FRED[®] easyport[®] plus Trainer

Automated external defibrillator (AED)



User Guide



Sales and service information

The SCHILLER sales and service centre network is world-wide. For the address of your local distributor, contact your nearest SCHILLER subsidiary.

In case of difficulty, a complete list of all distributors and subsidiaries is provided on our internet site:

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Sales information can also be obtained from: sales@schiller.ch

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SCHILLER FRED[®]easyport[®]plus Trainer

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1 Safety Notes

1.1 Intended Purpose

▲ The **FRED** easyport plus[®] **TRAINER** is a training device designed to train the intended functions of the intended users in the intended environment of the FRED easyport plus device.

Indication

▲ The **FRED easyport plus[®] TRAINER** is ONLY used for training and simulation **NOT** for the use on a patient.

Intended user

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▲ The **FRED** easyport plus[®] **TRAINER** is intended to be used for training purpose of the same intended users as the FRED easyport plus device. The following people may use the FRED easyport plus® Trainer:

Anyone who wants to be trained in the application of an AED under supervision and with instructions of a trainer.

1.2 Contraindication

Limitations

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▲ No contraindications for the system known.

Contraindication for the patient

▲ The **FRED easyport plus[®] TRAINER** is **not** indicated to be use for patient treatment.

1.3 Responsibility of the User

- ▲ Damaged or missing components must be replaced immediately.
- Properly dispose of the packaging material and make sure it is out of children's reach
- ▲ Do not store the training electrodes together with the normal electrodes or with the normal defibrillator.
- This user guide is only for the trainer and not for the trainee.

1.4 Safety-Conscious Operation

- Immediately report any changes that impair safety (including operating behaviour) to the responsible person.
- ▲ Only use original SCHILLER training electrodes.
- Immediately replace a damaged unit, or damaged cables and connections.
- Only operate the device in accordance with the specified technical data.





1.5 Maintenance and Cleaning

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- Before cleaning, switch the unit off and remove the battery.
- Do not use aggressive or abrasive cleaners.
- ▲ Do not, under any circumstances, immerse the device or cable assemblies in liquid.

1.6 Additional Terms

1.6.1 Terms of Warranty

Your SCHILLER **FRED** easyport plus[®] **TRAINER** is warranted against defects in material and manufacture according the general terms of condition. Excluded from this warranty is damage caused by an accident or as a result of improper handling. The warranty entitles to free replacement of the defective part. Any liability for subsequent damage is excluded. The warranty is void if unauthorised or unqualified persons attempt to make repairs.

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

- assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorised by him,
- spare parts used for assembly operations, extensions, readjustments, modifications or repairs are recommended or supplied by SCHILLER, and,
- the SCHILLER FRED easyport plus[®] TRAINER and approved attached equipment is used in accordance with the manufacturer's instructions.

There are no express or implied warranties which extend beyond the warranties hereinabove set forth. SCHILLER makes no warranty of merchantability or fitness for a particular purpose with respect to the product or parts thereof.

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1.7.1 Symbols used in this user guide

The safety levels are classified according to ANSI Z535.6. The following overview shows the safety symbols and pictograms used in this user guide. The terms Danger, Warning, and Caution are used in this User Guide to point out potential dangers and to indicate risk levels. Familiarise yourself with their definitions and significance.



For a possibly dangerous situation which could lead to severe personal 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 section.

Important or helpful user information.

1.7.2 Symbols used on the device

General used symbols see 5 Appendix - Symbols.





Reading the instruction for use is mandatory before using the device!

Dangerous voltage! Used for electrical dangers during defibrillation.



The enclosure is protected against foreign solid objects of $\geq 1 \mbox{ mm}$ and splashing water from all directions



Cover battery housing replacement instruction



Bluetooth inside

Attention: non ionising electromagnetic radiation. Some of the devices contain an HF transmitter (Bluetooth).

The **FRED** easyport plus[®] **TRAINER** radiates high-frequency electromagnetic energy and can disturb other devices if not installed and operated in accordance with the user guide. However, there is no guarantee that no interference can occur in certain installations. If the **FRED** easyport plus[®] **TRAINER** causes interferences, these can be determined by switching the device off/on or by transmitting/not transmitting ECG data. The user can take the following measures to prevent electromagnetic interferences:

- Increase the distance between the disturbed device and the FRED easyport plus[®]
 TRAINER A minimum distance of 20 cm must be kept between the device and a pacemaker.
- Turn the device to change the angle of radiation.

For more details, see page 29.



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2 Components and Operation

2.1 General Information

The following instruction uses the Name FEP+ TRAINER instead of the full name FRED easyport ${\sf plus}^{\textcircled{0}}$ TRAINER

The **FEP+ TRAINER** is a simple and cost-effective simulator of the **FRED easyport plus**[®] that is designed to be used exclusively for training.

The **FEP+ TRAINER** doesn't deliver any energy, it simply plays through the resuscitation process with different scenarios. It is powered by a standard 9 V battery

The **FEP+ TRAINER** equipped with Bluetooth, identified by the symbol (()) on the device label, can be controlled and configured via your smart-phone/tablet PC with the "Defi training application" which can be downloaded from:





The **FEP+ TRAINER** provides simulation that aim to help to familiarise with the **FRED easyport plus**[®] and shows that the users have the knowledge required to use it if necessary.

The operating mode can be selected by configuration. One device is enough to train both the fully automatic, semi-automatic mode and Manual mode

- One scenario can be predefined and downloaded to the FEP+ TRAINER.
- Scenario can be changed live by using the Defi training application.

All languages available on the FEP+ TRAINER are also available on the Trainer.

Language selection as well as scenario selection is done by configuration.

The **FEP+ TRAINER** standard package includes:

- 1 FEP+ TRAINER
- 1 set of training electrodes
- 1 training electrodes cable
- 9V battery

ARGUS LifePoint (optional)

Operating modes

Languages

Standard package

CPR feedback sensor for additional training on chest compression

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Configuration	Values
Device	Normal
Simulation of the following device types:	by weath trainer
Semi-automatic	
Manual	• • •
Automatic	FEP+ Manual
	FEP+ Auto
Audio language	List of available language

2.1.1 Configurations via Simulation App

2.1.2 **Configurations on the FEP+ TRAINER**

The following programming should be adapted for the organisation to be trained.

Note: This **bold** settings have been entered during the initial setting. The initial setting screen appears only after the device is set to factory default.

For all settings please refer to the user guide of the FRED easyport plus

Co	onfigurable device parameters	Detail see cross reference below or F IFU of the FRED easyport Plus	assword required
•	Selftest	-	No
•	Bluetooth pairing	2.3.2 Device-smartphone pairing	No
•	Device Settings >>>	Device Setting >>> CPR setting,	Yes
	– CPR settings >>>	page 13	
	 CPR feedback >>> 		
	- Communication >>>		
	- Transmission mode >>>		N
	- System settings >>>	Cyclem Cetting >>> Legel esting	Yes
	- Local settings /// Language, Country, Time, Date, Time-	System Setting >>> Local Setting,	
	- Volume settings	page 14	
	- ECG and HR display		
	- Restore Factory Defaults		
Se	econd page		
	- Import Settings		
	– Export Settings		
	- Trainer Device Variant		
	– First (Normal)		
	– Auto (FEP+ Auto),		
	 Manual (FEP+ manual) This can be obspread also via Simulation App but after power 		
	cycling it will start with the programmed mode		
	 Restore Default Scenario 		
	(Electrode not applied, shock/no shock/ shock)		

Access to the device setting menus:

To get access to the settings:

→

- 00:30 Configuration Selftest >>> Bluetooth pairing Start Device information >>> Device Settings >>> Device Update >>> Pads Expired >>> Production Log Files >>>
- Press and hold the button while switching the device on → (**~~**) The Configuration menu appears
 - Enter the password (9<u>c</u>)

for the Device setting menu.

Please note: This access code is only for the training organisation.

Device Setting >>> CPR setting

Default settings are **bold**

Parameter	Values	Description
Start with Analysis	• No • Yes	If Yes is set, the device starts with the analysis as soon as defibrillation electrodes are applied. If No is set, the device prompts the user to perform CPR before the analysis. Analysis will start once the 2-minute CPR interval has ended.
Show CPR Timer	• No • Yes	Display of the CPR timer on the status line.
CPR Timer counting	• Up • Down	Timer counting up or down
Metronome AED	OnOffCPR	Metronome default behaviour only for AED mode
Metronome Ratio	 30:2 15:2 Cont 	Metronome Setting
Metronome rate	100 cpm100-120	Sets the frequency of the metronome

Additional settings for the AED MANUAL

Manual Settings >>>

Metronome MAN	• On / Off / CPR	Metronome default behaviour in manual mode
Metronome Ratio	 30:2 / 15:2 / Cont 	Metronome Setting in Manual mode
CPR Voice Prompts	YesNo	Voice prompt in manual mode yes or no.

Device Setting >>> CPR Feedback

Parameter	Values	Description
CPR Voice prompts	 Yes No 	Yes activates the voice prompt during CPR

System Setting >>> CPR setting

Parameter	Values	Description
	• Low (>50)	Sets the volume of audio prompts and notifications.
Volume	Mid (>55)High (>60)	 Caution: ▲ Ensure that the environmental noise is below the set sound volume (Low/Mid/High)
ECG and HR	• No • Yes	Display HR and ECG curve (not displayed for the AED manual because it is standard activated)

2.1 General Information

System Setting >>> Local setting

Note: This settings have been entered during the initial setting. The initial setting screen appears only after the device is set to factory default.

Parameter	Values	Description
Language	 English* German French Spanish Italian etc 	Sets of the language in which the device will always start by default.
Country	 Other France, Germany, UK, USA 	-
Date	• -	Sets the date
Time	• -	Sets the time

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2.2 Operating and Display Elements

The status LEDs are not active!

2.2.1 Overview FEP+ TRAINER

The picture below shows the user interface for an AED with ECG and CPR feedback display.



Fig. 2.1 Operating Elements

- (1) Green button to switch the device on/off and RTU LED (Ready -to-use LED) Additionally the button is used to "Pause" the algorithm.
- (2) Orange indicator lamp; lit as long as no electrodes are connected
- (3) Electrode connector
- (4) LCD screen
- (5) Switching to child mode when using adult electrodes (PATIENT button)
- (6) USB connector for Argus LifePoint sensor or USB memory stick
- (7) Orange button: key to trigger a defibrillation impulse (SHOCK button)
- (8) Battery at back
- (9) Loudspeaker
- (10) Microphone
- (11) Data transfer (COM) button
- (12) Ambient light sensor



2.2.2 FRED easyport plus TRAINER with bag (optional)





- (1) RTU LED (Ready -to-use LED) transparent window
- (2) Defibrillation electrode compartment
- (3) Scissor and razor compartment
- (4) Connection ARGUS LifePoint CPR feedback sensor (USB Port)
- (5) ARGUS LifePoint compartment



A WARNING

2.3 Inserting the batteries

- ▲ **Danger of explosion!** The battery must not be exposed to high temperatures or disposed of with household waste.
- ▲ Do not short-circuit, cut, destroy, burn or charge a battery.
- Replace the battery if the device indicates a battery problem. A defective battery must not be used.
- 1. Open the battery cover by pressing the locking mechanism in the direction of the arrow (1).
- 2. Lift up the battery, disconnect the cable and remove the battery
- 3. Insert the new battery into the device as shown on the picture (2) and connect the cable.
- 4. Close battery compartment with the battery cover.





2.3.1 Switching device On and Off

	Switching ON	→ Press the "ON/OFF" (1) button
1	Switching OFF	→ Press the "ON/OFF" (1) button for 3 seconds.
	i	Forced shutdown procedure If the device cannot be switched off via the above procedure, remove the battery and insert it again.
	i	The running AED algorithm can by paused during CPR by the Green ON/OFF button (press 1 second) and continued by pressing again the ON/OFF button.

2.3.2 Device-smartphone pairing

00:30		
Configuration		
Selftest	>>>	Dress
Bluetooth pairing	Start	Prev
Device information	>>>	(
Device Settings	>>>	
Device Update	>>>	OK
Pads Expired	>>>	\frown
Production	>>>	
Log Files	>>>	Next

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Before the **FEP+ TRAINER** can be selected from the device list on the App (Step 9), it must first be paired with the smart-phone

- 1. Press and hold the button while switching the device on
- 2. The configuration menu is displayed.
- Start Bluetooth pairing. The blue message bar shows bluetooth discoverable (blinking Bluetooth icon).
- 4. Open on your smart-phone the menu Setting > Connected devices (bluetooth) and select paring new device. The Name FEP+Trainer 9010.xxxxxx is displayed.
- 5. To pair the device with your smart-phone select the name and confirm the pairing.
- 6. If successfully paired with the smart-phone "Bluetooth paired" is displayed on the device
- 7. Open the Schiller Defi training App on your smart-phone or tablet PC.
- 8. Select the icon the Device list of Defi training application. Select the device you want to use in the list.

For additional information on the application, refer to the application: Settings



3 Training

- As soon the FEP+ TRAINER is switched on, the voice prompt starts.
- Advise the trainee to follow the instruction from the device.
- The running AED algorithm can by paused during CPR by the Green ON/OFF button (press 1 second) and continued by pressing again the ON/OFF button
- Depending on the configuration the **FEP+ TRAINER** may start with Step 1 or 8 (see chapter 2.1.2 Menu Start with analysis Yes/No).
- When a scenario have been saved with the App the **FEP+ TRAINER** start with Step 2, because the electrode status is set to electrode applied.

3.1 Training procedure semi automated AED

- The following instructions comply with the scenario "shock recommended" and then twice shock not recommended. The scenarios can be selected and saved.
- The following procedure should be checked by the trainer:
 - call emergency service dial number
 - use only if patient is unresponsive
 - remove clothes from upper body cut if necessary
 - tear open electrode package located in device packaging
 - as shown on package peel off the packing and apply both electrodes to the upper body

As soon the connection to the App is established, you can press the electrode button and then "Next Step on the App if the electrodes have been not right applied. This will cause that the trainer starts with step 1.

- 1. Check that electrodes connector is correctly fitted in machine^a
- → Trainer confirms that the above procedure was correctly performed by the trainee. Otherwise, the instructions step 1 is repeated. After the third repetition, the instructions jump to step 8.
- 2. Do not touch the patient analysis will begin
- 3. Do not touch the patient analysing
- 4. Shock advised
- 5. Stand clear of patient
- 6. Press orange button now (if shock button is not pressed within 20 seconds it jumps to 8.)
- 7. Shock delivered
- 8. Advise to do chest compression: according to configuration
- 9. Repeat until next instruction (the next instruction starts with step 2)
 - After the instruction "no shock advised" (step 4), it jumps to step 8.
- → To finish the resuscitation process and switch the device to standby mode, press the Green ON/OFF button (press 3 second).

a. If **FEP+ TRAINER** start with Step 8, check configuration, if it starts with Step 2 set the Scenario to Default in the Menu **Device Setting > Restore Default Scenario.**

Trainee starts by switching on the device

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Trainer has to confirm correct performance with the button on the device or via Defi training application

Finishing resuscitation process



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3.2 Training procedure fully automated AED

- The following instructions comply with the scenario "shock recommended" and then shock not recommended.
- Depending on the configuration the **FEP+ TRAINER** may start with Step 1 or 11 (see chapter 2.1.2 Start with analysis Yes/No).
- When a scenario have been saved with the App the **FEP+ TRAINER** jumps from Step 1 direct to Step 5, because the electrode status is set to electrode applied.
- The following not advices procedure from the device should be checked by the trainer:
 - call emergency service dial number
 - remove clothes from upper body cut if necessary
 - tear open electrode package located in device packaging
 - as shown on package peel off the packing and apply both electrodes to the upper body

As soon the connection to the App is established, you can press the electrode button on the App if the electrodes have been not right applied. This will cause that the trainer follows up with step 2.

- 1. Make sure the patient is unresponsive
- 2. Plug and apply the electrodes (repeated 3 times)
- 3. Check that electrodes connector is correctly fitted in machine
- → Trainer confirms that the above procedure was correctly performed by the trainee. Otherwise, the instructions step 3 is repeated. After the third repetition, the instructions jump to step 10.
- 4. make sure the patient is unresponsive
- 5. Do not touch the patient analysis will begin^b
- 6. Do not touch the patient analysing
- 7. Shock advised
- 8. Warning! Shock will be delivered
- 9. 3-2-1
- 10. Shock delivered
- 11. Advise to do chest compression: according to configuration^c
- 12. Repeat until next instruction (the next instruction starts with step 4
 - After the instruction "no shock advised" (step 7), it jumps to step 11.
- → To finish the resuscitation process and switch the device to standby mode, press the Green ON/OFF button (press 3 second).

- b. If FEP+ TRAINER jumps from Step 1 direct to Step 5, set scenario to Default in the Menu Device Setting > Restore Default Scenario.
- c. If FEP+ TRAINER start with Step 11, check configuration.

Trainee starts by switching on the device

Trainer has to confirm correct performance with the button on the device or via Defi training application

Finishing resuscitation process



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3.3 Training procedure manual AED mode

- The **FRED easyport plus** version including the manual option is clearly labelled with a red foil. If the user does not activate the manual mode, the unit will run in the semi-automatic mode.
- The **FEP+ TRAINER** is only available with the dark grey foil and the indication to press simultaneously the Data transfer (COM) button and the shock button is not shown on this foil. Please advice the trainee accordingly.
- The device cannot be switched over to the manual mode during the defibrillation process (analysis, charging, shock release).
- To operate the **FEP+ TRAINER** in semi-automatic mode again, it must be shut off and on again.
- Depending on the configuration the **FEP+ TRAINER** may start with Step 1 or 8 (see chapter 2.1.2 Menu Start with analysis Yes/No).
- When a scenario have been saved with the App the **FEP+ TRAINER** start with Step 2, because the electrode status is set to electrode applied.
- The following instructions comply with the scenario "shock recommended" and then twice shock not recommended. The scenarios can be selected and saved.
 - The following procedure should be checked by the trainer:
 - call emergency service dial number
 - use only if patient is unresponsive
 - remove clothes from upper body cut if necessary
 - tear open electrode package located in device packaging
 - as shown on package peel off the packing and apply both electrodes to the upper body.

As soon the connection to the App is established, you can press the electrode button and then "Next Step on the App if the electrodes have been not right applied. This will cause that the trainer starts with step 1.

- → before the connection to the patient is established (before step 2) you can switch to manual mode by simultaneously pressing the Data transfer (COM) button and the shock button, press Orange (Shock) button to charge the energy. Release shock by the Orange (Shock) button
- 1. Check that electrodes connector is correctly fitted in machine^d
- → Trainer confirms that the above procedure was correctly performed by the trainee. Otherwise, the instructions step 1 is repeated. After the third repetition, the instructions jump to step 8.
- 2. Do not touch the patient analysis will begin
- 3. Do not touch the patient analysing
- 4. Shock advised
- 5. Stand clear of patient
- 6. Press orange button now (if shock button is not pressed within 20 seconds it jumps to 8.)
- 7. Shock delivered
- → After shock delivered /no shock advices message you can switch to manual mode by simultaneously pressing the Data transfer (COM) button and the shock button.
- 8. Advise to do chest compression: according to configuration.
- d. If **FEP+ TRAINER** start with Step 8, check configuration, if it starts with Step 2 set the Scenario to default in the Menu **Device Setting > Restore Default Scenario.**

Trainee starts by switching on the device

Trainer has to confirm correct performance with the button on the device or via Defi training application



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- 9. repeat until next instruction (the next instruction starts with step 2)
 - After the instruction "no shock advised" (step 4), it jumps to step 8.

Finishing resuscitation process

→ To finish the resuscitation process and switch the device to standby mode, press the Green ON/OFF button (press 3 second) i

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3.4 Training on thorax compressions (optional)

This training is only avalibel with the ARGUS LifePoint CPR feedback sensor.

The training with the Argus LifePoint sensor is only allowed on a chest manikin.

42 60 01:56 01:56 * **n**ô Text and voice advice CPR Measured value from ARGUS Depth 5.0 cm to improve the CPR LifePoint sensor **CPR OK** 00:59 quality Rate 101 /min **30 CHEST CPMPRTESSIONS** THEN 2 RESCUE BREATH Metronome speed **CPR OK Press Slower Press Faster** [/min] CPR OK 100 ≤ 90 ≥120 CPR OK 110 ≤ 100 ≥130 CPR OK 120 ≤ 110 ≥140 Depth [mm] **Press Deeper CPR OK Press Shallower** 1-127 ≤ 45 CPR OK ≥ 62

3.4.1 Setup of the sensor

The recommended securing pads during real CPR keeps the LifePoint sensor in position. It is not always needed for training purpose.

- 1. Connect the LifePoint USB cable to the USB connector.
- 2. Switch on the device.



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- 3. Attach the adhesive securing pad on the patient's chest and peel off the foil.
- 4. Place the LifePoint on the patient chest and start CPR.



5. Place your hand on the sensor so that the heel of your hand (1) is in the middle of the sensor.



6. Start with CPR and monitor the compression quality on the device and follow the instructions given by the device (see page before).

hour glass sensor

User Guide

7. The displayed measurements in the middle of the screen informs you about your CPR quality.



The following limits are set for speed and depth:

Douth [mm]	Dress desper		
120	≤ 110	≥ 140	
110	≤ 100	≥ 130	
100	≤ 90	≥ 120	
Metronome speed [/min]	Press faster	Press slower	

Depth [mm]	Press deeper	Press shallower
1 to 127	≤ 45	≥ 62

3.5 Accessories and disposables

Risk to Persons, Equipment Damage — Always use SCHILLER replacement parts and disposables, or products approved by SCHILLER. Failure to do so may endanger life and/or invalidate the warranty.

Your local representative stocks all the consumables and accessories for the **FRED easyport plus[®] TRAINER**. A full list of all SCHILLER representatives can be found on the SCHILLER website (<u>www.schiller.ch</u>). In case of difficulty, contact SCHILLER. Our staff will be pleased to help process your order or to provide details for all SCHILLER products.

3.5.1 Order Information

Devices

Part No.	Description
3.940069	FRED easyport plus [®] TRAINER
2.230366/0-21-0019	1 Reusable training electrodes cable
2.230398/0-21-0031	1 Training electrode

Accessories/Disposable

Part No.	Description
2.230325/0-21-0031	Set of 10 training electrodes

Optional Accessories

Part No.	Description
2.100860	CPR Feedback Sensor ARGUS LifePoint
2.100870	CPR Feedback Sensor ARGUS LifePoint (hour glass)
2.100519	CPR Feedback Sensor Securing Pads (5x)
2.310420	USB A 90-90 Adapter
2.156095	Carrying Bag red

3.5.2 Required accessories

- User Guide
- 1 set of training electrodes
- 1 training electrodes cable
- 9 V alkaline battery

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A WARNING

3.6 Disposal information

3.6.1 Battery Disposal

- ▲ Danger of explosion! The battery must not be incinerated, exposed to high temperatures or disposed of with household waste.
- ▲ Do not expose the battery to chemicals that could dissolve ABS, polypropylene, polyvinyl chloride, nickel, mylar or steel.
- ▲ Do not cut, destroy, or incinerate the battery.
- ▲ Danger of acid burns! Do not open or heat up the battery.



The battery is to be disposed of in municipally approved areas or sent back to SCHIL-LER.

3.6.2 Disposal at the end of its useful life

At the end of their service life, the device and its accessories must be recycled in compliance with local regulations. Apart from the internal and plug-in batteries, the device does not contain hazardous material and can be recycled like any other piece of electronic equipment. In accordance with national law, the battery must be disposed of at an appropriate waste disposal station or returned to SCHILLER.

According to European legislation, this device is considered as electronic waste equipment. It can be returned to the distributor or manufacturer where the device will be disposed of in compliance with legal requirements. The customer must bear the shipping costs. This unit must be disposed of in a municipally approved collection point or recycling centre when no longer used.

If no such collection point or recycling centre is available, you can return the unit to your distributor or the manufacturer for proper disposal. In this way, you contribute to the recycling and other forms of utilisation of old electrical and electronic equipment. Improper disposal harms the environment and human health due to the presence of dangerous substances in electrical and electronic equipment.

3.7 Troubleshooting

3.7.1 Troubleshooting

Problem	Possible causes	Re	medy
The ON/OFF LED is off and the device cannot be turned on.	Battery depleted or inserted with the wrong polarity.	\rightarrow \rightarrow	Replace the battery. Insert the battery correctly.
	Device defective.	→	Have the device repaired.

3.8 Preventing electromagnetic interferences



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The user can help avoid electromagnetic disturbances by keeping the minimum distance between **portable** and **mobile** HF telecommunication devices (transmitters) and the **FEP+ TRAINER**. The minimum distance of 0.3 m has been tested according to IEC 60601-1-2 for a wide range of telecommunication equipment, as shown in the following table:

"Non ionising electromagnetic radiation"

HF source Wireless communications devices	Transmitter fre- quency [MHz]	Testing fre- quency [MHz]	Max. power P [W]	Distance d [m]
Various radio services (TETRA 400)	380-390	385	1.8	0.3
- Walkie-talkies (FRS) - Rescue service, police, fire brigade, servicing (GMRS)	430-470	450	2	0.3
LTE band 13/17	704-787	710/745/780	0.2	0.3
- GSM800/900 - LTE band 5 - Radio telephone (microcellular) CT1+, CT2, CT3	800-960	810/870/930	2	0.3
- GSM1800/1900 - DECT (radio telephone) - LTE Band 1/3/4/25 - UMTS	1700-1990	1720/1845/ 1970	2	0.3
 Bluetooth, WLAN 802.11b/g/n LTE Band 7 RFID 2450 (active and passive transponders and reading devices) 	2400-2570	2450	2	0.3
WLAN 802.11a/n	5100-5800	5240/5500/ 5785	0.2	0.3

	 Portable HF telecommunication devices must not be used within a radius of 0.3 m from the FEP+ TRAINER and its cables. Do not place the FEP+ TRAINER on top of other electric/electronic devices - i.e. maintain a sufficient distance to other devices (this includes the patient cables).
d = recommended minimum distance in meters P = transmitting power in Watts	For permanent HF telecommunication devices (e.g. radio and TV), the recommended distance can be calculated using the following formula : $d = 1.2 \times \sqrt{P}$ for 150 kHz to 800 MHz and $d = 2.3 \times \sqrt{P}$ for 800 MHz to 2.7 GHz
3.8.1	 Measures to prevent electromagnetic interferences Further measures to prevent electromagnetic interferences: The user can take the following measures to prevent electromagnetic interferences: Increase distance to the source of interference. Turn the device to change the angle of radiation. Only use original accessories (especially patient cables) The device should not be used adjacent to or stacked with other equipment.
	▲ However, there is no guarantee that no interference can occur in certain installations. If the FEP+ TRAINER causes interferences, these can be prevented by switching off the device.

4 Technical Data

4.1	System Specifications	
Manufactured by	SCHILLER	
Device name	FRED easyport plus [®] TRAINER	
Dimensions	46 x 150 x 143 mm (h x l x w)	
Weight	Approx. 0.44 kg with battery	
Protection class of the device housing	IP44 (The enclosure is protected against foreign solid objects of \geq 1 mm and splashing water from all directions)	
Power supply Voltage with battery type Power consumption Runntime	9V 9 V alkaline battery max. 3 W approx. 3 hours depending of the used battery quality.	
Environmental conditions Device Operation Storage before use	 040 °C at a relative humidity of 30 to 95% (no condensation) 040 °C with the battery inserted Atmospheric pressure 700 to 1060 hPa / 0 to 3000 m 	
Storage and transport	 -20 50 °C at a relative humidity of 30 to 95% (no condensation) Atmospheric pressure 500 to 1060 hPa 	
Modules	PAN1026	
Bluetooth FCC ID IC ID	T7VPAN10 216Q-PAN10	
Transmission standards	Bluetooth BT version 4.0 BR/LE	
Frequency range	2.4022480 MHz	
Max. power output	+4 dBm	
Conformity	Hereby, SCHILLER AG declares that the radio equipment type FRED easyport plus TRAINER is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet	

address: https://www.schiller.ch/en/conformity

5 Appendix – Symbols

This appendix lists all general symbols that may be present on the device, label and accessories. Not all of those symbols are necessarily present on your device.

This appendix has its own article number, which is independent of the user guide's article number.

	Identification of the manufacturer
	Identification of the manufacturing date
	Identification of the distributor
	Identification of the importer
MD	Medical device
SN	Serial number
REF	Reference number
LOT	Batch code
GTIN	Global Trade Item Number
CAT	Catalogue number
QTY	Quantity
UDI	UDI: unique device identification as QR code machine readable and human readable as number (e.g. (01) 0 7613365 00210 2 (21)xxxx.xxxxxx))
5	Number of pieces in the packaging
EC REP	Authorised European representative
(Notified body (e.g. C E 0123 marking notified body TÜV SÜD)

CE	CE marking, affirms its conformity with European standards
Â	Regulatory Compliance Mark for the Australian standards
	The device is recyclable
	Symbol for the recognition of electrical and electronic equipment. Device must not be disposed of in the household waste.
	Symbol for the recognition of a battery. Battery must not be dis- posed of in the household waste.
	The packaging is made in low density polyethylene and can be recycled.
R	Federal law (USA) restricts this device to sale by or on the order of a physician
(((;_))	Non ionising electromagnetic radiation. To indicate that the device contains a Radio Frequency (RF) transmitter to transmit data (e.g Bluetooth or WiFi)
*	Contains a Bluetooth module
(Do not reuse
LATEX	Latex-free
	Use-by date (expiry date of battery, electrodes or other consuma- bles)
	Temperature range for storage or transport, respectively
\$••\$	Pressure range for storage or transport, respectively
<u>%</u>	Humidity range for storage or transport, respectively
Ĩ	Consult instruction for use (indicates the need for the user to con- sult the instructions for use)
₩ Sector Action	Use within X days after opening (electrodes or other consumables)

Ť	Keep dry (store in a dry location)
*	Keep away from sunlight (protect from direct sunlight)
Ţ	Fragile, handle with care
<u> 11 1 1 1 1 1 1 </u>	Transport upwards (this way up)
Ł	Do not use hooks
®	EIP = electronic information product (does not contain any toxic and hazardous substances or elements above the maximum concentra- tion values (product can be recycled and re-used)).

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