AT-10 plus

12-Channel ECG Device



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1 Safety notes

This Service Handbook is for qualified service personnel only, trained by Schiller AG. Refer to the operating instruction manual 2.510526 for operation the device.

1.1 Responsibility of the user

- ▲ Specify the competencies of the personnel for operation and repair.
- ▲ Ensure that service personnel have read and understood these service instructions. In particular this section "safety notes" must be read and understood.
- ▲ Have damaged or missing components replaced immediately.
- ▲ The service personnel is responsible for compliance with all applicable accident prevention regulations and safety regulations.

1.2 Intended use

- ▲ The AT-10 plus is a 12-channel, ECG device used for the recording, analysis and evaluation of ECG Recordings. Recordings made with the AT-10 plus can be used as a diagnostic aid for heart function and heart conditions. The AT-10 plus is designed for indoor use and can be used for all patients of both sexes, all races, and all ages.
- Only operate the device in accordance with the specified technical data.
- ▲ Do **not** use or repair this unit in areas where there is any danger of explosion or in the presence of flammable gases such as anaesthetic agents.

1.3 Organisational measures

- Before servicing the unit, ensure that an introduction regarding the unit functions and the safety precautions has been provided by Schiller AG
- ▲ Keep these service instructions in an accessible place for reference when required. Make sure that they are always complete and legible.
- ▲ Observe the operating instructions and service instructions.
- ▲ These service instructions do not override any statutory or local regulations, or procedures for the prevention of accidents and environmental protection.



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1.4 Safety-conscious operation



- ▲ Do not place any liquids on the unit. If liquid should be spilled over the device, immediately disconnect the device from the mains and wipe it. The device must be serviced before reusing.
- ▲ Danger of electric shock! Do not open the device without disconnecting the device from the mains.
- Before cleaning and to isolate the mains power supply, switch the unit off and disconnect it from the mains by removing the plug.
- ▲ Do not use high temperature sterilisation processes (such as autoclaving). Do not use E-beam or gamma radiation sterilisation.
- ▲ Do not use solvent or abrasive cleaners on either the unit or cable assemblies.
- ▲ Do not, under any circumstances, immerse the unit or cable assemblies in liquid.

1.5 Safety facilities



- Operating the device without the correctly rated fuse, or with defective cables, constitutes a danger to life. Therefore:
 - Do not operate the unit if the earth connection is suspect or if the mains lead is damaged or suspected of being damaged.
 - Damaged cable connections and connectors must be replaced immediately.
 - The electrical safety devices, such as fuses, must not be altered.
 - Ruptured fuses must only be replaced with the same type and rating as the original.

1.6 Operation with other devices



- ▲ Use only accessories and other parts recommended or supplied by SCHILLER AG. Use of other than recommended or supplied parts may result in injury, inaccurate information and/or damage to the unit.
- ▲ Ancillary equipment connected to the analogue and/or digital interfaces must be certified according to the respective IEC standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC/EN 60601-1-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC/EN 60601-1-1. If in doubt, consult the technical service department or your local representative.
 - EC/EN 60601-1-1 states that the patient must remain at least 1.5 meters clear of the unit. If this is not possible, a safety isolating transformer must be installed.

1.7 Safety Symbols and Pictograms

1.7.1 Used symbols in this document

The safety level is classified according ANSI Z535.4. The following overview shows the used safety symbols and pictograms used in this manual.

For a direct danger which could lead to severe personal injury or to death.



DANGER

For a possibly dangerous situation, which could lead to heavy bodily injury or to death.



For a possibly dangerous situation which could lead to personal injury. This symbol is also used to indicate possible damage to property.

For general safety notes as listed in this chapter.



Used for electrical dangers, warnings and other notes in regarding operation with electricity.

Note For possibly dangerous situations, which could lead to damages to property or system failure. **Important** or helpful user information



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Reference to other guidelines

Observe precautions for handling electrostatic sensitive devices

Tools required for a procedure.

1.7.2 Used symbols on the device

Potential equalization





Inappropriate disposal can lead to environmental pollution.

Units/components and accessories no longer required can be returned to SCHILLER AG for disposal. Alternatively, the unit should be disposed of in a municipally approved recycling centre.

CF symbol. This unit is classified safe for internal and external use. However, It is only

defibrillation protected when used with the original SCHILLER patient cable!





Attention: Consult accompanying documents.

1.8 Terms of warranty

The SCHILLER AT-10 plus is warranted against defects in material and manufacture for the duration of one year (as from date of purchase). Excluded from this guarantee is damage caused by an accident or as a result of improper handling. The warranty entitles free replacement of the defective part. Any liability for subsequent damage is excluded. The warranty is void if unauthorized or unqualified persons attempt to make repairs.

In case of a defect, send the apparatus to your dealer or directly to the manufacturer. The manufacturer can only be held responsible for the safety, reliability, and performance of the apparatus if:

- assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by him, and
- the SCHILLER AT-10 plus and approved attached equipment is used in accordance with the manufacturers instructions.

2 Introduction

2.1 Features

The SCHILLER AT-10 plus is a 12-channel ECG unit designed to record, display, and measure resting ECGs. The AT-10 plus has the following features:

2.1.1 Standard

- Pacemaker Detection
- Manual (real time) mode (leads, speed and amplitude can be changed as required)
- · Auto mode with user defined presentation formats
- Rhythm recording with user defined formats (planned)
- Measurements

2.1.2 Options

- Interpretation
- Thrombolysis (with C version (interpretation) only)
- Stress testing with standard test protocols and user defined protocols, analysis program with ST measurement, average complexes and trends (EXEC)
- Extended Memory (planned option)
- Full disclosure of all 12 leads (planned option)
- Spirometry (planned option)
- · Pacemaker measurement (planned option)
- Heart rate variability (planned option)
- Late potential analysis (planned option)

2.1.3 Connectors

- VGA interface for the connection of an external monitor
- · DC input connector for on-screen presentation or printout of external signals
- DC Output connector for output of recorded signals
- · RS-232 interfaces for control of digital treadmills and digital bikes
- Analogue interface for control of an analog ergometer
- · RS-232 interface for a spiro flow sensor

Schiller Communication Module (SCM)

- Analogue Modem connecter (with optional internal modem)
- RS-232 interface for external Blood pressure unit (BP200 or ergo device with NIBP).
- RJ-45 ethernet connector (network)
- Two USB connectors
- SDCARD slot (with 64MB SD Card) for removable storage of recordings

2.2 LCD screen

The display will vary according to the current task being carried out. In all screens however, the top, middle and bottom areas always display the same information groups. The following is an example of a typical resting ECG screen.



- (1) The heart rate (HR) averaged over the last 4 beats.
- (2) The patient name below is the last auto mode recording intervals (if an auto mode recording has been taken).
- (3) Message field this area displays any status messages.
- (4) Message Field this area displays technical and system error messages.
- (5) Current mode of operation (resting, stress, spiro).
- (6) Electrode lead status when an electrode indication flashes (an audible indication is also given), it indicates that the electrode resistance is too high
- (7) Current power source mains (~), or battery () (see page 18).
- (8) Selected baseline frequency (0.05, 0.15, 0.30, or 0.60 Hz) (see page 51).
- (9) Myogram filter cut-off frequency (25Hz, 35Hz or 150Hz (off)).
- (10) Auto sensitivity reduction on ('A' in box), or off (box empty) to help reduce overlapping traces (see page 51).
- (11) The central section of the screen displays the measured ECG traces.
- (12) Manual Print settings
 - speed in mm/s
 - sensitivity in mm/mV
 - selected leads
- (13) System time and date.







The keyboard is divided into the following functional areas:

- (1) Alphanumeric and Dual Purpose Keys. The numerical keys are dual purpose as follows:
 - Key 1 switch myogram filter on or off
 - The following keys change the speed, amplitude and lead group during manual printing:
- Key 2 and 3 changes to next / previous lead group
- Key 4 to 7 printout speed
- Keys 8 to '-' printout Amplitude (sensitivity)
- (2) Resting and Stress ECG Function Keys:
- ECG Keys
 - ECG key select ECG menu settings
 - Monitor Lead key display next lead group
 - Monitor Channel key change the number of leads displayed
 - Monitor mm/s key toggle display speed
 - Monitor mmV key toggle display sensitivity
 - Cal key reset ECG signal to baseline and insert calibration signal on the screen or on the printout



- Exercise Keys
 - Exercise key exercise ECG settings and function
 - Protocol key display/select/ edit exercise protocols
 - **Symptoms** key manual input of symptoms
 - Begin key start exercise test (beginning of warm-up phase) according to protocol set
 - End key stop exercise test (start of recovery phase)
 - **Print Report** key print final report (end of recovery phase)
 - Print Rhythm key print rhythm strip
 - Next Stage key switch to next stage
 - Interrupt Stage key interrupts the test i.e. releases load on bike/stops treadmill - this function can be used, for example, to administer medication - when this key is again pressed, the test resumes from the same position
 - Load key overwrite protocol and define load
- (3) Memory, Storage and transmission Keys:
- Memory key gives access to the stored recordings memory and transmission settings are also defined here
- Store Data key initiates data storage to internal memory of the current recording - the location where the recording is stored in defined in the memory settings.
- Send Data key initiates transmission over the defined interface of the current recording - the location where the recording is sent is defined in memory settings
- Get Data key initiates data reception from another location the location from where the data is received is defined in the memory settings
- (4) Patient Data key Input of patient data
- (5) Direct function keys including:
- Print Screen key print the displayed screen
- Copy 1 and Copy 2 keys print a copy of current recording in format 1 or format
 2
- Man Start key imitate real time printout
- Auto Start key take auto recording
- Stop key stop real time printout / advance paper to beginning of new page
- (6) Replace Paper key extend or retract the paper tray for paper replacement
- (7) On/Off key switch the unit on or off
- (8) Menu navigation keys including:
- Menu key give access to system settings
- Confirm key confirm current / displayed setting
- Left arrow key move cursor to the left / select next menu option
- Right arrow key move cursor to the right / select previous menu option
- Up arrow key move cursor or menu bar up
- Down arrow key move cursor or menu bar down
- (see page 19)
- (9) Further Function Keys for:
- NIPB key take or enter non-invasive blood pressure measurements
- SPIRO key spirometry program (requires spiro sensor connected to the spiro RS-232 interface)

2.3 External connections

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▲ All externally connected hardware must be approved by SCHILLER. Connection of any hardware not approved by SCHILLER is at the owner's risk. The unit guarantee may also be invalid.

2.3.1 Back Panel

 \bigcirc RS-232 \checkmark () (*****) SCHILLEP CARDIO AT-10plu ఉప్ప 2 3 4 5 6 8 11 1 7 9 10 (1) RS-232 connector for Treadmill. (2) RS-232 connector for Ergometer. (3) Potential equalisation stud. The potential equalisation stud is used to equalise the ground potential of the unit to that of any nearby mains powered equipment. Use the hospital or building common ground for all mains powered units. If an external printer, monitor or ergo device is connected to the AT-10 plus, the potential equalisation stud must be connected to common ground when the AT-10 plus is working on battery power i.e. when the mains lead (with grounding lead) is not connected to the unit (see page 17). (4) Mains connector and fuse box (fuses: 2 x T 160 mA / 250 V). (5) VGA connector for external monitor. Note that before an external monitor can be used, the VGA output must be enabled in system settings (see page 57). The following connectors are situated on the communications module. i (6) RJ-45 Ethernet LAN connector (Local Area Network). (7) USB connector for an external printer. (8) RS-232 for an external BP unit. (9) SD card slot for (removable) data storage (64MB). (10) USB connector. (11) RJ-11 telephone connector (with optional internal modem).

2.3.2 Side panel



(1) EKG/ECG patient cable input socket.



- The unit is only CF rated and defibrillation protected if used with the original SCHILER patient cable.
 - (2) RS-232 connector for pneumotach sensor (SP-250/SP-260) for pulmonary function testing.
 - (3) DC input DCIN 1, 0.5 V/cm.
 - (4) DC output DCOUT, 0.5 V/cm.
 - (5) ERGO connector for connection of analogue ergometers.





3 Operation Overview

3.1 Start-up and initial preparation

Danger of electrical shock. Do not operate the unit if the earth connection is suspect or if the mains lead is damaged or suspected of being damaged.

3.1.1 Location

- Do not keep or operate the unit in a wet, moist, or dusty environment. Avoid exposure to direct sunlight or heat from other sources.
- Do not allow the unit to come into contact with acidic vapours or liquids.
- The AT-10 plus should not be placed in the vicinity of X-ray or diathermy units, large transformers or electric motors. It must also be positioned at least one meter from the mains supply.

3.1.2 Connection of external cable assemblies and ancillary equipment

- 1. Check the voltage setting (115V or 230V) (see page 43).
- Connect the power cable at the rear of the unit. The Mains indicator lamp is lit. Leave the AT-10 plus connected to the mains for 7 hours to fully charge the battery.
- 3. Connect the patient cable (side panel).
- 4. Connect any ancillary and optional equipment (see page 15). These may include the following:
 - Ergometer (analogue or digital) for exercise testing
 - Blood pressure unit
 - Spiro sensor (for spirometry)
 - External monitor
 - Network cable
 - External printer

3.1.3 Potential equalisation

The potential equalisation stud at the rear of the unit is used to equalise the ground potential of the AT-10 plus to that of all mains powered equipment in the vicinity. Use the hospital or building common ground. A yellow/green ground cable is supplied as an option (Article number 2. 310 005).

To avoid possible interference from the ergometer when carrying out an exercise test, it is recommended that both the AT-10 plus and the ergometer are connected to the same common ground.

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▲ To prevent the possibility of leakage current when an external printer, external monitor, or ergo device is connected, always ensure that the mains lead (with earth grounding connection), and / or the potential equalisation, is attached to the AT-10 plus.

3.1.4 Switching on and off

The unit is switched on and off with the On / Off key.

.5 Power supply and battery operation

The unit can be operated either from the mains supply or from the built-in rechargeable battery. The power source is indicated on the top line of the LCD and a mains and battery indicator on the unit. The mains indicator lamp is lit all the time the unit is connected to the mains supply. The mains symbol is also displayed in the top right corner of the screen when the unit is switched on.

Mains and battery LED indicators

The LED indicators on the unit casing indicate the power operation as follows:

| Function | Battery LED | Mains LED |
|--|------------------------------|-----------------------|
| | | \sim \blacksquare |
| Mains Connected: | | |
| Battery Charging | • On | • On |
| Battery Full | • Off | • On |
| Battery Working: | | |
| Battery Capacity OK | • On | • Off |
| Battery Capacity Limited (reconnect mains) | Blinking | • Off |

Battery Capacity

Full Half full Empty The internal battery provides power for up to four hours. When the unit is running on battery power a battery symbol replaces the mains symbol and indicates the battery status. When the battery is full, the symbol is solid.

The battery is charged when the unit is connected to the mains supply. The unit can remain connected to the mains supply without damage to either the battery or the unit.

3.1.6 Isolating the mains supply

To isolate the power supply, remove the mains plug from the wall socket.

3.1.7 System and ECG settings

- The System Settings (time, date, user ID, etc.), and other general settings (macros, ergometer, etc.), are found in the System Settings section (see page 57).
- Resting ECG settings (auto format, user defined leads, print options, lead test, QRS beep, interpretation, rhythm lead definition, etc.), (see page 51).
- Exercise settings (Heart rate target, protocol HR target, treadmill settings, recovery settings etc.) are found in the Exercise Section (see page 55).





3.2 Selecting menu options using the arrow keys

When any of the setting keys are pressed (ECG, Exercise, NIBP, Menu etc.), menu tabs are displayed and menu options displayed, as given in the ECG example below.

The general principal of navigating and option selection is the same for all menu keys as follows:

- 1. Press the left /right keys to select (highlight) the tab on the top of the screen.
- 2. Use the **up/down** keys to select the field/icon the entry field appears blue (as shown in the example below for 'signals').

| | HR Variability Autom. Forma Lead Test Pacemaker Int | at Prog. Leads Lead Filter General erpretation Rhythm Rec Late Potential |
|-----|--|---|
| ECG | Lead Sequence Signals Auto-Centring Rhythm lead group Left posterior (V4 - V9) | Standard simultaneous sequentiai NO NO |

- 3. Press Confirm to select.
- 4. Use up/down keys to toggle through the options available.
- 5. Press Confirm to set.
- When all entries are made, press the Esc key to exit and register the entered data.



CONFIRM

ESC

4 Service Screen

To enter the service screen press the following key sequence:

| '.' > '.' > 'S' (full stop key pressed twice, followed by 's'). | by 's'). | \cdot |
|---|----------|---|
|---|----------|---|

A number of tabs at the top of the screen give the following options:

| Service | | | | | | |
|----------|----|--------|---|-------|------------|-------------|
| Characte | er | Colour | 1 | Test | Battery | Software |
| ECG | | NIBP | | Spiro | HW-Config. | I/O + ports |

4.1 ECG

| Chapacter Colour Test Battery Software ECG NIBP Spiro HW-Config. I/O + ports Lead Test (mV) RA 5 LA 5 C1 5 C2 5 C3 5 C4 5 C5 5 | Service | | | | |
|---|------------------|---|--|-----------------------|-------------------------|
| Lead Test (mV) RA 5 LA 5 C1 5 C2 5 C3 5 C4 5 C5 5 | Character ECG | Colour NIBP | Test Spiro | Battery HW-Config. | Software I/O + ports |
| C6 5 C7 5 C8 5 C9 5 | | Lead Test RA LA C1 C2 C3 C4 C5 C6 C6 C7 C8 C9 | (mV) 5 5 5 5 5 5 5 5 5 5 5 5 5 5 | | |

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The electrode resistance check is provided as an integrity check for the electrode resistance and patient cable if suspected of being faulty.

To check the electrode resistance and the integrity of the cable, click the ECG icon.

This gives electrode dc offset and is the voltage drop in the patient cable and electrodes. The result column gives the detected voltage for each electrode in millivolts measured between the electrode on the left leg and each of the individual electrodes. It can indicate any faults in the patient cable or patient electrode. The measured voltage value will depend on where the electrodes are connected. The voltage readings that can be expected are as follows:

 \pm 100mV: Good connection, low resistance. An offset of up to $\pm 300 \text{mV}$ will give an acceptable recording.

 \pm 20 mV: This will depend on the patient simulator used and must be taken as a flexible measurement.

With all electrodes shorted together: ± 20 mV.

-350 to -550mV.

No patient cable connected:

With patient simulator connected:

With patient connected:

SCHILLER AT-10 plus

4.2 NIBP

| Service | | | | |
|-----------|------|--------|-----------|---------------|
| Character | Сори | r Test | Battery | Software |
| ECG | NIBP | Spiro | HW-Config | . I/O + ports |
| | | | | |

Not available at the time of print.

4.3 Spiro

| Service | | | | |
|------------------|----------------|---------------|-----------------------|-------------------------|
| Character ECG | Colour NIBP | Test Spiro | Battery HW-Config. | Software I/O + ports |
| | | | - | |

Not available at the time of print.

4.4 HW-Config

| Service | | | 4 | |
|------------------|----------------|---------------|-----------------------|-------------------------|
| Character ECG | Colour NIBP | Test Spiro | Battyry HW-Config. | Software I/O + ports |
| Display | rotation 0° | Save it an | d power off to get | effect |
| | | | | |
| | | | | |
| | | | | |

Use this setting to rotate the display by 180°. The procedure is as follows:

- 1. Set the rotation as required $(180^{\circ} \text{ or } 0^{\circ})$.
- 2. Press the Escape key.
- 3. Press the Menu key and select the Software tab.
- 4. In the software screen click the **Save as Default** icon to ensure that the option is saved (see page 31).
- 5. Switch the unit off and on again. The defined setting is displayed.



4.5 I / O ports



This screen enables the Input output ports to be tested / checked. Signals are send from the AT-10plus and checked for correct reception. Both the RS-232 ports and the analogue ports can be tested.

The testing of the ports requires the following test equipment. Details of this test equipment is given at the end of this book (see page 72).

RS-232 test plug

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- DC In / DC Out test cable assembly
- Test plug and switch (ERGO check)

4.5.1 Checking the RS-232 ports

The following ports can be checked:

- Treadmill (back panel)
- · Ergo (back panel)
- RS-232 (side panel)

Proceed as follows:

- 1. Position the RS-232 test plug (pin 2 (TX) and 3 (RX) shorted together) in the port to be tested.
- 2. The red square (1) changes to green to indicate that the port is functioning.

The Spiro and NIBP RS ports are internal and cannot be checked with the test plug.



4.5.2 Checking the analogue ports

The following ports (on the side panel) can be checked:

- DC In
- DC Out
- ERGO

DC In / DC Out Ports

Proceed as follows:

- 1. Using the test cable assembly, connect the DC in and DC out ports together.
- 2. After a few moments while the circuit counts up, the red squares (2) change to green to indicate that the port is functioning.

Checking the ERGO Port

- 1. Plug the test plug and switch assembly in the ERGO port on the side panel.
- 2. With the switch in the TMUP position, the TMUP red square changes to green to indicate that the port is functioning.
- 3. With the switch in the TMDOWN position, the TMDOWN red square changes to green.

4.6 Character

| Servic | | | | |
|-----------|--------|-------|------------|-------------|
| Character | Colour | Test | Battery | Software |
| ECG | NIBP | Spiro | HW-Config. | I/O + ports |
| | | | | |

Select this screen to display the complete character set of the unit.

4.7 Colour



In this screen the default background colour can be selected. Choose between:

- Cyan
- Grey
- Blank
- Blue

To set the background colour proceed as follows:

1. Set the colour.



- 2. Press the Escape key.
- 3. Press the Menu key and select the Software tab.
- 4. In the software screen click the **Save as Default** icon (see page 31).
- 5. Switch the unit off and on again. The defined setting is displayed.

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The ECG display can also be inverted. This is carried out in the ECG menu:

• ECG key > General > 'In. ECG Monitor'.

4.8 Test



In this screen some test and check functions can be performed as follows:

- · Battery capacity test
- Print quality and print alignment check

4.8.1 Battery capacity test



Battery settings and calibration procedure are detailed on the following page.

To check the battery capacity proceed as follows:

- 1. Leave unit connected to the mains for eight hours to fully charge the battery.
- 2. Disconnect the mains supply to the unit.
- 3. Enter the test screen and press the character sequence 032.
- 4. A printout will be initiated and then a printout will be given every hour.
- 5. Check that at least 2 printouts are obtained (minimum capacity one hour).
- 6. The time of each printout is given on the bottom of the printout (1). The final printout gives the time that the battery capacity was exhausted (2).



7. Quit the test by switching the unit off.

4.8.2 Print quality and printer alignment check



Also see page 36 for print speed and parallelism checks.

To check the print quality proceed as follows:



- 1. Enter the test screen.
- 2. Press the Man Start key.
- 3. A continuous test print will be given.
- 4. Use the Lead selection keys (2 and 3), to toggle though the four test patterns. The five print patterns are shown on the next page.
- 5. Stop the printout by pressing the Stop key.
- 6. Check the printout for:
 - fading
 - alignment
 - faulty pixels

 blackness for regularity and good readability on the complete print width.
 If individual pixels are missing, the printout fades or is darker in one area the problem is usually with the thermal print head. If the print quality is not good:

- clean the print head with alcohol (see page 50).
- check that fresh good quality SCHILLER paper is installed in the unit.
- check the electrical / mechanical settings of the print head.
- change the printer (see page 46).









4.9 Battery



This screen displays the charge capacity of the battery. Two battery types are available with the AT-10 plus.

- Lithium
- NiMh

The battery type is automatically detected by the unit and is calibrated in the factory. It should not need recalibrating during its life. However, if the battery capacity seems limited when the battery gets older, it can be recalibrated at any time. The battery must also be recalibrated when a new one is installed. The information given on this screen is as follows:

This is a hardware counter directly from the battery charge controller. It counts (to a maximum of 16000), to show battery discharge when the unit is switched on (but not connected to the mains).

This is a counter directly from the (hardware) charge controller. It is a counter (to max 16000) showing battery charge rate when the battery is charging.

This is a counter directly form the (hardware) charge controller. It is a counter (to max 16000) showing battery leakage rate when the unit is not switched on and not connected to the mains.

The three counters (registers) above, have a maximum count of 16000. When any counter reaches 16000, all the hardware counters are reset. The saved energy count here is an accumulative figure of the three counts above (when reset) i.e.

· (Charge count) - (Discharge count) - (Self dis. Count)

This is the capacity of the (NiMh) battery (calculated when the battery is calibrated). The typical value of a new battery is 4000 - 6000.

This is the capacity of the (Li) battery (calculated when the battery is calibrated). The typical value of a new battery is 2500 - 4000.

Note: the battery type is automatically detected by the unit and only one of the above values ('NiMh full value' or 'Li full value') will be displayed. The type of battery installed in shown in the Li / NH field (see following).

NiMh full value

Discharge Count

Charge Count

Self dis. Count

Saved Energy

Li full value

| Cal Energy | This is the current capacity of the battery and is calculated from: | | |
|--------------|---|--|--|
| | (Saved energy) - (discharge count) - (self discharge rate) + (charge count) | | |
| Total Power | The ratio of battery capacity to current capacity. This value is used to calculate the battery capacity icon on the display. | | |
| Battery Down | Hardware flag, based on battery voltage, to indicate when the battery is almost empty. When this flag is set the battery capacity beep is activated. | | |
| NH/Li | Battery type installed in the unit. | | |
| Mains / Bat | Power supply source. | | |
| | | | |
| | | | |

4.9.1 Calibrating the battery

The procedure is as follows:

- 1. Switch the unit on with the mains removed and wait until the battery is empty and unit switches off.
- 2. Reconnect the mains supply and enter the service screen > battery.
- 3. Start / Stop icon (1) will say Cal Off.
- 4. Click the icon and the **Cal On** is displayed.
- 5. Switch the unit off and leave for 8 hours.
- 6. Switch the unit back on and then the calibration off.

The information given on this screen is as follows:

| Start Time | Calibration start time. |
|----------------|---|
| End Time | Calibration end time. |
| Clear Register | |
| Cal offset | The offset between the original (last) calibration and current calibration. |
| Total recal | The number of times the battery has been recalibrated. |



4.10 Software



4.10.1 Installing software options

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All software options are embedded in the unit and can be upgraded with a code. To upgrade an option(s), obtain the option code from SCHILLER, (you will need to state the serial number of the unit (1) to get the code), and proceed as follows:

- 1. Click the 'Program Upgrade' icon (2) to display an entry field to the right of the icon (3).
- 2. Enter the option code (obtained from SCHILLER).
- 3. Press the **Enter** key and the program option is installed.
- 4. To ensure that the option is saved, press the menu key and enter the Software screen to save (see page 31).

The number to the right code entry (4), indicates the number of unsuccessful attempts to upgrade the program. If this numbers appraises or exceeds approximately 10, the unit will freeze and cannot be upgraded. If this happens the unit must be returned to SCHILLER for reprogramming.

4.10.2 Updating the unit software

The unit software is updated using a PC program called SWUP. Before updating the unit software, the update program must first be downloaded from the SCHILLER server to a PC.

The procedure to update the unit software is a follows:

- The operating system of the PC must be Win NT4, Win 98, Win 2000 or Win XP.
- Do not power off during update.
- RS-232 cable assembly.
- 1. Access the SCHILLER extranet (details from the service department) and install the software on your pc (Install_AT10plus.exe).
- 2. Connect the RS-232 cable assembly between the PC and the RS-232 on the side of the AT-10 plus.

3. In the service screen click the Program Update icon (to enter receive mode).



Program Upgrade Program Update i

DC IN

(RS-232)

...)e

4. Start the AT10 plus SWUP program from the computer Start menu.



- 5. Click the config icon (1).
- 6. Define pc settings:
 - Select the pc com port (2) to which the pc cable is connected.
- Select baudrate = auto.
- 7. Click the update AT-10plus icon (3).
- 8. The bargraph shows the progress of the download. After downloading, the device will restart automatically.



4.11 Saving the settings

All changed settings are remembered until the unit is switched off. If you wish to keep the settings as default, the **Menu** key must be pressed and software screen must be entered (1), and the 'save as default' icon (2), pressed before the unit is switched off. To set the default to the factory setting, click the 'Factory Default' icon (3).



SCHILLER

AT-10 plus

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5 Functional Checks

5.1 Service interval

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The device must be checked at regular intervals. The test results must be documented and be compared with the values in the accompanying documents.

The following table gives information about interval and competence of maintenance which can be required.

| Interval | Service | | Responsible |
|-----------------|--|---|---|
| Every 6 months | Visual inspection of the unit and cables (see page 34).General unit integrity check (see following). | → | User |
| Every 12 months | Electrical safety tests according to IEC 60601-1, Clause 18 and 19 (see page 41). The visual, general, measuring and calibration tests and checks according to the checklist at the end of this book (see page 73). | → | By SCHILLER AG author- ised technician |

5.2 General unit integrity check

The procedure detailed here is a general confidence check of the unit if a fault is suspected. It is not a full functional test but is intended to provide a general confidence check in all the main functional areas.

- ▲ Comprehensive instructions for operating the unit are provided in the AT-10 plus User Guide. This are available from SCHILLER on request.
- Patient simulator.
 - 1. Connect mains power to the unit and ensure that the (green) mains LED lights.



AUTO START

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- 2. Switch the unit on by pressing the **On** key. Ensure that after a few moments the LCD screen lights and the ECG acquisition screen is displayed.
- 3. Check the screen for missing pixels.
- 4. Using the SCHILLER patient cable, connect the patient simulator to the unit and switch the simulator on.
- 5. Check that ECG traces are displayed on the screen



7. Check the printout for faulty pixels. The ECG data remains in the temporary unit memory until it is overwritten by another recording or the unit is switched off. The interpretation statements can be edited and further printouts obtained in different formats all the time the ECG is stored.



- → To obtain a second copy in format 1 press the Copy 1 key.
- → To obtain a copy in format 2 press the **Copy 2** key.



Continuous printout



8.

Press the **Man Start** key to start a continuous printout. Check the printout changes when the following keys are pressed:

Lead Group*

Sensitivity (Amplitude)

Speed

| ■ " | ▶3 | | |
|--------------------------------|----------------------|--------------------|-----------------|
| 2.5 * | 5 < 9 | 0 | 20 + |
| 5/10 4 | ^{12.5} 5 | ²⁵ 6 | ⁵⁰ 7 |

STOP

9. To stop the printout, press the ${\color{black}{Stop}}$ key.

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If any function is suspected of malfunction, calibration is not correct, or the printout is not correct for any reason etc., the full functional check must be carried out -see following.

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5.3 Functional checks and tests

Required equipment

- Safety Tester IEC/EN 60601-1
- Calibrated ECG Patient Simulator (e.g Müller & Sebastiani MS410 ECG Simulator)

IMPORTANT!

The measurement devices listed above are subject to the instructions according to ISO 9000 in regards to Test Equipment Control.

5.3.1 External sight control

6-monthly

Check the following :

- · Mechanical condition of the device:
 - no cracks or chips in the casing.
 - mains, patient and all other cable assemblies are in good condition with no crushing, chafing or cuts, etc.). All plugs and sockets are straight and in good condition.
- · no soiling which could hamper the safety of the device.

12-monthly

Check the following:

- · Mechanical condition of the device as detailed above.
- · Voltage selector is set correctly.
- Correct fuse rating according table (see page 43).
- The following safety labels are on the device and are readable:
 - Back Panel, type designation and fuse rating label.
 - Side Panel (patient connector), CF label and 'attention' symbol.



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2 Mains and battery indicators (LED) test

- 1. Connect the power cable at the rear of the unit.
 - Check that the mains indicator lamp is lit (1) when the unit is connected to the mains supply.
- 2. Switch the unit on.
- Check that the relevant symbol is displayed on the LCD (3).
- 3. Disconnect the power cable.
 - check that the mains indicator lamp switches off (1)
 - the battery lamp is lit (2).
 - the battery symbol is displayed on the LCD (4).

The LED indicators on the unit casing indicate the power operation, and the battery symbol indicates battery capacity. Both of these are detailed in the operation overview (see page 18).

5.3.3 Charging the battery

- 1. Connect the device to the mains but do not switch it on.
- 2. The LED for mains supply (1) is lit.
- 3. Charge the battery for at least 8 hours.

5.3.4 Battery capacity check

Carry out the Battery capacity check as detailed in the service screen (see page 25).

5.3.5 Keyboard test

Check following items:

- Check the keyboard for mechanical damage and excessive wear. If any can be seen, the keyboard must be replaced.
- Check all function keys for their proper operation. An acoustic confirmation appears whenever a function key is pressed.
- · Test the alphabetical keyboard as follows:
 - With a C device (interpretation), press the ECG key and select the Interpretation icon. Enter the edit screen to test all keys.
 - In all other devices, the test can carried out by pressing the Patient data key to enter the patient screen and test all keys.

5.3.6 LCD screen test

- Visually check the screen for spots, or black fields. If many are apparent, the LCD must be replaced (a few faulty pixels is normal).
- Check that the LCD shade (contrast and brilliance) is even and the same all over. If not it indicates that the back light may be faulty and the LCD must be replaced.

25 mm

5.3.7 Printer checks

Paper Feed

1. Start the printer by pressing the Man Start

. Press the Stop key

twice to stop the printout and transport the paper to the paper perforation point.

MAN

- 2. The paper must stop exactly at the perforation. If this is not the case:
 - Check that SCHILLER paper is used.
 - Clean the paper detection opto window with an alcohol solution.
 - Check the paper mark detection circuit.

Print Quality Test

Carry out the print quality check as detailed in the service screen (see page 25).

Printing Speed

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- 1. Connect the calibrated simulator to the ECG device using the patient cable and select a HR of 60 / min. No arrhythmias.
- 2. Check that the HR shows exactly 60 on the LCD.
- 3. Set the printing speed to 5 mm/s and press the Man Start key MAN START
- 4. Select printing speed 10. 12.5, 25 and 50 mm/s

 $5^{12.5}$ 6^{50} $7^{12.5}$ print one page in turn at each speed.

- 5. Stop the printout and check calibration waveform on the paper grid. A ruler can be used or the paper grid scale can be used to do this.
 - On the 10 mm/s printout the distance between two peaks must be 10 mm \pm 0.5 mm.
 - On the 25 mm/s printout the distance between two peaks must be 25 mm ± 0.5 mm (example shown).
 - $-\,$ On the 50 mm/s printout the distance between two peaks must be 50 mm \pm 0.75 mm.

Parallelism test

This will test the mechanical adjustment of the print head to the paper grids.

- 1. Remove the simulator
- 2. Press the Man Start key
- 3. Press any speed key

7 twice. This will

generate a calibration waveform on the printout.

4. Stop printout and check the calibration waveforms on the paper grid.

5

All calibration waveforms for each lead must be lined up vertically. The maximum deviation must not be more than ± 0.5 square (0.5mm). If the values are outside this tolerance, the mechanical adjustment of the print head has to be corrected.

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| Servi | | | |
|------------------|--|---|-----------------------------|
| Character ECG | r Colour NIBP | Printer Key Spiro H | Battery Softwar W- I/O + |
| | Lead Test RA LA C1 C2 C3 C4 C5 C6 C7 C6 C7 C8 C9 C10 LOFF | (mV) 5 5 5 5 5 5 5 5 5 5 497 495 498 498 498 0F00 | |

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5.3.8 ECG amplifier and patient cable test

- 1. With a patient simulator connected, press the **ECG** key **ECG**. The electrode
 - screen is displayed (this screen is also displayed in the service screen (see page 20).
- 2. Disconnect ECG patient simulator. Check the following:
 - device beeps 4 times
 - all lead designations highlighted
 - the mV reading for all leads is -350 to -550 mV
- 3. Connect ECG simulator and setup HR to 60 b/min, no arrhytmias.
- 4. Check the following:
- all leads stops blinking
- the mV reading for all leads is -15 ...+15 mV
- When a standard 10-lead cable is connected, check RA, LA, and C1 to C6 only.
- Additionally check C7, C8, and C9 when a 13 lead patient cable is used.
- Additionally check C7, C8, C9 and C10, when a 14 lead patient cable is used.
- · LOFF is a register for factory use only (for lead confirmation).

5.3.9 External printer test

Only with the Comms Module. At the time of print this was not available

5.3.10 Communication (RS-232) test

Only with the Comms Module. At the time of print this was not available.

1

5.3.11 ECG printout reference

Required Equipment

- Calibrated test ECG Patient Simulator (e.g Müller & Sebastiani MS410 ECG Simulator)
- Connect the simulator to the unit and select the calibrated ECG reference waveform EN 60601-2-51 > CAL 20160.
- 2. Press the Auto Start key AUTO START to make an auto mode recording printout.
- 3. Check measurement table (given on the printout) against the following table.
- 4. Check the waveform and polarity against the reference waveform given on the following page. Note that the printout is representative of the waveform shape only and is not accurately scaled.
- If the printout waveform shape does not match the template, check the auto mode settings (see page 51).

| Curve | Measurement | Value | Tolerance | Minimum | Maximum |
|----------|-------------|-----------|---------------|---------|---------|
| Interval | RR | 1000 (ms) | <u>+</u> 10 | 990 | 1010 |
| | Р | 116 (ms) | <u>+</u> 10 | 106 | 126 |
| | PR | 178 (ms) | <u>+</u> 10 | 168 | 188 |
| | QRS | 56 (ms) | <u>+</u> 6 | 50 | 62 |
| | QT | 356 (ms) | <u>+</u> 12 | 344 | 386 |
| V1 | Р | 0.15 (mV) | <u>+</u> 0.02 | 0.13 | 0.17 |
| | R | 2.00 (mV) | <u>+</u> 0.1 | 1.90 | 2.10 |
| | Rd | 56 (ms) | <u>+</u> 6 | 50 | 62 |
| | J | 0.2 (mV) | <u>+</u> 0.02 | 0.18 | 0.22 |
| | ST | 0.2 (mV) | <u>+</u> 0.02 | 0.18 | 0.22 |
| | Т | 0.4 (mV) | <u>+</u> 0.03 | 0.37 | 0.43 |

Reference Table







5.3.12 Language, date and time



5.3.13 External monitor

1. Connect an external VGA monitor to the external monitor connector on the back panel.



| ME | :NU | System Menu RS-232 Network Modem Peripherals Identification Macro System Config. Software | |
|----|------------|---|--------|
| 2. | Press the | Menu key MENU . | |
| 3. | Select the | e Config. tab. | |
| 4. | Set the E | xternal Display to Yes , and press the confirm key | CONFIF |
| 5. | Press the | Escape key to set and leave ESC. | |

6. Check that the external monitor displays the same data as the LCD display.

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5.4 Safety tests

Bender Safety Tester (recommended)

HA2000D High voltage measuring unit (recommended)

The safety test is carried out in accordance with the EN 60601-1, Clause 18 and 19. This test may only be carried out with a tester that fulfils the above mentioned norms and has been calibrated in accordance with ISO norms.

Carry out the high voltage leakage test in accordance with the EN 60601-1, Clause 20.

To carry out all tests, follow the instructions of the manufacturers.

Documentation

Note the results or have them printed by the tester. Always include one copy of the results with the repair report. The original remains with the device and is given to the customer for his files.

5.4.1 Maximum values safety test

Ground Resistance:≤ 0.2Ω

| Voltage | | Type BF | Type CF | |
|---|------------------|-------------|------------------|--------------|
| | normal condition | first error | normal condition | first error |
| Earth current general [mA] | 0.5 | 1.0 | 0.5 | 0.5 |
| Shell current [mA] | 0.1 | 0.5 | 0.1 | 0.5 |
| Patient current [mA] | 0.1 | 0.5 | 0.01 | 0.05 |
| Patient current [mA] (Mains voltage at signal entrance and exit) | | | | |
| Patient current [mA] (mains voltage at used part) | | 5.0 | | 0.05 |
| Patient independent current [mA] Direct Alternating Current [mA] | 0.01 0.1 | 0.05 0.5 | 0.01 0.01 | 0.05 0.05 |



6 Replacing Major Components

6.1 Safety notes

- ▲ Danger of electrical shock. When working on a open device connect the device via an isolation transformer.
- ▲ Follow the procedures for the prevention of accidents and environmental protection according your national guidelines.

Observe precautions for handling electrostatic sensitive devices when opening the device.

6.2 Replacing the battery

6.2.1 Maintenance interval for the battery

- The battery is maintenance free during its normal life.
- The battery should remain charged during storage. If the storage period exceeds three months, recharge the battery.
- Replace the battery approximately every 4 years (depending upon application) if the actual running time falls substantially under 2 hours.

Philips screwdriver 1



- 1. Disconnect the device from the mains.
- 2. Loosen the 3 Philips screw from the back housing.
- 3. Remove the cover.
- 4. Remove the old battery.
- 5. Insert a new battery.
- 6. Charge and calibrate the battery.

When a battery is replaced, the new battery must be calibrated to check capacity and ensure correct charging. This is carried out from the service screen (see page 28).



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6.2.2 Battery disposal



The battery is to be disposed of in municipally approved areas or sent back to SCHILLER AG.

Danger of explosion. Battery may not be burned or disposed of domestic refuse.

6.3 Changing the fuse and mains voltage

Danger of acid burns! Do not open the battery.

A DANGER

- ▲ Before the fuse and mains voltage are changed, the device must be disconnected from the mains and the mains plug removed for the wall socket.
- ▲ The fuse may only be replaced by the fuse type the table below.

6.3.1 Fuse types

| Voltage range | Number | Fuse type |
|---------------|--------|--------------------------------|
| 220 - 240 VAC | 2 | 250 V / 160 mA (T = slow blow) |
| 100 - 115 VAC | 2 | 115 V / 300 mA (T = slow blow) |

6.3.2 Changing a fuse

- 1. Disconnect the device from the mains and remove the mains plug.
- 2. Loosen the fuse inset using a screwdriver and remove it.
- 3. Replace existing fuses with the same type. See table above.
- 4. Re-insert the fuse inset.



Changing the mains voltage

- 1. Disconnect the device from the mains and remove the mains plug.
- 2. Loosen the fuse using a screwdriver and remove it.
- 3. Remove the grey inset, turn it by 180° and re-insert it.
- 4. Check the voltage indication in the window.
- 5. Replace both fuses with the new value as defined in the table above.
- 6. Re-insert the fuse assembly.

6.4 Opening the case

| | Before commencing any removal or replacement procedures ensure that the mains power supply is switched off and that the mains cable is removed. |
|----------|--|
| | |
| \wedge | The AT-10 plus contains static sensitive CMOS components; observe antistatic precautions: |
| | When carrying out any maintenance procedures always place the unit on an earthed antistatic mat. |
| | Personnel must be earthed when handling any boards or components. |
| | Always use an antistatic bag when transporting boards or components. |
| | The unit is susceptible to abrasion damage. To prevent scratching, always place the unit on a soft, non-abrasive cloth when carrying out maintenance procedures. |
| | Take care not to place any strain on the connecting ribbon cable when removing the top assembly. Ensure that the cable assembly is not crimped or twisted and that the top assembly is not placed on the cable assembly. |
| | Care must be taken when removing and replacing connectors. Never use force. Never strain the cable assemblies. |
| | A Refere reassambly a full sight must be carried out (see page 40) |
| | After reassembly the functional and safety tests must be carried out according to the checklist at the end of this book (see page 73). |
| 31 | Philips screwdriver 1 |
| T | Low abrasion antistatic mat |
| | |
| | |

The top assembly is secured to the base assembly with seven recessed screws. Access to the screws is gained from the underside of the unit. To remove the Top Assembly, proceed as follows:

- 1. Turn the unit up-side-down and rest on a soft antistatic cloth.
- 2. Unscrew and remove the countersunk retaining screws and washers situated in the extreme corners and edges of the unit.
- 3. Grasping the top and bottom of the unit to ensure that the two assemblies cannot part, carefully return the unit to the standing position.

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4. Gently lift the Top Assembly sufficiently to gain access to the interconnecting cables. Disconnect the cable assembly between the main board and the printer (two cable assemblies) and the power cable between the main board and the battery.



5. Gently lift the Top Assembly away from the Base Assembly and place on a soft cloth.

Thermal Printer



6.4.1 Printer

- 1. Loosen the four Philips screws (1).
- 2. Loosen the screw for the ground cable.

Thermal paper handling

The thermal paper used in the AT-10 plus requires slightly different handling to normal paper as it can react with chemicals and to heat. However, when the following points are remembered, the paper will give reliable results:

The following points apply to both storage, and when archiving the results.

- 1. Before use, keep the paper in its original cardboard cover. Do not remove the cardboard cover until the paper is to be used.
- 2. Store in a cool, dark and dry area.
- 3. Do not store near chemicals e.g. sterilisation liquids.
- 4. In particular do not store in a plastic cover.
- 5. Certain glues can react with the paper do not attach the printout onto a mounting sheet with glue.

6.4.2 ECG Amplifier MK 22-2

- 1. Remove the securing screws (including the patient connector screws).
- 2. Gently lift the board to gain access to the connector and remove.



6.4.3 Communication module

- 1. The complete electronic assembly must be removed to remove the communication module.
- 2. Remove the recessed screws securing the assembly to the casing.



3. Gently lift the assembly away from the casing and remove connectors.





4. Remove the two connector screws.



5. Remove the board.



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6.5 Reassembling the unit

6.5.1 Internal sight control

If the device has been opened, the device must be given a full sight control before it is screwed back together.

Check following items:

- All printed boards are securely screwed.
- · Plugs are properly in the socket and secured.
- All protective cable (green/yellow) are properly laid out and securely connected to an earth point (potential equalisation).
- All Cable connections between the individual boards are not crushed or lying on or close to, a sharp object (e.g. protective shields). If cables are positioned by a sharp object, it is important that they are protected by a special shield.
- Isolation foils and shields are inserted and correctly positioned.
 - Check that no loose parts are inside the device by tipping the device, or turning it upside down.

6.5.2 Functional Test

Once the sight control has been completed, the device can be closed and the functional and Safety Test must be carried out according to the checklist at the end of this book (see page 73).

7 Cleaning

7.1 Cleaning the casing

WARNING Switch the unit off before cleaning and disconnect the mains. Do not, under any circumstances, immerse the apparatus into a cleaning liquid or sterilise with hot water, steam, or air.

The casing of the AT-10 plus can be cleaned with a soft damp cloth on the surface only. Where necessary a domestic non-caustic cleaner can be used for grease and finger marks.

7.2 Cleaning the patient cable

The patient cable must not be exposed to excessive mechanical stress. Whenever disconnecting the leads, hold the plug and not the cable. Store the leads in such a way as to prevent anyone stumbling over them or any damage being caused by the wheels of instrument trolleys.

The cable can be cleaned with luke warm soapy water holding the cable in the middle and gently wiping from the centre.

To disinfect the cable, wipe the cable (from the middle) with a chemical disinfectant containing:

- ethanol (70% 80%)
- propanl (70% 80%)
- aldehydes (2% 4%)

Sterilization, if required, must only be carried out with gas and not with steam.

7.3 Cleaning the thermal print head

If the printer is used a lot, a residue of ink from the grid on the paper can build up on the print head. This can cause the print quality to deteriorate. We recommend therefore that every month the print head is cleaned with alcohol as follows:

Extend the paper tray and remove paper. The thermal print head is found under the paper tray.

With a tissue dampened in alcohol, gently rub the print head to remove the ink residue. If the print head is badly soiled, the colour of the paper grid ink (i.e. red or green) will show on the tissue.



8 Unit Settings

Menu navigation, selection and confirmation is detailed in the Introduction, see page 19.

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All changed settings are remembered until the unit is switched off. If you wish to keep the settings as default, the 'save as default' icon (Menu key > Software > Save as Default), must be pressed before switch off - see page 31.

8.1 ECG settings

When the **ECG** key is pressed a screen is shown with a number of tabs at the top. When the tabs are selected further ECG options and settings are available. This section gives an overview of all the settings and tabs available in the following table.



| Parameter | Options | Description | |
|--|--------------|--|---|
| Lead Test | | Displays the resista integrity of the cable | nce of all leads to ensure good electrode contact and the e, see user guide. |
| Pacemaker (Not available at time of print) | PM Detection | Yes or No. When a vertical line on the t duration or amplitud option and is detaile | a pacemaker pulse is detected it is indicated by a single race. Note that this line is not representative of either the e of the pulse. Measurement of the pacemaker pulse is an ed earlier in this table. |
| | Start / Stop | Starts/ Stops pa measurements are o | cemaker measurement. When started Pacemaker displayed at the top of the screen. |
| | | HR: 63 / min PACEMAKER FF INTERVAL DURATION Two columns of data | Andrea Blocker Pacemaker ~ REQ.: 60/min AV: 134 ms R L F V7 V8 V9 V10 VV: 1000 ms AV: 134 ms V1 V2 V3 V4 V5 V6 V: 22 ms A: 4 ms A |
| | | Pacemaker Freq | The number of stimulations per minute (pacemaker frequency) |
| | | Interval VV | The time interval between two stimulations (V-V) |
| | | Duration | The duration of each stimulation |
| | | | If a dual-chamber pacemaker is being measured then the right hand column gives the following: |
| | | A-V | The time interval between atrium and ventricle stimula- tions |
| | | Α | The duration of the atrium stimulation |

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| Parameter | Options | Description |
|--|------------------------------------|--|
| Interpretation | Interpretation Screen | Edit/ Enter interpretation. |
| | Write Unconfirmed Report | Yes or No. 'Unconfirmed Report' is added/not added to the interpretation state- ments on the auto ECG printout (if applicable). |
| | Write Abnormal ECG | Yes or No. 'Abnormal ECG' is added/not added to the interpretation statements on the auto ECG printout (if applicable). |
| | Sensitivity | High or low sensitivity. Low sensitivity will suppress certain non-specific ECG diagnoses; this may be advisable when carrying out ECGs for screening. |
| | Thrombolysis (option) | On or Off. Thrombolysis is the breaking up of a blood clot. When Thrombolysis option is off, the interpretation text " possible infarct or other abnormality " is disabled. |
| Rhythm Rec (not available at time of print) | Rhythm Lead R1, R2, R3 and r1 | Defines the rhythm leads used for rhythm recording |
| | Format | Defines the printout format (and by default the speed of the trace). Select between: |
| | | 90 sec/page - printout every 90 seconds |
| | | 5 min./page - printout every 5 minutes |
| | | 10 min./page - printout every 10 minutes |
| | Amplitude | Defines the amplitude of the trace. Select between: |
| | | |
| | | • Normal |
| | | Low (half amplitude) |
| | Print current page | For Rhythm recording see user guide. |
| | Print last page | For the recording procedure see user guide. |
| | Start / Stop | Starts / Stops Rhythm recording. For the recording procedure see user guide. |
| Late Potentials (Not available at time of print) | High Pass Filter | Select between 25Hz, 40Hz and 80Hz - late potential analysis RR is a future option and not available for this release |
| | No. of QRS | |
| RR Variability (Not available at time of print) | Window Type | RR variability is a future option and not available for this release |
| | No of RR | |
| | FFt Type | |
| | Phase - space plots | |
| | Correction of RR | |
| | Lower bound of VLF | |
| | Lower bound of LF | |
| | Lower bound of HF | |
| | Upper bound of HF | |
| | Signal Acquisition Start / Stop | |



| Parameter | Options | Description | |
|--|------------------------------|---|---|
| Autom. Format (Automatic mode for formats 1 and 2) | ECG Printout | No Printout | No printout of the ECG given at the end of an auto mode recording (the recording can be stored in the memory and printed at a later time if required). |
| | | 4*3 + 1 Rhythm (r1) | Leads are printed in a 4 * 3 format at 25mm/s, with the selected rhythm lead (r1)at the bottom of the page at 25mm/s. |
| | | 1*12 at 25 mm/s | Leads are printed in a 1 * 12 format at 25mm/s. |
| | | 8*5 + 4*10s | Five seconds of 8 Leads, and 10 seconds of four leads are printed at 25mm/s. |
| | | 2*6, 25mm/s, 1p | Leads are printed in a 2*6 format at 25mm/s (one page). |
| | | 2*6, 50mm/s, 1p | Leads are printed in a 2*6 format at 50mm/s (one page). |
| | | 2*6, 25mm/s, 2p | Leads are printed in a 2*6 format at 25mm/s (two pages). |
| | | 2*6, 50mm/s, 2p | Leads are printed in a 2*6 format at 50mm/s (two pages). |
| | Average Cycles | No Printout | No printout of average cycles. |
| | | 4*3, 25mm/s + 2 Rhy | /Leads are averaged over the entire 10 second recording and printed in 4 groups of 3 leads at 25mm/s, with the two selected rhythm leads (R1, R2) at the bottom of the page at 25mm/s. |
| | | 4*3, 50mm/s + 2 Rhy | Four groups of 3 leads at 50mm/s, with the two selected rhythm leads (R1, R2) at the bottom of the page at 50mm/s. |
| | | 2*6, 50mm/s + 2 Rhy | 7 Two groups of 6 leads at 50mm/s, with the two selected rhythm leads (R1, R2) at the bottom of the page at 50mm/s. |
| | Rhythm Lead R1 | Select lead for the fir | st rhythm lead on the screen and printout. |
| | Rhythm Lead R2 | Select lead for the se | econd rhythm lead on the screen and printout. |
| | Measurements | Select yes or no to p | rint a detailed table of measurement results. |
| | Markings | Select yes or no to p A vertical marker sho end of the T wave. | print reference markings on the ECG average cycle print. bws the beginning and end of P wave and QRS, and the |
| | Interpretation | Select yes or no to p | rint interpretation statement (C version only). |
| Programmable Leads | Lead 1 to Lead 12 | In addition to the co define an individual I | onventional lead order (Standard or Cabrera), you can ead sequence (user defined). |
| | | The screen lead disp Also see user guide. | olay (and printout) is changed in the Lead tab (next tab) . |
| Lead | Lead Sequence | This sets the lead se screen. Set to Stand | equence for manual and auto printouts as well as on the ard, Cabrera. or User Defined. |
| | Signals | Sequential of Simulta | aneous. |
| | Auto Centring | Yes or No. Printer t automatic printout. A after a new number or or before printing, or keys during printing. | race alignment affects both the manual as well as the change of the current setting is only valid on the printout of printer channels is selected by pressing the key during after a new lead group is selected by pressing the lead |
| | Auto Sensitivity (Reduction) | Yes or No. In auto r However, if the am overlap, the sensitivi an 'A' appears in the | node a default recording sensitivity of 10 mm/mV is set. plitudes are high meaning that the QRS peaks would ty is reduced automatically to 5 mm/mV. When this is set information line on the bottom of the screen see page 15. |
| | Rhythm Lead Group | Print/ don't print (On | or Off) |

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| Parameter | Options | Description |
|-----------|-------------------------|--|
| | Left Posterior (V4-V9) | Print/ don't print (On or Off) |
| | Right Pectoral (V5r) | Print/ don't print (On or Off) |
| | Right Pectoral (V6r) | Print/ don't print (On or Off) |
| | Nehb (D, A, J) | Print/ don't print (On or Off) |
| Filter | Baseline Filter | The cutoff can be set for 0.05Hz, 0.12Hz, 0.25Hz or 0.50Hz, for both resting and Exercise recording. NOTE: The 'standard value set is 0.05 Hz. The higher settings should only be used when absolutely necessary because it could affect the original ECG sig- nal, especially the ST segment. |
| | Myogram Filter | The Myogram filter suppresses disturbances caused by strong muscle tremor. The filter is applied by pressing the Filter key (or programmed on as default when the unit is switched on). |
| | | The cut off frequency is displayed in the information box -see user guide. |
| | | The cutoff frequency is user defined at 25Hz or 35Hz. |
| | | Note : An ECG recorded in auto mode is stored unfiltered. It is therefore possible to print the stored ECG either with or without passing the myogram filter. |
| | Mains Filter | The mains filter is an adaptive digital interference filter designed to suppress ac interference without attenuating or distorting the ECG. Set the mains filter in accordance with the frequency of your local mains supply. |
| | SBS Filter (baseline) | The baseline stabiliser greatly reduces the baseline fluctuations without affecting the ECG signal. The purpose of the stabilizer is to keep the ECG signals on the baseline of the printout. This filter is only effective in auto mode printout. The Baseline Stabiliser is applied to a recording (on), or not applied to a recording (off). The cutoff frequency is set above. |
| | SSF Filter (smoothing) | The smoothing filter (SSF: SCHILLER smoothing filter) is a low pass filter to suppress high frequency artefacts between the QRS complexes. When this filter is switched on, 'SSF' is shown on the bottom line of the automatic printout. |
| General | QRS Beeper | On or Off |
| | Show Results on Display | At the end of an AUTO test, display the results on the screen (YES) or don't display (NO). |
| | Inv. ECG Monitor | Inverse the screen display. Select Yes or No. |



8.2 Exercise settings

When the **Exercise** key is pressed a screen is shown with a number of tabs at the top. When the tabs are selected further exercise options and settings are available. This section gives an overview of all the settings and tabs available in the following table.

| | Rhythm settings | QRS Settings | Interpretation |
|--|-----------------|--------------|----------------|
| | HR target | Stage report | Final Report |
| | | | |
| | | | |
| | | | |

| Parameter | Options | Description |
|--------------|-------------------------|---|
| HR target | Heart Rate Target Mode | An audible and visual target (heart rate indication flashes) is initiated if the HR target is breached. The target setting is shown in parenthesis after the HR measurement. The HR target can be automatically set or manually defined as follows. |
| | | Off - no HR target set 'Use formula below' - Manual input: This option allows for any heart rate target setting to be defined. See below |
| | | 90% of 220 – age |
| | | 220 – age 200 - age |
| | Percent of Target HR | This factor is applied to the defined target HR, or the Target HR - age, as defined below. |
| | HR Target | Manually define a target HR within the range of 100 to 250 beats/min. |
| | Age | Age - yes or no - the patient's age is/is not subtracted from the target HR. |
| | | Notes: |
| | | The age is calculated from the patient data. |
| | | • When automatic calculation mode is set, the heart rate target limit is calcu- lated automatically for any new patient for which data has been entered. When manual input is set, or changed from an automatically calculated val- ue, the target HR is not automatically recalculated for a new patient. |
| | | Regardless of the settings made in this menu, only the formula '220 - age' is used in the final report to give the percentage that the maximum heart rate achieved during the test, against the maximum calculated heart rate. |
| Stage Report | Stage print format | During the exercise and recovery phase, periodic printouts can be obtained at preset intervals defined below. The format of the printout can be either $4*3 + 1$ rhythm (r1), or $2*6$ at 25mm/s. |
| | Print Resting ECG | Select Yes or No to print the resting ECG format (auto format 1). |
| | Stage printout Interval | Set the writing interval at any interval between every minute and every 9 minutes (applies to bicycle and treadmill). This interval is also set during the recovery phase if set (see next entry). |
| | Recovery print interval | Define the print interval as for the stage printout or select 'Non cyclic' and define the time intervals (below). |
| | Printout after | Select the time interval for up to 5 printouts in the recovery phase (when set to 'non cyclic' above. |

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Unit Settings Exercise settings 8.2

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| Doromotor | Ontiona | Description |
|-----------------|---|---|
| Farameter | options | Description |
| Final Report | ST Trends | A graph of the ST amplitude and slope. Select Yes to print, or No to suppress printing. |
| | ST-HR Diagram (not available at time of print) | A graph of the ST amplitude against heart rate. Select Yes to print, or No to suppress printing. |
| | Interpretation (not available at time of print) | Yes (print) or No (suppress printing). |
| | Average Cycle (not available at time of print) | Print Average cycles. Select Compact, All or No. |
| | Speed (not available at time of print) | Printing speed (for average cycles when 'Compact' or 'All' selected above). Set to 25mm/s or 50 mm/s. |
| | Print Rhythm (R1) | Print rhythm lead R1 Yes or No. |
| Rhythm settings | Rhythm record lead (R1) | Select the lead for rhythm recording (for rhythm strip when Rhythm (R1) selected in Final Report above) - select either I, II, III, aVR, aVL, aVF, V1 - V6. |
| | Speed | Select Rhythm strip printing speed. Set to 6.25 mm/s or 12.5 mm/s. |
| | Sensitivity | Select Rhythm strip sensitivity (amplitude). Set to 5 mm/mV or 2.5 mm/mV. |
| QRS Settings | ST Amplitude Measurement | During the exercise test, the ST amplitude is measured continuously. The position of the amplitude measurement point can be set to 20, 40, 60 or 80 ms after the j-point. |
| | Lead for Enlarged QRS | Select lead for zoom view. The enlarged QRS complex appears to the right of the screen when the exercise test is started. This enlarged lead is averaged over 10 beats. This lead is also used for ST measurements. |
| | Unit of ST Measurement | Select between mm or mV. |
| Interpretation | | Enter / Edit exercise interpretation. |
| | Validated by and date | Enter who validated the recording and the date of validation. |



8.3 General and unit settings

When the **Menu** key is pressed a screen is shown with a number of tabs at the top. When the tabs are selected system and general options and settings are available. This section gives an overview of all the settings and tabs available in the following table.

| System Menu | | | |
|----------------|---------|------------|--------------|
| RS-232 | Network | Modem | Peripherals |
| Identification | Macro | System Com | ig. Soltware |
| | | | |

| Parameter | Options | Description | |
|--|-------------------------|--|--|
| Identification | MTA Identification | This function is to register the name of the medical assistant or doctor carrying out the recording. The MTA is identified on each automatic printout. The maximum number of characters is 23. | |
| | User Identification | This function is to register the name of the practice, department, or hospital, clinic etc. It is identified on each automatic printout. The maximum number of characters is 23. | |
| Macro (not available at time of print) | | Enables a series of key stokes or actions, to be stored and recalled by pressing a single key. | |
| System | Language | Select required language between German, English, French, Swedish, American, Italian, Spanish or Portuguese. Note that the difference between 'English' and 'America' is that some of the designations used on the display and prinout are different. For example, American use V1-V6 lead designation, and the heart rate is BPM. | |
| | Time | Set current time | |
| | Date | Set current date | |
| System (continued) | Date Format | Set required date format | |
| | Time Format | Set required time format | |
| | Colour | Set the display colour to Cyan, Grey, Black or Blue. The colour must be confirmed as default as follows: | |
| | | 1. Set colour in this menu option. | |
| | | 2. Click the software tab , and in the software screen confirm Save as Default. Exit the menu. | |
| | | 3. Switch the unit off, and then on again to confirm. | |
| | | Note that the screen can also give a reverse image. This is defined in ECG > General tab - see page 51. | |
| Config. | Patient Data Input | Add an additional data field in the patient data input menu as follows: | |
| | | Med./Rem. (Medication / Remarks) Med./Doc. (Medication / Doctors Name) Med./Room (Medication / Room No.) Room/Doc.(Room No. / Doctors Name) Room/Rem.(Room No. / Remarks) Doc./Rem.(Doctors Name / Remarks) The selected field will be displayed in the patient data entry - see user guide. | |
| | Units | Define units in cm/kg or inch/lbs | |
| | Speed | Define speed in k/ph or mph | |
| | Temperature | Celsius or Fahrenheit | |
| | Ambient Pressure | mmHg or hPa | |
| | External Display Output | Set to Yes or No | |

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| Parameter | Options | Description | | |
|---|--------------------------|---|--|--|
| Software | Software Version Display | The current software version for the AT-10 plus. Also displayed is the serial number of the unit and any options that are installed as follows: | | |
| | | Base configuration (upper case) | M = Measurements (Standard) C = Interpretation | |
| | | Options (lower case) | m = memory extension | |
| | | | t = thrombolysis | |
| | | | s = stress | |
| | | for example Cmt is a C unit (int thrombolysis. | terpretation), with memory extension and | |
| | Save as default | Save current settings as the default | | |
| | Restore default | Restore settings to the defined default | | |
| | Factory default | Restore settings to the factory default | | |
| | Send default | Store current default setting to a PC | | |
| | Receive default | Retrieve current default settings from a PC | | |
| RS-232 (not available at time of print) | Baudrate | This defines the maximum communication rate for the modem (when Modem is selected in the Mode field (below)).Tick the rate defined in the modem handbook. Select a Baud rate between 115200 and 14400 Baud, according to the modem/computer used. Most computers can connect at 115200 Baud and the standard modem speed is 57600 Baud. If problems are experienced during transmission reduce the Baud rate. | | |
| | Mode | Select between Line and Modem . Line is for when a PC (or other SCHILLER unit) is connected directly to the RS-232 interface of the AT-10 plus), and Modem is for transmission over the phone network. | | |
| | Phone Number | If it is necessary to enter a pause in the number. The comma gives a required, two or more commas c example, if you have to wait for an a pause after a national or international | the dialling sequence enter a comma (,) in one second pause. If a longer pause is an be entered. This may be required for outside line. It is also a good idea to insert ional code. | |
| | Modem Init | The code will be found in the user of available, the standard Hayes code default setting. | guide for the modem. If the handbook is not e should work for most modems. This is the | |
| | | The modem initialisation must commands with the prefix `AT`. | contain at the minimum, the following | |
| | | `Q0`- modem sends response | | |
| | | `V0`- numerical response codes | 3 | |
| | | `E0`- no command echo | | |
| | | The standard modem initialisation | on code is: ATB0L1V0Q0E0S0=0 | |
| | | If in doubt about any of these sett and/or modem supplier. | tings, please contact your phone company | |
| Network At the time of print this function was not fully defined. | IP Address | These settings must be made administrator. | or obtained from the network system | |



| Parameter | Options | Description |
|---------------------------|---------------------|--|
| Modem At the time | Phone Number | Enter the telephone number preceded by `T` or `P` (tone or pulse). |
| was not fully defined. | | A comma `,` gives a one second pause in dialling - this may be necessary for example, if an outside line is required. |
| | Phone User Name | |
| | Phone Password | |
| | Server | |
| | Page | |
| | User Name | |
| | Password | |
| | Country ID | |
| Peripherals | Blood Pressure unit | Select the way the blood pressure will be taken. Select between Off (the BP entry screen is not displayed automatically during the test, however, the BP screen can be displayed at any time during the test by pressing the NIPB key), Manual Input (the BP screen is displayed at the time interval defined in the protocol - see user guide - the BP in taken by an external BP device and entered during the test, or Ergo 900 (an external, digitally controlled blood pressure unit). With this unit BP is taken a defined intervals defined in the protocol. The latest BP measurement is displayed on the monitor and all BP measurements are stored with the exercise recording. |
| | Bicycle | Select the type of bicycle connected - analogue or digital as follows: ERG900 / 911 / Ergosana (digital) |
| | | SECA CT100 mod. 545 (digital) |
| | | Analogue 1V / 100W |
| | | Note: the communication protocol for most digital bikes is standard. If you have a bike not specified above, one of these two protocols should work. |
| | Treadmill | Select the type of treadmill connected - analog or digital as follows: |
| | | • TM425 / TM400FS km/h |
| | | • TM425 / TM400ES mph |
| | | RAM 770CE km/h |
| | | RAM 770CE mph |
| | | • MTM-1500 km/h |
| | | • MTM-1500 mph |
| | Format SDRAM Card | Click the START icon to format the card. This can be used when a new card is inserted. |
| | | All data on the card is lost when an SD card is re-formulated. |

9 Technical Data

9.1 System

348 x 288 x 87 mm, approx. 4.2 kg.

- Backlit for graphic and LCD alphanumeric representation
- Resolution: 800 x 600 dots
- 220 240 V (nominal), 50 / 60 Hz; 100 115 V (nominal), 50 / 60 Hz;
- 14VA to 28VA (Max)
- Operation with built-in rechargeable battery

Nickle Cadnium 9.6 V

- 2 hours normal use, 3 hours Standby
- Under normal operating conditions, 4 years
- 90 %: approx. 7 hours, 100 %: approx. 15 hours

High-resolution thermal printing, 8 dots/mm (amplitude axis), 40 dots/mm (time axis), @ 25 mm/s

- 0.05 ... 150 Hz (IEC/AHA)
- Thermo reactive, Z-fold, 14 x 21 cm (DIN A4; letter size)
- 5/12.5/25/50 mm/s (manual print)
- 5/10/20 mm/ms (manual print)
- 3 to 12 channels, positioned optimally on 200 mm, automatic baseline adjustment

• RS-232 connector for Treadmill

- RS-232 connector for Ergometer
- RS232 connector for pneuotach sensor
- · VGA connector for external monitor
- · ECG cable Interface
- DC input 0.5V/cm
- DC output 0.5V/cm
- · Further interface options with the Communications Module

Storage for up to 40 ECG recordings. Further memory available with the extended memory option.

• 10 ... 40 °C

- -10 ... 50 °C
- 25 ... 95 % (no condensation)
- 700 ... 1060 hPa

Dimensions

Monitor

Power supply

Mains Voltage Power consumption Battery

Battery

Capacity Battery Life Recharging time

Printer

Frequency range Chart paper Chart print-out speed Sensitivity Recording tracks

Interfaces

Memory

Environmental conditions

Operating temperature,

Pressure during operation

Storage temperature,

Relative humidity

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9.2 ECG

| Patient input | Fully floating and isolated, defibrillation-protected (only with original SCHILLER pa- tient cable) |
|--|---|
| Leads | 12 simultaneous leadsStandardCabrera |
| Monitor display | |
| Leads | 3 - 12 channel display of the selected leads selectable speed of 5, 10, 20 mm/s selectable amplitude 10 or 20 mm/mV |
| Status | Filter status (on/off) Power source |
| | Lead selection |
| | Electrode contact status |
| | Heart Frequency HE |
| | Date and Time |
| Filters | |
| Myogram filter (muscle tremor) | • Adjustable at 25 or 35 Hz |
| Line frequency filter SSF SCHILLER Smoothing fil- | Distortion-free suppression of superimposed 50 or 60 Hz sinusoidal interferences by means of adaptive digital filtering |
| SBS SCHILLER Baseline Stabi- lizer | |
| Automatic lead programs | 3/12-channel presentations of 12 simultaneously recorded leads |
| Long-term rhythm recordings | 1 lead, 10min, 5min or 90sec/page |
| Exercise ECG with final report | Automatic control of bicycle ergometer and treadmill (user programmable) Final report showing trend plots of heart rate, load and blood pressure, physical working capacity (PWC 150, PWC 170, PWC max.) Options C: QRS and ST measurements |
| Data record | Patient data (name, age, height, weight, BP), user IDListing of all ECG recording conditions (date, time, filter) |
| With optional interpretation (C) program | ECG measurements results (intervals, amplitudes, electrical axes) Average complexes with optional measurement reference markings Guidance on interpreting adult and paediatric ECGs |
| ECG amplifier | Simultaneous recording of all 9 active electrode signals (= 12 leads) |
| Sampling frequency | • 1000 Hz |
| Resolution | • 5 μV / 12 bit |
| Pacemaker detection | • $\geq \pm 2 \text{ mV}$ /pulse widths $\geq 0.1 \text{ ms}$ |
| Frequency range | • 0.05 150 Hz (IEC/AHA) |
| Measurement range | dynamic ±10 mV, DC ±300 mV |
| CMRR | • > 100 dB |
| Input Impedance | • 100 MΩ |
| Defibrillation protection | • 5000 VDC |
| Patient leakage current | • < 5µA |

9.3 Safety standards

| Safety standard | IEC/EN 60601-1 |
|---------------------------|--|
| | IEC/EN 60601-2-25 |
| EMC | IEC/EN 60601-1-2 |
| Protection class | I according to IEC/EN 60601-1 (with internal power supply) |
| Conformity/Classification | CE/IIa according Directive 93/42/EEC |
| Safety class | CF according to IEC 601-1, IEC 601-2-25, CSA, UL; IIb according to MDD 93/42/ EEC |
| Protection | This device is not designed for outdoor use (IP 20) |

10 Construction Drawings

Exploded views 10.1

10.1.1 **Base casing**



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10.2 Circuit and functional illustrations

The circuit diagrams are confidential. Therefore only the high level drawings are provided here.

10.2.1 Connection block diagram





10.2.2 Microprocessor (main board) functional block diagram

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AT-10 plus



10.2.3 Communication module functional block diagram



















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AT-10 plus



10.2.7 Communication module component layout

11 Special Test Equipment

The following test plugs and equipment must be fabricated to carry out the interface tests (see page 24).

11.1 RS test plug



11.2 DC In/Out cable assembly



11.3 ERGO connector and switch




12 Checklist

The following procedural checklist must be carried out by authorised SCHILLER trained personnel. The recommended interval is that the unit is checked every 12 months.



It is a requirement of EN 60601 that the unit undergoes a safety test at least every 12 months (see page 41), and a complete functional check at least every 24 months (detailed in the following checklist).

12.1 AT-10plus checklist table

| Name of tester: | Signature: | |
|-----------------------|-------------------|--|
| Device serial number: | Software Version: | |
| Customer: | Date: | |

| Reference | | False | Remark |
|---|--|-------|--------|
| 5.3.1 External sight control (page 34) | | | |
| 1. Mechanical condition of the device: | | | |
| no cracks or chips in the casing | | | |
| mains, patient and all other cable assemblies are in good condition with no crushing, chafing or cuts, etc. | | | |
| All plugs and sockets are straight and in good condition. | | | |
| 2. No soiling which could hamper the safety of the device. | | | |
| 3. Voltage selector is set correctly. | | | |
| 4. Correct fuse rating (see page 43). | | | |
| 5. Safety labels: | | | |
| back panel, type designation and fuse rating label readable. | | | |
| side panel (patient connector), CF label and 'attention' symbol readable. | | | |
| 5.3.2 Mains and battery indicators (LED) test (page 35) | | | |
| 1. Mains indicator lamp lit when the unit is connected to the mains supply. | | | |
| 2. Relevant symbol is displayed on the LCD. | | | |
| Mains indicator lamp off and the battery lamp is lit when mains disconnected. | | | |
| 4.8.1 Battery capacity test (page 25) | | | |
| 1. Unit operates for a minimum of 1 hour on battery power. | | | |
| 5.3.5 Keyboard test (page 35) | | | |
| 1. No mechanical damage or excessive wear. | | | |
| 2. All keys function - a beep is heard when every key is pressed. | | | |
| 5.3.6 LCD screen test (page 35) | | | |
| 1. No spots or black fields on the screen. | | | |
| 2. LCD shade (contrast and brilliance) is even all over. | | | |

| Reference | | ОК | False | Remark |
|---|--|----|-------|--------|
| 4.8.2 Print quality and printer alignment check (page 25) | | | | |
| 1. | | | | |
| 2. | Alignment OK | | | |
| 3. | No faulty pixels | | | |
| 4. | Blackness, regularity and good readability on the complete print width | | | |
| Р | aper Feed (page 36) | | | |
| 1. | Paper stops at the perforation (paper mark) | | | |
| P | rinting Speed (page 36) | | | |
| 1. | On the 25 mm/s printout the space between 2 R peaks is $25 \text{ mm} \pm 0.5 \text{ mm}$. | | | |
| P | arallelism test (page 36) | | | |
| 1. | Calibration waveforms line up vertically and the maximum deviation is not | | | |
| | more than ± 0.5 mm. | | | |
| 4. | 5 I / O ports (page 22) | | | |
| 1. | RS-232 Ports change colour when the test plug inserted. | | | |
| 2. | DC IN and DC OUT ports change colour when the test cable assembly is connected between the two connectors. | | | |
| 3. | ERGO square changes colour when the test plug inserted. | | | |
| 4. | ERGO square changes colour when the switch set. | | | |
| 5. | 3.8 ECG amplifier and patient cable test (page 37) | | | |
| 1. | Disconnect ECG patient simulator. Check the following: | | | |
| | device beeps 4 times | | | |
| | all lead designations highlighted | | | |
| | the mV reading for all leads is -350 to -550 mV | | | |
| 2. | Connect ECG simulator: | | | |
| | all leads stop blinking | | | |
| _ | the mV reading for all leads is -15+15 mV | | | |
| 5.3.11 ECG printout reference (page 38) | | | | |
| 1. | The measurements table on the printout gives the following values: | | | |
| • | Intervals | | | |
| | RR 1000 <u>+</u> 10 | | | |
| | P 116 <u>+</u> 10 | | | |
| | PR 176 <u>+</u> 10 | | | |
| | QRS 56 <u>+</u> 6 | | | |
| | QT 356 <u>+</u> 12 | | | |
| • | V1 | | | |
| | P 0.15 <u>+</u> 0.02 | | | |
| | R 2.0 <u>+</u> 0.01 | | | |
| | Rd 56 <u>+</u> 6 | | | |
| | J 0.2.0 <u>+</u> 0.02 | | | |
| | ST 0.2 <u>+</u> 0.02 | | | |
| | T 0 4 +0 03 | | | |
| 2 | Wayoform shape and polarity same as reference printeut | | | |
| ۷. | wavelorm shape and polarity same as relerence printout | | | |



| Reference | | ОК | False | Remark |
|--|--|----|-------|--|
| 5.3.12 Language, date and time (page 40) | | | | |
| 1. | Set Language. | | | |
| 2. | Set Time. | | | |
| 3. | Set Date. | | | |
| 5.3 | 3.13 External monitor (page 40) | | | |
| 1. | Connect external monitor - monitor displays the same data as the integral LCD. | | | |
| 4.7 | ′ Colour (page 24) | | | |
| 1. | Set and change colour as required. | | | |
| 5.4 Safety tests (page 41) | | | | |
| 1. | The safety test is carried out in accordance with the EN 60601-1, Clause 18 and 19. This test may only be carried out with a tester that fulfils the above mentioned norms and has been calibrated in accordance with ISO norms. | | | Add protocol with results to this checklist. |
| 2. | High Voltage Leak test in accordance with EN 60601-1, Clause 20. | | | Add protocol with results to this checklist. |



Other remarks