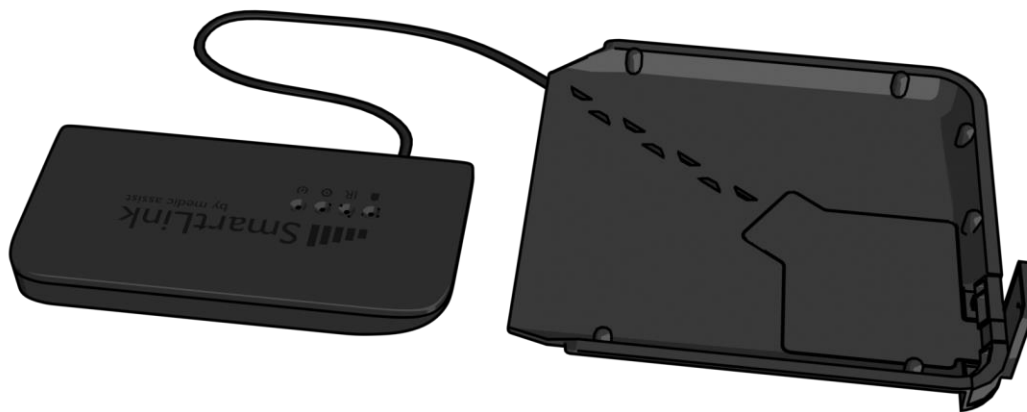


User Manual SmartLink

Philips FRx AED Remote Monitoring

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

Edition 1

Publication date: September 2021

Device manufacturer: medic assist GmbH & Co. KG, Friederikastrasse 148, 44789 Bochum, Germany

Please contact your local Philips representative for information on revisions.

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 be harmful and may cause the loss of type approval 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. Infrared port needs to be turned on for AED (default setting) for proper function. AED needs to be placed as shown on cradle, so that the Infrared receiver of the cradle is aligned to the Infrared port of the AED.

Flammable Gas If the SmartLink used in the presence of flammable gases such as in an oxygen tent, there is a risk of explosion as with mobile phones. 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. The battery is field exchangeable by the user.

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 directly adjacent (less than 10 inches) to medical appliances (except AED) and avoid long term exposure to the human brain / body due.

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 and report any damages to the owner. SmartLink 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 directions as given by the owner or on the online customer portal.

Mobile Connectivity Never replace existing emergency call or other safety or wired communication devices by SmartLink. Due to its mobile net 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. SmartLink solely monitors the AEDs self-test function. Besides the basic functionalities SmartLink may offer additional functions. These are described in a separate IFU.

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

Putting in and changing battery, also restart the device and triggers the Install Routine.

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. **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 FDA Class I Medical Device Data System (MDDS) FCC ID: 2A2C5-SL-MA-1550-5X

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.

Please contact your local Philips representative for information on revisions.

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.

Reproductions of any kind, completely or in part and in particular photocopy or digital copies, as well as translations are permitted only with the written consent of the copyright holder. This manual complies with the technical state at the date stated on the title page. In the context of technical changes, such as improvement or further development, changes may occur at any time. Actual product characteristics may also differ from the behavior described in this document, for example due to remotely installed updates.

The trademarks, logos, and product names are trademarks of their respective owners.

© 2021 Philips & medic assist All rights reserved.