Field Safety Notice

CARDIOVIT AT-102 Plus
FSCA-identifier: 29.03.2018
Type of action: FSCA

Date: 10.04.2018

Attention: Schiller subsidiaries and customers

Details on affected devices:

Product:	CARDIOVIT AT-102 Plus
Article number:	0.075000
Serial number:	all

Description of the problem:

Schiller has received notice where the batteries of AT-102 plus had an issue. Investigation showed that the replacement of the batteries in these cases was overdue (batteries in service for over 5 years). Lacking battery replacement at the recommended interval may lead to battery overheating, generation of smoke and deformation of device housing. To reduce these small risks the user shall respect the replacement interval for the batteries. According to the current *User Guide 2.510858 Ver. h* the life time of the battery is 24-month. The battery shall be replaced with a 24-month interval and shall be inspected according to the above mentioned User Guide. This interval reduces any remote risk from batteries with exceeded lifetime to a minimum.

Advise on action to be taken by Schiller subsidiaries and distributors:

Please note that according to *User Guide 2.510858 rev.h* AT-102 plus battery shall be replaced with 24-month interval.

1. Read *User Guide 2.510858 rev.h, Section 10* which is annexed to this field safety notice.
2. Complete acknowledgement form and return to Schiller AG's contact person a.m. below
3. Contact your local Schiller technical support team for any technical support

Publication of the information described in this statement:

Please make sure that all users of the aforementioned device and other relevant person within your organization will be aware of this field safety notice. If you have passed the devices to third parties, please forward a copy of this information or inform the below mentioned contact person.

The obligation for regular maintaining battery according to the instruction of the *User Guide 2.510858 rev.h, Section 10* shall be ensured.

Always follow the instructed intervals for preventive maintenance and safety checks.

Please keep this information at least until the action has been completed.

The responsible Swiss Health Authority Swissmedic has a copy of this field safety notice.

Contact person:

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10 Maintenance

The regular system maintenance must include a software check according to the manufacturer's instructions. The test results must be recorded and compared to the values in the accompanying documents.

Maintenance work not described in this section may only be performed by a qualified technician authorised by SCHILLER AG.

The following table indicates the intervals and responsibilities of the maintenance work required. Local regulations in your country may stipulate additional or different inspection intervals and tests.

Interval	Maintenance step	Responsible
Every 6 months	• Keypad test. • Visual inspection of the unit and cables (see below).	➜ User
Every 12 months	• All six-monthly maintenance steps as well as the battery capacity test according to section 10.5.2	➜ User
Every 12 months	• Safety test according to IEC/EN 62353 incl. visual inspection of the battery.	➜ SCHILLER AG authorised technician
Every 24 months	• Replacement of the battery, regardless of its capacity.	➜ SCHILLER AG authorised technician

10.1 Visual Inspection

Visually inspect the unit and cable assemblies for the following:

➜ Device casing not broken or cracked.
➜ LCD screen not broken or cracked.
➜ Electrode cable sheathing and connectors undamaged.
➜ No kinks, abrasion or wear in any cable assembly.
➜ Input/output connectors undamaged.

In addition, at the same time as the visual inspection, the CARDIOVIT AT-102 plus should be switched on, the menu scrolled through, and some sample functions tested. Ensure a beep is heard when a key is pressed. This will:

- Provide a basic software integrity check
- Check the LCD display
- Check basic keypad function

▲ Do not use the unit if the unit, or any cable assembly or accessory, is damaged.
▲ Defective units, damaged cables, or damaged accessories must be replaced immediately.

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10.2 Cleaning the Casing and Cable Assemblies

⚠WARNING

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

⚠ CAUTION

▲ Do not autoclave the unit or any accessories.

▲ Do not immerse in liquid when cleaning.

▲ Use of cleaning solutions which have a high acid content or are otherwise inappropriate can cause damage to the equipment, including cracking and deterioration of the plastic case.

▲ Always follow the mixing/diluting instructions provided by the manufacturer of the cleaning solution.

▲ Never use any of the following solutions or similar products to clean the equipment: ethyl alcohol, ethanol, acetone, hexane, abrasive or scouring powder or material, any cleaning material that damages plastic.

▲ The patient cable and other cable assemblies must not be exposed to excessive mechanical stress. Whenever disconnecting the leads, hold the plugs and not the cables. 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.

▲ When cleaning, ensure that all labels and safety statements, whether etched, printed or stuck to the unit, remain in place and remain readable.

Before cleaning the unit or any accessories, thoroughly inspect them.

- Look for any signs of damage and any improper mechanical function of buttons or connectors.
- Gently bend and flex cables, inspecting them for damage or extreme wear, exposed wires, or bent connectors.
- Confirm that all connectors engage securely.

The casing of the CARDIOVIT AT-102 plus and the cable assemblies can be cleaned with a cloth slightly moistened (not wet) on the surface only. Where necessary a domestic non-caustic cleaner or 70% alcohol solution can be used for grease and finger marks. Wipe the equipment with a cloth slightly moistened (not wet) with one of the approved cleaning solutions listed below.

Thoroughly wipe off any excess cleaning solution. Do not let the cleaning solution run into or accumulate in connector openings, latches, or crevices. If liquid gets into connectors, dry the area with warm air, and then check the equipment to confirm that it operates properly.

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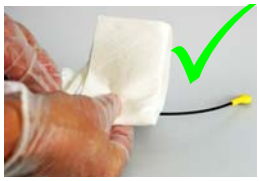
10.2.1 Cleaning Cable Assemblies

1. Before cleaning, inspect the cable for damage. Gently bend and flex all parts of the cable. Inspect for splits in the sheathing, damage or extreme wear, exposed wires, or bent connectors.
2. Wipe the equipment with a cloth slightly moistened (not wet) with one of the approved solutions listed below.
3. Gently grip the cable with the damp cloth in the centre of the cable and slide the cable through the cloth 20 cm at a time until clean. Do not clean the whole length in one single action as this may cause bunching of the insulation sheathing.
4. Wipe off any excess cleaning solution. Do not let the cleaning solution run into or accumulate in connector openings, latches, or crevices. If liquid gets into connectors, dry the area with warm air.



10.2.2 Approved Cleaning Solutions

- 70% solution isopropyl alcohol
- Neutral mild detergent solution
- All products designed for cleaning plastic.

10.2.3 Cleaning Materials that must not be used

Never use products containing the following:

- Ethyl alcohol
- Acetone
- Hexane
- Abrasive cleaning powder
- Plastic-dissolving products

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10.3 Disinfection

Disinfection removes certain bacteria and viruses. Please refer to the manufacturer's information. Use commercially available disinfectants intended for clinics, hospitals and practices to disinfect the device.

Disinfect the units in the same way as described for cleaning the units (previous page).

10.3.1 Admissible Disinfectants

- Isopropyl alcohol 70%
- Propanol (70-80%)
- Ethyl hexanal
- Aldehyde (2-4%)
- Ethanol (70-80%)
- all products that are suitable for ABS plastic

10.3.2 Non-admissible Disinfectants

Never use products containing the following:

- Organic solvents
- Ammonia-based detergent
- Abrasive cleaning agents
- 100% alcohol, Virex, Sani-Master
- Sani-Cloth®, Ascepti® or Clorox® wipes
- HB Quat®
- Conventional cleaner (e.g. Fantastic®, Tilex® etc.)
- Conductive solution
- Solutions or products containing the following ingredients:
  - Acetone
  - Ammonium chloride
  - Betadine
  - Chlorine[1], wax or wax compound
  - Ketone
  - Sodium salt

The disinfectants that can be used to clean the spirometry mouthpiece are specified in the Spirometry section (see Cleaning and Disinfecting, page 80).

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1. *Disinfectants that contain small amounts of chlorine or that separate chlorine (less than 1200 ppm) may be used.To prevent excessive ageing of the patient cables due to chlorine, the disinfectant needs to be wiped off with a neutral detergent or with water once the specified application duration has elapsed.*

10.4 Cleaning the Thermal Print Head

A residue of printers ink (from the grid on the paper) can build up on the print head over a period of time. 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.

10.5 Battery Maintenance

- Check the battery capacity every 12 months. If the battery capacity is below 60%, or the running time is less than 2 hours 45 min, the battery must be replaced.
- Regardless of its capacity, the battery must be replaced after 2 years.
- Make sure that the battery remains charged during storage. If the storage period exceeds three months, recharge the battery to prevent deep discharge.

10.5.1 Charging the Battery

A totally discharged battery requires approximately 3hours to be 100 % charged. It is possible to use the unit when the battery is being charged; however, charging time may be longer.

No harm will be done to the battery by leaving the unit connected to the mains supply.

1. Connect the device to the mains supply.
2. The green mains LED is lit.
3. Charge the battery for at least 3 hours.

10.5.2 Battery Capacity Test

⚠ CAUTION

▲ If the battery running time is approx. 2 hours 45 min or less, the battery needs to be replaced.

▲ Do not perform a battery calibration.

To test the battery capacity, proceed as follows:

1. Leave the unit connected to the mains until the battery is fully charged.
2. Unplug the mains cable.

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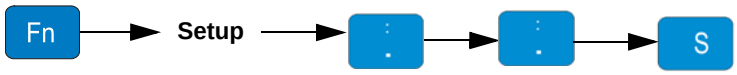
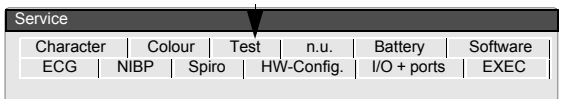
3. Open the Settings menu and press the following key combination:



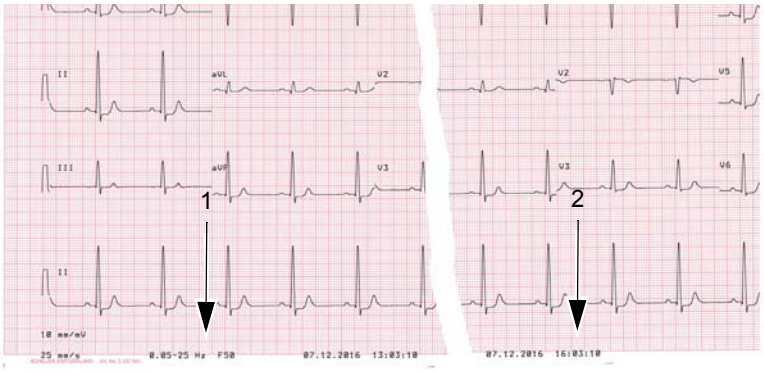
‘.’ ‘.’ ‘S’ (key "full stop" twice, followed by the letter "s").

The Service menu with several tabs is displayed:

4. 

5. Select the tab called Test and press 032  .

6. A printout is generated, followed by further printouts at intervals of one hour.
7. Wait for at least three printouts (three hours) to be able to determine if the battery needs to be replaced.
8. On every printout, the time is indicated **(1)**. The last printout gives the time at which the battery capacity has reached 30 % **(2)**.



9. Terminate the test by switching off the device. Connect the device to the mains supply to again fully charge the battery.

➜ Calculate the difference in time between the first and last printout. If the battery running time is less than 2 hours 45 min, have the battery replaced by your SCHILLER representative.

⚠WARNING

➜ Explosion hazard! The battery must only be replaced by service technicians authorised by SCHILLER AG.

➜ The test may be terminated at any time by switching off the device.

10.5.3 Battery Disposal

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

⚠WARNING

▲ Explosion hazard! The battery must not be burned or disposed of in domestic waste.

▲ Danger of acid burns! Do not open the battery.

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10.6 Inspection and Check List Report

In accordance with the maintenance interval detailed previously, the following check list should be copied and followed.

Unit Serial Number:

10.6.1 Every Six Months

Inspection	Results	Inspection				
General Examination						
➜ Visual inspection of the unit.	• Device casing not broken or cracked.	❒	❒	❒	❒	❒
➜ Visual inspection of the LCD.	• LCD screen not broken or cracked.	❒	❒	❒	❒	❒
➜ Visual inspection of all cable assemblies and sensors.	• Electrode cable sheathing and connectors undamaged.	❒	❒	❒	❒	❒
➜ Plug and socket connectors.	• No kinks, abrasion or wear in any cable assembly.	❒	❒	❒	❒	❒
	• Input/output connectors undamaged.	❒	❒	❒	❒	❒
Self-test (initiated when the device is switched on)						
➜ Switch the device on by pressing the On key.	• The standard screen is displayed.	❒	❒	❒	❒	❒
	• Check the LCD display for response.	❒	❒	❒	❒	❒
Basic Functional Check						
➜ Scroll though some menus	• Check basic keypad function.	❒	❒	❒	❒	❒
Safety checks and inspections						
➜ Confirm the date of last factory inspections and test.	• If the unit is due the safety inspection / battery capacity check, carry out the 12-monthly checks.	❒	❒	❒	❒	❒
Battery capacity check		❒ Not required on this inspection	❒ Not required on this inspection	❒ Not required on this inspection	❒ Not required on this inspection	❒ Not required on this inspection
➜ Confirm the date of last battery capacity check						
	Date Of Inspection:					
	Inspector:					

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10.6.2 Every Twelve Months

Inspection	Results	Inspection				
Battery Capacity Test ➜ Test according to section 10.5.2	• Replace the battery if the battery running time is approx. 2 h 45 min hours or less.	❒	❒	❒	❒	❒
Safety Checks and Inspections ➜ Safety test according to IEC/EN 62353 incl. visual inspection of the battery.	• Return the unit to your nearest authorised SCHILLER agent.	❒	❒	❒	❒	
	Date of inspection:					
	Inspector:					

10.6.2 Lifed Item Replacement Every 2 Years

Inspection	Results	Replacement				
Internal Battery ➜ Replace the internal battery every two years (regardless of capacity).	• Unit sent to SCHILLER service centre for battery replacement.	❒	❒	❒	❒	❒
	Date of replacement:					
	Inspector:					

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