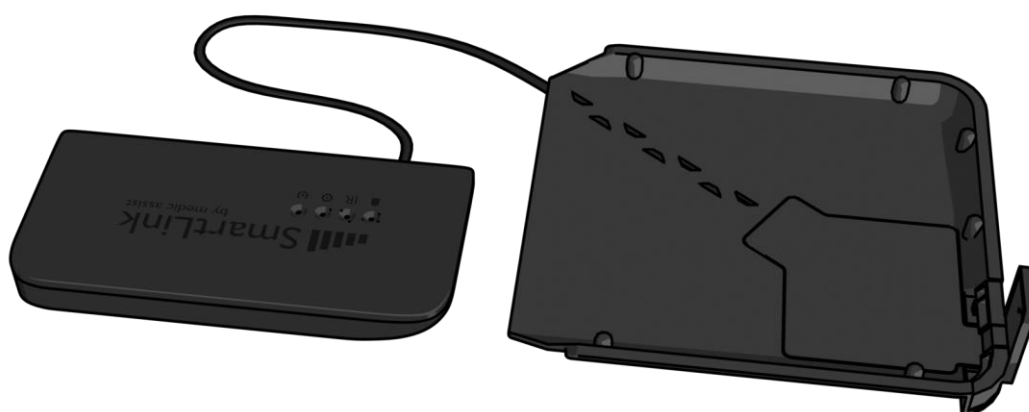


User Manual SmartLink FRx - AED Remote Monitor

Product Code PMS-SL-1550-52-FRx



PACKAGE CONTENTS

Check the contents of the SmartLink box to be sure it contains:

- SmartLink Remote Monitoring unit with installed battery pack and SD/ SIM card (or SIM Chip)
- Sensor-Cradle connected to SmartLink
- User Manual
- Quick Setup Guide
- Spare Pads Pouch

Edition 1

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Device manufacturer: medic assist GmbH & Co. KG, Friederikastrasse 148, 44789 Bochum, Germany,
support@medicassist.eu, www.medicassist.eu

Please contact your local Philips representative for information on revision of this document.

It is important to understand how to use your SmartLink safely.
Please read these warnings and precautions carefully.

A **warning** describes something that could cause serious personal injury or death. A **precaution** describes something that could cause minor personal injury, damage to the SmartLink, loss of data stored in the SmartLink, or less chance of successful remote checking of the defibrillator including data transfer.

WARNINGS

Any visible damage or disassembly of SmartLink may cause harm and result in the loss of type approval, functionality and warranty. Do not use SmartLink if the environmental conditions do not meet its specified temperature and humidity range as described hereinafter. Do not remove the SIM-Card or SD-RAM-Card (hidden mounted within the battery compartment). These parts are not user serviceable and the SmartLink will not be able to work with any other SIM or memory card. AutoSend periodic self-test feature must be "On" (default setting on the AED) for proper function. AED needs to be placed on the cradle as shown in the Quick Setup Guide, so that the Infrared receiver of the cradle is aligned to the Infrared port of the AED.

Flammable Gas Do not use the SmartLink in the presence of flammable gases such as in an oxygen tent. Move supplemental oxygen and oxygen delivery devices and other flammable gases away from the SmartLink.

Battery The SmartLink battery is not rechargeable. Do not try to recharge, open, crush, or burn the battery, or it may explode or catch fire.

Fluids Do not let fluids get into the SmartLink. Avoid spilling any fluids on the SmartLink or its accessories. Spilling fluids into the SmartLink may damage it or cause a fire. Do not sterilize the SmartLink or its accessories.

Accessories Using damaged or expired equipment/ accessories or non-approved accessories may cause the SmartLink to perform improperly, and/or injure the user.

Interference Do not use SmartLink within 10 inches of another medical appliance (except AED). Avoid long term exposure to Smartlink due to RF radiation exposure.

Children Keep SmartLink out of reach of children to avoid the potential risk of inhalation or swallowing of small parts or strangulation by sensor cable.

Sensor Cable Be cautious when closing the AED case, so that the sensor cable does not get pinched. Pinched sensor cable may impact remote monitor functionality.

PRECAUTIONS

Device Handling The SmartLink was designed to be sturdy and reliable for many different use conditions. However, handling the SmartLink too roughly can damage it or its accessories and will invalidate the warranty coverage. Check the SmartLink and accessories regularly for damage, according to directions. Your SmartLink version may only be used for fixed installations and shall not be moved without need – this may result in delay in messaging and higher drainage of the battery.

Maintenance Improper maintenance may damage the SmartLink or cause it to function improperly. Maintain the SmartLink according to guidance provided in the User Manual.

Mobile Connectivity Never replace existing emergency call or other safety or wired communication devices by SmartLink. Due to its mobile network dependency SmartLink should only act as an additional emergency device.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: -- Reorient or relocate the receiving antenna. -- Increase the separation between the equipment and receiver. -- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. -- Consult the dealer or an experienced radio/TV technician for help.

IMPORTANT NOTE

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be operated with minimum distance 20 cm between the radiator & your body.

INTRODUCTION

SmartLink is a battery-powered device intended to be used only for supervision of the Philips defibrillators (HS1, FRx) built-in self-test functionality using a special patented sensor, which needs no fixed connection to the defibrillator.

SETTING UP SMARTLINK

Setting up the SmartLink is simple and quick. The SmartLink Quick Setup Guide provides illustrated instructions for setup (Install Routine).

USAGE AND FUNCTIONALITY DESCRIPTION

SmartLink system consists of the mobile and battery powered SmartLink unit which is stored in the AED carrying case, the cradle containing the sensors and the remote computer based host center. This SmartLink solely monitors the AEDs self-test function (basic functionality). Besides the basic functionality SmartLink may offer additional functions in other versions.

Power supply SmartLink is powered by a primary LiMnO₂-cell. It delivers the processor-controlled functionality described above. The battery is field exchangeable by the user.

Reinstalling or replacing the battery will restart the device and trigger the Install Routine.

SmartLink is intended to not send data in a time frame of 30 minutes after any movement was detected. Therefore the intended use case for monitoring function is the SmartLink and AED standing still. To ensure monitoring of the AED is not delayed, SmartLink should remain stationary when the AED is not in use.

CLEANING SMARTLINK

The outside of the SmartLink can be cleaned with a soft cloth dampened in soapy water, chlorine bleach (2 tablespoons per quart or liter of water), or ammonia-based cleaners with up to 10% ammonia by volume or by weight. **Caution:** Do not use isopropyl (rubbing) alcohol, strong solvents such as acetone or acetone-based cleaners, abrasive materials, or enzymatic cleaners to clean SmartLink. Do not immerse the SmartLink in fluids or allow fluids to spill onto it. Do not sterilize the SmartLink or its accessories.

TECHNICAL DATA

Module Dimensions	213 x 118 x 27 mm
Weight (Module w/o battery)	205 g
Sensor-Inlay	passive featuring IR and inductive receiver with cable connection to Module
Storage temperature range	-20 - 60°C
Operating temperature range	0 - 50°C
Humidity range	0% - 95% rel. humidity, non condensing
SIM	built-in 3V SIM-Card
Battery supply	3V LiMnO ₂ , 4 x 1,5Ah
Battery Weight	140 g (4 cells)
Battery dimensions	82 x 24 x 110 mm
LTE Module	BG95 Quectel, Cat M1, Cat NB2 (FCC, GCF, PTCRB, IC and others), FCC ID: XMR201910BG95M3
Certifications	USA: FCC part15b, PTCRB FCC ID: 2A2C5-SL-MA-1550-5X PMS-SL-1550-52-FRx is hardware identical to MA-1550-25 FRx

The SmartLink is located directly adjacent to the defibrillator in the carrying case.
The SmartLink device has no user interface.

Declaration of conformity We, medic assist GmbH & Co. KG, Friederikastrasse 148, 44789 Bochum, hereby declare that this product conforms with the basic requirements and the other relevant regulations of the named certifications above.

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ENVIRONMENTAL CONSIDERATIONS

The battery cells contain chemicals. The chemistry used in each battery is identified by a symbol on the label. You should be informed about your local laws and legal requirements regarding disposal of batteries. In case of any questions please refer to your local authorities. Recycle the battery at an appropriate recycling facility.

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