1, P2, P3, P4.

Enabling a lead and marking it by "*" is analogous to chapter 7.2.
If desired to go back to the AUTOMATICS setup menus, use the cursor to select "AUTO 1" and then "AUTO".

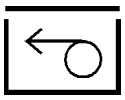
go back to AUTOMATICS 

7.4 Language

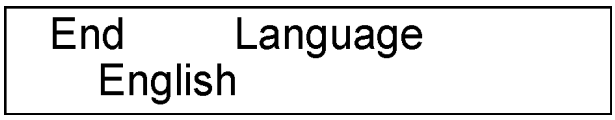
The language selection comes after the AUTOMATIC selection menu.

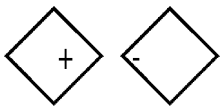
select language menu 

The LANGUAGE dialogue box appears:

open language menu 

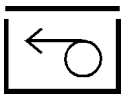
The LANGUAGE 1 dialogue box appears:



select language 

Customisations:
- variant 1: German, English, French
- variant 2: German, English, Russian
- variant 3: German, English, Spanish

If desired to go back to the LANGUAGE setup menu, move the cursor to "End".

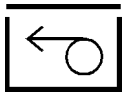
go back to LANGUAGE 

7.5 Electrodes

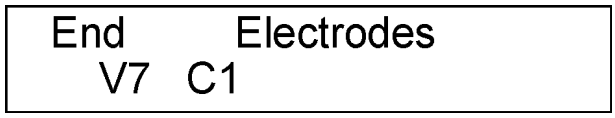
The electrode setup comes after the LANGUAGE selection menu.

select electrode menu 

The ELECTRODE dialogue box appears:

open electrode menu 

The ELECTRODE 1 dialogue box appears:

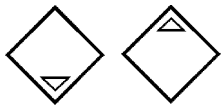


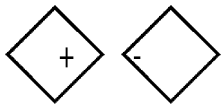
Customisations:

- electrode allocation:

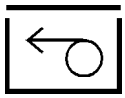
V7	C1
V8	C2
V9	C3
V3R	C3
V4R	C4
V5R	C5
V6R	C6

In the above menu it is also possible to modify the electrode allocations (C1…C6) for the extended chest wall leads.

select electrode allocation 

modify allocation of the C electrode 

If desired to go back to the ELECTRODE setup menu, move the cursor to ”End”.

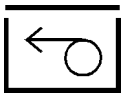
go back to ELECTRODE 

7.6 Interfaces

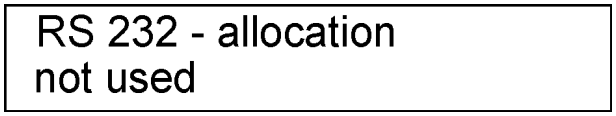
The interface setup comes after the ELECTRODE setup menu.

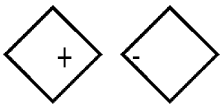
select interface menu 

The INTERFACE dialogue box appears:

open interface menu 

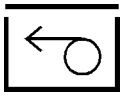
The INTERFACE 1 dialogue box appears:



modify interface setup 

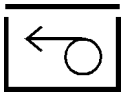
Customisations:
- reception of information: disabled, remote control, Medicount 100, Ergometrics, PC-Link
(PC Link is an online data transfer format “0002” by HOERMANN)

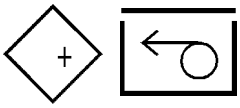
If desired to go back to the INTERFACE setup, so

go back to INTERFACE 

7.7 Factory Setup

Enabling factory setup will replace all customised settings by the manufacturer’s settings, i.e. all customisations are discarded.
On selecting the factory setup, a safety dialogue box ”Factory setup execute? no”
appears.

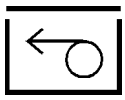
do not enable factory setup 

enable factory setup 

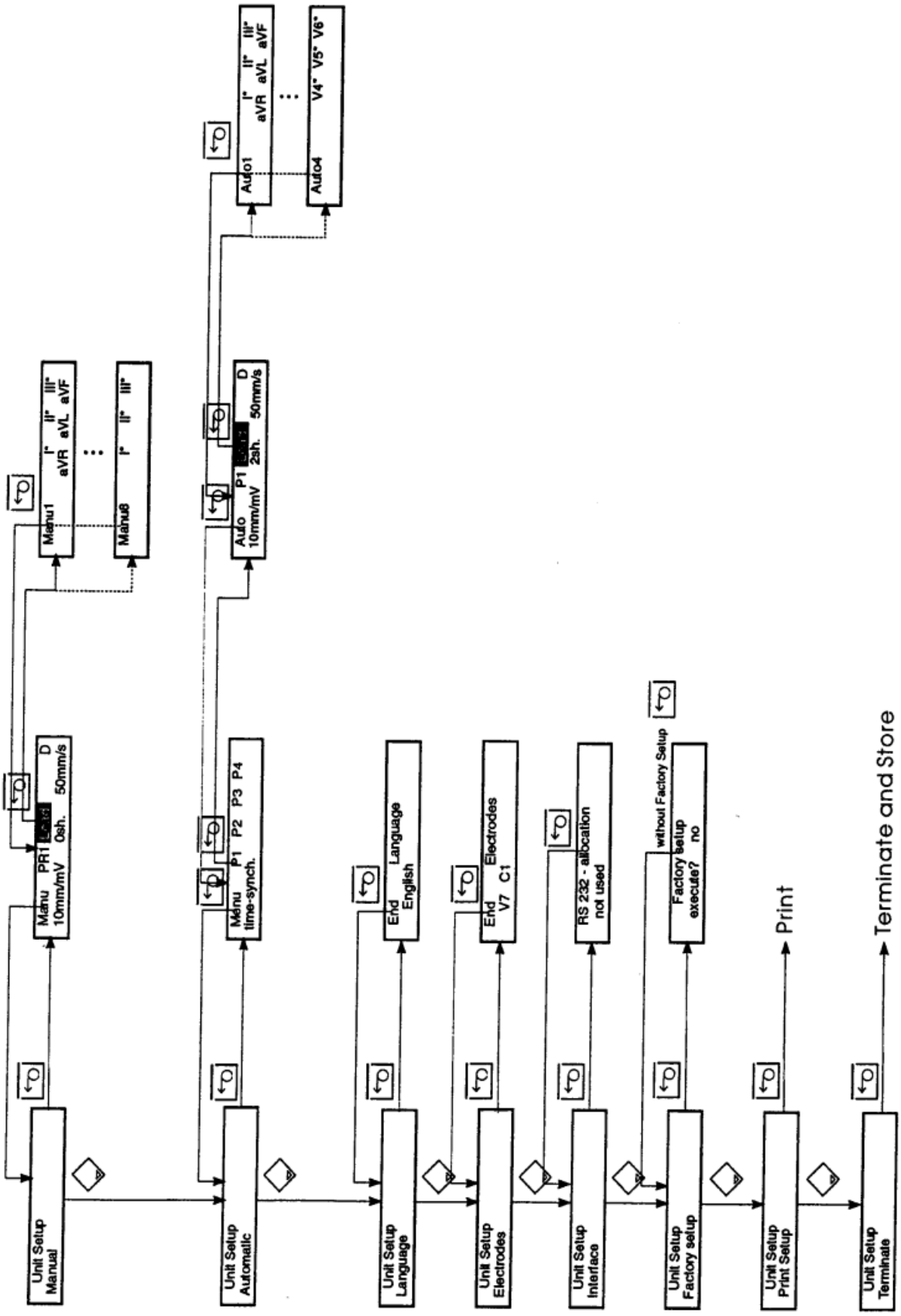
7.8 Print Unit Setup

Enabling PRINT UNIT SETUP will print all customised settings. This print-out gets invalid after having performed the factory setup.

After completion of the customisation, the menu is closed saving all settings by selecting ”Terminate”.

complete unit setup 

7.9 Unit setup structure

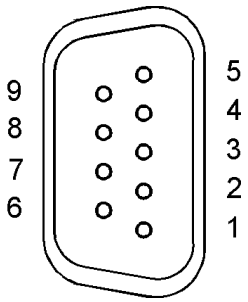


8 Interfaces

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. In case of questions, please contact your local dealer or the technical service.

8.1 Analogue (1V) Outlets

Connection scheme (seen onto socket)

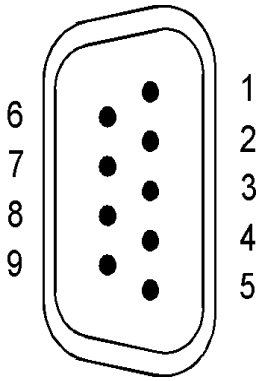


1	—
2	GND
3	outlet 2
4	QRS trigger
5	—
6	—
7	outlet 1
8	outlet 3
9	—

Any channel can be connected to the outlets according to chapter 7.2.

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

9.1 General Data

mains voltage range	95V ... 230 V ± 10%, AC
power drain	250 ... 150 mA
mains frequency range	50 Hz ... 60 Hz
mains connection	mains lead, plug-in type
optional: battery	accumulator pack 9.6 V, 1.8 Ah
charging	charge indicator; overload protection
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	
”Guideline 93/42/EC”	class IIa
dimensions (w x d x h)	330 x 235 x 110 (80) mm^3
weight with battery	£ 3 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 +35 °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	thermoreaktive
writing element	thermoline 104 mm wide, 8 dots per mm,
resolution of registration in Y direction	8 dots per mm
resolution of registration in X direction	20 dots per mm 50 mm/s
	40 dots per mm 25 mm/s
	200 dots per mm 50 mm/s
	400 dots per mm 25 mm/s
transmission range	0,05...120 Hz +5 % - 30 %
zero adjustment	automatic write centring

recording paper	continuous stationary, 180 sheets, 110 mm wide, 18 m long, with red grid imprint, side logo, sheet control marks
paper type	thermoreactive, e.g. O51OH, order No. 2300-000-021
recording speeds	2,5, 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,
Frank	F,N,C1=I,C2=E,C3=C,C4=A, C5=M,C6=H
electrode test	monitoring before and during ECG acquisition
lead programmes	12 standard leads, Cabrera, Nehb, Frank,
number of channels	6 (3)
programming of channels and leads:	freely programmable with I, II, III, aVR, aVL, aVF, -aVR,V1, V2, V3, V4, V5, V6, V3R, V4R, V5R, V6R, V7, V8, V9, D, A, J, Vx, Vy, Vz, XAC1, XAC2, XAC3, XDC1, XDC2, XDC3, XDC4, "0" channel short-circuited, "-" channel faded
MANUAL programmes	8
programmes of automatic mode	max. 4 lead programmes (optional with time-synchronous or non-time-synchronous recording)
rec. duration per lead programme	optional 1 - 5 sheets, 5-20s or start/stop
application unit	F insulated
input resistance	≥2 x 20 MOhm
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
transmission range	0,05 ...150 Hz
calibration	1 mV ± 5 %
superposed DC voltage	± 0,3 V
sensitivities	5, 10, 20 mm/mV ± 5 %
muscle filter	fg = 35 ... 45 Hz (slope: 4 ...6 dB/Okt.)
mains frequency filter	50Hz, 150Hz (damping: ≥ 20 dB, ≤10 % overshooting)
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: > 12 bit
heart frequency indication	
measuring range	30 - 240/min
display	indication of instantaneous value
recording paper	print-out of average
indicator	optical, acoustic
pacemaker	recognition, marking (pacemaker voltage on body surface ≤ 700 mV, pacemaker pulse width ≤2 ms; also double-chamber pacemakers)

9.4 Operation Section

keyboard	plastic-foil keyboard; wipe-resistant
LC display	2 x 20 characters, 5 m high

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 inlets and 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 output signal 5 V, 150 ms; time-synchronous to the ECG inlet

Computer interfaces:

type	RS 232 C, 9-pole
function	PC Link for PC coupling, data communication with ergometer Medicount/SECA 100 and Ergometrics

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.

Note:

- Do not use ether, petrol, propyl alcohol, or acetone.
- Prevent fluids from getting into instrument, inside transducers, or connecting sockets.

Special care must be taken that no moistures get inside trough the edges of the keyboard.

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 BIOSET3700, inspections and checks are specified. If deficiencies concerning safety and serviceability are thereby detected, inform your service partner.

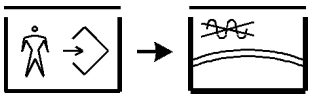
Checking when putting into operation

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

Function Checks

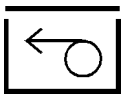
- With the unit test, important unit functions are checked.

start unit test



Test performance:
- keyboard test: press all keys (with except for ON/ OFF key)
- cover and paper test: follow the instruction; always confirm by

confirm test



- registration section test: 3 parallel declined lines are registered several times.

Periodic Checks

- Check the instrument acc. to the national safety-engineering regulations.
- A close functional test should be accomplished every 12 months. For this, advantageously use an ECG simulator.

Checks should be executed as follows
- visual inspection of patient cable and electrodes
- accurately evaluate the self-test
- check all parameters printed out
- for optional interfaces, simulate the external ”start” function and monitor signals

Thermoprinting Line

- In case of a possible contamination of the thermoprinting line, extremely cautiously clean the printing edge using an alcohol-wet swab. Therefore, disconnect the unit from mains and patient.

Battery (optional)

- The battery is maintenance-free. Contact the service if on battery operation the duration of registration as indicated is not attained anymore.

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