INSTRUCTIONS FOR USE

EN

English

FLASHLIGHT

FLASHLIGHT
Rest ECG System for PADSY

from Version 3.5b

CE 0124

medset MEDIZINTECHNIK We have sound ideas.

designed for PADSY

General Information

Note:

This user's manual contains essential safety information in addition to information on the operation, care and maintenance of your FLASHLIGHT Rest ECG system for PADSY. The safety information must be read and fully understood before installation and start up. Only in this manner will the safety of patients and staff be guaranteed. This user's manual must always be kept with the equipment and accessible to all users.

Due to continual development, equipment specifications and graphics are subject to change without notice.

The following pictograms are used:

!	**Safety notes,** non-compliance with which represents a danger to patients, operators or the equipment and visually emphasized by the adjacent graphic symbol.
	Attention, **Refer to the User's Manual**
	Defibrillation protected **applied part type BF.**

General Information

GBA 13.00.002-06
Instructions for Use
FLASHLIGHT Rest ECG system for PADSY Rest ECG from version 3.5b
Version 6
Modified 01/2006

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General Information

The FLASHLIGHT-Rest ECG System for the Patient Diagnostic System PADSY bears the CE mark

CE 0124

according to Directive 93/42/EEC of the Council with respect to medical products, and complies with the fundamental requirements of Annex I of this Directive.

The CE mark includes only those parts listed in the section "Accessories" and in the EC Declaration of Conformity.

Contents

1 Application and Function

1.1 Basic principles

The the ECO and SCOPE versions of the FLASHLIGHT Rest ECG System consists of an ECG sensor module with a serial interface cable, a patient cable, and evaluation software.

The ECG is recorded using a 10-core patient cable attached to the patient's skin, and processed by the ECG-sensor module for transmission to the PC.

The FLASHLIGHT SENSOR Type SE ECG sensor module conveys the surface ECG to a USB port using a PC interface cable.

The ECG-amplifier FLASHLIGHT SENSOR USB transmits the surface ECG through a interface cable to the USB interface of a computer.

The 3, 6, or 12-channels of the ECG signal can be shown on the monitor .

The FLASHLIGHT Rest ECG Software for PADSY is an application of the patient diagnosis system PADSY. FLASHLIGHT cannot be used without the PADSY software. Please refer to the **"PADSY – The Patient Diagnostic System"** user's manual supplied together with the FLASHLIGHT PADSY for all relevant information.

ECO and SCOPE versions of the FLASHLIGHT Rest ECG System:

The ECO and SCOPE versions of the FLASHLIGHT Rest ECG system is used by medical personnel and doctors. It is used for in-patient and out-patient diagnosis and treatment monitoring.

The ECO and SCOPE versions of the FLASHLIGHT Rest ECG system is attached to patients by doctors and medical personnel and is used for recording and evaluation of 12-lead Rest ECG tests.

Once started, the system records a 12-lead superficial ECG of the patient through the patient cable and electrodes for a period of up to 180 seconds and saves the data.

The saved ECG is immediately made available to the doctor for interpretation, evaluation, on-monitor viewing, and printing out.

The evaluation software can be run on all standard PCs with a Windows operating system or MACOSX. The results of evaluation can be printed out on a standard Windows printer.

The SCOPE version includes an additional ECG analysis program based on the "HES" system ("The Hannover ECG program system for computer-assisted evaluation of electrocardiograms") with automatic complex formation and ECG measurement. The SCOPE version can also be expanded with the "HES"-interpretation module, which can be used to automatically suggest evaluation hints and diagnostic opinions. These hints and opinions naturally must be verified by the physician and corrected, if necessary.

It is assumed that attending physicians have adequate specialist knowledge to interpret and diagnose ECG results correctly. The patient does not influence the recording.

1.2 Rest ECG Indication

The Rest ECG is an important source of information in cardiac diagnosis. The Rest ECG is used for the clarification of thoracic pain and to diagnose cardiac arrhythmias, lesions in the coronary arteries, and enlargement of the heart muscle.

1.3 Safety

This user's manual forms an integral part of the FLASHLIGHT Rest ECG system, and must therefore be kept in the vicinity of the product at all times. Precise compliance with the user's manual is an essential condition for normal use, correct application, and thus safety of patients and users.

! The FLASHLIGHT Rest ECG system must only be used by personnel who, due to their training, knowledge and practical experience, are inclined to use the system correctly.

! The FLASHLIGHT Rest ECG system **user's manual** must be kept in the vicinity of the system at all times for reference purposes. They are an integral part of the system. Precise compliance with the user's manual is an essential condition for correct application, use, and guarantees the safety of patients and users.

! The FLASHLIGHT Rest ECG system is a type BF appliance, with increased voltage spike protection. **It is not intended for direct application to the heart.**

! When a **defibrillator** is used on the patient, all safety precautions for defibrillator use should be complied with.

! The FLASHLIGHT sensor module is a type BF **defibrillation-protected applied unit**.

! All parts of the system, particularly electrodes and leads, may only be applied to **healthy skin** on a patient.

! Please note that the conductive sections of the electrode cables must not be allowed to contact any electrical equipment, electrical sockets, conductive, or grounded objects. Check that the electrodes are safely separated from all electrical devices and sockets before the patient is connected to the recorder via the electrode cables.

! When electrodes are applied, **RF equipment,** e.g. electrosurgical equipment, must not be operated. There is an elevated risk of localized burns to the patient.

! Patient safety, maintenance of equipment function and optimum interference immunity are ensured exclusively with original Medset accessories or with the accessories and consumables recommended by Medset. Medset cannot guarantee the safe and accurate operation of equipment used with different accessories and consumables.

! Only use **accessories** that are listed in this user's manual, because they have been tested in conjunction with the equipment. If non-Medset accessories are used, Medset cannot guarantee their safe operation and function.

! No **claims under warranty** can be validated for damage resulting from the use of non-Medset accessories and consumables.

! **Software programs** can conflict with one another. Where it is not absolutely beyond doubt from the documents supplied with the program that such conflicts are not possible, the user must avoid such conflicts by, for example, consulting the manufacturers concerned or an expert.

! The **software** for **the SCOPE** version includes the measurement function and automatic interpretation of the ECG according to "HES". This can lead to false readings for measurements and incorrect interpretation by the analytical software. For this reason, the attending physician must perform a quality check to validate the results.

! Medset Medizintechnik accepts responsibility for its products in respect of their safety, reliability and function only when the **products are used according to the instructions outlined in this user's manual**.

! Disposal of the equipment and accessories at the end of its life must be performed according to local electronics disposal regulations, or by sending the old equipment to Medset at the customer's cost, where Medset will dispose of the equipment appropriately.

! Liquids must never penetrate the interior of electrical equipment. If liquid has entered the recorder, it must be returned to Medset customer service for testing before it is used again.

! Dispose of packaging material appropriately. Ensure that it is out of reach of children.

! The user is responsible to ensure that, before each use, the functional safety and operating condition of the equipment is checked.

! These products are not intended for operation in explosion hazard designated areas (resulting from anaesthetic, skin cleaning or disinfectant substances) or in areas with flame promoting atmospheres (as a result of >25% oxygen in the ambient air or nitrous oxide) in rooms used for medical purposes.

! **Mains operated equipment** must only be connected to grounded socket outlets. Extension cords and multiple socket outlets must not be used with medical equipment.

! Before connecting the equipment, it must be ensured that the **mains voltage and frequency** correspond to the specifications on the nameplates fitted to all mains operated equipment.

! Mains connections and cables must be checked before connection. **Damaged cables** represent an extreme danger to all persons who knowingly or unknowingly come into contact with them. They also endanger the electronic circuitry of the connected equipment . Damaged cables and mains connections must therefore no longer be used for the operation of electrical equipment, They must be returned to Medset for exchange

! Disconnect the equipment from the mains supply before removing the connecting cables from the equipment by first removing the plug from the socket outlet. Only then remove the connecting cables from the equipment. Otherwise there is a danger of personal contact with the mains voltage resulting from accidental introduction of metal parts into the sockets of the equipment connecting cables.

! There must be no obstruction to equipment cooling **air circulation**. Air vents must remain open. Compliance is required with the stated ambient conditions.

! **Magnetic and electrical fields** can influence the recorder function. Ensure that during operation all non-Medset equipment operating in the vicinity complies with the relevant EMC requirements. X-ray equipment, tomographs etc. can cause interference in other equipment as a result of their authorized higher emission of electromagnetic interference.

! Equipment shall be interconnected or connected to parts of systems only when it is ensured that the safety of patients, personnel and the environment is not endangered by this connection. Where safe **connection** is not directly indicated in the equipment data sheet, the user must ensure, for example by checking with the manufacturers involved or by consulting an expert, that the safety of the patient, personnel and the environment is not endangered by the intended connection. Compliance is required in all cases with the standard IEC 601-1-1/EN 60601-1-1.

! **Coupling of several appliances** can lead to a summation of leakage currents and thereby represents a possible danger to the patient. The ECG signal can be corrupted in this fashion.

! Avoid **pulling on the electrical supply cables.** Electrical supply cables should never be unplugged by pulling on the cable, but by gripping the plug to pull it out of the socket outlet.

! **Mechanical stresses on supply cables** can be further reduced by coiling them loosely and preferably hanging them up.

! If a **non-stationary multiple socket (power bar)** is used, connection of equipment may only be possible with the help of tools or the non-stationary multiple socket (power bar) has to be supplied by an isolating transformer.

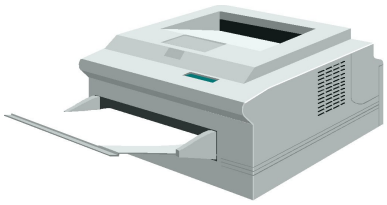
The norm DIN EN 60601-1-1 should be observed.

! If the system is connected via an **isolating transformer**, all other parts of the system must also be operated via this transformer, otherwise the electrical isolation will be ineffective.

2 System Elements and Components

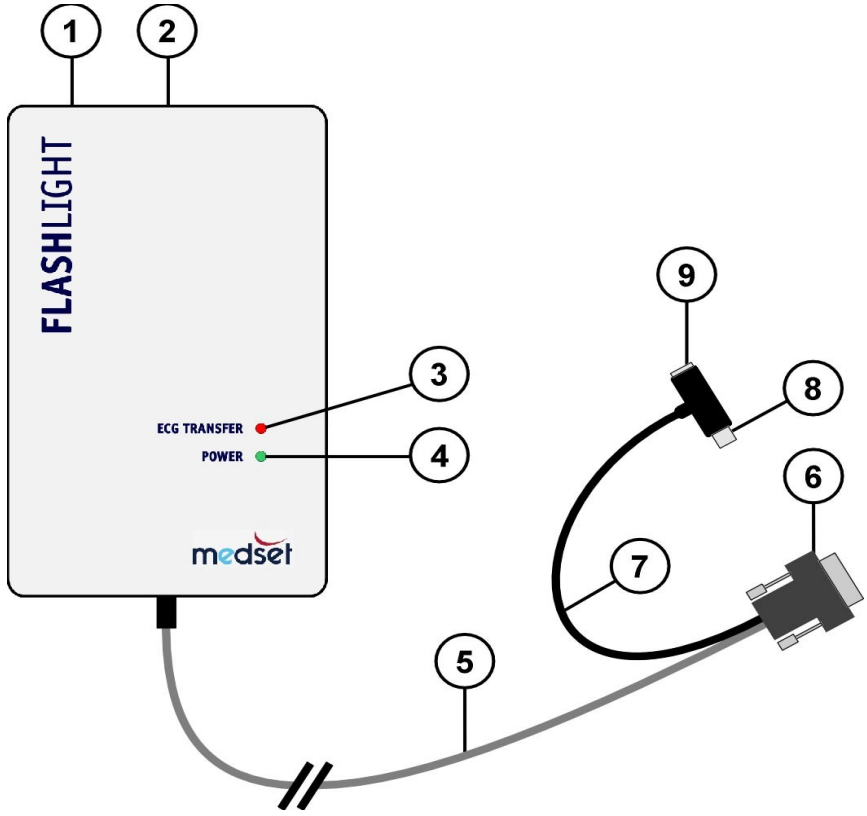
2.1 PC with peripherals

PC with monitor, keyboard and mouse



Printer

2.2 Sensor with PC interface cable



1. Rest ECG sensor FLASHLIGHT SENSOR Type SE or Type USB

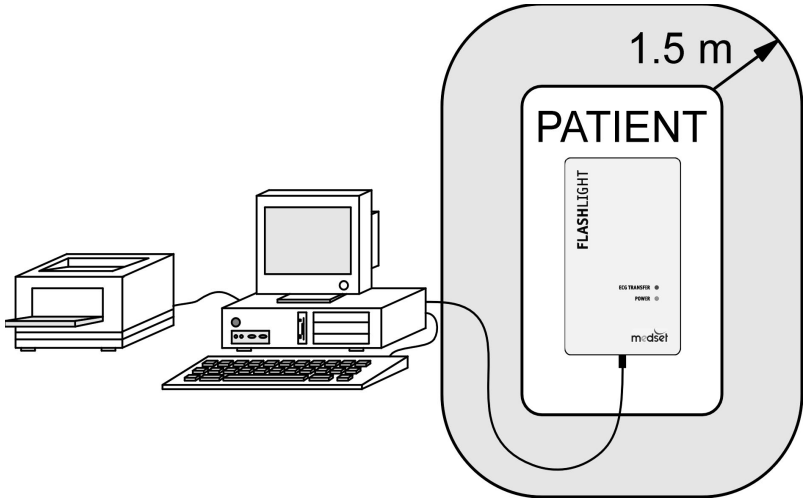
2. Socket for patient cable
   There is a Sub-D socket at the top of the unit for connecting a 10-pole patient cable with a Sub-D plug.
3. ECG transfer indicator(ECG TRANSFER)
   The red LED lights up when ECG data is transferred via the PC interface cable (5).
4. Status indication (POWER)
   The green LED lights up when the Rest ECG sensor is supplied with power from the PS/2 adapter (7).
5. PC interface cable
   The PC interface cable is used to transfer ECG data to the PC and is hard wired to the sensor.
6. PC interface cable plug
   Type SE: The 9-pole plug connects to a RS232 interface (COM 1 to 4) on the PC.
   Type USB: The USB plug connects to a USP port. The sensor is then powered by the USB port. Components 7, 8, and 9 are not present on the Type USB sensor.
7. PS/2 adapter (Type SE)
   The FLASHLIGHT sensor is supplied with power from the PS/2 adapter.
8. PS/2 plug (Type SE)
   The PS2 plug of the adapter (7) is connected to the PS/2 socket (keyboard connection) of the PC.
9. PS/2 socket (Type SE)
   The PS/2 plug of the keyboard is inserted into the PS/2 socket of the adapter (7).

2.3 Bringing Equipment into use

PC, monitor and printer required for the FLASHLIGHT PADSY application are classified as office equipment under IEC 950. The regulations contained in IEC 950 (manufacturing requirements for office equipment) do not meet the higher safety requirements for electromedical equipment.

To ensure safe operation of equipment that draws its power from the building supply, a ground fault detection and disconnect system has been incorporated into the ECG sensor module, because according to IEC 950 a ground leakage current and a chassis leakage current in the event of an initial fault of >0,5 mA is permitted.

! Following **DIN EN 60601-1**, all types of Recorder Opto Interface Cables have been designed so that they can be operated fully isolated and with complete electrical decoupling from the PC. This measure, in conjunction with the following method of installation (see illustration below), allows PC-supported online monitoring of the ECG signal from the patient in rooms used for medical purposes.



PC, monitor and printer must be installed so as to maintain a minimum distance of 1.5 m from the patient.

If the ECG sensor module with the PC interface cable is operated **solely** within the patient environment, and a distance to the patient is maintained of at least 1.5 m to the PC or to other office equipment connected to it, no further measures are necessary to ensure the safety of the patient.

If it is not possible to comply with the distance of 1.5 m between patient and office equipment, acceptable measures for reducing the case leakage current are required.

These measures include:

- additional grounding conductor connecting parts, or
- an isolating transformer with safe electrical isolation, or
- equipotential bonding, or
- an additional non-conductive case.

All these measures should be carried out strictly according to the regulations of DIN EN 60601-1 and DIN EN 60601-1-1.

2.4 Connection of the FLASHLIGHT SENSOR

The Type SE sensor should be connected to the PC as follows:

! The Rest ECG sensor FLASHLIGHT SENSOR Type SE may only be installed with the **PC switched off**.

1. Remove the keyboard connection plug.
2. Now plug in the Rest ECG sensor power supply by inserting the plug of the PS/2 adapter into the keyboard socket of the PC. If necessary, use the adapter components for the connection.
3. Insert the keyboard plug into the socket of the PS/2 adapter.
4. Connect the 9-pole plug of the PC interface cable to a vacant serial interface (COM port) on the PC. ECG data is transferred to the PC via this connection and can be displayed with the FLASHLIGHT ECO and SCOPE software.
5. Connect the patient cable to the Sub-D socket of the FLASHLIGHT sensor located at the top of the equipment.

The Type USB sensor may be connected as follows:

Connect the USB plug to a vacant USB port on the computer. If the Type USB drivers have not been installed yet, the „new hardware found“ message will be displayed. Clicking on this message opens the New Hardware assistant that will perform the driver installation. Follow the assistants instructions.

The required drivers are found in the installation CD in the \Windows\Flashlight Sensor USB directory.

! The Type SE and Type USB FLASHLIGHT SENSOR Rest ECG sensors have integral defibrillation protection. The **patient cable** therefore does not need to be provided with additional defibrillation protection.

2.5 Installation of the FLASHLIGHT Rest ECG Software

The PC ECG software is an application of the PADSY Patient Diagnostic System. For this reason, carry out the installation according to the **"PADSY - The Patient Diagnostic System"** user's manual.

After the license file has been installed, the FLASHLIGHT Rest ECG software is ready to operate. The license file allows the applications ordered and listed on the delivery note to be operated.

2.6 Hardware installation

Once the software has been successfully installed, the FLASHLIGHT sensor and optionally a blood pressure monitor must be installed. This installation is described in the „PADSY- The Patient Diagnostic System“ user's manual, in the „Installation of Hardware Components“ section.

Before the completion of the installation, set the serial port for the device. This setting must only be made once, as long as the device is always connected to the same serial port.

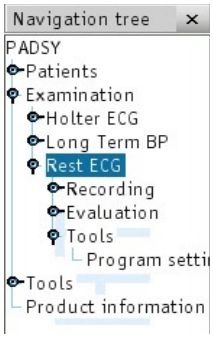
2.7 Starting FLASHLIGHT Rest ECG

Using The FLASHLIGHT Rest ECG Software displays the recorded ECG signals on the screen in real time. To prevent any display delays occurring, ensure before starting the software that

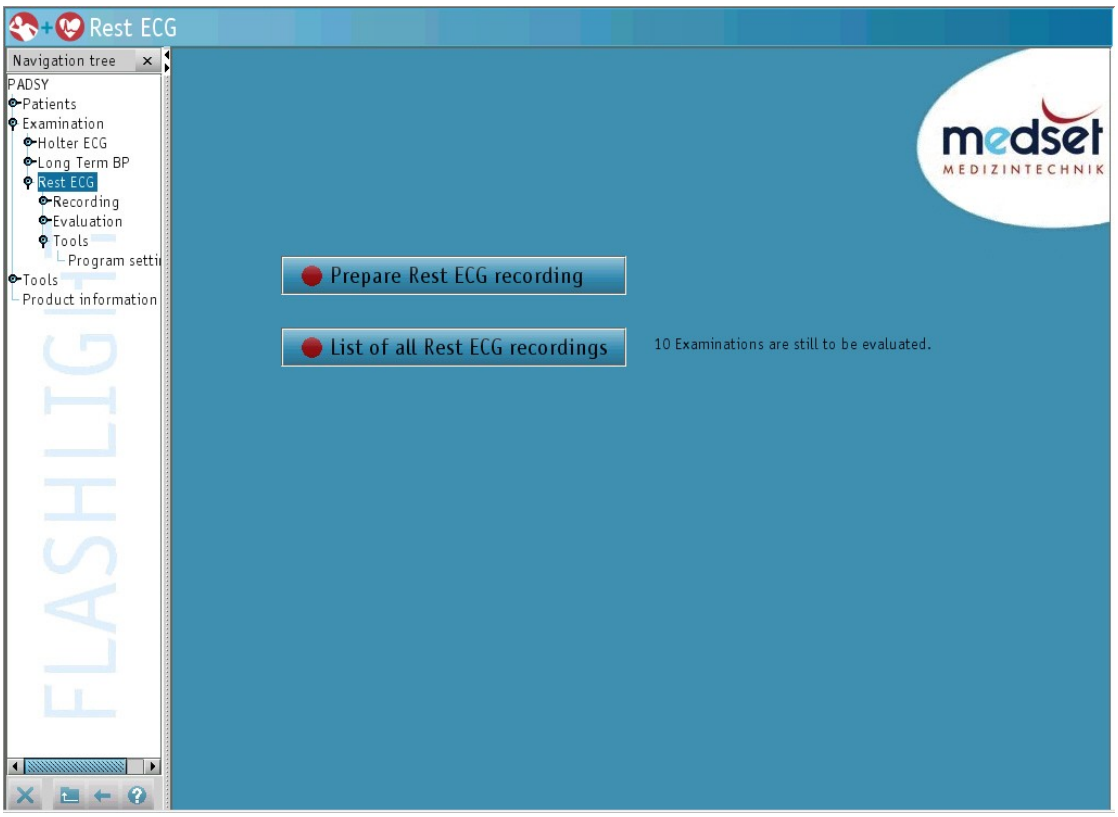
- no other Windows application is activated on your PC in addition to the practice DP system.
- no screen saver has been set up under Windows display options.

The FLASHLIGHT Rest ECG application can only be started under PADSY. Perform the following steps:

1. Start PADSY as described in the "PADSY - The Patient Diagnostic System" user's manual.
2. Select the navigation tree "Examination" and then "Rest ECG"



The following screen appears:

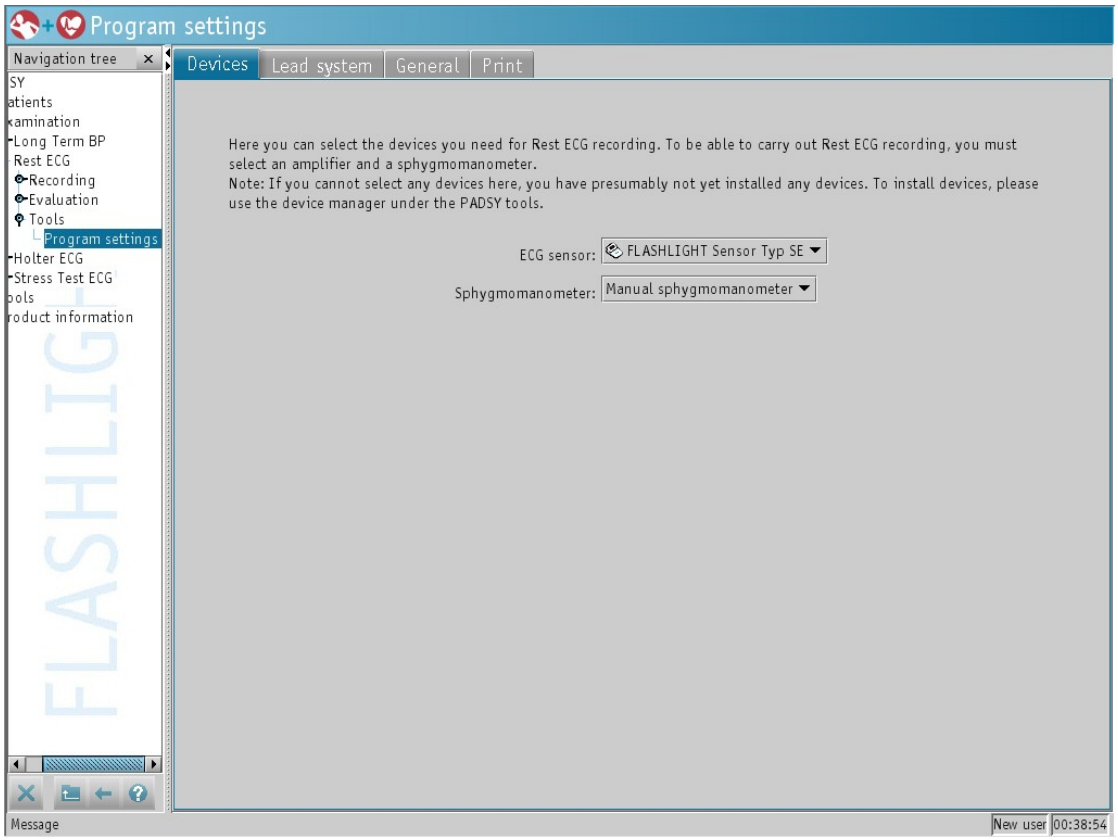


From this screen, the "**Recording**" window may be opened by clicking on "**Prepare Rest ECG recording**" or the "**Evaluation**" window may be opened by clicking on "**List of all Rest ECG recordings**".

2.8 Configuration of Rest ECG settings

Once the software has been installed, please continue with the configuration of the settings Rest ECG settings.

Select the **"Program settings"** bullet in the navigation tree from the Rest ECG **"Tools"** window. The following window appears in the "**Devices**" register:



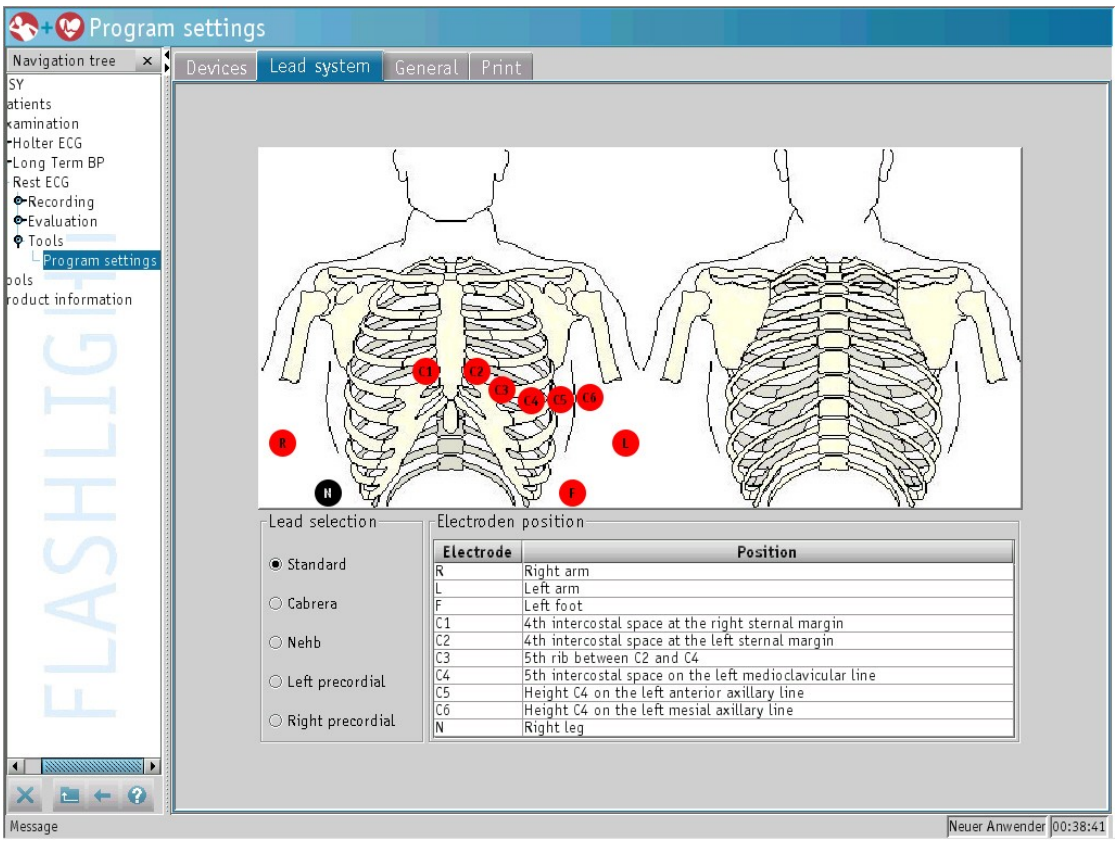
This window allows the equipment required for recording the Rest ECG to be selected. It is necessary to select an sensor and a blood pressure monitoring device.

A drop-down menu is available for the ECG sensor and the blood pressure monitoring device, from which already installed devices can be selected.

If no equipment appears in this menu, then no equipment has been installed. In order to install equipment, use the device manager under PADSY tools, which is the second to the last bullet in the PADSY navigation tree. Follow the instructions in the "PADSY – The Patient Diagnostic System" user's manual.

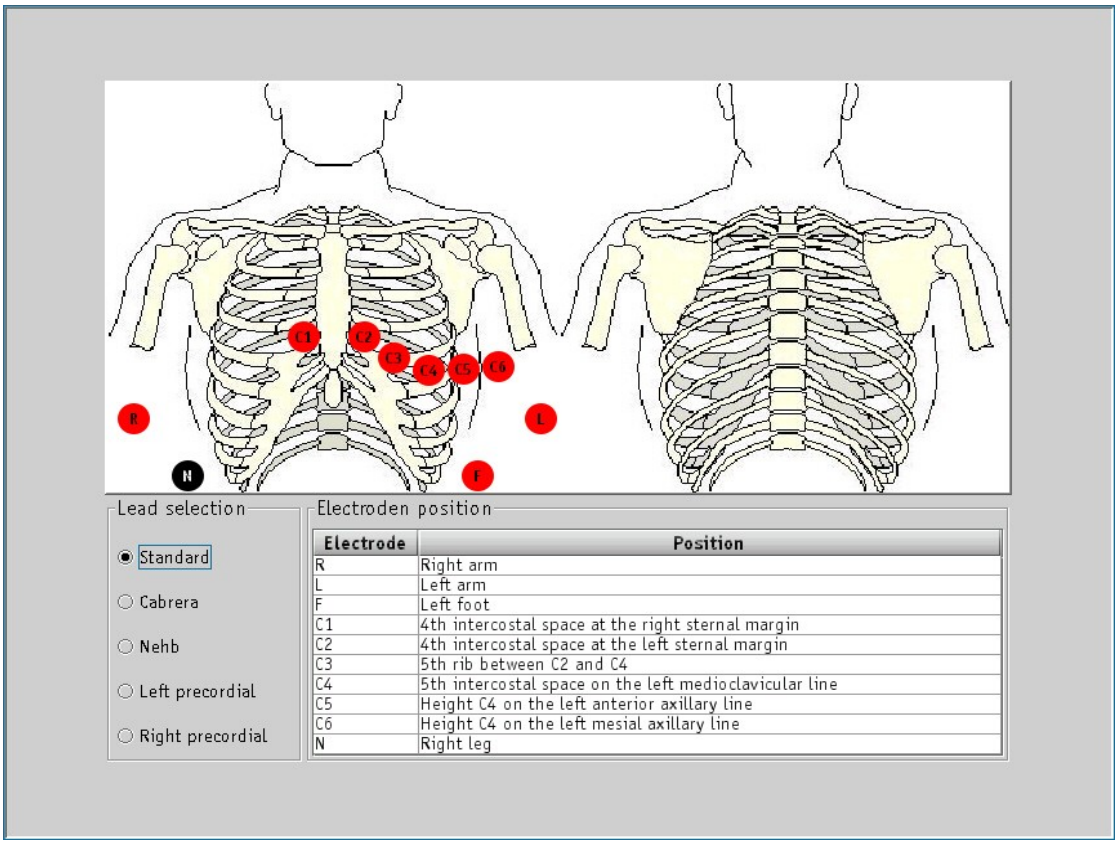
2.8.1 Lead system

The following window is displayed:

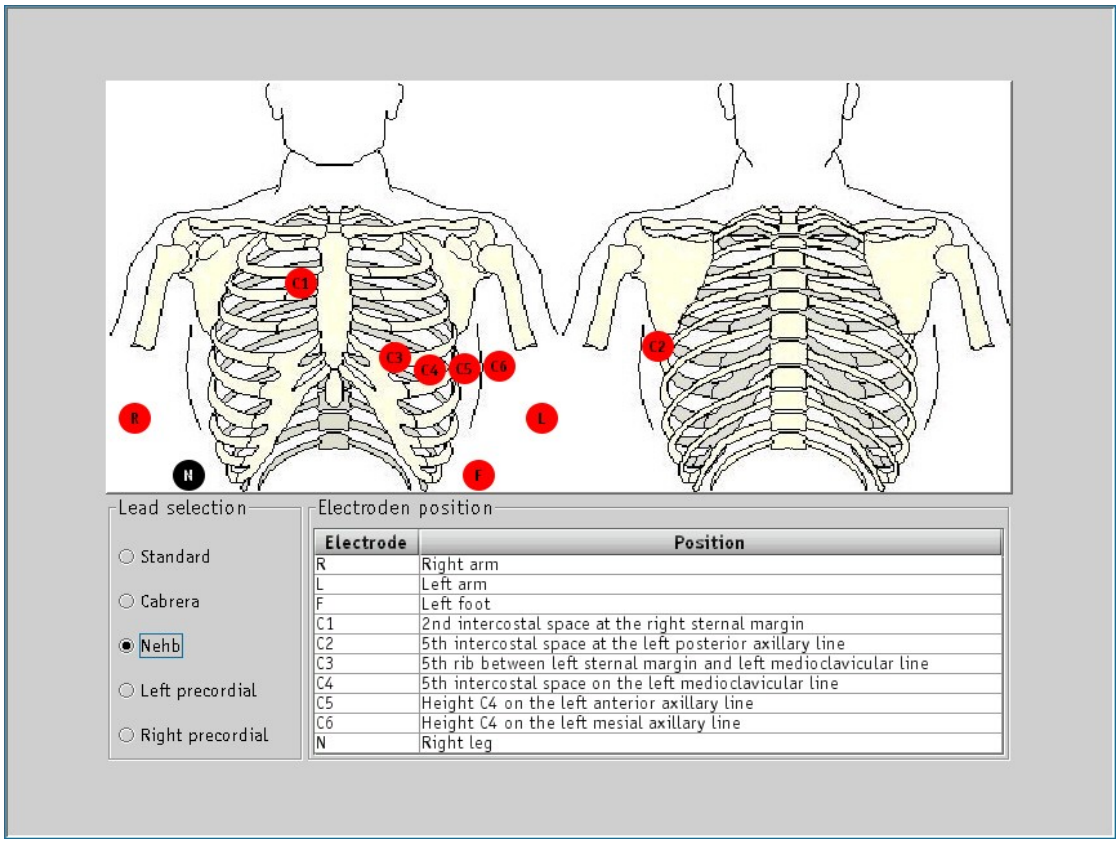


In the **"Lead selection"** field, select the desired lead system by clicking in the check box in front of the respective designation.

Standard and Cabrera



Nehb



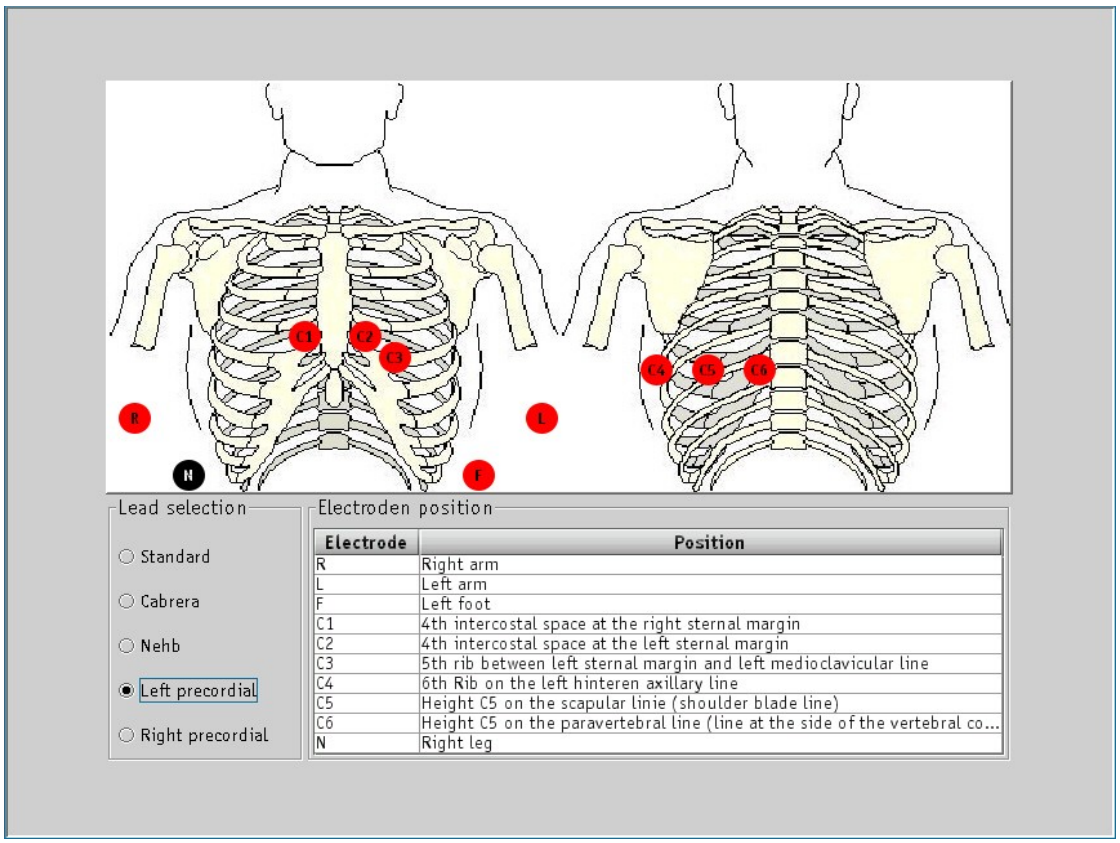
Lead selection

- Standard
- Cabrera
- (•) Nehb
- Left precordial
- Right precordial

Electroden position

Electrode	Position
R	Right arm
L	Left arm
F	Left foot
C1	2nd intercostal space at the right sternal margin
C2	5th intercostal space at the left posterior axillary line
C3	5th rib between left sternal margin and left medioclavicular line
C4	5th intercostal space on the left medioclavicular line
C5	Height C4 on the left anterior axillary line
C6	Height C4 on the left mesial axillary line
N	Right leg

Left precordial



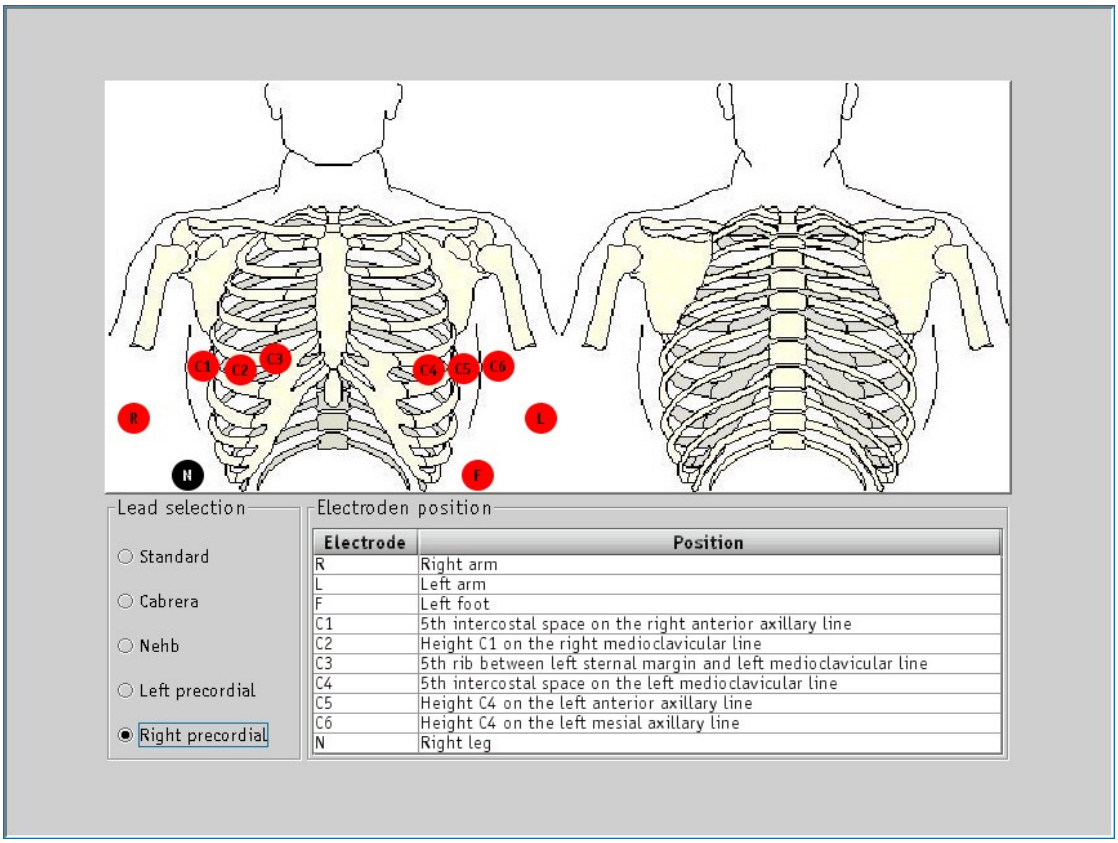
Lead selection

- Standard
- Cabrera
- Nehb
- (•) Left precordial
- Right precordial

Electroden position

Electrode	Position
R	Right arm
L	Left arm
F	Left foot
C1	4th intercostal space at the right sternal margin
C2	4th intercostal space at the left sternal margin
C3	5th rib between left sternal margin and left medioclavicular line
C4	6th Rib on the left hinteren axillary line
C5	Height C5 on the scapular linie (shoulder blade line)
C6	Height C5 on the paravertebral line (line at the side of the vertebral co...
N	Right leg

Right precordial

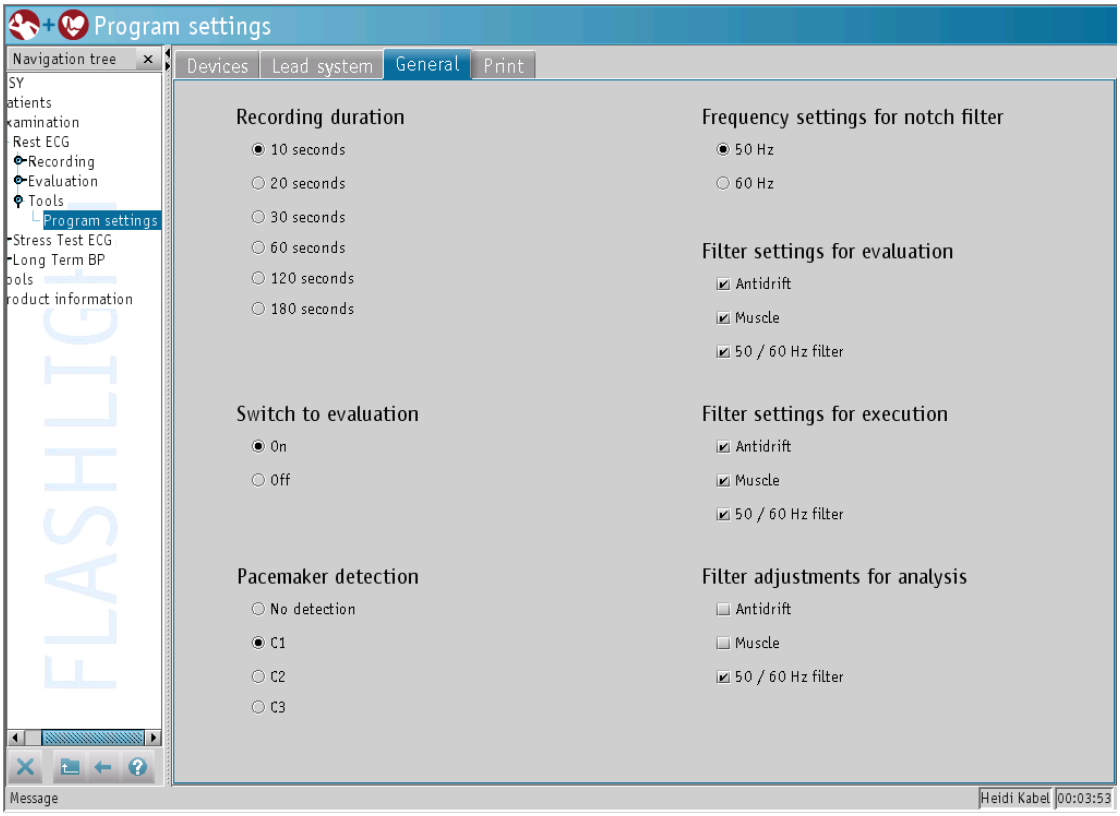


User defined

The electrode system for the **"User defined"** lead system corresponds to the standard electrode system.

2.8.2 General

The following display appears under the "**General**" tab:



In this display, the settings that are preselected for performing and evaluating a Rest ECG can be defined.

A recording time of 10, 20, 30, 60 and 180 seconds can be selected by clicking on the appropriate check boxes. Furthermore, it can be selected whether or not to switch directly into evaluation after the Rest ECG has been recorded. For this purpose, select **"on"** or **"off"** by clicking the respective button.

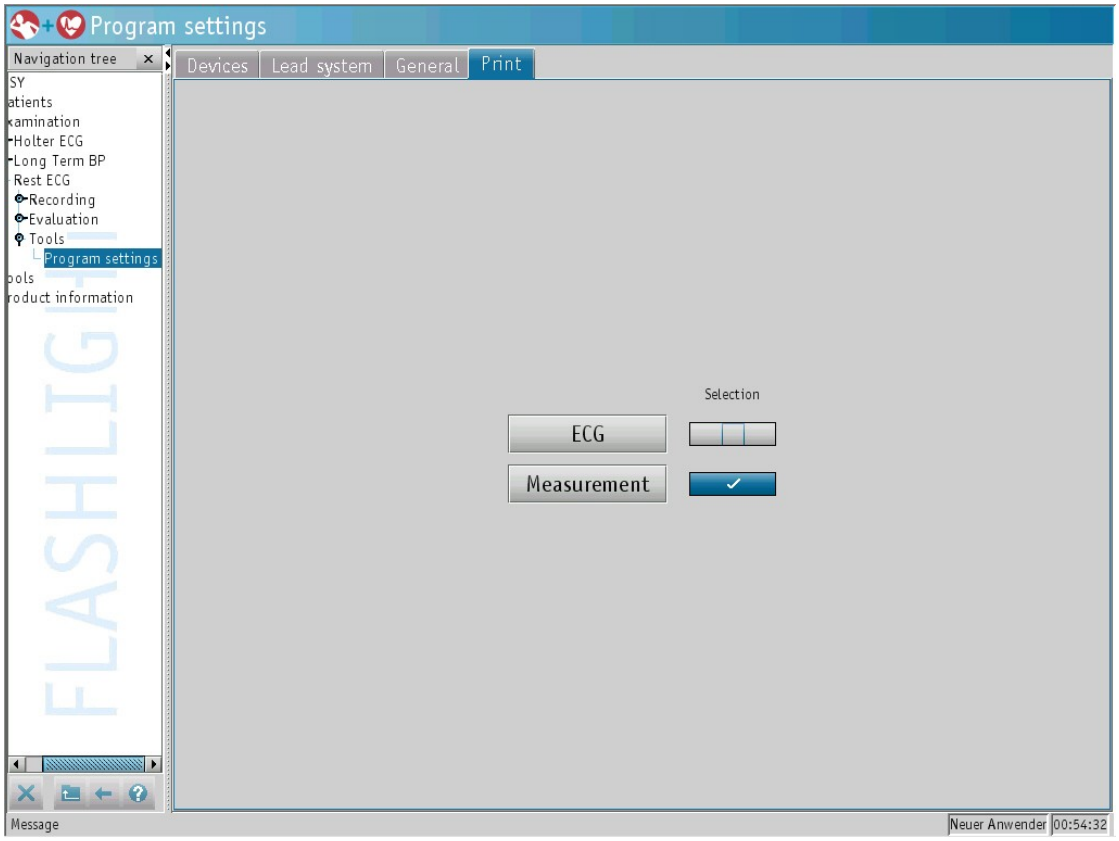
Filter settings to be used for the evaluation, analysis, and recording can be defined. The antidrift or baseline filter serves to equalize fluctuations in the ECG signal around the baseline. The 35 Hz muscle filter suppresses muscle artefacts. The 50 and 60 Hz supply filter compensates for noise that is generated by the PC power supply.

Likewise, select the frequency for the supply filter of 50 or 60 Hz by clicking on the respective buttons.

Settings for pacemaker recognition may also be defined in this view. Select whether no recognition should be made or whether C1, C2, or C3 should be recognized by clicking on the appropriate buttons.

Print

The following display appears:

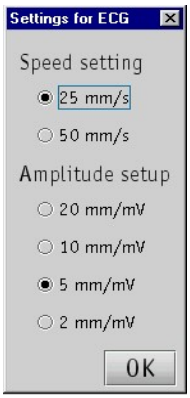


In this view the print settings can be configured.

The printouts which should always be made may be selected by clicking on the appropriate buttons. These will then always be selected in the evaluation for new recordings.

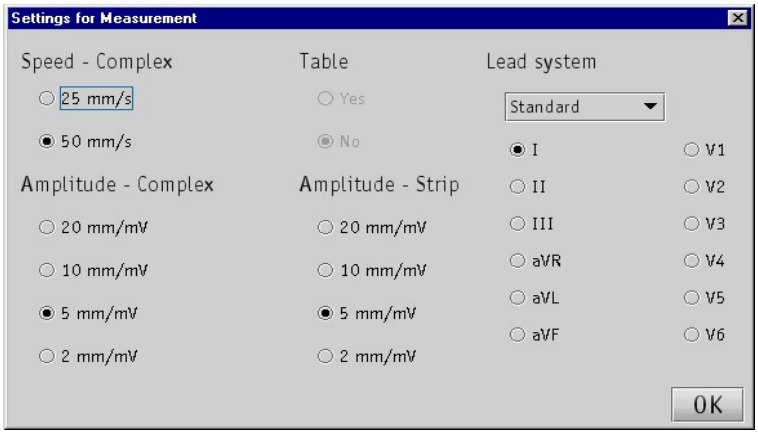
Furthermore, presettings for the individual printouts can be selected.

The following window appears by clicking on the **"ECG"** button:



Presettings for the feed and amplitude of the printout can be defined here.

The following window appears by clicking on the button **"Measurement"** button:



Settings for the feed and amplitude of the representative cycles can be made here. In addition, the table with the measurement values can be faded in and out. A drop-down menu to select the lead system is also available. Furthermore, the amplitude and the leads of the rhythm strip can be selected.

Confirm all changes to the settings by clicking on the **"OK"** Button.

3 Operation

The basis for working with FLASHLIGHT Rest-ECG is the PADSY Patient Diagnostic System. First familiarize yourself with PADSY by reading its user's manual before Rest ECG recordings are made.

3.1 General

3.2 Window separator

In the **"ECG"** view, there is a window separator under the ECG signal window, with which the window size can be increased or decreased.

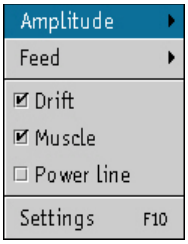
The window size can be changed by operating the window separator with which the width of the navigation tree can be altered: the height of the window above and below the window separator is determined by shifting the gray bar with the mouse.

3.3 Settings

In windows where additional setting options are available, such as the **"Start"** and **"ECG"**windows, a menu is available which makes function selection or quick settings changes possible.

- **Right mouse button**

Once the right hand mouse button in the ECG signal field has been pressed, the mouse pointer can be positioned at the desired attribute and the selection can be confirmed by clicking the left mouse button. If an arrow appears in the right-hand margin of the menu, as it does for example in the ECG signal window in the **"Start"** display next to the attribute **"Amplitude"**, an additional menu opens from which the desired selection, e.g. 5, 10, 15, 20, 25 or 30 mm/mV can be made.



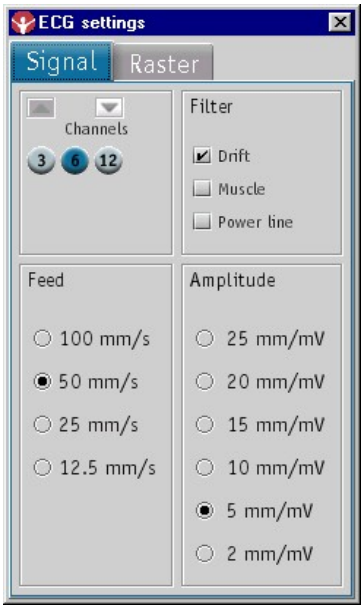
For setting the feed rate, please proceed similarly to what was done to set the amplitude.

Here the filters can be switched on or off. The antidrift or baseline filter serves to equalize fluctuations in the ECG signal around the baseline. The 35 Hz muscle filter suppresses muscle artefacts. The 50 and 60 Hz main filter compensates for noise which is generated by the PC power supply.

- **Settings**

Choose **"Settings"** in this menu **or press <F10>** in order to select the channels displayed, switch filters on or off, or to specify the feed rate and amplitude.

The following window appears:



The field **"Channels"** allows the selection of the number of channels displayed.

By activating the buttons, it is possible to directly select 3, 6 or 12 channels. If 3 channels were selected to be shown one below the other 9 channels can be displayed by clicking on the arrow keys in the **"Channels"** field. The arrow pointing upwards causes the previous set of channels to be displayed, and the arrow pointing downwards causes the next set of channels to be displayed.

Keyboard abbreviations for the settings of the channels:

Display 3 leads <1>

Display 6 leads <2>

Display 12 leads <3>

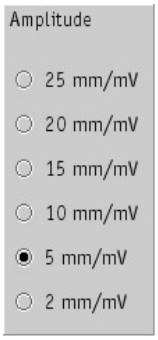
Leads up <Page up>

Leads down <Page down>

The respective filter can be switched on or off by clicking on the check box in the field **"Filter"**.

The feed rate of the signals to be shown on the monitor can be selected in the **"Feed"** field.

In the "**Amplitude**" field the amplitude of the signals shown on the monitor can be set.



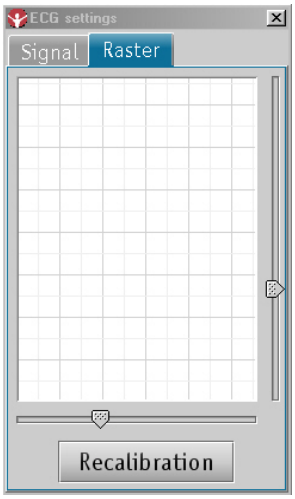
Confirm the choice by clicking on the "**Save**" button.

These settings will be saved when exiting PADSY.

- **Raster adjustment**

In the **"ECG settings"** window under the **"Raster"** tab adjustments to the grid can be made.

The following window appears:

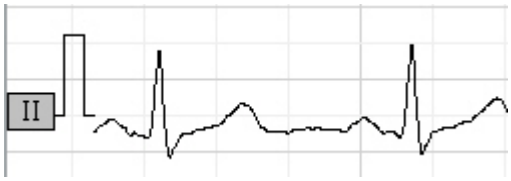


This setting only needs to be performed once and does not have to be reset every time PADSY is started. The grid can be expanded or compressed by moving the arrows next to the grid horizontally or vertically.

The grid adjustment serves to set the grid exactly to 1 cm x 1cm. In order to make the adjustment, please use a ruler as a guide. The new setting of the grid adjustment is shown immediately by clicking on "Recalibration" button.

Settings in the ECG signal window

There are also a wide range of adjustment capabilities in the ECG signal window of the Rest ECG system:



Shifting ECG channels

After positioning the mouse pointer on an ECG channel designation, you can drag the ECG channels horizontally with the left-hand mouse button pressed.

Re-establishing the arrangement

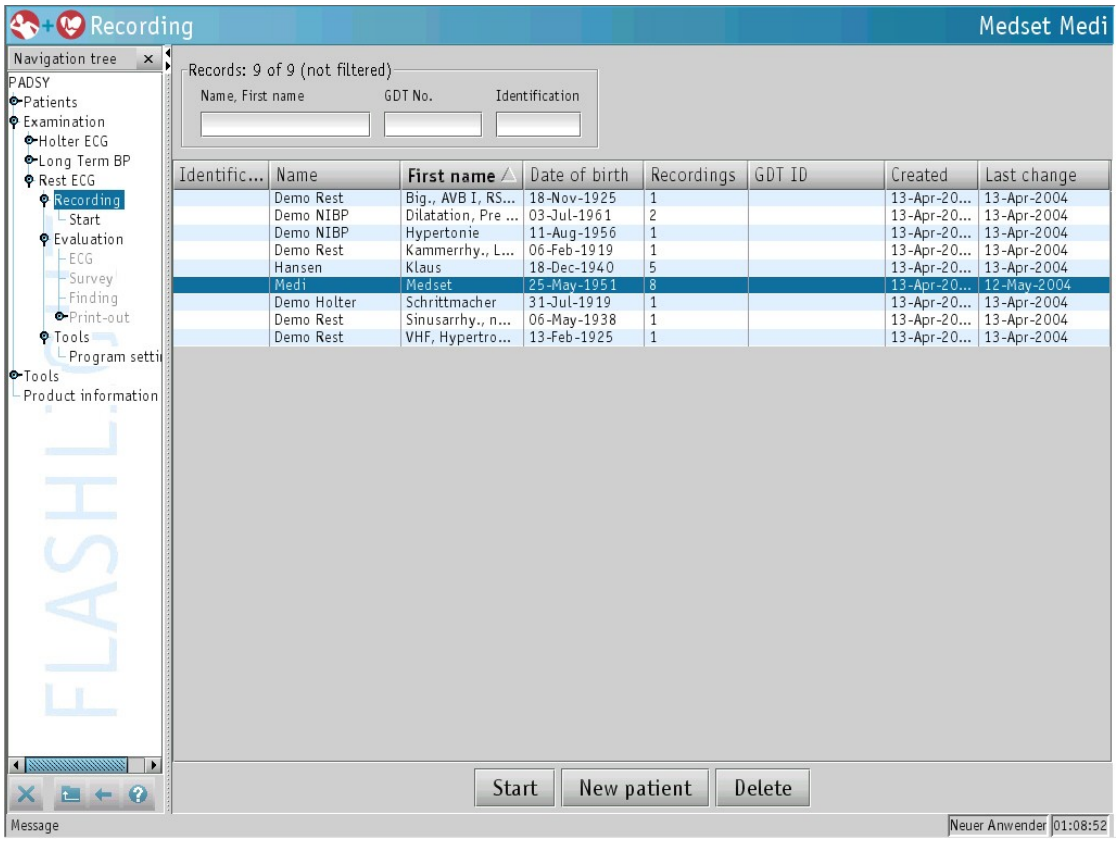
Press the **<F9>** key on the keyboard.

Changing the amplitude

Position the mouse pointer on the 1 mV calibration waveform in front of the ECG signal. You can now increased or reduce the amplitude of all ECG channels simultaneously with the left-hand mouse button pressed.

3.4 Recording a Rest ECG

Selecting the menu option **"Recording"**, causes the following display to appear on the monitor:



All patients existing in the PADSY patient diagnostic system are shown in the patient list. The following information is displayed for each patient: first name, surname, last change, last examiner, the number of recordings which have already been made of the patient, GDT ID, Identification and date of birth. The **"Table configuration"** window may be displayed by pressing the **<F10>** key or via the right mouse button menu. The settings for the patient list can be configured in this menu.

Start the recording of a Rest ECG by first selecting a patient from the list with a double click. Alternatively, a single click on the patient record followed by clicking on the **"Start"** button in the lower part of the window will start the recording.

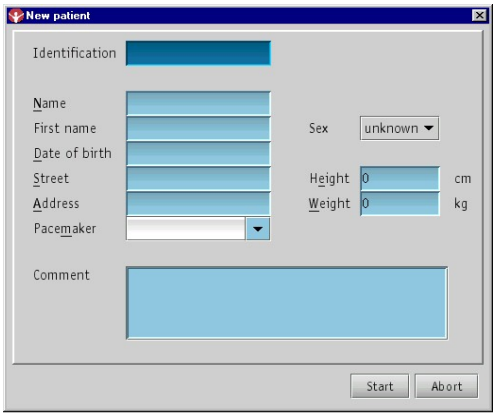
To find patients more quickly, the patient list can be filtered and sorted as described in the **"PADSY – The Patient Diagnostic System"** user's manual.

A patient can be deleted from the list simply by marking the record with a click and then clicking on the **"Delete"** button.

To include a new patient on the list, click the button **"New patient"**.

The following window appears:

In the **"New Patient"** view, the data for a patient not yet listed in PADSY may be entered. To do this, click on the required field. The fields can be changed with the key combination <⇥> or <Ctrl> + <⇥> to select the next field, or <⇧> + <⇥> to select the previous field or using a mouse click.



For clear identification of the patient, a minimum of **"Name"** and **"First name"** along with **"Date Of Birth"** in the format DD.MM.YYYY or DD.MM.YY must be entered in the appropriate fields.

Field assignment, i.e. patient identification number, address with road/street and place name, pacemaker, i.e. whether the patient is fitted with a pacemaker or not, sex, height in cm, weight in kg and comments, e.g. on the patient's case history, must be entered as necessary.

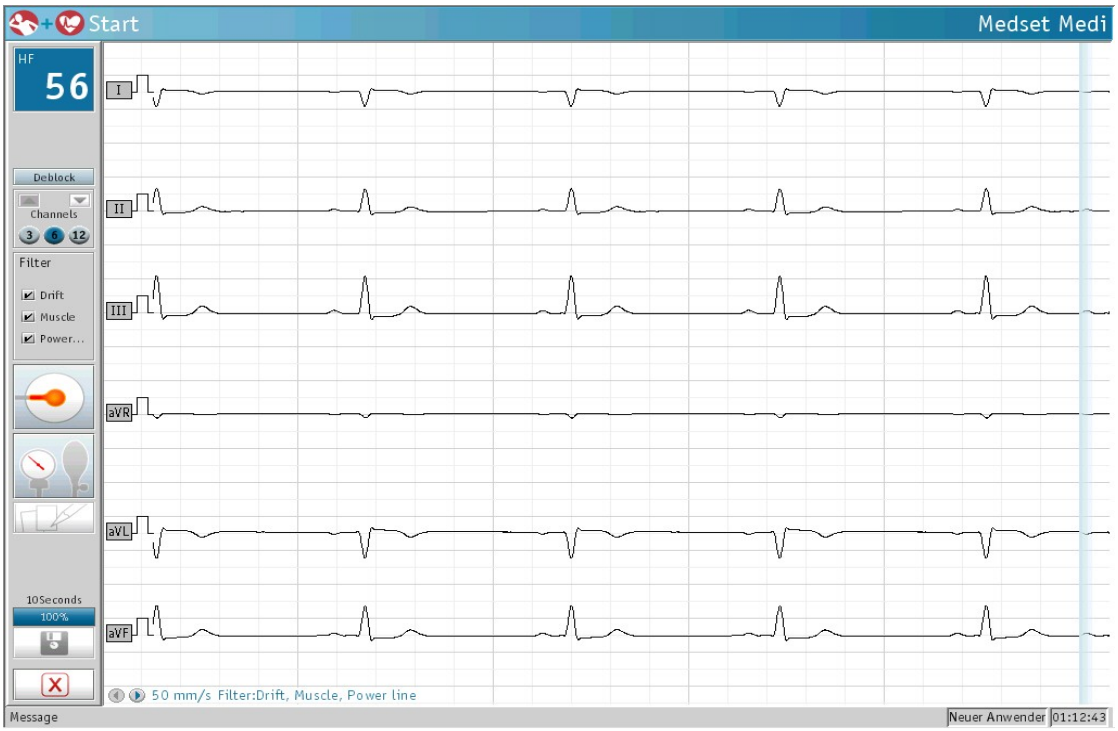
In the appropriate field on the right there is a pull-down menu available for selecting standard entries for the **"Pacemaker"** and **"Sex"** data. When the **"Sex"** field is highlighted, the keyboard can be used to select **<M>** or **<F>**.

After entering the data in the patient sheet, confirm the input with the **"Start"**button. In doing so, the **"Start"** Window will be loaded directly.

Click the **"Cancel"** button to exit the window without making any changes.

3.4.1 Start

The recording of a Rest ECG begins by changing to the **"Start"** window.



• **Information and operating field**

The information and operating field shows the currently measured heart rate:

! The **heart rate** that is displayed can be di 

eart pacemaker impulses or by atrial fibrillation.

The field **"Channels"** allows selection of the number of channels to display.

By activating the buttons, it is possible to directly select 3, 6 or 12 channels. If 3 channels were selected to be shown one below the other 9 channels can be displayed in the field **"Channels"** by clicking on the arrow keys. The arrow pointing upwards displays the previous set of channels and the arrow pointing downwards displays the next set of channels.

Furthermore, the following display appears in the ECG signal field:

This displays the feed rate and filter that have been selected. By clicking on the arrow keys, the leads shown may be changed when 3 or 6 channels are displayed.

The respective filter can be switched on or off by clicking on the check box (control box) in the field **"Filter"**:

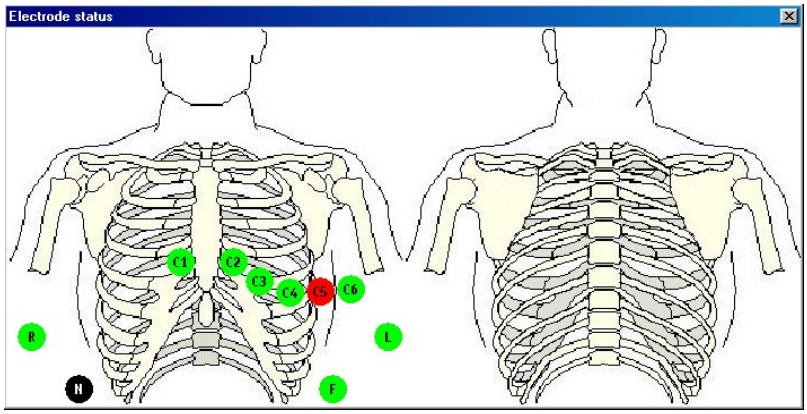
The antidrift or baseline filter serves to equalize fluctuations in the ECG signal around the baseline. The 35 Hz muscle filter suppresses muscle artefacts. The 50 and 60 Hz supply filter compensates for noise which is generated by the PC power supply.

The electrode display in the software has an electrode recognition function with the following color coded meanings:

red:
The electrode is not correctly attached. If the electrode is correctly positioned and the display is nevertheless still red, the electrode should be re-attach after repeating the skin preparation procedure.

green:
The electrode is properly attached.

The following window appears by clicking on the electrode display:

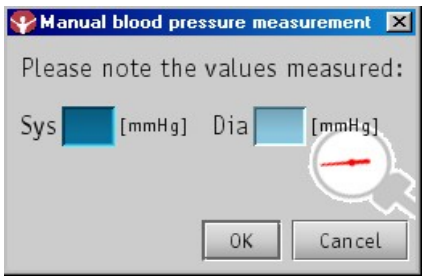


The **"Electrode status"** window shows electrodes that are not correctly applied, and specifies the positions where the electrodes are to be attached properly.

In order to initiate a blood pressure measurement, press the following button:

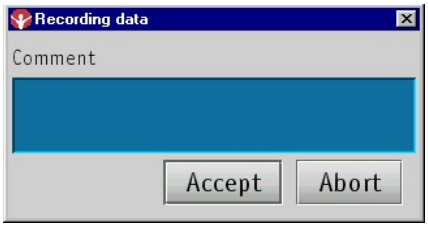
Keyboard shortcut: **<Enter>**

For manual blood pressure monitoring, an interactive dialogue box is available to enter the systolic and diastolic blood pressure values:



In order to enter recording data, press the following button or use the keyboard shortcut **<M>**:

The following window will appear, in which a note about the patient's comments during the recording can be saved:



Confirm the entry by clicking on the **"Accept"** button. Clicking the **"Cancel"** button will close the window without saving the comment.

The channels are reset using "Deblock".

The channels are also automatically reset after the electrodes are re-attached, however, this automatic control can be considerably accelerated by resetting the sensor with the **"Deblock"** button.

The selected recording time and the state of examination progress are also shown.

In order to save the ECG recording, left click on the following button:

Alternatively, the **<Space bar>** on the keyboard will also actuate the saving process.

FLASHLIGHT PADSY has a ring memory at its disposal, allowing the ECG data to be continuously saved over the set period. When the save button is actuated, the last 10, 20, 30, 60 or 180 seconds from the ring memory are permanently stored.

! If at least one ECG channel over modulates or the serial data flow is interrupted, this time period is marked across all ECG channels with a **grey background**. Nothing should be saved at this time.

To exit the **"Start"** window, click the following button to interrupt the connection:

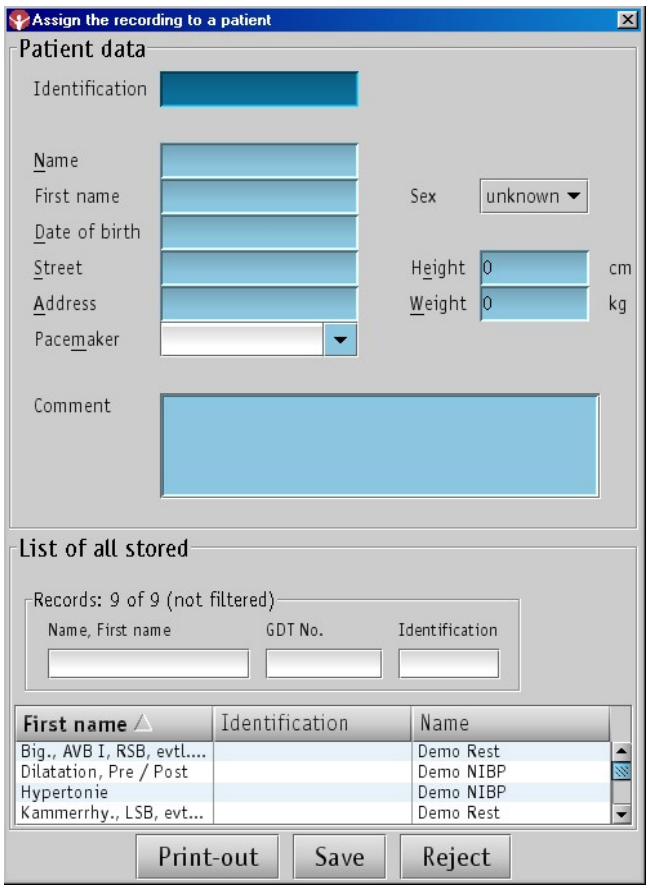
Or use the following keyboard shortcut: **<Q>**

3.4.2 Recording an emergency ECG

An emergency ECG is already integrated in the system. This means that FLASHLIGHT PADSY is able to produce and print a Rest ECG recording in the shortest possible time. Please read the previous section for a more detailed description.

The procedure for an emergency ECG, after starting the Rest ECG, is as follows:

1. In the navigation tree, switch directly to the **"Start"** view, or press the **"Start"** button in the **"Record"** view.
2. Carry out the standard electrode placement.
3. Click on the memory button. The ECG recording can be saved according to the presettings.
4. The following window appears:



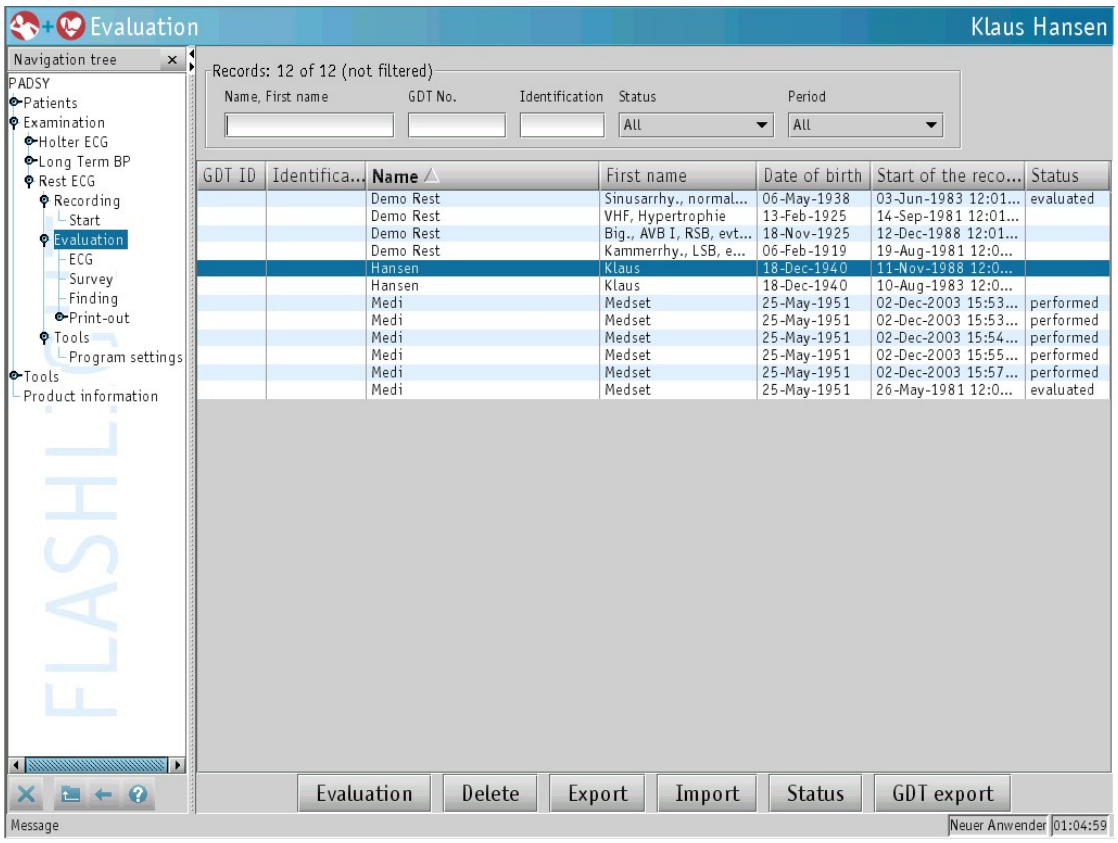
The following actions are carried out by clicking on the buttons at the bottom of the window:

- Print
  Direct printing of the ECG recording using the standard windows specified printer.
- Save
  Before saving, the minimum data: "Name", "First Name" and "Date Of Birth" for the patient must be entered in the "Patient Data" field. If the patient's data is already present in the system, select it from the "List of Stored Patients" with the scrollbar and mouse.
- Reject
  The ECG recording is neither saved nor printed. The user is returned to the "Start" view enabling a further ECG recording if necessary.

3.5 Evaluation

Selecting **"Evaluation"** from the navigation tree, a list of all Rest ECG recordings that have been stored on the system appears:

The recordings are sorted by patient. For multiple name entries, a corresponding number of Rest ECG recordings have been made with this patient.



Any Rest ECG recording to be evaluated, deleted, exported or imported can be selected by clicking on it.

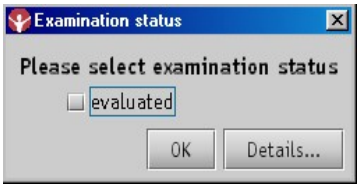
The buttons at the bottom part of the window perform the following actions:

- Evaluation
  Opens the "ECG" view directly and where the recording can begin to be evaluated. The "ECG" window can be directly opened for evaluation by double clicking on the ECG recording required.
- Delete
  Individual recordings can be deleted, but this does not delete the patient from the database. This will, however, delete the recording irretrievable if it has not been previously exported.
- Export
  Recordings saved in the PEF file format can be exported. Please read the section "Patient sheet" in the PADSY user's manual.
- Import
  Files saved in the PEF format can be imported into the list of saved recordings.
- Status
  The status list of the selected recording is displayed. This will be discussed further in the next section "Setting the status".
- GDT export
  Recording information can be exported via the practice EDP program. Note the settings for the GDT interface described in the "PADSY - The Patient Diagnostic System" user's manual or in the help system.

Setting the status

Exiting one of the windows in **"Evaluation"** view for a higher level or selecting the **"Print"** window, the following status query appears:

The status is set by clicking on the check box. The settings become effective by clicking **"OK"**.



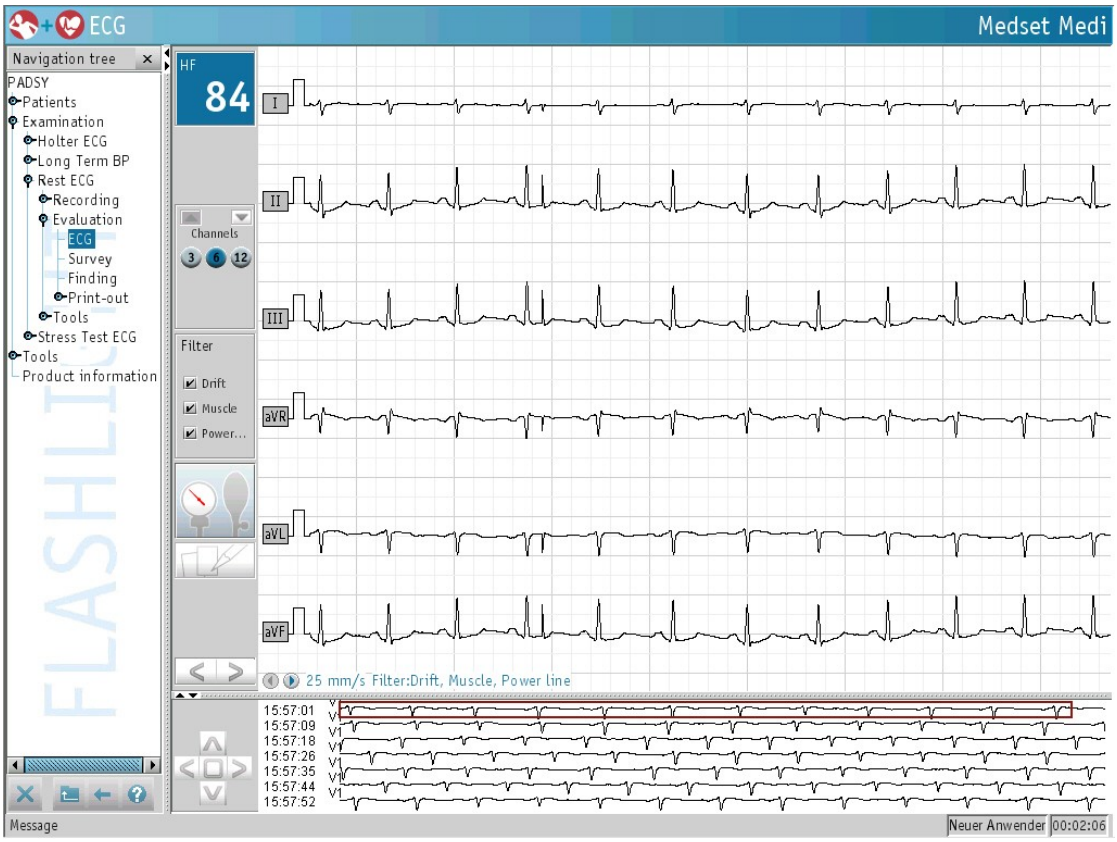
With **"Details..."**, the **"User"** and the **"Date"** corresponding to the current status is shown.

When a recording is marked as **"evaluated"**, the relevant user appears in the printout with the designation **"Examiner"**, and no further status query appears.

! Please note that a status, once set, **cannot** be reset.

3.5.1 ECG

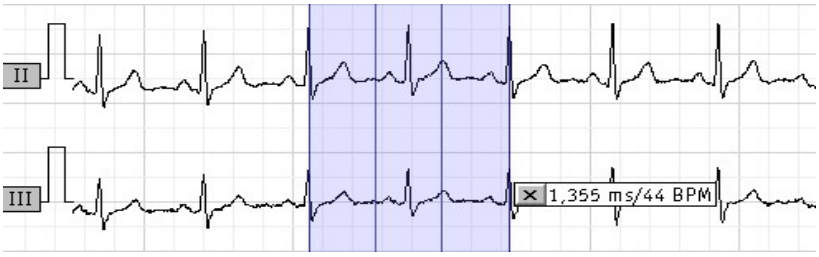
The **"ECG"** window is used for retrospective observation of Rest ECG recordings. It differs only slightly from the **"Start"** window.



Measuring the ECG signal

Calipers are used to measure the ECG signal, which can be called up in the ECG signal field. Move the mouse pointer to the position which desired to be the first measuring point. Keeping the left hand mouse button pressed, the calipers can be opened by moving the mouse horizontally and thus defining further measuring points. In order to allow exact positioning, the calipers are divided into three parts.

The caliper appears as follows:



With the left mouse button pressed, the calipers can be moved provided that the mouse pointer is placed on the measuring range of the calipers when the button is first clicked. Clicking outside of the calipers on the ECG signal causes the calipers to jump in the direction of the mouse pointer. Alternatively, the calipers can also be folded to the right with the **<Z>** button or to the the left the with **<Ctrl>** and **<Z>** buttons. The calipers can be closed by pressing [X].

Information and operating field

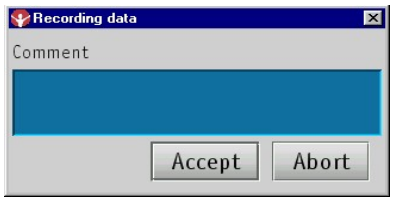
The **"Channels"** field enables selection of the number of channels shown. By activating the appropriate buttons, 3, 6, or 12 channels can be selected to be displayed. By clicking on the arrow keys, the leads to be shown on the monitor can be selected.

The respective filter can be turned on or off by clicking on the check box in the **"Filter"** field.

If the patients blood pressure has not yet been measured for the examination, the blood pressure value can be entered using the following button:

In order to enter recording data, click on the following button:

The following window will appear, in which a note about the patient's comments during the recording can be saved:



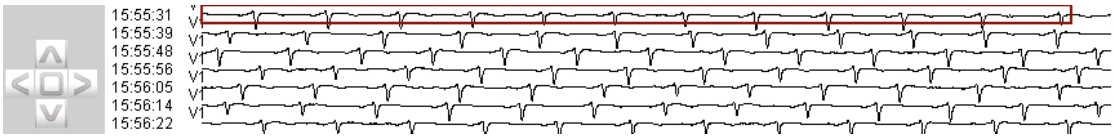
Confirm the entry by clicking on the **"Accept"** button. Clicking the **"Cancel"** button will close the window without saving the comment.

In the lower part of the information and operating field there is a navigation field with the following functions, which can be activated using the left mouse button:

By activating the arrow keys, the current ECG recording page can be moved forwards and backwards.

Sprint Window

The sprint window is located below the ECG signal window.



In this view, an overview of up to 3 minutes per page of the ECG can be seen.

The control pointers make it possible to scroll within in the sprint window. The individual symbols have the following functions:

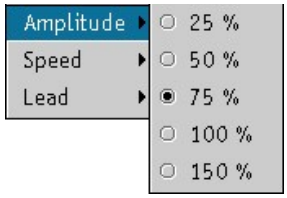
Scroll backwards line by line

Scroll forwards page by page

Scroll forwards line by line

Scroll backwards page by page

Clicking the right hand mouse button, allows the settings for the sprint window to be configured.

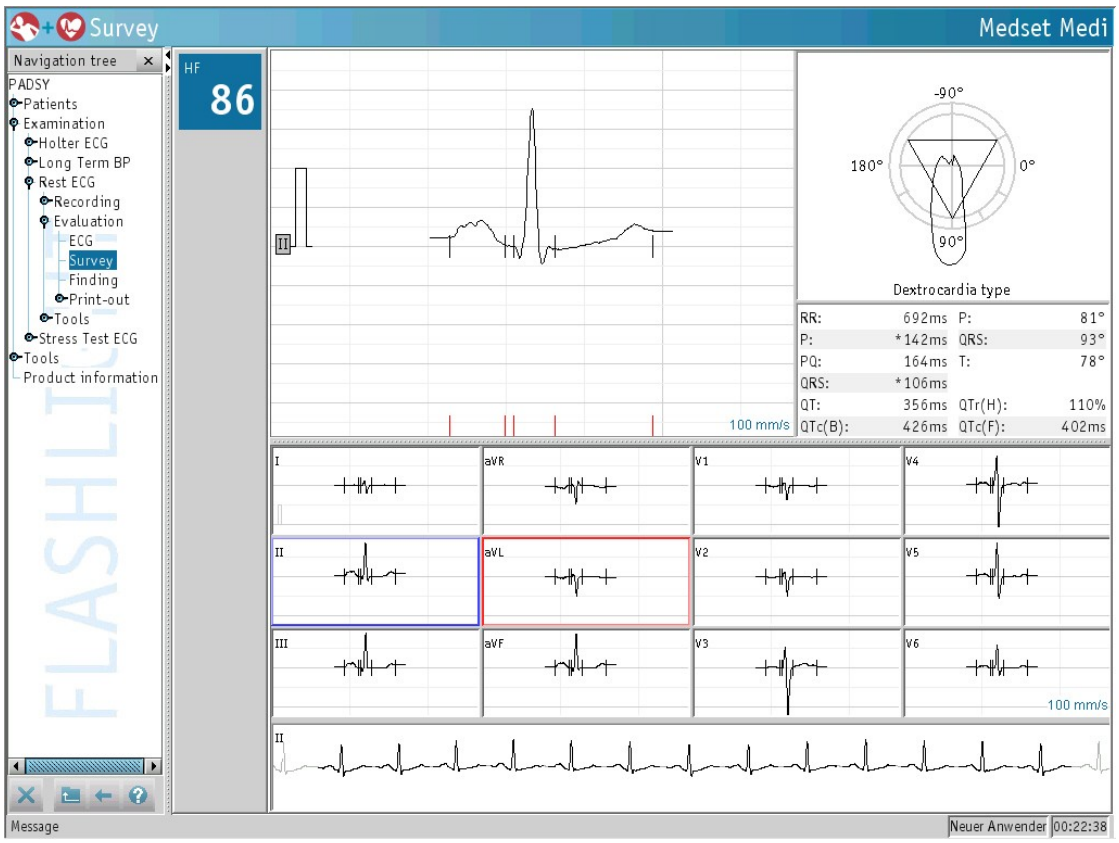


The signal amplitude can be changed from 25% - 150% by clicking on the desired value under **"Amplitude"**. In the **"Speed"** menu, the time shown per page can be chosen (10 seconds – 3 minutes). Under **"Leads"**, the ECG leads to be shown in the sprint window can be selected.

Measurement is made using the **"HES"** program integrated in PADSY ("The Hannover ECG program system for computer-assisted evaluation of electrocardiograms").

The representative cycles, also called average value cycles of the "normal" ECG complexes, are automatically created with their characteristics by the program. A "typical" ECG complex for the patient being examined will thus be shown.

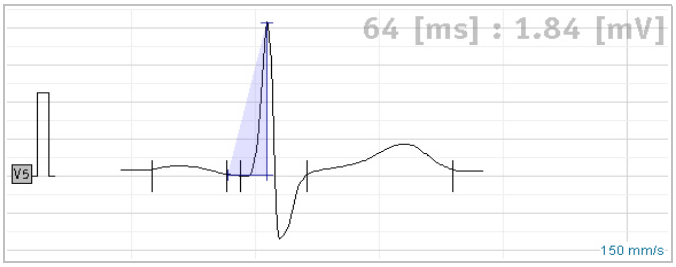
The "**Survey**" view is allocated in the following windows: **"Zoom Window", "Measurement Window", "Single Complex Selection", "Rhythm Strip", "ST-Overview"** and **"Histogram"**.



Zoom Window

In this window, the average cycle of the selected lead, as well as its measuring points are shown.

The measurements can be performed with a two-dimensional caliper. Move the mouse pointer to the position desired as the first measurement point. Keeping the left hand mouse button pressed the calipers can be opened. Move the mouse to the desired final point. The opened calipers can be made larger or smaller by placing the mouse pointer at the final point of a side, and moving the mouse while keeping the left hand mouse button pressed. The calipers can be moved keeping the left hand mouse button pressed, provided you have positioned the mouse pointer on the blue area of the calipers before clicking. The respective measured values are shown in gray letters on the upper right. The calipers are closed again by clicking the left hand mouse button twice in quick succession in the zoom window.

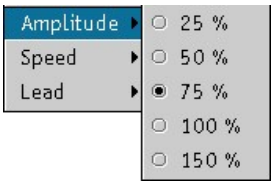


Furthermore, the measuring points set by the system can be moved in the lower part of the zoom window. The changes to the resulting measuring points are visible at the same time in the measurement window. The changed measuring points are shown in red, for easy comparison with the original points, shown in black.

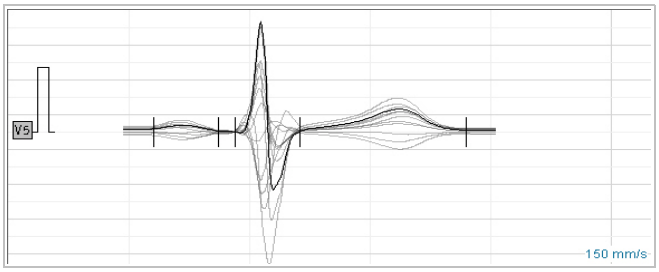
! Please note that the statement **"Automatic HES analysis"** in the lower part of the printout will only appear if the measuring points have not been changed.

Using the right mouse button, the amplitude and feed can be set and all cycles can be superimposed over each other. The original values of the HES-analysis can also be restored.

The right mouse button will open the "Zoom window settings" menu. Using the settings menu in the zoom window, all of the representative cycles can be displayed in addition to the known settings.



Selecting "All" will superimpose all representative cycles. The selected cycle appears in black, all others in gray.



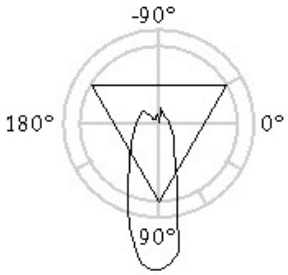
If the measuring points set by the system in the lower part of the zoom window were moved, they can be reset by clicking on: **"Original values"**.

As in the **"Start"** window, the amplitude can be changed via the 1mV calibrating peak, and the ECG channel can be moved vertically using the ECG channel designation.

Measurement Window

The measurement window contains the Cabrera circle showing the vector diagram of the ECG, the automatically assigned position type, and all measured values.

Explanations relating to the individual measurements can be found in the Appendix under **"Representative Cycles"** and **"Intervals"**.



Vertical type

RR:	692ms	P:	80°
P:	*142ms	QRS:	89°
PQ:	164ms	T:	84°
QRS:	*104ms		
QT:	336ms	QTr(H):	104%
QTc(B):	402ms	QTc(F):	379ms

Single Complex Selection

In the **"Single complex selection"** window, all averaged QRS complexes for the individual leads can be viewed. Clicking on a QRS complex will cause it to appear in the zoom window.

The settings can be edited in the **"Single complex selection"** using the right mouse button. The amplitude and the feed for individual complexes can be selected here.

Rhythm bar

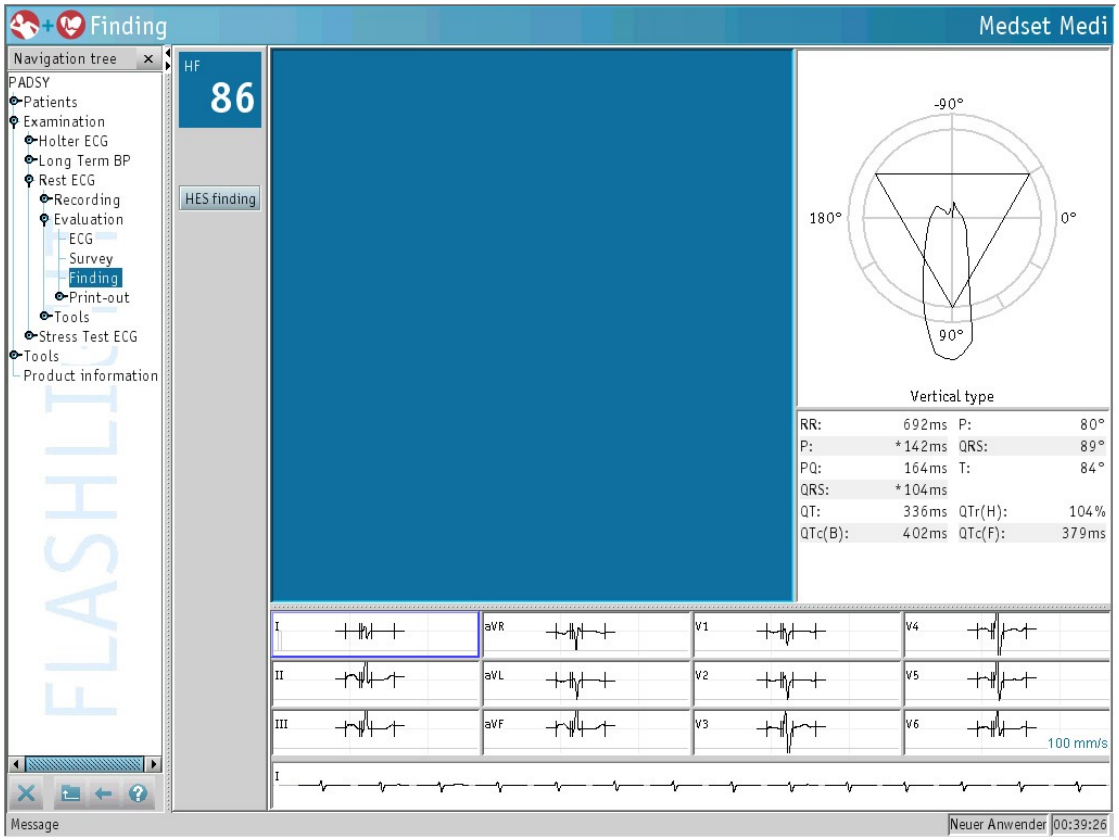
The rhythm bar shows the last 10 seconds of the ECG bar for the selected channel, in which cycles which may be evaluated are shown in **"black"** and cycles which may not be evaluated are shown in **"gray"**.

The amplitude can be changed using the amplitude setting in the selection window.

! The last 10 seconds of the ECG are used for measurement in the **"HES analysis"**. There must be at least 3 cycles capable of evaluation.

! As well as checking the wave point marks, a short visual check on the rhythm bar and its main cycles should also be a permanent feature of quality control during automatic evaluation.

3.5.2 Finding



This window allows the findings to be compiled.

To enter the medical data, click on the light blue **"Finding"** window. Its color will turn dark blue, and the findings can be edited using the keyboard. The data entered is included directly in the printout.

To avoid having to spend the time to type commonly used passages of text repeatedly, it is possible to insert text templates. To get more information about the creation of text templates please see the user's manual for **„PADSY- The Patient Diagnostic System“**.

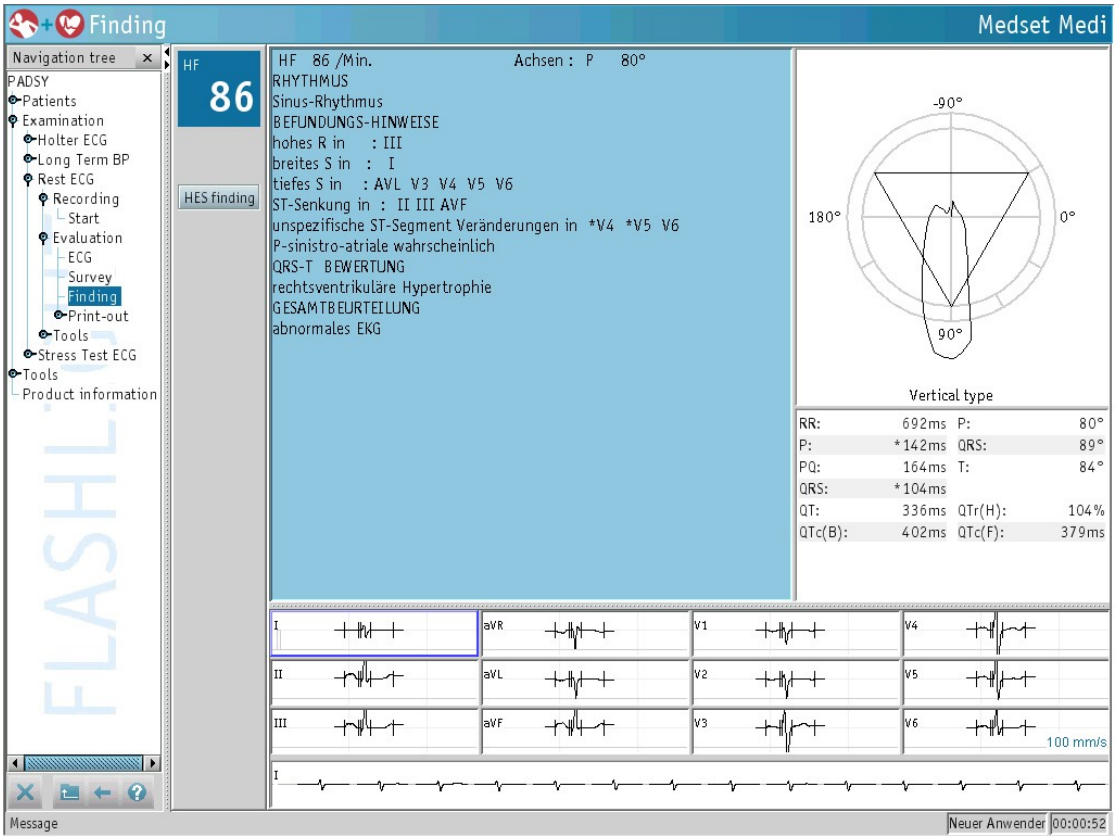
The button **"HES finding"** is inactive in this view. This function is a software option of the **"Automatic interpretation"**.

The other 3 windows are identical to the **"Measurement"** window.

3.5.3 Automatic Interpretation (Software Option)

In contrast to the **“Finding“** without **“Automatic Interpretation“**, the evaluated data must not be manually entered. After the ECG has been analyzed under PADSY (by HES), a finding for this ECG is automatically produced and displayed.

! An **Automatic Interpretation** takes place **only in use of the standard lead system**. If another lead system than the standard is used, non automatic interpretation takes place, i.e. the text field for the interpretation remains empty.



This software option checks all easily visually detectable ECG criteria important for diagnosis and makes them available as analytical indications, together with the rhythm, overall assessment, and QRST-T evaluation.

With the help of the keyboard, the finding can be further extended. To do this, click in the evaluation window. Click the "HES finding" button in the information and operating field to reset the finding. This is made automatically by the analytical software.

An attempt has been made to provide the user with the essential information about the special features of the ECG in a condensed form.

The findings are divided into the following 4 different sections:

Rhythm

In this section, "Rhythm" analysis are made, e.g. the extent to which a rhythm is regular or irregular, and whether it is determined by the sinus nodes or by a different excitation center.

The rhythm analysis takes into account the RR-intervals, the P-wave and PQ-interval, the morphology of the QRS-complex and coupling relationships.

Information on findings

The information on findings should draw the attention of the physician to abnormalities. In many cases, therefore, the subsequent QRS-T evaluation will be simplified or confirmed. Specific information is provided on retardations, incomplete as well as complete bundle-branch blocks, preexcitation problems (WPW), hemiblocks and (non-specific) intraventricular disturbance to ventricular stimulus. With an abnormal ST-T wave, repolarization disturbance of the inner or outer layer type is assigned according to grades 1-4.

The findings are provided on the basis of time and amplitude of P, Q, R and S for all 12 leads and their deviations from normal values.

These limits or normal values are tabulated in the Appendix. The information on findings briefly explained in the Appendix consists of **“Notes on the P-wave”, “Notes on the QRS-complex”, “Notes on ventricular stimulus disturbance”** and **“Notes on repolarization disturbance”.**

QRS-T evaluation

In this section, the ECG is assigned to the groups **"Normal", "Right ventricular hypertrophy", "Left ventricular hypertrophy", "Biventricular hypertrophy ", "Anterior myocardial infarction", "Infarction"** as well as any combination of infarction and left ventricular hypertrophy.

Interpretation of the representative ECG cycle is made using complex logic and statistical decision functions. This involves checking the ECG recorded for **"Similarity"** to normal and pathological electrocardiograms. To accomplish this the isolated Q-waves or large R/S intervals in addition to a large number of parameters from the depolarization and repolarization phases are evaluated.

Overall assessment

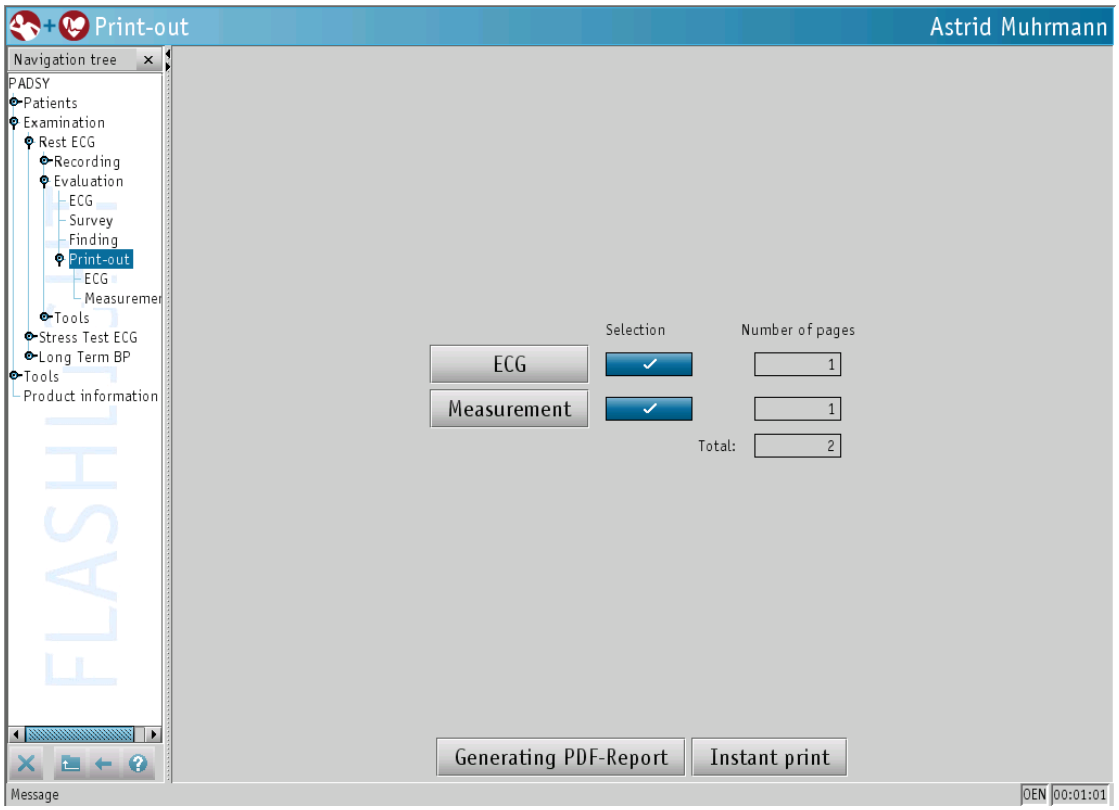
Here, the program produces an overall assessment from the rhythm obtained, the information on findings, and the QRS-T evaluation (e.g. **“normal ECG“**).

Further information can be found in the Appendix under **"Automatic Interpretation"**.

! Please note that every **"Automatic Interpretation"** must be checked by a physician and will only be recorded as the medical finding after manual entry of the **"evaluated"** status.

3.5.4 Print-out

Selecting the **"Print-out"** view from the navigation tree causes the following window to appear:



Clicking the fields under "Selection" allows to select the sections that are to be printed. The fields signify the following:

This section is **selected** for printing.

This section is **not selected** for printing.

The number of pages of a section are shown on the right-hand side of the window, and the total number of pages are found at the bottom.

The report print out can be made in two ways. It can be created either as a hard copy from a printer, or as a .pdf file.

To start the report printing from a printer, select the **„Instant Print“** button at the bottom of the window. To save the report as a .pdf file, click on the **„Create PDF report“** button at the bottom of the window.

By clicking **"Instant print"** at the bottom of the window, the marked section is printed without closing the data record. The user must wait until all pages have been transferred to the Windows print manager before closing the application.

Selecting „Create PDF report“ opens a window that allows the user to select the folder where the .pdf report is to be saved. To open a .pdf file, Acrobat reader is required.

Buttons with the following meanings are located in the lower part of the various print preview screens:

Save the page as a **PDF** file format. The folder in which the file is to be saved can be selected as with the import and export of data records. If you scale more or less then 100%, the mm-Raster of the ECG-print-out is not correct any longer.

Save the page as a file in **JPG** format. The image file may be viewed later in a graphics processing program. The folder in which the file is to be saved can be selected as with the import and export of data records.

Print the page displayed

Show **first** page

One page **back**

One page **forward**

Show **last** page

Show entire page **width**

Show entire page **height**

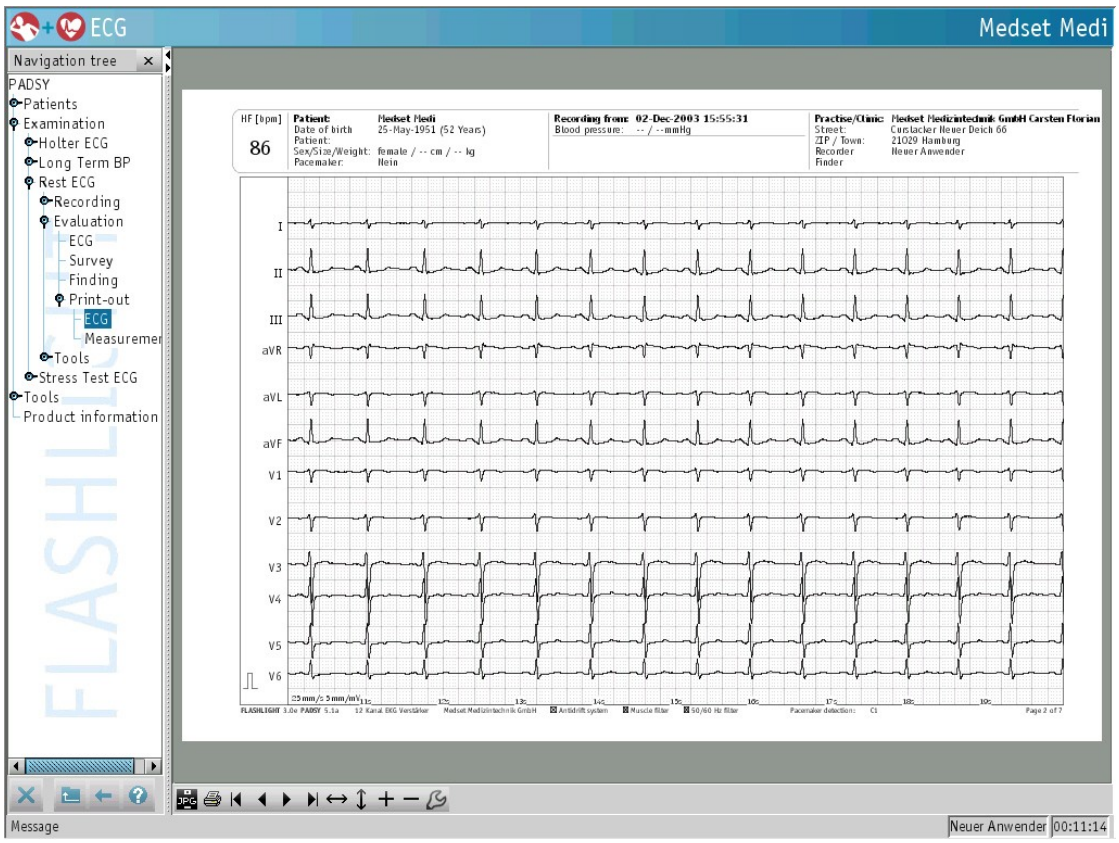
Print window **zoom in**

Print window **zoom out**

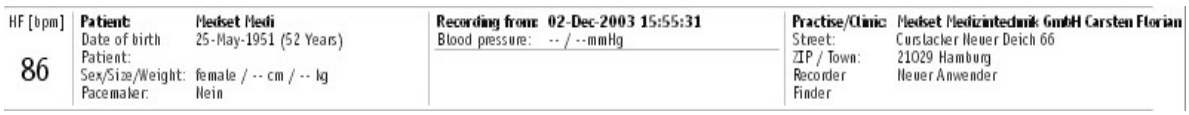
Call up **print settings**

ECG

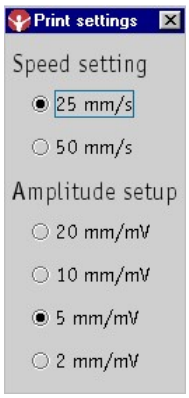
Selecting this window, will load the ECG print preview.



The header of the printout consists of heart rate, patient data, recorded data, and practice or hospital data including the name of the examiner and analyst.



The following window appears when the print settings are recalled:

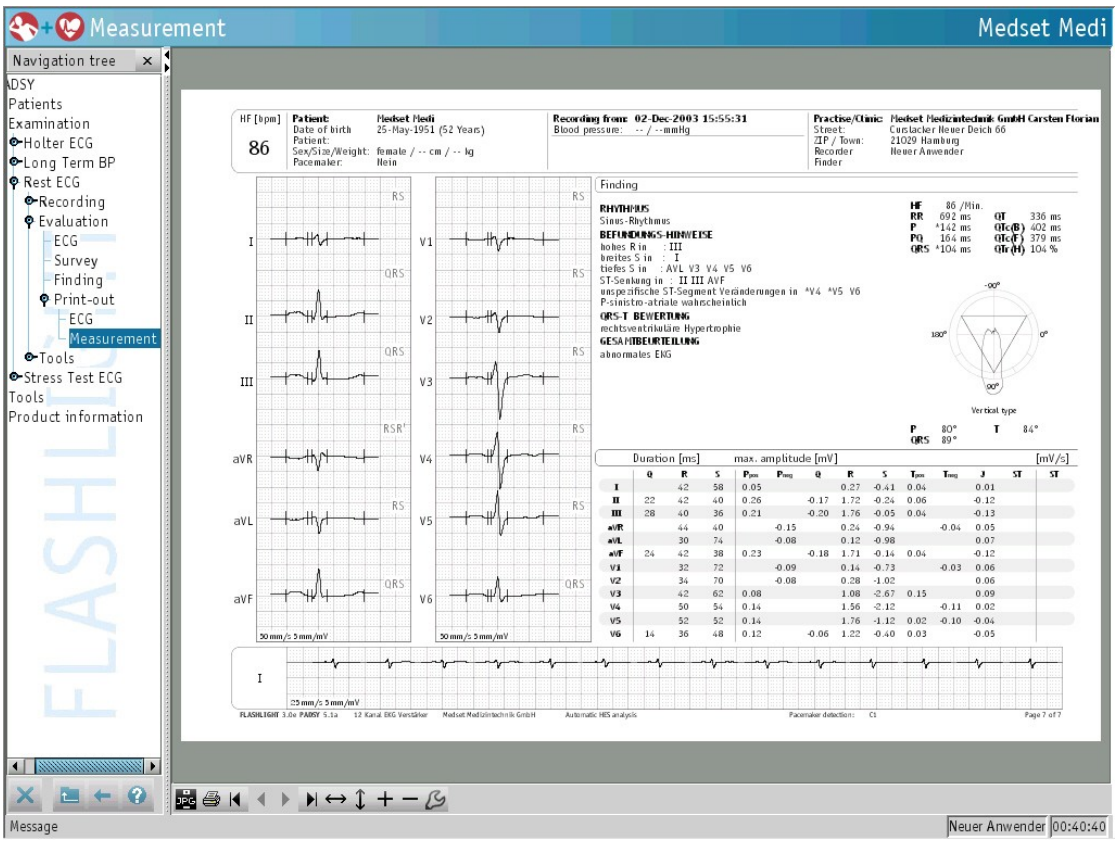


It allows the settings for feed and amplitude to be changed. For this purpose, click on the field in front of the desired parameter with the left mouse button. The changes are directly visible in the print preview.

Measurement

Selecting the **"Measurement"** window automatically loads the associated print preview.

In this window, the findings, the type of cardiac position, the tabulated ECG values obtained with the **"HES"** analysis, as well as the rhythm strip can be seen beside their representative cycles.



The complex detected for each lead is shown in the display of representative cycles.

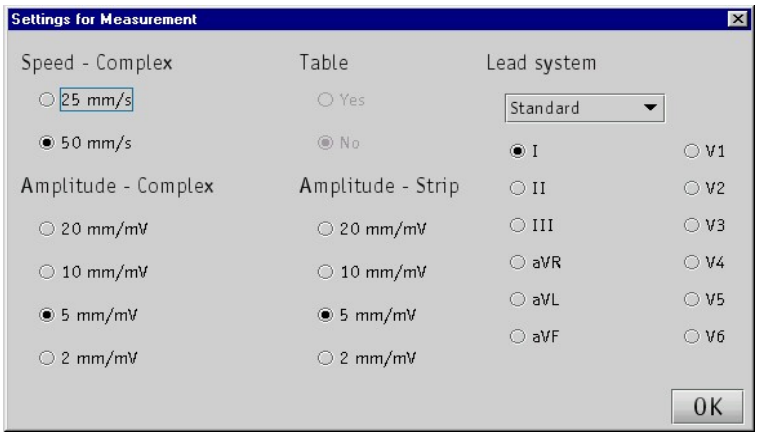
The measured values above or under the Cabrera circle are marked with an asterisk if the limits are exceeded.

If the measuring points are changed in the **"Zoom Window"** of the **"Measurement"**, the HES value table display is extinguished, and the **"Automatic HES analysis"** label in the base line of the printout changed to **"Manually Edited"**. The table of values with the original HES values can be superimposed again using the upper settings bar.

The **"Manually Edited"** label also appears after editing of the finding in the **"Automatic Interpretation"** software option.

Short explanations on the individual measurements are given in the Appendix under **"Representative Cycles"** and **"Intervals"**.

The following window appears after recalling the print settings:



The settings for the feed and the amplitude for the representative cycles can be specified in this window. Additionally, the table with the measurement values can be faded in and out. Similarly, a drop-down menu is available for selecting the lead systems. The amplitude and the leads of the rhythm strip may also be chosen.

4 Cleaning and Maintenance

4.1 ECG sensor module

The ECG sensor module can be cleaned with a damp cloth with a mild household detergent and any standard hospital detergents and disinfectants containing alcohol (<70%).

Abrasive substances and disinfectants with a phenol base and peroxide compounds are not suitable for surface disinfection and cleaning. Please pay attention to the information written in the instructions included in the detergent and disinfectant packaging.

! During cleaning and disinfecting, ensure that no **liquids** enter the electrode through its apertures.

4.2 Electrode and interface cables

Cleaning

Connectors, patient cables, and connecting cables can be cleaned with lukewarm soapy water or a neutral detergent.

Disinfection

All hospital standard disinfectants free of phenol and peroxide compounds containing alcohol (up to 70%) can be used for disinfection.

! Leads must not be autoclaved, since this could damage the insulation.

Leads with damaged insulation are extremely dangerous for all persons who knowingly or unknowingly come into contact with them.
Defective leads also endanger the electronic circuitry of the connected electrode.

Leads with damaged insulation cannot be used for further operation of the electrical electrode.

! Plug and socket connections must always be kept well away from live sources of electricity.

Never immerse **cables or connectors** in liquids.

Protect cables against strong UV radiation.

4.2.1 Maintenance

The FLASHLIGHT Rest ECG system does not require regular calibration or safety checks.

! However, immediate **repair work** will be necessary if:

- the electrode has been subjected to extreme mechanical stress,
- liquid enters the electrode,
- cables, case and/or connectors suffer damage or
- covers are missing.

5 Function Testing and Troubleshooting

This chapter describes a complete test of the FLASHLIGHT Rest ECG system for PADSY, which is recommended after the installation phase.

The **"Troubleshooting"** section looks at typical errors.

5.1 Function test

The procedure for a complete test of the FLASHLIGHT Rest ECG system for PADSY, is as follows. Refer to the relevant sections in Chapter 4 **"Operation"** to carry out individual functions if unfamiliar with them.

5.1.1 Testing the sensor connection

1. Connect the sensor to the PC.
2. Start the FLASHLIGHT software.
3. Set up the sensor in the system.
4. Open the **"Record"** view and check that the sensor connected has the status **"Ready to operate"**.

5.1.2 Testing the record function

1. Click on the **"Record"** view and then the **"Start"** view in the navigation tree.
2. Record a Rest ECG while pressing the red memory button.
3. Save the Rest ECG under a test name.

5.1.3 Testing the hard copy

1. Select the **"Evaluation"** view and then the recording saved.
2. Switch on the printer.
3. Select the **"Hard copy"** view in the navigation tree.
4. Click on the **"Instant Print"** button and check the hard copy.

5.2 Troubleshooting

If the software does not function at any time, the following problem solutions are suggested. The Medset customer service will be pleased to provide additional support if these suggestions do not solve the problems.

Please refer to the "**Troubleshooting**" chapter in the "**PADSY - The Patient Diagnostic System**" user's manual as well.

No sensor is detected by the system

1. Shut down the PC.
2. Check whether the sensor has been connected to the PC in accordance with the section **"Connecting the FLASHLIGHT sensor"**.
3. Start up the PC and the FLASHLIGHT software for PADSY.
4. Check that the sensor has been set up on the PC according to the section **"Hardware Installations"**.

6 Technical Description

Classification:	Class IIa medical product with measuring function according to EU Directive 93/42/EEC Annex II Regulation 10

6.1 Hardware

Protective class:	Protective Class II equipment according to EN 60601
Safety class:	BF according to EN 60601 for ECG sensor module (without accessories), defibrillation-protected according to EN 60601
DIMDI / UMDNS-No.:	10-981

Electrical data

Status display:	Green LED
Measuring interface:	8 AD channels with 12 bit resolution
Frequency response:	0.05 to 150 Hz
Sampling rate:	approx. 1,400 Hz with 4-channel ECG, approx. 500 Hz with 12-channel ECG
Accuracy:	2.44 µV per bit with a sensitivity of ± 5 mV, 4.88 µV per bit with a sensitivity of ± 10 mV
Sensitivity:	automatic ± 5 mV or ± 10 mV
Common mode rejection:	>100 dB (with power line filter selected)
Input resistance:	>10 MOhm
Calibration:	Automatic detection of zero voltage
Calibration voltage:	1 mV
Electrical isolation:	Via optocoupler with an insulation voltage of 4 kV
Power supply:	Via keyboard interface with a PS/2 adapter
Power consumption:	approx. 400 mA at 5 V
PC interface:	RS 232 or USB
Transmission rate:	approx. 115,000 baud
Transmission indication:	Yellow LED
Immobilization:	Automatic rapid discharge of block capacitors, e.g. after defibrillation

Physical data

Dimensions:	approx. W 67 mm, H 45 mm, D 158 mm
Weight:	approx. 440 g (incl. PC interface cable)

Operating conditions

Temperature:	+10 °C to + 40 °C
Relative humidity:	25 % to 95 % (without condensation)
Atmospheric pressure:	700 hPa to 1,060 hPa

Storage conditions

Temperature:	-20 °C to + 50 °C
Relative humidity:	15 % to 95 % (without condensation)
Atmospheric pressure:	500 hPa to 1,060 hPa

6.2 Software

Display

Immobilization:	Manual rapid discharge of block capacitors, e.g. after defibrillation
Electrode detection:	Automatic display of electrode status
Overload display:	Superimposition of all ECG channels with a red bar

Lead systems

Standard:	Einthoven, Goldberger and Wilson V1 to V6
Cabrera:	Einthoven, Goldberger and Wilson V1 to V6
Nehb:	Einthoven, Goldberger, Nehb and Wilson V4, V5 and V6
Left precordial:	Einthoven, Goldberger and Wilson V1, V2, V3, V7, V8 and V9
Right precordial:	Einthoven, Goldberger and Wilson VR5, VR4, VR3, V4, V5, V6

Pacemaker spike detection

Detection:	optionally via electrode C1, C2 or C3

Heart rate display

Frequency range:	Lower limit: 1 Hz, no upper limit
Calculation:	Averaging over 4 beats from all channels

Filter

Power line filter:	Notch filter with a frequency of either 50 or 60 Hz for the suppression of power line hum
Muscle filter:	Low pass filter with a cut-off frequency of 35 Hz to suppress muscle artifacts
Antidrift filter:	High pass filter with a cut-off frequency of 1 Hz to suppress fluctuations in polarization at the electrodes

7 Accessories and Consumables

7.1 Accessories

Order Code	Article Designation
FL-ZU	**FLASHLIGHT set of accessories** Delivery schedule: 1 patient cable, 10-lead with 4mm banana plug 4 extremity clip electrodes 6 chest wall suction electrodes 1 250 ml bottle of electrode cream
FLZ-PKB	**FLASHLIGHT patient cable** 10-lead with 4 mm banana plug
FLZ-PKK	**FLASHLIGHT patient cable** 10-lead with clip adapters
FLZ-PKD	**FLASHLIGHT patient cable** 10-lead with push-button connection
FLZ-BWS	**Set of chest wall suction electrodes** Delivery schedule: 6 electrodes with banana plug, Type BSE/C, Ag/AgCl sensor
FLZ-KO	**Set of extremity clip electrodes** Delivery schedule: 4 electrodes with banana plug, Type KO 9F/C, Ag/AgCl sensor
FLZ-GPSE	**"FLASHLIGHT - Rest ECG system for PADSY" User Instructions** (please state version when ordering)

7.2 Consumables

Order Code	Article Designation
CVE-H92	**ARBO disposable electrodes** with pushbutton connection and foam plastic support, Type H92LZ, Ag/AgCl sensor

8 Appendix

8.1 Measurement

8.1.1 Representative cycles

To produce the representative cycles, the individual ECG complexes are first extracted from the recorded ECG. A complex is then analyzed to determine which of the recorded ECG cycles is suitable for producing an average “Representative Cycle“. The following must be determined:

- Which cycles have the same QRS-T morphology?
- Which cycles have the same P-morphology?
- Which cycles are extrasystoles and which correspond to a “normal beat“?
- Which cycles are unsuitable for the evaluation due to excessive base line fluctuations or other disturbances?
- Which RR-intervals are between the cycles?
- This ensures that no ECG cycles are evaluated which do not actually have the same morphology.
- All cycles are shown in relation to one another in the **“Evaluation” -->“Measurement”** window under the various cycles. A section shown in gray (here: at the beginning) shows that this has not been included in the algorithm.
- The following criteria lead to the exclusion of individual cycles from the representative cycle:
  - Base line fluctuations
  - Interference (e.g. hum)
  - Interval to the previous and/or subsequent beat too short
  - Deviation from the main type in the QRS-morphology
  - Deviation from the main type because of deviating P-contour and/or T-contour.
  - At least three cycles of the main type are necessary to create a representative cycle.

8.1.2 Intervals

"Global“ measurements are determined, i.e. those jointly valid for the leads, such as Q, R, and S times in milliseconds as well as spatial values, e.g. frontal vectors. After selection of the **“Printout”--> “Measurement”** view, these measured values will be found under the Cabrera circle.

Interval measurements are marked with a "*****" if they deviate from the following values.

P-time	>=	128 ms
PQ-interval	>=	128 ms
QRS-time	>	100 ms

The so-called frequency-corrected QT-times shown are determined using the following formulae:

$$QTc\ (B) = \frac{QT}{\sqrt{RR\ [s]}}$$ following Bazett

$$QTc\ (F) = \frac{QT}{\sqrt[3]{RR\ [s]}}$$ following Fridericia

$$QTr\ (H) = \frac{QT}{0{,}39 * \sqrt{RR\ [ms]}} * 100\%$$ following Holzmann

8.1.3 Amplitudes

The maximum amplitudes are output for Q, R, S, J, and ST. For better differentiation, the maximum amplitudes obtained for the P-wave and T-wave are output separately for the positive and negative value ranges.

8.2 Interpretation

All visually easily recordable ECG criteria important for diagnosis are investigated in the program and made available to the user as evaluation information:

The P, Q, R, and S times and amplitudes are measured in each of the twelve leads and compared with the associated 96% limits in normal groups.

Lead	Q-amplitude [µV]	Q-time (ms)
I	-180	30
II	-200	30
III	-350	30
AVL	-200	30
AVF	-200	30
V1	-50	20
V2	-50	20
V3	-90	20
V4	-200	25
V5	-230	30
V6	-230	30

Table: 96%-quantile of Q-amplitude and Q-time in normal groups

When these limits are exceeded, there is a high probability that an abnormal situation exists for this criterion. It is important to note, however, that there can be individual cases (4%!) in which a normal ECG can take on these values. Further information is given to describe bundle branch blocks, including information on a second R-wave in the QRS-complex, M-form etc. With this information, however, the limit values are set so high that they are exceeded only in the relevant blocks.

References to the P-wave

1. Atrial lead interference PD > 126ms
2. Abnormal P-vector Angle < -30° or Angle > +90°
3. P-Sinistro-atrial
4. P-Dextro-atrial
5. P-Bi-atrial

For this reference the P-amplitudes (>250µV) the predominance of the first or second peak and the Morris index are checked and a score produced from this check.

References, criteria, and threshold values for the QRS-complex

- Widened QRS
  This reference appears when the QRS-time exceeds 115 ms in a man and 105 ms in a woman.
- M-Form in...
  An M-form is present when two R-waves exist in a lead which have an amplitude of at least 300 µV.
- Q in...
  No reference is made to a Q-wave for the AVR lead because of its negative polarity
  For the other leads, a reference to Q-waves occurs when the amplitude and Q-time are above the 96 % quantile from NORMAL. See table 96%-quantile of Q-amplitude and Q-time in normal groups.

- QS in...
  This information is provided in the case of a missing R-wave if the negative amplitude is below –500 µV.
- R-loss in...
  This information does not indicate a missing R-wave, but refers to a R-amplitude below 100 µV. It is thus adding emphasis to the reference for a "small" R-wave.
- Small R in...
  A deviation of 4% quantile of the R-amplitude in normal groups is checked in the leads (not in AVR lead as with Q-waves).

Lead	R-amplitude [µV]
I	250
II	350
III	50
AVL	50
AVF	50
V1	50
V2	150
V3	290
V4	450
V5	750
V6	550

4% quantile of the R-amplitude in normal groups

Wide R in...

This information appears if the R-time exceeds the limits stated below.

Lead	R-time [ms]
I	80
II	80
III	80
AVR	55
AVL	80
AVF	80
V1	45
V2	60
V3	80
V4	80
V5	80
V6	80

96% quantile of the R-time in normal groups

High R in...

This information appears if the R-amplitude exceeds the limits stated below.

Lead	R-amplitude [µV]
I	1500
II	2100
III	1700
AVR	360
AVL	1100
AVF	1900
V1	750
V2	1700
V3	2400
V4	3000
V5	2800
V6	2100

96% quantile of the R-amplitude in normal groups

Wide R' in...

The 3 leads AVR, V1 and V2 are checked. This information appears if:
in lead AVR the R'-time is > 55ms or
in lead V1 the R'-time is > 45ms or
in lead V2 the R'-time is > 60ms.

High R' in...

If two R-waves exist in a lead and if the later one has an amplitude of at least 300 µV, the following information appears.

Late R in...

The information is given for the leads AVR, V1 and V2. A QR-configuration is required and in lead AVR a Q-time > 30 ms,
Q-amplitude < -200 µV and R-amplitude > 200 µV
or in lead V1 (V2) a Q-time > 30 ms,
Q-amplitude < -200 µV and R-amplitude > 300 µV.

A reference to a late R also occurs if the QRS-configuration not only consists of a Q-wave and a R-wave, but also when either a small R-wave with an amplitude < 50 µV appears in front of the Q-wave or with an amplitude > -50 µV at the end of a S-wave.

Abnormal R/S in...

The R/S ratio is investigated only in the leads V1 and V2. This information is given only if the amplitudes of the waves exceed 500µV and if
in lead V1 the R-amplitude is > 0.85 * S-amplitude (in men)
or the R-amplitude is > 0.65 * S-amplitude (in women),
and
in lead V2 the R-amplitude is > 1.80 * S-amplitude (in men)
or the R-amplitude is > 1.50 * S-amplitude (in women).

Small S in...

This information also applies only to the leads AVR, V1 and V2 for which the following criteria must be met:
in lead AVR S-amplitude > -500 µV or
in lead V1 S-amplitude > -300 µV or
in lead V2 S-amplitude > -300 µV.

Wide S in...

S-waves play a major role in the detection of infarctions, right bundle-branch blocks and left anterior hemiblocks. They are checked only in leads I, II, AVL and V3 to V6. Table 05 represents the minimum S-time in ms, which when exceeded produces this information.

Lead	R- time [ms]
I	55
II	55
AVF	55
V3	65
V4	55
V5	55
V6	50

Minimum S-time for message "Wide S"

Low S in...

If the 96% quantile in normal groups is exceeded, the following information appears automatically.

Lead	R- amplitude [µV]
I	-480
II	-480
III	-950
AVR	-1500
AVL	-900
AVF	-500
V1	-2100
V2	-3100
V3	-2400
V4	-1600
V5	-800
V6	-350

96% quantile of the S-amplitude in normal groups

Information on ventricular stimulus disturbances / bundle-branch blocks

Every ECG is investigated for ventricular stimulus disturbances during ventricular depolarization. The primary criterion for a reference to a delayed conduction is the QRS-complex, not necessarily a R-R' configuration, e.g. in AVR or V1, V2, if the QRS-complex is not simultaneously extended. The previously published criteria are neither uniformly nor quantitatively defined accurately enough for a computer evaluation.

Therefore, in the HES program, several (at least four) criteria (measured variables) are therefore checked for each type of block and a score determined according to intensity. Then, depending on the score value, a reference is made to incomplete, complete bundle-branch block, hemiblock or – in mixed symptoms – to "intraventricular stimulus disturbances".

The possible bundle-branch block data of the HEW program with the variables tested are listed below. In addition, the QRS-complex is measured as an additional criterion and accordingly a rising number of points added for a time of over 100 ms.

In the case of a QRS-complex of over 134 ms, information is provided on infarctions and left ventricular hypertrophy with a “reduced“ confidence value ("uncertain", " check").

Bundle branch block data and variables tested

- Complete right bundle branch block:
  QRS-start to ENB* in ??
  Amplitude of the negative T-maximum in V!
  R-amplitude in V1
  R1-amplitude in V1 > R0-amplitude in V1(**)
  R1-amplitude in AVR
  Sum of S-time in V5
  S-amplitude in V1
  Sum of S-time in V6

S-amplitude in V6
QRS-frontal angle

- Complete left bundle branch block:
  Q-time, S0-time and S1-time in V1
  Amplitude of the negative T-maximum in V 5
  Amplitude of the negative T-maximum in V6
  QRS-start to ENB in I
  Q-time in V5=0
  Q-time in V6=0
  QRS-start to ENB in AVL
  QRS-start to ENB in V5
  QRS-start to ENB in V6
- Incomplete right bundle branch block:
  R1-amplitude in V1
  R1-amplitude in AVR
  R1-tIme in AVR
  S-time in V5
  S-time in V6
- Incomplete left bundle branch block:
  QRS- start to ENB in I
  QRS- start to ENB in AVL
  QRS- start to ENB in V5
  QRS- start to ENB in V6

ENB* = Start of final negativity movement

(**) = R0, R1 here represent R, R' etc.

- Left posterior hemiblock:
  Q-amplitude in I=0
  Q-amplitude in AVF
  Initial QRS frontal angle
  Maximum QRS- frontal angle
  S-amplitude in I/ Q-amplitude in II
  S-amplitude in I/ Q-amplitude in III
- Left anterior hemiblock:
  Q-amplitude in I
  Initial QRS frontal angle
  Maximum QRS- frontal angle
  S in II and III simultaneous and S-amplitude in II
  S in II and III simultaneous and S-amplitude in III
  Q-amplitude in AVR
  S-amplitude in AVR
  QRS-start to ENB in AVL
  S-amplitude in V5/ S-amplitude in V6
- Trifascicular block:
  Possible and certain (incomplete) RSB
  Possible left anterior and left posterior hemiblock
  Possible and certain (incomplete) LSB
  PQ-interval > 200 (AV-block)
- Left bundle-branch block:
  QRS- start to ENB in I
  QRS- start to ENB in AVL
  QRS- start to ENB in V5
  QRS- start to ENB in V6

Pre-excitation syndrome

Every lead is checked for △-waves or slow QRS-rise and appropriate information given.

A reference is, however, made to pre-excitation syndrome only if
the PQ-segment (interval P-end – QRS-start) is shorter than 30 ms,

there is no atrial fibrillation/flutter present (because then no PQ can be defined)
there is no anterior myocardial infarction present.

Information on re-polarization disturbance

In principle, the re-polarization phases are checked in all leads. Special information, however, is only provided for the leads I, AVL and V3- V6. “Inner layer“ and “outer layer“ damage are distinguished according to different degrees of intensity.

Inner layer damage

Grade 1:
Flattened T-waves

When this finding is present for an ECG alone, then the overall assessment of normal is possible.

Grade 2:
I-point reduced by less than 0.1mV with a slightly trough-shaped ST-segment with a transition into predominantly positive T-waves.
Compatible with slight re-polarization disturbances of the inner layer type.

Grade 3:
I-point reduced by at least 0.1mV with horizontal or descending ST-segment with a transition into a T-wave inverted by greater than 0.5mV, which does not rise again above the iso-electric.
Compatible with medium severe re-polarization disturbances of the inner layer type.

Grade 4:
I-point reduced by at least 0.1mV, of which the ST-segment descends more steeply with complete T-inversion by more than 0.5mV.
Compatible with severe re-polarization disturbances of the inner layer type.

Outer layer damage

Re-polarization disturbance of the outer layer type are graded according to the development stage.

Grade 1:
Slightly sagging ST-deflections rising out of the descending R-deflection with a transition into exclusively positive T-waves; ST-deflections raised by at least 0.2 mV in the chest lead and 0.1 mV in the extremities lead. Compatible with early stage re-polarization disturbances of the outer layer type.

Grade 2:
Raised, outgoing ST-deflections from the descending R-deflection with transition into a slightly terminal T-negativism. Compatible with transitional stage re-polarization disturbances of the outer layer type.

Grade 3:
Isoelectric ST-deflection with transition into terminal-negative T-wave of less than 0.5 mV. Compatible with later stage slight re-polarization disturbances of the outer layer type.

Grade 4:
Isoelectric ST-deflection with transition into terminal-negative T-wave of more than 0.5 mV. Compatible with later stage severe re-polarization disturbances of the outer layer type.

8.3 EC Declaration of Conformity

EC Declaration of Conformity

Document No. / Month.Year: QKE 13.00.002-04 / 02.05

Manufacturer:
Medset Medizintechnik GmbH
Curslacker Neuer Deich 66
D-21029 Hamburg, Germany

We hereby declare that the product:

FLASHLIGHT
PC ECG System

consisting of:

FLASHLIGHT **SENSOR** type **SE, USB**
ECG amplifier module
from version A

with

FLASHLIGHT **PADSY**
Rest ECG Software
for version 3.5a and higher
in the following models
ECO, SCOPE
and
FLASHLIGHT **ERGO PADSY**
Stress Test ECG Software
from version 1.0a
in folgenden Ausführungen
E, T, ER, TR

with the following accessories: **FLASH**LIGHT **patient cable 10 leads**

complies with European Directive 93/42/EEC of the Council of 14th June 1993 concerning medical products.
It bears the mark:

CE 0124

Hamburg, 28th February 2005

Medset Medizintechnik GmbH

Legally binding signature:

Klaus Kophstahl
- Managing Director -

The technical documentation is kept in quality department.