M4Medical Sp. z o.o.

M-TRACE
Electrocardiograph

user's manual

Edition II

Edition	Date	Changes	Editor
02	08.02.09	– Format changes – Added CE Declaration of Conformity – Improved functionality – added configuration option of AUTO Examination printout	DM

Contents

Introduction

Electrocardiogram is the graphic presentation (ECG diagram) of electrical activity of the heart over time. It allows to examine the mechanism and place where electrical impulses occur. It also enables to check how it works in electrical system and heart muscle and allows to learn its reactions.

Indirectly, it allows to examine and diagnose heart muscle behavior, its perfusion, oxidation and tightness. Deviations in ECG record can help to recognize morbid conditions causing invalid heart muscles work, or its reaction to electrical stimulus reducing perfusion and oxidation of that muscle, what causes bad impulses to occur or their incorrect flow. Consider emphasized that ECG is only one of the supplementary examinations which reveals its full potential only with full clinical view of patient's condition. Some exception can be the myocardial infraction (not always) where the ECG record is evident and unequivocal what enables to make right diagnosis – showing also the exact place in heart muscle area – without seeing the patient. In the rest of heart illness cases ECG seems to be rare authoritative, but it is a vital supplemental examination.

M-TRACE Electrocardiograph allows to record on thermal paper heart impulses in full range of 12 standard channels. The device is compact. It has small dimensions and a built-in battery. It allows to conduct examinations in all conditions. It is crucial for cardiologic departments as much as for family doctor's job.

Precautions and Safety Instructions

- All the safety and operating instructions should be read before the appliance is operated. It will help in correct using and servicing of the device making it long-time life and safe tool.
- It is vital to check periodically the correct work and quality of accessories and device itself. In case of doubts, please contact qualified service personnel.
- Most vital thing is to instantly pay attention to power cord which should be free from any damage. It will eliminate a risk of electric shock to persons.
- Using the device simultaneously with cardio stimulators or any other kind of electric stimulators does not expose both patients and personnel to any danger.
- It is very important not touch neither patient nor any device connected to him during defibrillation.
- Electrocardiograph can not be used simultaneously with any surgical devices operating on high frequency.
- To keep ECG record long-time archived, it is needed to make Xerox copy of printouts or print them on outside printer operating on regular copy paper. Thermal paper which is used to work with the device is fragile to environmental factors what can cause the printouts unreadable after some time.
- The device is not adjusted to work in places where inflammable fumes or combustibles occur.
- In case of simultaneous connecting the electrocardiograph with other devices to patient, it is necessary to check the risk that may occur of summarizing of leakage currents.
- Electrocardiograph has CF safety protection type. It allows to do examinations directly on patient's heart.
- Always connect electrodes with maximum caution avoiding connectors not touch any metallic parts, including ground.

- Do not attempt to service the appliance yourself as opening or removing covers may expose you to dangerous voltage or other hazards. Refer all servicing to qualified service personnel.
- Relocating the device between places with extremely different temperature may cause moisture condensation inside. If condensation does occur, neither plug the appliance to the power nor turn it on. Wait a few hours till the unit will have warmed up and any condensation will have evaporated.

Description

M-TRACE electrocardiograph is a sophisticated and modern electronic device. It is dedicated to record ECG impulses in full range of 12 standard channels. Printout is made on thermal paper. The device is equipped with high resolution linear thermal printing unit and color LCD. The built-in battery allows to use it quickly wherever it is necessary. Aesthetic plastic cover together with membrane keyboard makes the device easy to keep clean.

Inside the box (supplied accessories)

Make sure you have the following accessories:

	In Box	Qty.
1.	The device – M-TRACE electrocardiograph	1 pc.
2.	Clamp electrodes	4 pcs.
3.	Sucker electrodes	6 pcs.
4.	ECG cord	1 pc.
5.	Power cord	1 pc.
6.	ECG thermal paper 112mm wide	1 pc.
7.	ECG gel	1 pc.
8.	User's manual	1 pc.

If some of above accessories are missing please contact your reseller or supplier.

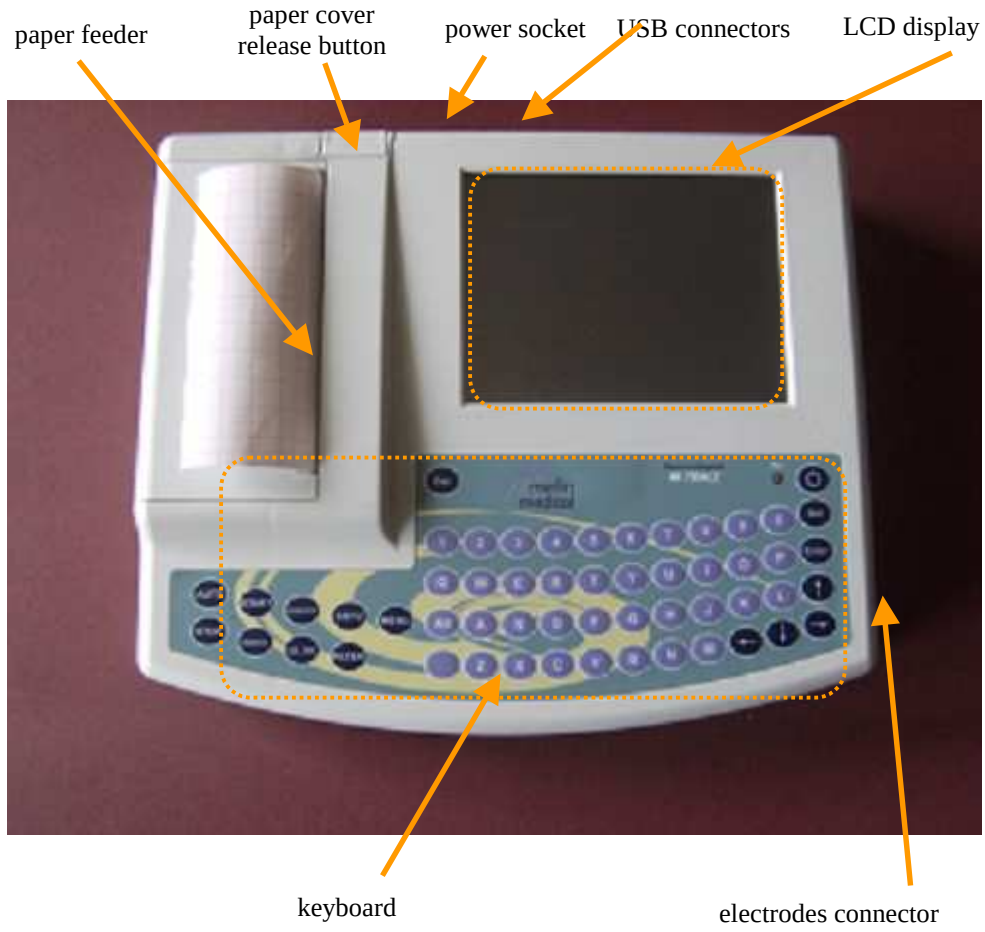
MANUFACTURER

CE **0197**

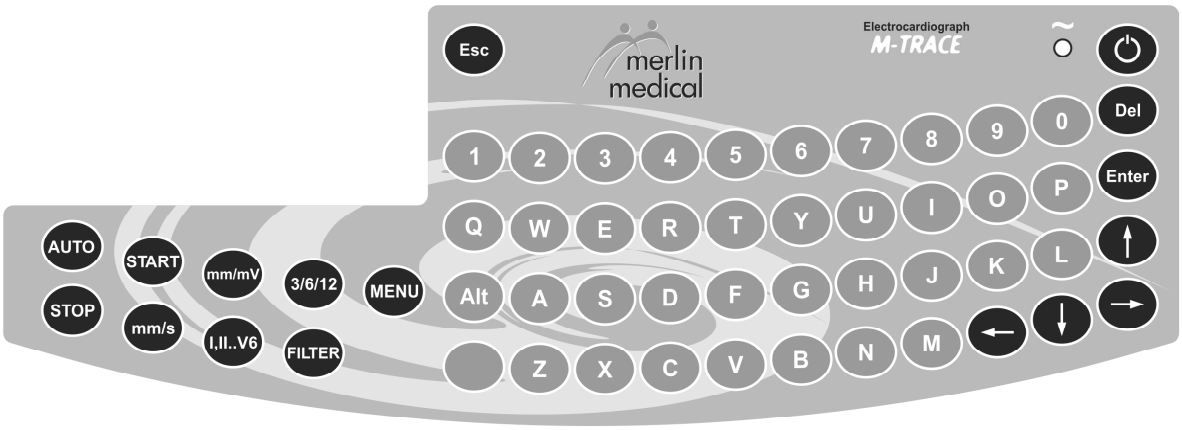
M4Medical Spółka z o.o.
Ul. Ogrodowa 10/7
20-075 Lublin
Poland

Overview

Electrocardiograph unit



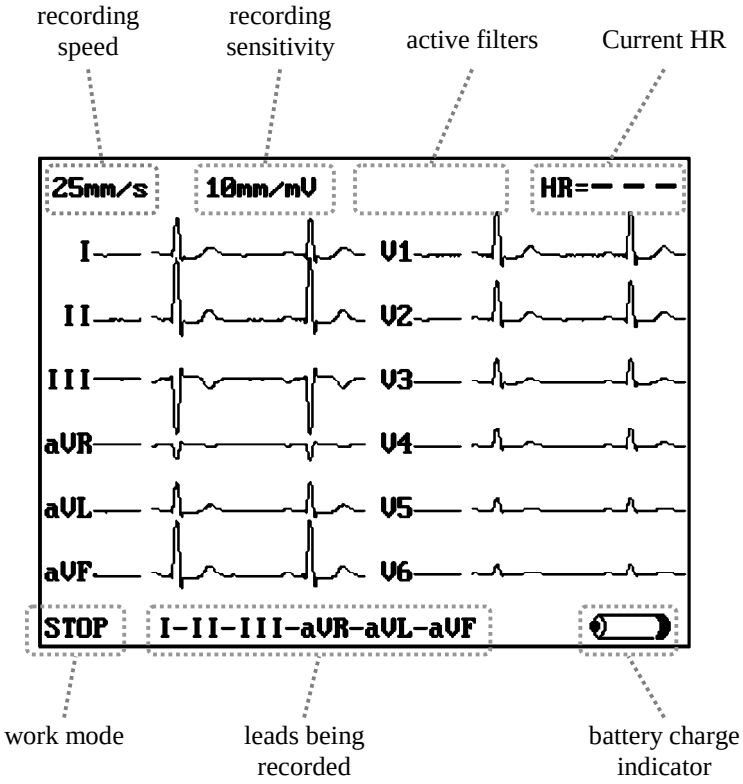
Steering top panel - keyboard



Function keys

AUTO	Recording – automatic mode
START	Recording – manual mode
STOP	Stop recording
mm/mV	Setting recording sensitivity
mm/s	Setting recording speed
FILTR	Setting active filters
3/6/12	Setting the number of leads to be recorded
I,II..V6	Setting the group of leads to be recorded
MENU	Configuration mode

LCD screen



Technical specifications

Dimensions (W x H x D)	260 W x 52 H x 220 D mm
Weight	<1,8kg
Power Supply	AC 90-240V, 50-60Hz
Built-in Battery	Li-ion 7,2V, 2,2Ah Can be replaced only by qualified servicing personnel
Power Consumption	<30VA
ECG leads	12 Standard ECG leads: – Einthoven's limb leads I, II, III – Goldberger's limb leads aVR, aVL, aVF – Wilson's precordial leads V1, V2, V3, V4, V5, V6
Sensitivity	2,5/5/10/20 mm/mV 5%
Recording Speed	5/10/25/50 mm/s 5%
Common Mode Rejection Ratio	>100dB
Frequency Band	0,05-150Hz
Input Impedance	>10MΩ
Control Range	>300 mVpp 10 mVpp
Resolution	2,5µV
Sampling Frequency	1000Hz
Digital Filters	50Hz, 60Hz, 35Hz, 25Hz, antidrift
LCD Screen	Color graphic display, 320x240
Safety	Protection Type CF (EN60601-1) Class I
Class / Group	Class A / Group 1 (CISPR-11)
Operating Environmental Conditions	– Temperature +10 to +40˚C (+50 to +104˚F) – Relative Humidity 25 to 95% (non-condensing)

Input circuit is protected against defibrillation impulse. After such impulse, ECG waveform will appear again up to next 10 seconds.

Using the appliance

Functional abilities

Electrocardiograph can record signals from 12-channel standard ECG leads. There are following operating modes available:

- **Automatic recording mode**
  All 12 lead signals are being recorded in one 10 second time block. Afterwards device automatically makes analysis including time and amplitude measurements of P-QRS-T complex, determining the electrical axis of the heart and the rhythm analysis. Full report printout includes the real ECG waveform, averaged P-QRS-T complex with particular marked waves, conclusions of the measurements and calculations, text ECG interpretation and the data of the patient.

- **Manual recording mode**
  This mode enables users to choose how many lead signals (3, 6 or 12) will be recorded at the same real time. That mode allows to switch between lead groups, change amount of recorded channels, sensitivity and the speed of the recording process during the examination. It is also available to activate or deactivate additional ECG signals interferences filters.
- **Copy printout**
  It provides function to make an automatic examination copy printout stored in appliance's internal memory. The memory can store up to 100 ECG examinations. The printout's form is similar to the automatic recording mode's one.
- **Outside printer printout**
  As connected to the electrocardiograph, the outside printer enables to make printouts on regular paper or any media which the particular printer operates on. The only thing required is that the outside printer uses USB port for connection and understands PCL5 script language.
- **Saving examination's copy to the external USB device (e.g. PenDrive)**
  The data is stored in accordance with the EN1064:2000 standard.

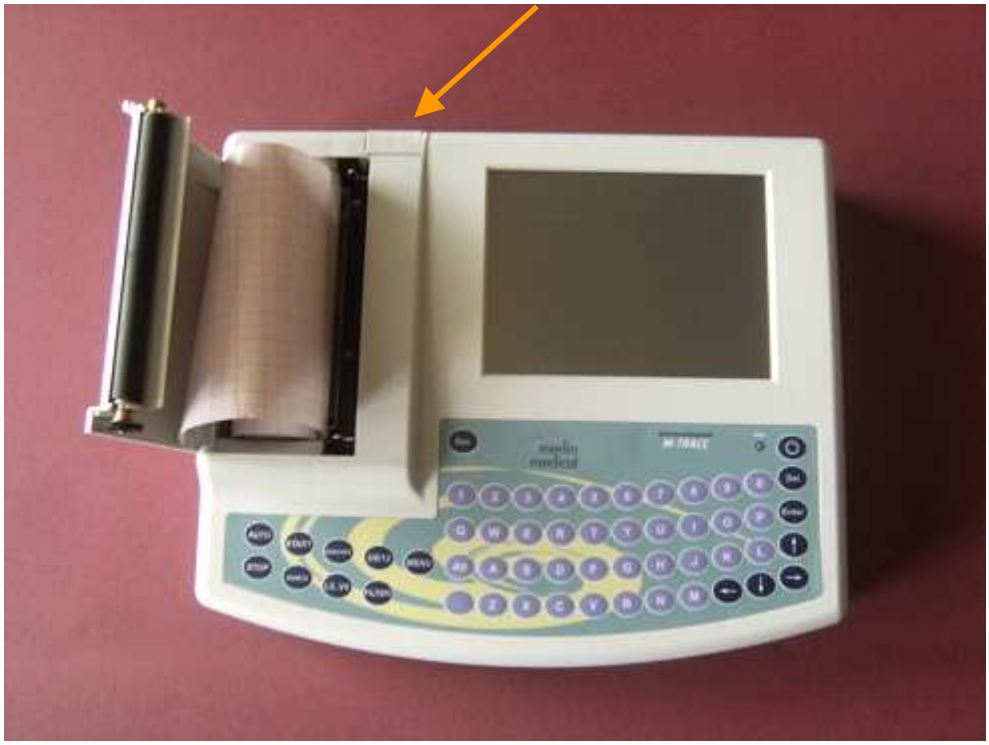
Preliminaries

The appliance is equipped with a built-in battery. To indicate the device turned on press  on the keyboard. Before the first turning on or after the long period of not using the device it is necessary to charge the battery. Plug the device in to a power and switch the button on rear side to on position. Constant light of the LED on the keyboard indicates the batteries are being loaded. Blinking of the LED informs that the battery is fully charged and ready to use.

Paper loading

The loading thermal paper in to the built-in printer is very easy. To do it open the paper cover releasing it with button located at the end of papers exit hole (refer to the picture below). Put the roll of the paper in its place in the printer and lead out the end of it outside of the cover. Pay attention to the paper's direction – head its active (squared) side up. Finish the whole process closing the paper cover. Push it till it's locked properly in the printing mechanism.

Paper cover release button



Setting up recording parameters

Before starting the examination it is needed to set up the required recording parameters. Turning the appliance on automatically recalls parameters last set in the setup menu. If adjusting of some of them is needed it can be done by pressing one of the following keyboard function buttons:

mm/mV

Setting recording sensitivity
Each single push changes the sensitivity value sequentially up:
2,5 → 5 → 10 → 20 mm/mV

mm/s

Setting recording speed
Each single push changes the speed value sequentially up:
5 → 10 → 25 → 50 mm/s

FILTR

Setting active filters
Each single push changes current active filters sequentially:
50 → 35 → 35/50 → 25 → 25/50 Hz

3/6/12

Setting the number of leads to be recorded
Each single push changes the number of leads to be recorded sequentially up:
3 → 6 → 12

I,II..V6

Setting the group of leads to be recorded

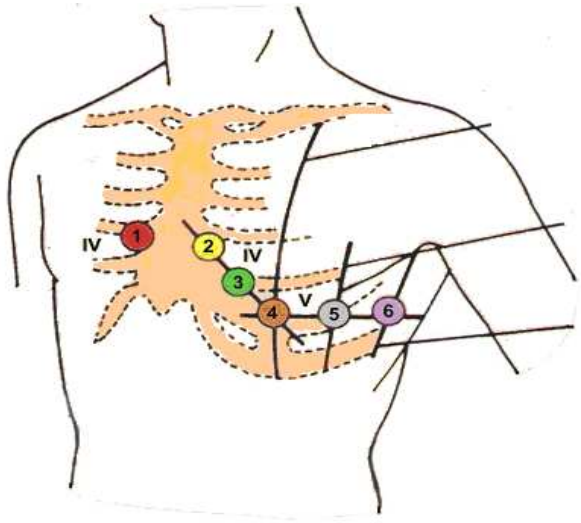
Number of leads set to be recorded	**Available number of groups that can be set**	**Available groups that can be set.** Each single push changes the group sequentially
3	4	I – II – III ↓ aVR – aVL – aVF ↓ V1 – V2 – V3 ↓ V4 – V5 – V6
6	2	I – II – III – aVR – aVL – aVF ↓ V1 – V2 – V3 – V4 – V5 – V6
12	1	12 Leads

Current settings are shown on the LCD screen.

Arrangement of electrodes

The appliance is equipped with 10-electrode wire cable. The standard arrangement:

Lead type	Lead	Connection – body location	
Einthoven's bipolar limb leads (4 electrodes)	Red	Right arm	
	Yellow	Left arm	
	Green	Left leg	
	Black	Right leg (reference point, ground)	
Strengthened Goldberger's unipolar limb leads	aVR	To Right arm electrode	
	aVL	To Left arm electrode	
	aVF	To Left leg electrode	
Wilson's precordial leads	V1	**refer to the picture below**	placed to the right of the sternum in the fourth (IV) intercostal space
	V2		placed to the left of the sternum in the fourth (IV) intercostal space
	V3		placed directly between leads V2 and V4
	V4		placed to the left of the sternum in the fifth intercostal (V) space in the midclavicular line (even if the apex beat is displaced)
	V5		placed to the left of the sternum in the fifth (V) intercostal space, horizontally with V4 in the anterior axillary line
	V6		placed to the left of the sternum in the fifth (V) intercostal space, horizontally with V4 and V5 in the midaxillary line



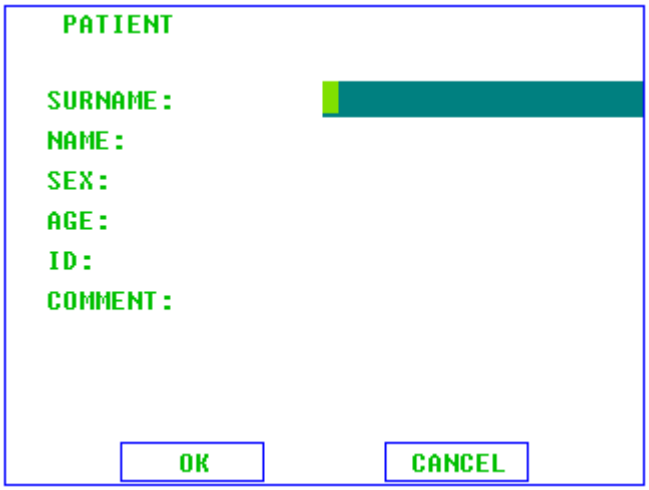
The appliance constantly monitors the connection status of all the electrodes. In case the electrode does not adhere the skin the diagram is shown in red color in the referring channel. In order to get the proper signals from precordial leads it is vital the limb ones are connected properly. That's why it is recommended to connect limb leads as first.

Entering personal information of the patient

The appliance allows to add the patient's personal information to his examination data. To add new information first press MENU then pick 'PATIENT'. Confirm the selection with Enter. Continuing pick one of the following options:

NEW	To add a new patient
CURRENT	To edit the information about the current patient
STORED	To recall patient's data stored in electrocardiograph's memory

Entering/Editing form screen



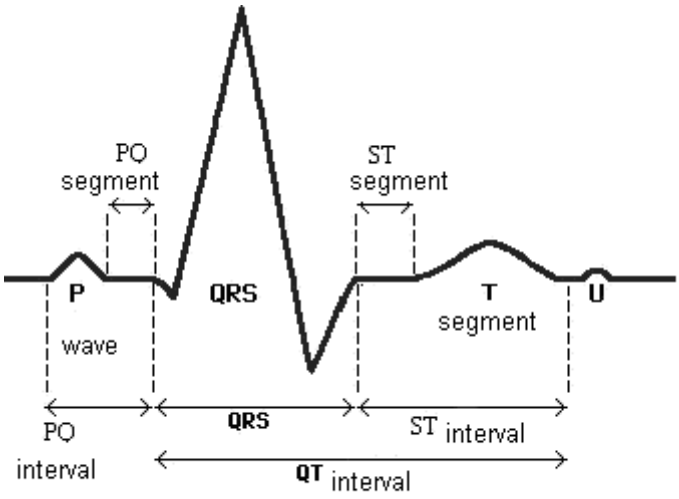
Use arrow buttons to navigate between the particular information to be edited. The chosen field is enlighten. Confirm entered data with OK or CANCEL if you want to reject any changes.

Examination in automatic mode

Automatic mode examination consists in the full 12-lead electrocardiogram recording. All 12 lead signals are being recorded in one 10 second time block. Afterwards device automatically makes analysis including time and amplitude measurements of P-QRS-T complex, determining the electrical axis of the heart and the rhythm analysis. Full report printout includes the real ECG waveform, averaged P-QRS-T complex with particular marked waves, conclusions of the measurements and calculations, text ECG interpretation and the data of the patient. To get proper results in the interpretation it is neccessary to input sex and age of the patient. Otherwise the analysis will set the patient as male 35 years old.
Each time the interpretation of ECG signals needs to be validated by a doctor.

The auto mode examination can be initialized by pressing AUTO. Before it, operator can determine the printout format. After examination the data can be either printed out or stored in electrocardiograph's internal memory. The capacity of the memory is up to 100 of complete ECG examinations.

Schematic representation of normal ECG



Part of RR	Action	Duration
P wave	Depolarization of atrial muscle	100ms
PQ segment	Depolarization of atrioventricular node and atrioventricular bundle	50ms
PQ interval	Conducting depolarization from sinoatrial node to ventricles' muscle	150ms
QRS Complex	Depolarization of the ventricles' muscle	90ms
ST segment	Slow repolarization of the ventricles' muscle	120ms
T wave	Fast repolarization of the ventricles' muscle	120ms
ST interval	Slow and fast repolarization of the ventricles' muscle	280ms
QT interval	Action potential of ventricles' muscle	370ms
U wave	Visible in 50-75% of ECGs	
RR interval	One full heart's electric cycle	800ms

The format of printout of automatic examination can be configured in the MENU: REPORT sub-section of the SETTINGS section.

Examination in manual mode

This mode enables users to choose how many lead signals (3, 6 or 12) will be recorded at the same real time. That mode allows to switch between lead groups, change amount of recorded channels, sensitivity and the speed of the recording process during the examination. It is also available to activate or deactivate additional ECG signals interferences filters. Every change is indicated on the printout instantly.

The manual mode examination can be initialized by pressing START and runs till it is stopped by pressing STOP.

Making the copy of examination

It is possible to print the copy of automatic mode examination. It can be made by pressing MENU followed by picking 'COPY' option and confirming it with Enter. Afterwards there are the following options to be chosen:

PRINT	To print the last examination copy
MEMORY	To recall patient's data stored in electrocardiograph's memory
PENDRIVE	To save data on the external storage device

After MEMORY-RECALL option is taken please pick up the patient from the list and then choose his particular examination. As confirmed, it will be followed by starting the printing. Just before the printing it is necessary to pick the destination:

THERMAL	To print on the internal thermal printer
PRINTER	To print on the external A4 USB printer

Before using the 'PENDRIVE' option please make sure if the proper device is connected to the electrocardiograph's USB socket. If so, use the function, pick the patient from the list, his particular examination and after confirming it provide the file name under which it will be saved. In case the file with the same name already exists, it will be overwritten by the new file. The data is stored in accordance with the EN1064:2000 standard.

Managing the memory

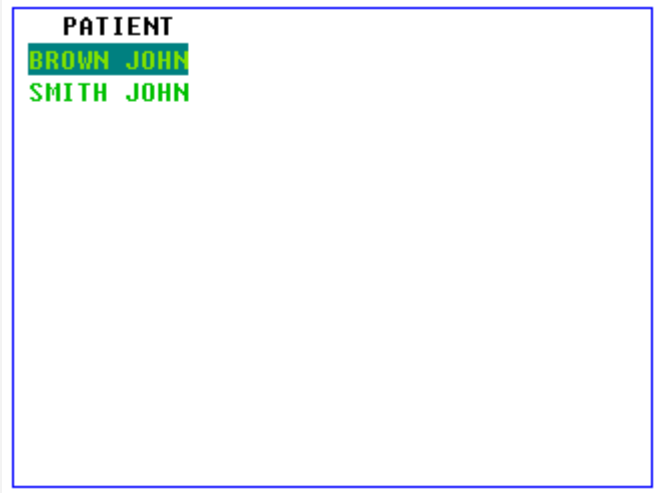
Electrocardiograph is equipped with an internal memory. Its capacity is up to 100 of complete ECG examinations. Storing to the memory is available on two cases – the patient's area or the ECG examination area.

Action	**How**
Saving the patient's data	Press MENU then pick PATIENT → MEMORY → SAVE. While saving the copy of an examination, the patient's personal information is being stored automatically.
Deleting the patient's data	Press MENU then pick PATIENT → MEMORY → DELETE. Afterwards pick the particular patient from the list and confirm the choice with Enter. With removing the patient from the memory, all his stored examinations are being deleted too. Caution! – This operation cannot be undone!
Saving the examination	The copy of the examination can be saved after the automatic mode recording is done. First press MENU then pick COPY → MEMORY → SAVE. If there is no previous data of the current patient stored in the memory, it will be stored now. Otherwise the current record will be added to his existing, previously

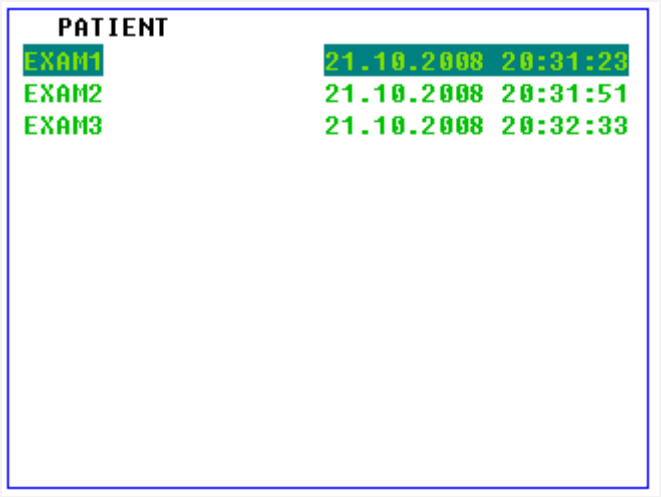
stored data. The patient can be identified by his surname, name and the ID assigned during the first data storing. The particular stored examination can be determined by its date and time.

Deleting the examination

Press MENU then pick COPY → MEMORY → DELETE. The screen should look like this:



With the arrow keys [←] [↑] [↓] [→] mark the particular patient on the list and pick him pressing Enter. Afterwards, the screen should look like this:

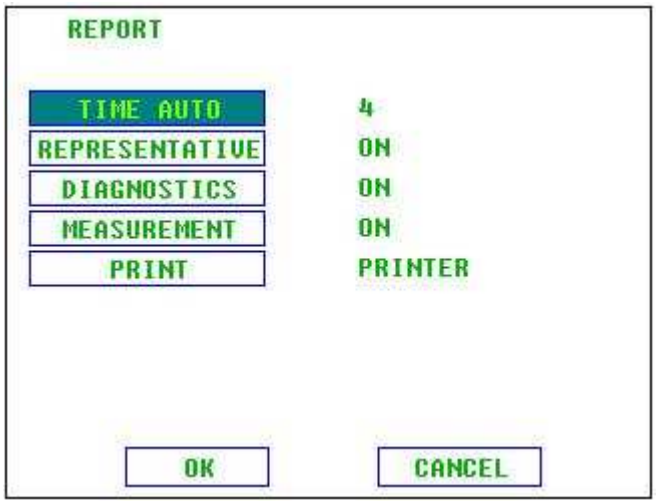


Now, chose from the appeared list the examination to be deleted and confirm with Enter.
Caution! – The chosen examination is permanently deleted and cannot be undone!

Configuration

The settings of M-TRACE Electrocardiograph configuration are adjustable in wide range. They can be set according the user's actual needs. Turning the appliance on brings the default initial settings and not adjustable – during the normal using – parameters (e.g. clock time, date, language).

To enter the configuration setup press MENU and then pick SETTINGS option.
To configure the automatic examination's report use REPORT option.
The REPORT configuration screen will look like this:

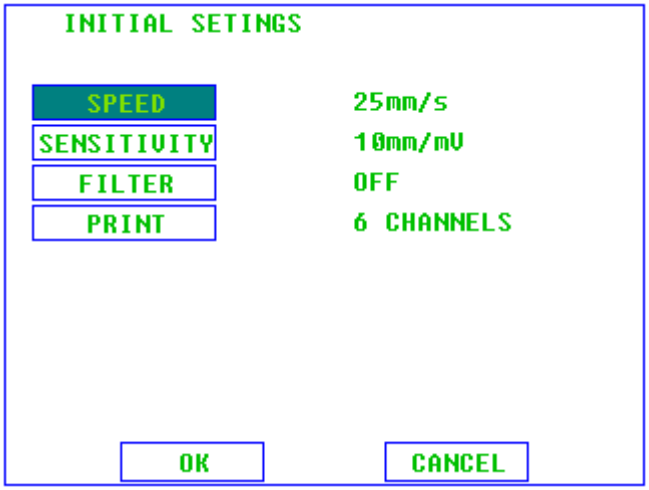


The following options available in the section

Option	Description
TIME AUTO	The duration of ECG examination in automatic mode
REPRESENTATIVE	The most characteristic representative of P-QRS-T will be shown
DIAGNOSTICS	Text description of examination of electrocardiogram will be shown
MEASUREMENT	All time and amplitude measurements of the representative will be shown
PRINT	Sets the printout target. Available are: – Roll – thermal paper – USB – external printer connected to the USB port

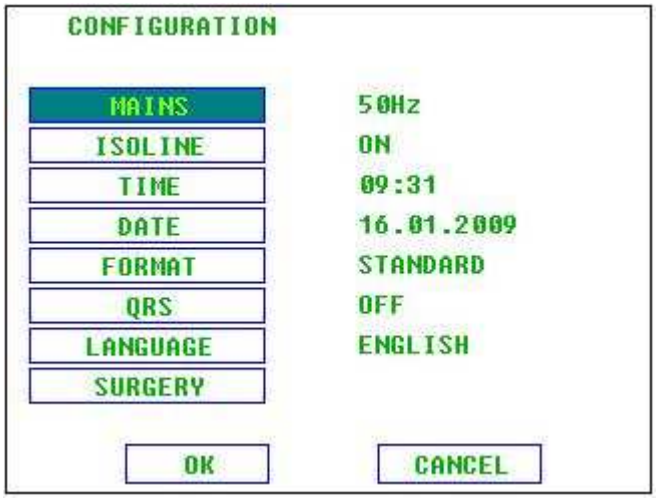
To configure the initial settings use INITIAL SETTINGS option. Initial settings can be easily changed during normal using with the navigation keys. The set presets will always appear after each turning on the device.

The INITIAL SETTINGS configuration screen should look like this:



Using the arrow keys [←] [↑] [↓] [→] mark the parameter to be changed and pick it pressing Enter. The available values for it will be shown. Accept the choice with Enter. When configuration is finished, confirm it with OK or reject any made changes with CANCEL. The rest of the parameters can be set in CONFIGURATION.

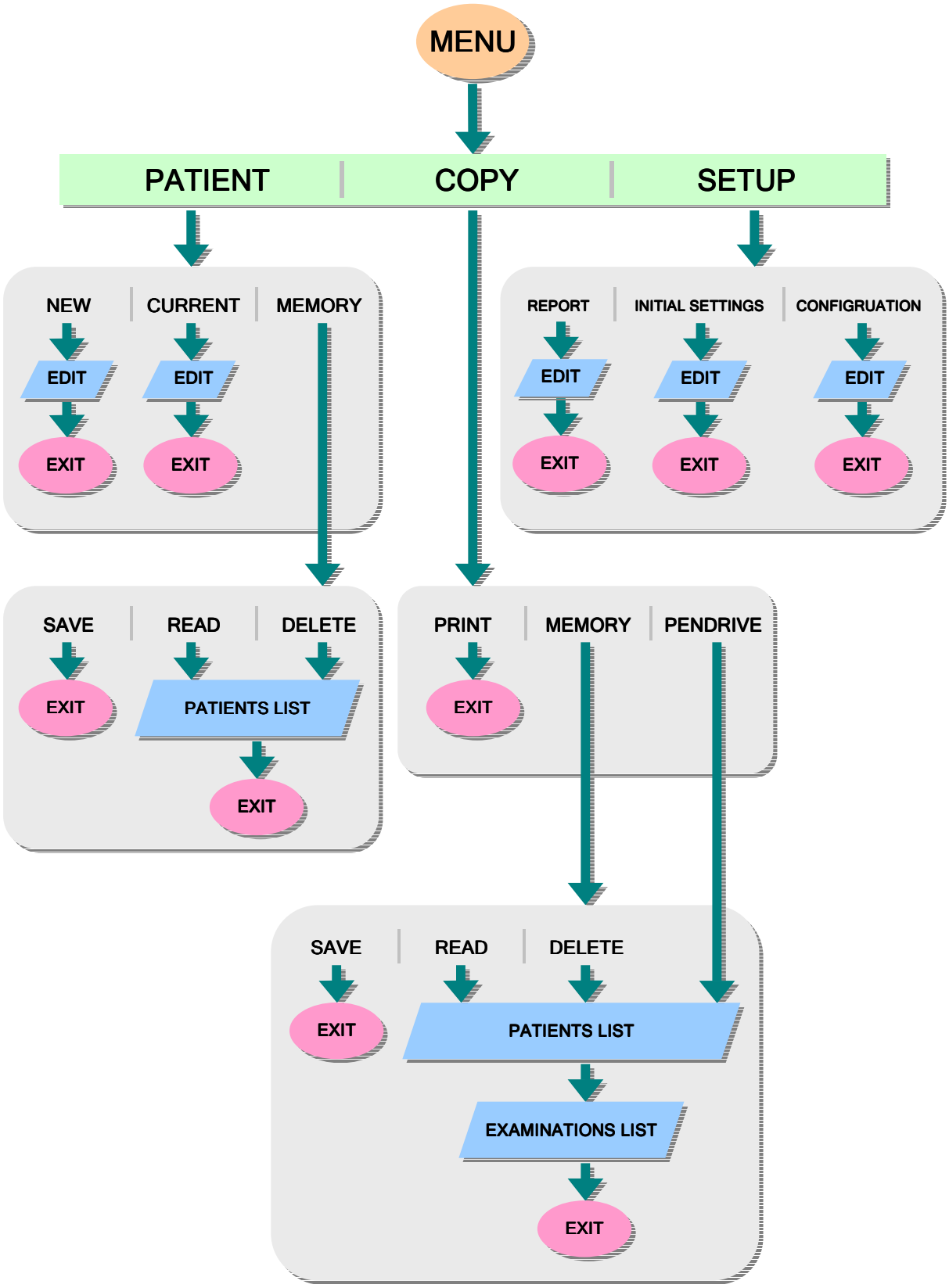
The look of the suitable screen is like this:



Managing the advanced settings is similar to the presets configuration.
The list of available options in the advanced settings section:

Option	Description
MAINS	Sets the frequency of the mains – 50Hz or 60Hz
ISOLINE	Activates or deactivates the antidrift filter
TIME	Sets the real time clock
DATE	Sets the date
FORMAT	Sets the printout format. Available are: – Standard format – Cabrera format
QRS	Sound indication of the QRS complex detection
LANGUAGE	Sets the interface language
SURGERY	Allows to put the name of the consultation's office

Menu navigation map



Cleaning, concurrent disinfection, maintenance

Caution! – Before any cleaning or maintenance unplug the appliance from the wall power outlet!
Do not use any abrasive cloths, thinners, alcohol, spray or other chemical solvents. Use only a soft clean cloth – dry or slightly dampened with clean water. It is recommended to do cleaning at least once per month. Upon the heavy-duty usage the cleaning should be done more frequently.
All the electrodes should be disinfected after each examination. They need to be subjected to the deproteinization process with a designated liquid, e.g. Sekusept Pulver 2% + activator 0,5%. The electrodes should remain in this bath for at least 30 minutes. Afterwards they need to be washed and dried.

Operating and transport environmental conditions

Operating Environmental Conditions

Surrounding Temperature	+ 10 to + +40˚C (+50 to +104˚F)
Relative Humidity	25 to 95% (non-condensing)
Atmospheric pressure	70 to 106 kPa

Transport and Storage Environmental Conditions

Surrounding Temperature	- 20 to + 60˚C (-4˚F to +140˚F)
Relative Humidity	25 to 95% (non-condensing)
Atmospheric pressure	70 to 106 kPa

In every condition the surrounding air should be free from corrosive pollutions.

On user's request the producer can provide the qualified servicing personnel with all the necessary information required to maintain correct repairs and adjusting.

Manufacturer's Declaration of Conformity for The Electromagnetic Compatibility

Electromagnetic emission tests

Tests	Conformity	Electromagnetic environment
CISPR 11 RF Disturbance	Group 1	M-TRACE Electrocardiograph is the equipment in which there is intentionally generated or used conductively coupled RF energy that is necessary for the internal functioning of the equipment itself.
CISPR 11 RF Disturbance	Class A	In household rooms the device can be the source of radio distortions. In such case please take appropriate actions.
IEC 61000-3-2 Harmonic Distortion	n.a.	
IEC 61000-3-3 Voltage Fluctuation and Flicker	n.a.	

Electromagnetic immunity tests

Tests	IEC 60601 Test level	Compatibility level	Electromagnetic Environment
IEC 61000-4-2 Electrostatic Discharge	6kV – Contact Discharge Mode 8kV – Air Discharge Mode		The floor should be wood, concrete, or glazed. If there's an synthetic lining the relative humidity should be at least 30%
IEC 61000-4-4 Electrical Fast Transients	2kV – AC and DC power lines 1kV – I/O lines		Typical hospital or commercial environment
IEC 61000-4-5 Surges	1kV – Line to Line 2kV – Line to Ground		Typical hospital or commercial environment
IEC 61000-4-11 Voltage Dips, Short Interruptions and Voltage Variations	**Voltage test level %Ut**	**Voltage dip %Ut**	**Duration**
	< 5	> 95	0,5 periods
	40	60	5 periods
	70	30	25 periods
	< 5	> 95	5 seconds

IEC 61000-4-8 Power Frequency Magnetic Fields	3A/m		Typical hospital or commercial establishments
IEC 61000-4-6 Conducted Disturbances	3Vrms 150kHz to 80MHz	3V/m	Mobile devices
IEC 61000-4-3 Radiated RF Electromagnetic Fields	3Vrms 80MHz to 2,5GHz	3V/m	

Declaration of Conformity
Deklaracja Zgodności

Manufacturer:
Producent:

M4Medical Sp. z o.o.
ul. Ogrodowa 10/7
20-075 Lublin, Poland

We declare under our sole responsibility that
Deklarujemy na naszą własną odpowiedzialność

the medical device:
medyczne urządzenie:

Electrocardiograph
Elektrokardiograf

models:
model:

M-TRACE

of class:
klasyfikacja:

IIa, Rule X

covered by the Technical Files rev. 1.00, dated 04.02.2009.
spełnione w Technical Files

meets all provisions of the directive 93/42/EEC which apply to it.
spełniają wszystkie regulacje dyrektywy 93/42/EEC, które mają zastosowanie.

Conformity assessment procedure:
Zgodność według procedury:

Annex II.3 of 93/42/EEC directive

Notified Body:

TÜV Rheinland Product Safety GmbH
Certification Office
Am Grauen Stein
51105 Cologne

CE 0197

Lublin; 08.02.2009

Company's Representative

M4MEDICAL sp. z o.o.
prezes zarządu
mgr inż. Dariusz Miszczak