# FRED easy®

## Automated external defibrillator (AED) FRED easy® - SD Card

- Ethernet/Online

- Life

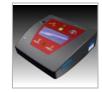
















## User Guide



#### Sales and service information

i

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:

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

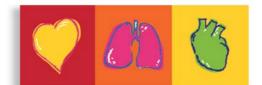
Manufacturer and responsible for the **( €** 0459 marking (first declaration 2002)

SCHILLER Medical S.A.S. 4, rue Louis Pasteur F- 67162 Wissembourg Web: Tel.: +33 (0) 388 63 36 00 Fax: +33 (0) 388 94 12 82 E-mail: quality@schiller.fr ; are@schiller.fr www.schiller-medical.com

#### **Address Headquarters**

SCHILLER AG Altgasse 68 CH-6341 Baar, Switzerland Web: Phone: +41 (0) 41 766 42 42 Fax: +41 (0) 41 761 08 80 E-mail: sales@schiller.ch www.schiller.ch

Article no.: 0-48-0013 Rev. m Issue date: 13.01.15 **FRED easy®** 2G software ≥ 07.04 (except 20.00) **FRED easy®** 1G software ≥ 9.08







# **Table of Contents**

1	Safety Notes	. 5
1.1	User profiles	. 5
1.2	Responsibility of the User	. 5
1.3	Intended Use	. 6
1.4	Organisational Measures	. 7
1.5	Safety-Conscious Operation	. 7
1.6	Operation with other Devices	. 8
1.7	Maintenance	. 8
1.8	General Notes Regarding the Unit	. 8
1.9	Additional Terms	. 9
1.9.1	Implied authorisation	
1.9.2	Terms of Warranty	
1.10	Display Symbols/Indicators	
1.10.1 1.10.2	Symbols used in this user guide Symbols used on the device	
1.10.2	Symbols used on the battery	
1.10.4	Symbols used on the electrode packaging	
2	Components and Operation	13
<b>2</b> 2.1	Components and Operation	
_		13
2.1	General Information	13 14
2.1 2.2	General Information Design	13 14 16
2.1 2.2 2.3	General Information Design Function Overview on the configurable settings Operating and Display Elements	13 14 16 17 18
<ul> <li>2.1</li> <li>2.2</li> <li>2.3</li> <li>2.3.1</li> <li>2.4</li> <li>2.4.1</li> </ul>	General Information Design Function Overview on the configurable settings Operating and Display Elements Overview on versions and operating modes	<ul> <li>13</li> <li>14</li> <li>16</li> <li>17</li> <li>18</li> <li>18</li> </ul>
2.1 2.2 2.3 2.3.1 2.4 2.4.1 2.4.2	General Information Design Function Overview on the configurable settings Operating and Display Elements Overview on versions and operating modes Operation and display	<ol> <li>13</li> <li>14</li> <li>16</li> <li>17</li> <li>18</li> <li>20</li> </ol>
2.1 2.2 2.3 2.3.1 2.4.1 2.4.2 2.4.3	General Information Design Function Overview on the configurable settings Operating and Display Elements Overview on versions and operating modes Operation and display Display	<ul> <li>13</li> <li>14</li> <li>16</li> <li>17</li> <li>18</li> <li>20</li> <li>21</li> </ul>
2.1 2.2 2.3 2.3.1 2.4 2.4.1 2.4.2	General Information Design Function Overview on the configurable settings Operating and Display Elements Overview on versions and operating modes Operation and display	<ul> <li>13</li> <li>14</li> <li>16</li> <li>17</li> <li>18</li> <li>20</li> <li>21</li> </ul>
2.1 2.2 2.3 2.3.1 2.4.1 2.4.2 2.4.3	General Information Design Function Overview on the configurable settings Operating and Display Elements Overview on versions and operating modes Operation and display Display	<ul> <li>13</li> <li>14</li> <li>16</li> <li>17</li> <li>18</li> <li>20</li> <li>21</li> <li>21</li> </ul>
2.1 2.2 2.3 2.3.1 2.4 2.4.1 2.4.2 2.4.3 2.4.4 3 3.1	General Information Design Function Overview on the configurable settings Operating and Display Elements Overview on versions and operating modes Operation and display Display Symbols used on the display Initial operation	<b>13</b> <b>14</b> <b>16</b> 17 <b>18</b> 20 21 21 <b>22</b> <b>22</b> <b>22</b>
2.1 2.2 2.3 2.3.1 2.4 2.4.1 2.4.2 2.4.3 2.4.4 3 3.1 3.1.1	General Information         Design         Function         Overview on the configurable settings         Operating and Display Elements         Overview on versions and operating modes         Operation and display         Display         Symbols used on the display         Initial operation         Switching device On and Off.	<b>13</b> <b>14</b> <b>16</b> 17 <b>18</b> 20 21 21 21 <b>22</b> <b>22</b> 23
2.1 2.2 2.3 2.3.1 2.4 2.4.1 2.4.2 2.4.3 2.4.4 3 3.1 3.1.1 3.2	General Information         Design         Function         Overview on the configurable settings         Operating and Display Elements         Overview on versions and operating modes         Operation and display         Display         Symbols used on the display         Initial operation         Switching device On and Off         Battery monitoring	<b>13</b> <b>14</b> <b>16</b> 17 <b>18</b> 20 21 21 <b>22</b> <b>23</b> <b>24</b>
2.1 2.2 2.3 2.3.1 2.4 2.4.1 2.4.2 2.4.3 2.4.4 3 3.1.1 3.1.1 3.2 3.2.1	General Information         Design         Function         Overview on the configurable settings         Operating and Display Elements         Overview on versions and operating modes         Operation and display         Display         Symbols used on the display         Initial operation         Switching device On and Off.         Battery monitoring         Sufficient battery capacity	<ul> <li>13</li> <li>14</li> <li>16</li> <li>17</li> <li>18</li> <li>20</li> <li>21</li> <li>21</li> <li>21</li> <li>21</li> <li>22</li> <li>23</li> <li>24</li> <li>24</li> </ul>
<b>2.1</b> <b>2.2</b> <b>2.3</b> 2.3.1 <b>2.4</b> 2.4.1 2.4.2 2.4.3 2.4.4 <b>3</b> <b>3.1</b> 3.1.1 <b>3.2</b>	General Information         Design         Function         Overview on the configurable settings         Operating and Display Elements         Overview on versions and operating modes         Operation and display         Display         Symbols used on the display         Initial operation         Switching device On and Off         Battery monitoring	<ul> <li>13</li> <li>14</li> <li>16</li> <li>17</li> <li>18</li> <li>20</li> <li>21</li> <li>21</li> <li>21</li> <li>22</li> <li>23</li> <li>24</li> <li>24</li> <li>25</li> </ul>

4	Defibrillation	27
4.1	Instructions and Safety Notes	
4.1.1	Instructions	
4.1.2	Safety notes for AED use	
4.2	Defibrillation procedure	
<b>4.3</b> 4.3.1	Applying the adhesive electrodes General information	
4.3.1	Apply the adhesive electrodes and connect them to the device	
4.3.3	Checking the electrodes	
4.4	Semi-automatic defibrillation	38
4.5	Automatic defibrillation	40
4.5.1	Functional description of automatic AEDs	
4.5.2	Safety notes for automatic defibrillation	
4.6	Manual Defibrillation (option)	
4.6.1 4.6.2	Manual defibrillation - description Manual defibrillation procedure	
4.6.3	Switching to semi-automatic operational mode	
4.7	Internal safety discharge	
4.8	Finishing the therapy	
4.0	Thisning the therapy	47
5	Versions	18
5.1	SD card version	48
5.1.1	Inserting the SD card	49
5.2	Ethernet version	
5.2.1	Connecting the Ethernet adapter	
5.2.2 5.2.3	Data transmission procedure Installing the ferrite core	
5.3	Online version	
5.3.1	Ensuring data transmission	
5.3.2	Placing the <b>FRED easy®</b> in the docking station	
5.3.3	Activating the maintenance mode	57
5.4	Configuration Ethernet/Online using FRECO	
5.4.1	Configuring the "Network" tab	
5.4.2 5.4.3	Configuring the "Online" Tab Configuring the date and time as well as IP addresses without	60
0.4.0	using FREDCO®	61
6	Options	62
6.1	ECG display	
6.2	Metronome	
6.3	Rechargeable NiCd battery	
6.4	Silent mode	
<b>6.4</b> .1	Silent mode	
6.4.2	Switching to silent mode	65
6.4.3	Deactivating silent mode	
6.4.4	Erasing the memory card	
<b>6.5</b> 6.5.1	Special operating conditions Maritime use	
0.0.1		07

User G	Guide	
7	Maintenance	69
7.1	Maintenance Intervals	. 69
7.1.1	Visual inspection of the device and accessories	
7.1.2 7.1.3	Green indicator Functional check	
7.1.4	Internal backup battery	
7.2	Cleaning and disinfection	. 71
7.3	Accessories and disposables	
7.4	Disposal information	. 72
7.4.1	Battery Disposal	
7.4.2 7.4.3	Disposal of accessories that come into contact with the patient Disposal at the end of its useful life	
7.5	Trouble Shooting	
7.5.1	Error messages	
7.5.2	Transmission error Ethernet/Online <b>FRED easy®</b>	
7.5.3 7.5.4	Trouble Shooting Measures to prevent electromagnetic interferences	
1.0.1		00
8	Technical Data	81
8.1	System Specifications	. 81
8.2	Classification and safety standards	. 82
8.3	Defibrillation pulse	. 83
8.4	Electromagnetic interferences	. 85
8.4.1	Electromagnetic emissions	
8.4.2 8.4.3	Electromagnetic immunity Recommended minimum distances	
9	Appendix	88
9.1	Order Information	. 88
9.2	Required accessories	. 88
9.3	Literature	. 89
9.4	Glossary	. 89
9.5	Inspection report	. 90
10	Index	92
10		

SCHILLER

FRED easy





# **1** Safety Notes

### 1.1 User profiles

The following people may use the FRED easy:

- · Physicians or other trained medical personnel
- other people (non-professionals) trained in early defibrillation
- other people not trained in early defibrillation, as long as they can understand and follow the spoken and displayed instructions.
- i

Even though untrained people may use the device, training and instructions are recommended to guarantee an optimal resuscitation procedure.

## 1.2 Responsibility of the User

- ▲ Regulations on who is allowed to use devices like the **FRED easy**® and which training is required, are country-specific. In any case, legal regulations have to be observed.
- Before using the device, a SCHILLER representative must perform a presentation on the device's operation and safety measures, if it's required by the local regulations.
- ▲ The indications given by this equipment are not a substitute for the regular checking of vital functions.
- ▲ The numerical and graphical results as well as any interpretation suggested by the device must be examined with respect to the patient's overall clinical condition and the quality of the recorded data.
- ▲ Make sure that the user has read and understood the user guide, and especially these safety notes.
- ▲ Damaged or missing components must be replaced immediately.
- ▲ The device must be stored in a place inaccessible to children.
- ▲ Properly dispose of the packaging material and make sure it is out of children's reach.

SCHILLER FRED easy

### 1.3 Intended Use



#### ▲ The **FRED easy**® is an automated external defibrillator (AED) used for the treatment of ventricular fibrillation (VF) and ventricular tachycardia (VT).

- ▲ The device may be used with the appropriate electrodes on either adults or children.
- ▲ The device must only be used if the following symptoms are found:
  - not responsive
  - no respiration
  - no pulse
- ▲ The device must **not** be used if the patient:
  - is responsive
  - is breathing
  - has pulse
- ▲ The **FRED easy**® is an emergency device and must be ready for operation at any time and in all situations. Make sure that
  - the device is always equipped with a sufficiently charged battery and that a spare battery is at hand
- An empty battery must not be reused and must be disposed of immediately.
- Only operate the device in accordance with the specified technical data.
- ▲ Do **not** use this device in areas where there is any danger of explosion or in the presence of flammable liquids, flammable anaesthetic agents or in places where the ambient air's oxygen concentration is higher than 25 %.



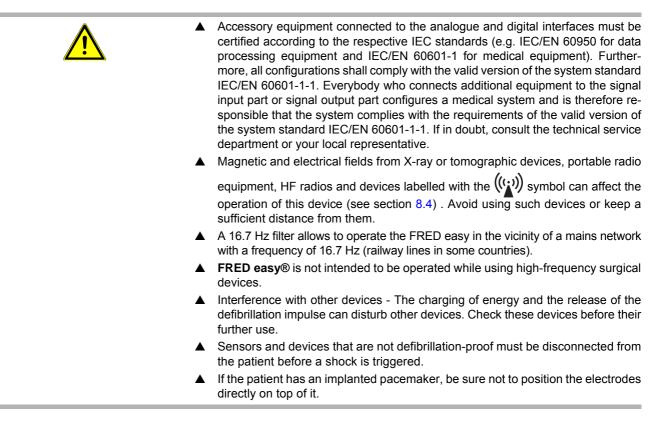
## 1.4 Organisational Measures

- Before using the unit, ensure that an introduction regarding the unit functions and the safety precautions has been provided and understood.
- ▲ Keep these operating instructions in an accessible place for reference when required. Make sure that they are always complete and legible.

## 1.5 Safety-Conscious Operation

- Danger of electric shock! Danger for user, rescuer and patient. The energy applied to the patient can be conducted through the patient to other persons, who may suffer a lethal electric shock. Therefore:
  - do not touch the patient, the electrodes or other conducting objects during defibrillation.
  - do not defibrillate the patient in a puddle of water or on other conducting surfaces,
  - switch the device off when it is no longer used.
- ▲ Danger of explosion! The device must not be used in areas where there is any danger of explosion . There might be a danger of explosion in areas where flammable products (petrol), flammable anaesthetic agents or products for skin cleaning/disinfection are in use, or where the ambient air's oxygen concentration is higher than 25 %.
- Immediately report any changes that impair safety (including operating behaviour) to the responsible person.
- ▲ Only use original SCHILLER electrodes.
- Before switching on, check that the unit's casing and electrode connections are not damaged.
- ▲ Immediately replace a damaged unit, or damaged cables and connections.
  - Operating the device with a defective casing or damaged cables constitutes a danger to life. Therefore:
    - immediately replace a damaged unit or damaged cables and connections.

## 1.6 Operation with other Devices



## 1.7 Maintenance



- ▲ **Danger of electric shock!** Do not open the device. No serviceable parts inside. Refer servicing to qualified personnel only.
- ▲ Before cleaning, switch the unit off and remove the battery.
- ▲ Do not use high-temperature sterilisation processes (such as autoclaving). Do not use E-beam or gamma radiation sterilisation.
- Do not use aggressive or abrasive cleaners.
- Do not, under any circumstances, immerse the device or cable assemblies in liquid.
- To ensure patient safety, the accuracy of displayed values and interference-free operation, only use original SCHILLER accessories. The user is responsible for the use of third-party accessories. The warranty does not cover damage resulting from the use of accessories or consumables other than those marketed by SCHILLER.

## **1.8 General Notes Regarding the Unit**

A defibrillation can fail with certain disease patterns.

CHILLER

**FRED** easy

### 1.9 Additional Terms

#### **1.9.1** Implied authorisation

Possession or purchase of this device does not convey any express or implied license to use the device with replacement parts which would alone, or in combination with this device, fall within the scope of one or more patents relating to this device.

#### 1.9.2 Terms of Warranty

Your SCHILLER **FRED easy®** is warranted against defects in material and manufacture for the duration of one year (as from date of purchase). 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 easy**® and approved attached equipment is used in accordance with the manufacturer's instructions.

i

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.

## 1.10 Display Symbols/Indicators

#### 1.10.1 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.

A DANGER	For a direct danger which could lead to severe personal injury or death.
	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.
A	For electrical hazards, warnings or precautionary measures when dealing with elec- tricity.
i	Important or helpful user information.
1.10.2	Symbols used on the device
1.10.2 ⊣★	Symbols used on the device BF symbol. The device's signal input is defibrillation-protected.
1.10.2 ⊣★ ∳	
1.10.2 	BF symbol. The device's signal input is defibrillation-protected.
1.10.2 	BF symbol. The device's signal input is defibrillation-protected. Caution! High voltage!
- <b> </b> ★ - <b>4</b> ▲	BF symbol. The device's signal input is defibrillation-protected. Caution! High voltage! Observe the user guide
- <b> </b> ★ - <b>4</b> ▲	BF symbol. The device's signal input is defibrillation-protected. Caution! High voltage! Observe the user guide CE-0459 marking (notified body LNE/G-MED)

#### 1.10.3 Symbols used on the battery



The battery is recyclable Do not recharge

Do not short-circuit

Do not incinerate

Do not cut

#### Do not crush

Battery storage:

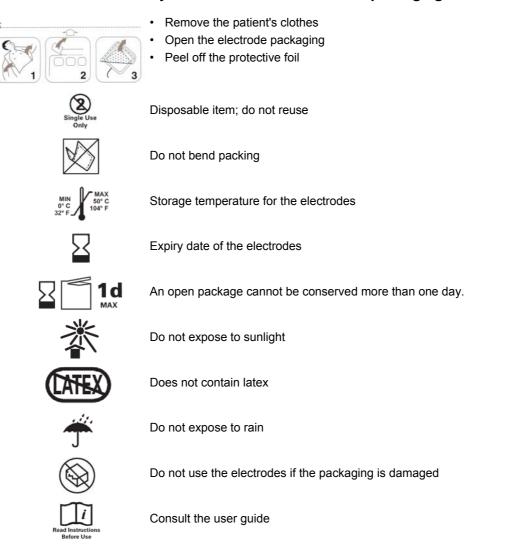
- unlimited storage duration between +15°C and +25°C (within the limit of the specified expiry date),
- max. 48 hours between +25 °C and +60 °C as well as between +15 °C and 0 °C.

Battery must not be disposed of in the household waste.

Observe the user guide

Battery expiry date

## SCHILLER FRED easy



#### 1.10.4 Symbols used on the electrode packaging

SCHILLER

**FRED** easy

# 2 Components and Operation

## 2.1 General Information

FRED easy® is an automated external defibrillator (AED).

AEDs are semi-automatic defibrillators or fully automatic defibrillators to be used by non-physicians.

FRED easy® is available as a semi- or fully automatic defibrillator.

The regulations governing the use and training requirements for AEDs such as **FRED easy®** differ from country to country. The laws and regulations for the use of automatic defibrillators need to be strictly observed.

Local laws and regulations regarding the use of an AED differs from country to country. While some countries allow laypersons to use AEDs without any special training, other countries restrict the use of AEDs to EMTs or First Responders after they have undergone special training.

For training purposes, SCHILLER offers the **FRED easy® TRAINER**.

Typical sites of operation for a FRED easy® are much-frequented places such as:

- airports
- train stations
- shopping centres
- public swimming pools
- sport centres
- public institutions

i

i

#### Biocompatibility

The parts of the product described in this user guide, including all accessories, that come in contact with the patient during the intended use, fulfil the biocompatibility requirements of the applicable standards. If you have any questions in this matter, please contact SCHILLER.

2.2

Design

#### Defibrillator FRED easy® is a defibrillator featuring the biphasic pulsed defibrillation impulse, Multipulse Biowave®. The patient is defibrillated using disposable electrodes. The ECG signal is analysed using the same electrodes. Moreover, the user is guided with acoustic and written instructions (display/loudspeaker). The device recognises the connected electrodes (adult or children elec-BIOWAVE trodes) and selects the defibrillation energy accordingly. Metronome When the "metronome" is activated, the FRED easy® sets a configurable pace for the cardiopulmonary resuscitation (CPR). Data memory The device is equipped with a memory card (SD card). During the intervention, data can therefore be saved, including the analysed ECG data, ambient noise and events (see 5.1 SD card version, 5.2 Ethernet version and 5.3 Online version). **Data transmission** The FRED easy® SD card version features a removable SD memory card, facilitating data transmission to other devices. For the Ethernet and Online versions, data transmission is performed via Ethernet network (for these device versions, the memory card cannot be removed). Power supply (standard) The device is operated with a non rechargeable, disposable lithium battery. The battery capacity is sufficient for: - 180 shocks at maximum energy (if the self-test is performed weekly), or, - 3.75 hours operating (alternately 30 minutes ON and 30 minutes OFF). Power supply (option) A rechargeable NiCd battery is available as option. The capacity of a new and fully charged battery is sufficient for: - 45 shocks at maximum energy, or

- 40 min operating

#### Available versions and options

**FRED** easy

SCHILLER

Version	Available options for automatic operation	Available options for semi-automatic operation	
SD card	<ul> <li>Metronome</li> <li>Rechargeable NiCd battery</li> </ul>	<ul> <li>ECG display</li> <li>Switchover to manual defibrillation</li> <li>Metronome</li> <li>Rechargeable NiCd battery</li> <li>Silent mode</li> </ul>	
Ethernet	<ul> <li>Metronome</li> <li>Rechargeable NiCd battery</li> </ul>	<ul> <li>ECG display</li> <li>Switchover to manual defibrillation</li> <li>Metronome</li> <li>Rechargeable NiCd battery</li> <li>Silent mode</li> </ul>	
Online	Metronome	<ul> <li>ECG display</li> <li>Switchover to manual defibrillation</li> <li>Metronome</li> <li>Silent mode</li> </ul>	

FRED easy Life

Standard features for this device are the metronome and a non rechargeable Li/MnO2 battery. All other options listed above for semi-automatic operation are not available.

SCHILLER's service centre is able to configure various device functions by means of a dedicated PC connection (see 2.3 Function).

i

**Patients with implanted pacemakers** — **FRED easy**® features an electronic pacer pulse suppression algorithm and therefore, pacemaker pulses are not taken into account for the analysis. Depending on the pacemaker model and on the position of the electrodes, the compensation pulse following every pacer pulse may exceptionally not work and be considered as a QRS complex. In this case, the analysis can be distorted and inaccurate. It depends on the pacer pulse parameters whether or not the compensation pulse is counted as a QRS complex.

## 2.3 Function

Immediately after a battery has been inserted, the **FRED easy®** performs a self-test of the device and battery. If this test is completed successfully, the green indicator starts blinking, showing that the device is ready for operation and the information is displayed.

Also, every time the device is switched on, a self-test is performed.

If a problem is detected in the course of this self-test:

- an acoustic alarm is issued,
- the green indicator stops blinking and
- an alarm message is displayed.

The acoustic alarm is issued until the battery is flat.

In addition, the device performs a daily or weekly self-test (this setting must only be configured by service personnel authorised by Schiller); the self-test is announced with a beep. If a problem is detected in the course of this self-test:

- an acoustic alarm is issued,
- the green indicator stops blinking, and
- A corresponding symbol or message is displayed when the device is switched on by pressing the green button

When a rechargeable Ni/Cd battery (option) is inserted, the device performs a self-test every day.



Fig. 2.1 Button to switch the device on and off, and to start the analysis (only in semi-automatic operation)

i

#### 2.3.1 Overview on the configurable settings

#### Important!

i

- ▲ The "FRED CO" software is only available to service centres authorised by Schiller.
- ▲ Modifications that can be made via "FRED CO" are only performed if requested by the customer, or if required by legal requirements.
- ▲ These modifications need to be registered in the device documentation as well as communicated to all users.

SCHILLER's service centre can configure the following parameters:

#### Configurable parameters (by means of FREDCO®)

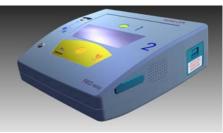
- Volume of language output
- Energy level for 1st, 2nd and 3rd shock (separate settings for adults and children)
- Manual or automatic start of the ECG signal analysis (only in semi-automatic operation)
- Activation/deactivation of the 16.7 Hz filter
- <sup>a</sup>Sound recording Yes/No
- Number of chest compressions for children (15 or 30)
- Self-test frequency (daily or weekly)
- Entering the device name
- Choice between "continuous chest compressions" or "alterning chest compressions/breathes" during CPR cycles
- Time and date On
- Update the software/change the device language

a. **Sound recording** — The owner needs to inform users that the device records ambient noise during interventions.

## 2.4 Operating and Display Elements

#### 2.4.1 Overview on versions and operating modes

SD Card version



Semi-automatic operational mode

Semi-automatic operational mode with option for switchover to manual mode



Semi-automatic operational mode with option for switchover to silent mode

#### Automatic operational mode

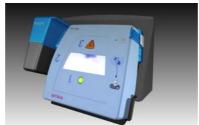
#### **Online/Ethernet version**

The Online/Ethernet versions are available with the same operational modes as the SD card version:

- semi-automatic
- · semi-automatic with option for switchover to manual mode
- Automatic
- · Silent mode



FRED easy® Online



FRED easy® Online with docking station

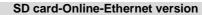


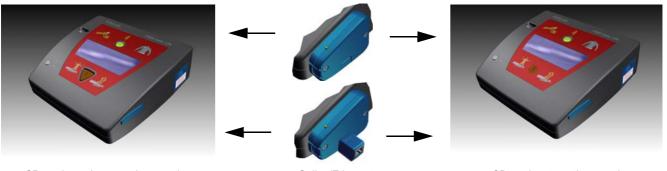
Online with Ethernet adapter

**SCHILLER** FRED easy

#### FRED easy Life

FRED easy Life has got the same functions as the versions listed above; the only exceptions are: different printing on the foil, not possible to switch to manual or silent mode.



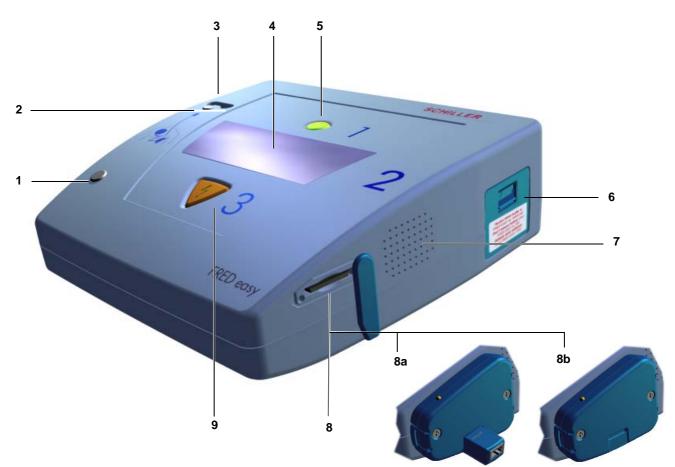


SD card, semi-automatic operation

Online/Ethernet

SD card, automatic operation

#### 2.4.2 Operation and display



The **FRED easy®** versions SD Card (removable memory card), ETHERNET (with Ethernet adaptor) and ONLINE (with docking station) only differ from each other in point 8.



i

Fig. 2.2 Green indicator blinking

- The green indicator is blinking if no problem was detected during the last selftest (see Fig. 2.2 Green indicator blinking).
- (2) The yellow indicator is lit when the device has not detected an acceptable resistance between the electrodes (i.e. when the electrodes are not applied and/or the electrode cable is not connected).
- (3) Port for the adhesive pads.
- (4) Display.
- (5) The green button has got the following functions:
- Switch on the device (press for max. 1 second)
  - Switch the device off (press and hold for 3 seconds)
- Start the analysis in semi-automatic mode (only press the button for 1 second!)
- (6) Battery.

\_

- (7) Speaker.
- (8) SD card slot. The Ethernet interface (8a) is used to connect the Ethernet adapter (Ethernet version) and to connect the device to the docking station (8b) (Online version).
- (9) Orange button for to trigger the defibrillation shock (in semi-automatic mode only).

SCHILLER

FRED easy



Fig. 2.3 FRED easy® display

- (1) Symbol display line.
- (2) Text display lines. The written instructions issued by the **FRED easy**® are displayed on these 3 lines.

#### 2.4.4 Symbols used on the display

Number of shocks delivered since the device was turned on.



Sufficient battery capacity (see 3.1 Inserting the battery).



4

Low battery capacity (see 3.1 Inserting the battery).



SD card detected, percentage of memory used.

SD card not recognised (see 5.1 SD card version).

Adult pads detected.

Paediatric pads detected.

Time elapsed since device was turned on (minutes : seconds).

### 3 Initial operation

Danger of explosion — The FRED easy® must not be used in areas where there is any

danger of explosion. Areas may be susceptible to explosion if flammable substances

**A** DANGER (gas), flammable anaesthetics, or products used to clean or disinfect the skin are used. Moreover, the defibrillator must not be used in an environment that is favourable to combustion. This is the case when ambient air contains more than 25% oxygen or nitrous oxide (laughing gas). Oxygenation in the vicinity of the defibrillation pads must be strictly avoided. Less than 25% oxygen in the ambient air is considered safe. Dangerous, high oxygen concentrations can only occur in oxygen masks or in enclosed areas, such as hyperbaric chambers.

#### 3.1 Inserting the battery

	Danger of explosion! The battery must not be exposed to high temperatures of disposed of with household waste.
	Do not expose the battery to chemicals that could dissolve ABS, polypropylene polyvinyl chloride, nickel, mylar or steel.
$\times \otimes \otimes \otimes \times$	▲ Do not short-circuit, cut, destroy, burn or charge (Li/MnO2 battery) a battery.
Li/MnO.	Patient hazard! — Incorrect battery capacity indication
	▲ A new battery is initialised by the device when inserting it and is allocated to th device. It must not be inserted in another device.
	Replace the battery if the device indicates a battery problem. A defective batter must not be used.
	Turn off the device before removing the battery.
	<ul> <li>Patient hazard — Ensuring operational readiness!</li> <li>Make sure that the device is always equipped with a sufficiently charged batter and keep a spare battery on hand.</li> <li>The expiration date of a new battery, stored in its original packaging at a tempe ature of 25°C, is indicated on its packaging. It must not be used beyond this date</li> <li>The battery must remained packed in its original plastic packaging (blister) du ing the entire storage time. The plastic packaging must only be removed whet the battery is used.</li> </ul>
	Do not expose the FRED easy® to direct sunlight or to extreme hot or cold. A ambient temperature higher than 25°C has an adverse effect on the battery life



i

- The device is normally operated with a non rechargeable lithium battery.
- Alternatively, a rechargeable NiCd battery can be used (see 6.3 Rechargeable NiCd battery).
- Each time the device is turned on, it verifies that the battery is functioning properly.

#### Equipment damage —

- ▲ The connector in the battery compartment must only be used for maintenance purposes.
- ▲ Do not use rechargeable batteries to operate the **FRED easy® TRAINER** because its voltage is not suitable for this device.
- Do not use the lithium battery to power the FRED easy® TRAINER, because its voltage is not adapted to this device.
- → Insert the battery as indicated in the illustration on the left.
  - Firmly press the battery into the battery compartment until it clicks into place.
  - As soon as the battery is inserted, the FRED easy® runs a self-test to check the condition of the device and the battery.
  - After this self-test, the date, time and IP configuration for the FRED easy Ethernet/Online can be set (see section 5.4.2 page 60).

If this test does not reveal any problems, the green indicator starts blinking and the information is displayed.

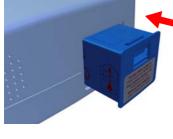


Fig. 3.1 Inserting the battery

#### 3.1.1 Switching device On and Off

- **Switching ON**  $\rightarrow$  Press the green button  $\bigcirc$  for max. 1 second.
- **Switching OFF**  $\rightarrow$  Press the green button  $\bigcirc$  and hold for 3 second.
  - i

#### Forced shutdown procedure

If the device cannot be switched off via the above procedure, remove the battery and inserting again.

i

Ĭ

### 3.2 Battery monitoring

- The **FRED easy**® checks the capacity of the rechargeable NiCd battery or the lithium battery and warns the user when the battery is "low" or "depleted".
- The lithium battery ensures that the device stays fully operative (and performs the self-test) for several years (at a temperature between 15 °C and 25 °C), provided that the device is not being used.
- · Battery service life depends on device use and ambient conditions.
- ▲ Whatever its remaining capacity, the battery must be replaced once the expiration date (indicated on the packaging) has been reached.
- ▲ The old battery must be recycled in accordance with local regulations.

#### 3.2.1 Sufficient battery capacity

**FRED easy**® displays the **ok** symbol to indicate that the battery capacity is "sufficient".

The **ok FRED easy**®symbol remains displayed on the screen for as long as the battery capacity is "sufficient".



Fig. 3.2 Sufficient battery capacity



#### 3.2.2 Low battery capacity during use

device emits an audible signal.

must be replaced as quickly as possible.

• Despite the acoustic and written warnings, the device can still be used as normal and is still able to perform defibrillations.

If the battery capacity falls below the "low" threshold while the device is in use, the green indicator is turned off, the provide starts blinking on the display and the

These warnings are issued until the battery is replaced (or recharged). The battery

- Always switch off the device before removing the battery.
- The remaining battery capacity depends on the use and ambient conditions.



i

i

Fig. 3.3 The green indicator is not lit



Fig. 3.4 Low battery capacity

Low battery capacity during self-test or after the battery has been inserted

• If low battery capacity is detected during a self-test or when the battery is inserted, the device emits an audible signal and the green indicator is not lit until the battery is replaced (see Fig. 3.3 The green indicator is not lit).

#### 3.2.3 Battery depleted during use, limited mode (CPR)

## WARNING

Patient hazard — Defibrillation is no longer possible if a depleted battery is detected. The battery needs to be replaced immediately.

If a depleted battery is detected while the device is in use, a message is displayed prompting the user to replace the battery and to perform CPR. An audible signal is emitted and the indicator remains off until the battery is replaced (or charged).

The message stays displayed until the battery is replaced.





Green indicator is off

#### Depleted battery during self-test

- When a depleted battery has been detected, the green indicator is off and an audible signal is emitted.
- When the device is next switched on, a message is displayed, prompting the user to replace the battery and continue with CPR until the device is fully operational again.

#### Depleted battery after the battery has been inserted

• If a battery inserted in the device is identified as depleted, an audible signal is emitted, the green indicator is turned off and a message indicating that the battery must be replaced is displayed.



# **4** Defibrillation

## 4.1 Instructions and Safety Notes

#### 4.1.1 Instructions

i

- **FRED easy**® is a high-voltage electrotherapy device. Only personnel authorised by local law are permitted to use these devices. Improper use can endanger life.
- Non medical personnel is only permitted to use an AED such as the **FRED easy®** if local law approves of this practice. Make sure that the **FRED easy®** is only accessible to persons who are legally authorised to use an AED.
- The success of the defibrillation depends on the correct application of the defibrillator but also on the heart's condition. It is the physician's responsibility to decide about any additional measures (e.g. adrenaline).
- According to AHA/ERC guidelines, even children under 8 years may be defibrillated.
- The electrodes should be applied in the anterior-anterior position. With infants, anterior-posterior placement can be advised to prevent a short-circuit between the two defibrillation electrodes.
- A defibrillation can fail with certain disease patterns.

#### 4.1.2 Safety notes for AED use

## 

- Before each use, the user must verify that the device operates reliably and is in proper working order. It is especially important to check that connection cables are not damaged. Damaged cables and connectors must be replaced immediately.
- ▲ Changes, including concerning operational behaviour, affecting safety must be immediately reported to the responsible.
- ▲ Equipment damage! Sensors and devices that are not defibrillation-proof must be disconnected from the patient before a shock is triggered.

#### Shock hazard — for patients

- In unfavorable situations, the possibility of ECG analysis errors should not be dismissed. The device must therefore only be used if the following symptoms are found:
  - not responsive,
  - no respiration,
  - no pulse.
- If, in the course of treatment, a patient spontaneously regains consciousness, a defibrillation shock that may have been advised just before must not be delivered.

## 

#### Shock hazard — for user and assistants

- ▲ Wear gloves when performing a defibrillation, if possible.
- Position the patient flat on a firm, electrically insulated surface.
- ▲ Make sure that there are no conductive connections between the patient and other persons during ECG analysis and defibrillation.
- The patient must not come into contact with metal parts, e.g. a bed or stretcher, in order to prevent secondary contacts or paths for the defibrillation current that could endanger the assistants. For the same reason, do not position the patient on a wet surface (rain, swimming pool accidents).
- ▲ Do not allow the defibrillation electrodes to come into contact with other electrodes or metal parts which are in contact with the patient.
- ▲ The patient's chest must be dry because moisture can cause unwanted pathways for the defibrillation current. For safety, wipe off flammable skin cleansing agents.
- ▲ The user and all assistants must be briefed regarding the defibrillation procedure (preparation and execution). The assistants' tasks must be clearly defined.
- During ECG analysis:
  - suspend CPR,
  - ensure that the patient lies as motionless as possible,
  - do not touch the patient, otherwise, artefacts may lead to incorrect analysis results.
- Immediately prior to the shock:
  - stop chest compressions and artificial respiration (CPR),
  - instruct bystanders to not touch the patient or conducting objects.

#### Risk of skin burns — for the patient

- ▲ Due to the high currents, there is a risk of skin burns at the electrode application site. This is why the electrodes must not be placed on or above:
  - the sternum,
  - the clavicle or,
  - the nipples.

#### Risk of malfunction of implanted pacemaker!

- Defibrillating a patient with an implanted pacemaker is likely to impair the pacemaker function or cause damage to the pacemaker.
   For this reason:
  - defibrillation pads must not be positioned near the pacemaker,
  - have an external pacemaker at hand.
- The pacemaker must be checked for proper functioning as soon as possible after defibrillation.



## 4.2 Defibrillation procedure

**User Guide** 

The user is informed of each step by a voice prompt as well as a text instruction on the display.

Both the voice prompts and text instructions can be issued as "**long instructions**" as well as "**short instructions**".

Contact your SCHILLER distributor for more information.

The following procedure is applicable when "long instructions" have been configured.

Switch on the device and call the emergency medical service

i

Once the device is turned on (by pressing thre green button ()), an instruction text reminds the user to call the emergency medical service.



> Assess the patient's condition

The device then prompts the user to assess the patient's condition.



The device must only be used if the following symptoms are found:

not responsive,no respiration,

no pulse.

> Preparing the patient

Once you made sure that the patient does not show any signs of circulation, you are prompted to remove the clothes from the patient's upper body.

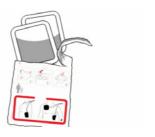


i

The patient's chest may be shaved, if necessary.

- > Open the electrode packaging
- and connect the electrodes

Open the electrode packaging and connect the electrodes to the device (unless the electrodes are pre-connected).





SCHILLER

**FRED** easy

> Applying the electrodes

FRED easy® prompts the user to apply the electrodes on the patient's chest.

i



- The yellow indicator is lit and the device repeats the instructions twice until the electrodes are applied, or until the electrode connector is connected to the device, respectively, and the electrode-skin resistance (impedance) has reached an acceptable level.
- After the second prompt to apply the electrodes, the device recommends to perform a cardiopulmonary resuscitation cycle. The device will switch off if it has not detected an acceptable impedance between the two electrodes after 5 minutes of CPR.

SCHILLER		Defibrillation 4	
FRED easy	User Guide	Defibrillation procedure 4.2	
➢ ECG analysis	Before each analysis, the device touched.	e informs the user that the patient must not be	
	In semi-automatic mode, the device prompts the user to start an ECG analysis by pressing the green button ().		
i	<ul> <li>If no analysis has been initiated after a few seconds following the prompt to start the analysis, the device recommends to perform a cardiopulmonary resuscitation cycle. At the end of the CPR cycle, the device repeats the prompt to start the anal- ysis.</li> </ul>		
	<ul> <li>The semi-automatic FRED easy® can be configured to automatically start the ECG analysis without pressing the green button</li> </ul>		
	In automatic as well as semi-automatic mode (with automatic analysis activated), the <b>FRED easy</b> ® informs the user that the analysis is going to be performed. The ECG analysis is started without any intervention by the user.		
	The analysis takes approximately	10 seconds.	
Motion detection	During ECG analysis, the patient must lie as still as possible and the user must suspend CPR; otherwise, artefacts may lead to an incorrect analysis.		

The **FRED easy®** includes a motion detection function. When the ECG analysis is disturbed by CPR or patient movements, the device informes the user via a voice prompt and a written message on the display. The analysis is automatically resumed as soon as the cause of disturbance has been eliminated.

If no correct analysis has been obtained by the time the instruction has been repeated 5 times, the device recommends to perform a cardiopulmonary resuscitation cycle.



➢ Shock advised	The device has detected a shockable rhythm.	
	Before each shock delivery, the device warns the user not to touch the patient.	
	If the analysis algorithm detects a shockable rhythm, the device will automatically charge the required defibrillation energy. Once the energy is charged, the user is prompted to deliver the shock by pressing the orange button $\sqrt[4]{7}$ (only in semi-automatic mode).	
	In automatic mode, the device alerts the user that the shock will be delivered, and then delivers the shock without user intervention.	
	Then the <b>FRED easy</b> ® informs the user via spoken and written message that the shock has been delivered.	
	Shockable conditions include:	
	<ul> <li>ventricular fibrillation or</li> <li>ventricular tachycardia with a rate higher than 150 bpm.</li> </ul>	
	If the device detects a shockable rhythm, the shock must only be released if the patient does not show any signs of circulation.	
i	If the device detects that the patient's heart rhythm has changed to an non shockable rhythm, the previously recommended shock is immediately cancelled and the energy is discharged internally. <b>FRED easy</b> ® informs the user that the shock has been cancelled.	
<ul> <li>Each shock is followed by CPR</li> </ul>	The <b>FRED easy</b> ® informs the user that the patient can be touched again and prompts the user to perform a cardiopulmonary resuscitation cycle.	
	According to the configuration of the device, a CPR cycle consists of:	
	<ul> <li>performing chest compressions during the set period of time, or</li> <li>performing alternatively 30 chest compressions and 2 breathes during the set period of time.</li> <li>Before each CPR cycle, the device informs the user that the patient can be touched.</li> </ul>	
	The device indicates the position of the hands and the rhythm of chest compressions with beeps ("metronome"), if applicable.	
i	<ul> <li>For children, the number of chest compressions can be configured to 15 or 30 using FREDCO®. The device recognises the connected electrodes (adult or child electrodes) and selects the number of chest compressions accordingly.</li> <li>CPR duration can be configured in FREDCO® and is the same for adults and children: it can be set between 30 seconds and 7.5 minutes, in steps of 30 sec-</li> </ul>	

onds.

Art. no.: 0-48-0013 Rev. m

SCHILLER		Defibrillation 4	
FRED easy	User Guide	Defibrillation procedure 4.2	
<ul> <li>Followed by a new analysis</li> </ul>	-	Once the CPR cycle has been finished, the device prompts the user to run a new ECG analysis (in semi-automatic mode).	
	In automatic as well as semi-automatic mode (with automatic analysis activated), this new analysis starts without any intervention required of the user.		
	-	kable rhythm, it will automatically charge the defi- 2 2nd or 3rd shock. For all subsequent shocks, the 3 <sup>rd</sup> shock.	
	The energy levels can be cont 8 Technical Data).	figured by SCHILLER's customer service (see	
<ul> <li>Successful shock followed by CPR</li> </ul>	After a successful shock (no f <b>FRED easy</b> ® prompts the user to	urther shocks advised by the ECG analysis), perform CPR.	
> No shock advised	The device has not detected a sho	ockable rhythm.	
		detect a shockable rhythm, the <b>FRED easy</b> ® incessary and prompts him or her to perform CPR.	
i	According to the configuration of th ence of pulse before performing th	ne device, the user may be asked to check the pres- ne CPR cycle.	
➢ Finishing the therapy		d, the defibrillation pads must be removed from the from the device. The defibrillation pads are not re-	
	The device can then be switched o	off by pressing and holding the green button 🛑 for	

3 seconds.

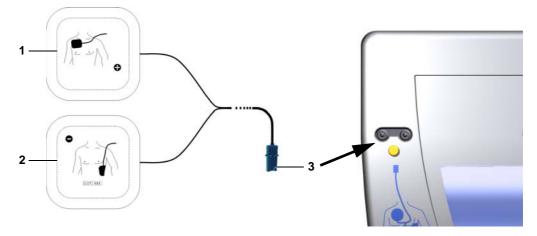
## 4.3 Applying the adhesive electrodes

#### 4.3.1 General information

- ▲ Only use the pads up to their expiration date. Please note that the expiration date of the pads only applies if the vacuum pack is intact.
- ▲ The pads are sufficiently pre-gelled. Do not use extra contact agent.
- ▲ Do not reuse the pads.

After having removed the clothes from the patient's upper body, perform the following steps:

- open the electrode packaging, connect the electrode cable to the device
- and apply the electrodes to the patient's chest.



- Defibrillation pad to be placed at the right sternal edge at the level of the 2<sup>nd</sup> intercostal space.
- (2) Defibrillation pad to be placed at the left axillary line at the level of the 5<sup>th</sup> intercostal space.
- (3) Electrode connector, to be inserted into the electrode port.
- The yellow indicator is lit and the device repeats the instructions twice until the electrodes are applied, or until the electrode connector is connected to the device, respectively, and the electrode-skin resistance (impedance) has reached an acceptable level.
- After the second prompt to apply the electrodes, the device recommends to perform a cardiopulmonary resuscitation cycle. The device will then switch off if it has not detected an acceptable impedance between the two electrodes after 5 minutes of CPR.
- If using "pre-connected" pads, it is only necessary to apply the pads to the patient's chest.



Fig. 4.1 Yellow indicator

i

Step 1

#### 4.3.2 Apply the adhesive electrodes and connect them to the device

Open the electrode packaging

Fig. 4.2 Opening the electrode packaging

When using pre-connected electrodes, go directly to Step 3 Applying the electrodes to the patient's chest.

Connecting the electrode cable to the device



Fig. 4.3 Inserting the connector into the port

Pre-connected electrodes, which are already connected to the device, only need to be applied to the patient's chest (Step 3). In this case, Step 2 is not required. Electrodes that are not pre-connected, need to be connected (Step 2) and applied (Step 3).

i

## Step 3 Applying the electrodes to the patient's chest Risk of skin burns/equipment damage - Do not apply the defibrillation pads on

WARNING top of: - the sternum or clavicle, the nipples, an implanted pacemaker or defibrillator device. Skin covered in sea water, sand, sunscreen, or skin or body care products may impair electrode contact or cause the electrodes to become disconnected. Adult and paediatric electrodes The large adult electrodes with a surface area of 80 cm<sup>2</sup> are used for adults and children weighing 25 kg or more. The small paediatric electrodes with a surface area of 42 cm<sup>2</sup> are used for children weighing less than 25 kg (younger than 8 years of age). electrodes and paediatric electrodes. 1. patient's chest are clean and dry. 2 contact impedance between the electrodes and the skin. Electrode application sites 3. Carefully shave the application sites if the patient's chest is hairy. 4 surface). 5. tal space.

The electrodes must have good contact with the patient's skin. Air bubbles under the electrodes must be avoided. To avoid air bubbles, place one edge of the adhesive electrode to the patient's chest, then gradually smooth it out toward the other edge to remove any air.

6. Place the electrodes on the patient's chest so that the connections point to either side of the patient in order not to hinder CPR.

When defibrillating small children, it is recommended to choose the anterior-posterior position to avoid short-circuiting the electrodes.

Large electrodes

Small electrodes



Fig. 4.4



Fig. 4.5 Electrode application sites for children

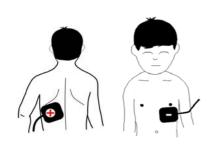


Fig. 4.6 Application sites for small children

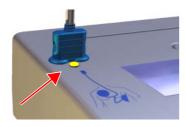
Ε no.: 0-48-0013 Rev. Ę.

Electrode placement is the same for adults and for children (see Fig. 4.5 Electrode application sites for children). The device automatically distinguishes between adult

- Before applying the adhesive electrodes, verify that the application sites on the
- The skin must be cleaned by rubbing the application points vigorously with a dry cloth. Do not use alcohol or alcohol wipes. This could significantly increase the
- Apply the positive electrode at the right sternal edge at the level of the 2<sup>nd</sup> intercostal space. Do not apply the positive electrode on top of the clavicle (uneven
- Apply the negative electrode on the left axillary line at the level of the 5<sup>th</sup> intercos-



#### 4.3.3 Checking the electrodes



i

If the resistance (impedance) reaches an unacceptable value, the device interrupts and prompts the user to check the electrode application and connection (CHECK CONNECTOR IS FITTED AND ELECTRODE APPLIED ON CHEST). In addition, the yellow indicator is lit.

This can occur if:

- the cable is diconnected from the device and/or,
- if the electrodes are not properly applied to the patient's chest.
- Then the device recommends to perform a cardiopulmonary resuscitation cycle.
- The device resumes the intervention where it has been interrupted when it detects that the resistance between both electrodes is again acceptable.
- The device switches off if it still does not detect acceptable resistance between both electrodes after 5 minutes of CPR.

Follow these steps to check the electrodes:

- 1. insert the connector as specified in Step 2 on page 35.
- 2. press strongly one after the other the defibrillation pads to the patient's chest to find which one makes the yellow indicator switched off,
- 3. Carefully press this electrode on the patient's skin.

If the electrode defect is not corrected:

- 1. remove both electrodes,
- 2. wipe the remaining contact agent off with a cloth,
- 3. shave both application points to improve the contact between the electrodes and the skin,
- 4. apply new defibrillation electrodes.

i

To remove the electrodes from the patient's chest, see 4.8 Finishing the therapy.

## 4.4 Semi-automatic defibrillation

Patient hazard — The guidelines given in 4.1 Instructions and Safety Notes must be observed.	Э
--	---

## Step 1



Fig. 4.7 Button to turn the device on/off and to start analysis

## Step 2

#### Semi-Automatic Defibrillation

### Switching on and preparing the device

- 1. Briefly press the green button (max. 1 second) (1) to switch on the device.
- 2. Assess the patient's condition (see 4.2 Defibrillation procedure).
- 3. Connect the electrode cable to the device (see 4.3 Applying the adhesive electrodes).
- 4. Apply the defibrillation electrodes to the patient's chest (see 4.3 Applying the adhesive electrodes).

### Analysing the ECG signal

5. Briefly press the green button (max. 1 second). A message prompts the user to stay clear of the patient.

|--|

Briefly press the green button (max. 1 second) to start the analysis. Otherwise, the device will switch off.

i

- The semi-automatic version of the FRED easy® can be configured so that the ECG analysis is initiated automatically. In this case, the device prompts the user to connect the electrodes and then automatically runs the analysis without any intervention by the user.
- If the device detects ventricular fibrillation or ventricular tachycardia with a heart rate exceeding 150 bpm, Step 3 Shock delivery follows; otherwise, continue with Step 4, Performing cardiopulmonary resuscitation.

## Step 3



Fig. 4.8 Button to deliver the shock

## Shock delivery

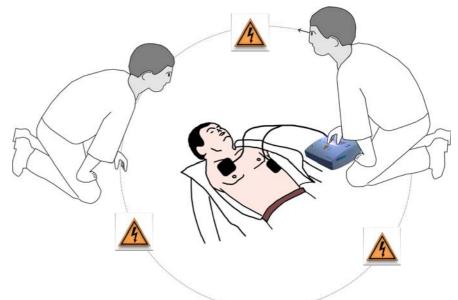
**User Guide** 

When the energy is charged, the user is prompted to trigger the shock by pressing the lit  $\P$  orange button.



#### Shock hazard!

- ▲ Do not, under any circumstances, touch the patient during shock delivery.
- ▲ Make sure that the patient does not touch any conducting objects.



Deliver the shock by pressing the button .
 After the shock delivery, proceed with Step 4 Performing cardiopulmonary resuscitation.

Step 4

## Performing cardiopulmonary resuscitation

- 7. Perform a CPR cycle. According to the configuration of the device, a CPR cycle consists of:
  - performing chest compressions for the set period of time, or
  - alternately performing 30 chest compressions and 2 breathes for the set period of time.
  - After the CPR cycle, the device continues with Step 2 Analysing the ECG signal.

If the device is configured to start the ECG analysis automatically, the device will not require any action from the user to run the ECG analysis.

Finishing the therapy

Ĩ

See 4.8 Finishing the therapy.

i

## 4.5 Automatic defibrillation

The laws and regulations for the use of automatic defibrillators differ from country to country. While some countries allow laypersons to use automatic defibrillators without any special training, other countries restrict the use of AEDs to EMTs or First Responders who have undergone special training.

#### 4.5.1 Functional description of automatic AEDs

This device delivers defibrillation shocks automatically, i.e. there is no need to start the analysis or trigger the shock.

Voice and text prompts displayed on the screen keep the user informed regarding the therapy.

If a shock is advised, the energy is automatically charged. A countdown accompanies the last 3 seconds before the shock is delivered.

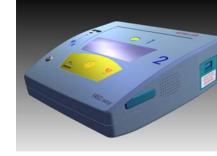


#### 4.5.2 Safety notes for automatic defibrillation

#### Risks for patient, users and assistants!

Once the device has been switched on with the green button ( and the electrodes have been applied, the ECG analysis is started automatically and a shock is delivered automatically if a shockable rhythm is present. The user is informed of an ongoing analysis or shock release via written and acoustic messages.

- ▲ Touching or transporting the patient during analysis may lead to an incorrect analysis. Analysis results are only valid if the patient remained unconscious during the entire analysis and was not touched.
- ▲ For this reason, chest compressions and artificial respiration must be suspended during the analysis.
- ▲ The patient must not be touched or transported (e.g. stretcher) during analysis and shock delivery.
- ▲ The notes in section 4.1 Instructions and Safety Notes page 27 must be observed.





## Step 1

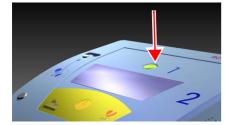


Fig. 4.10 Button to turn the device on/off and to start analysis

i

## Step 2

#### Automatic defibrillation

### Switching on and preparing the device

- 1. Briefly press the green button (max. 1 second) (1) to switch on the device.
- 2. Assess the patient's condition (see 4.2 Defibrillation procedure).
- 3. Connect the electrode cable to the device (see 4.3 Applying the adhesive electrodes).
- 4. Apply the defibrillation electrodes to the patient's chest (see 4.3 Applying the adhesive electrodes).

### Automatic ECG analysis

The analysis is automatically triggered, without user intervention. A message prompts the user not to touch the patient.

If the device detects ventricular fibrillation or ventricular tachycardia with a heart rate exceeding 150 bpm, Step 3 Automatic shock deliveryfollows; otherwise, continue with Step 4, Performing cardiopulmonary resuscitation.

## Step 3

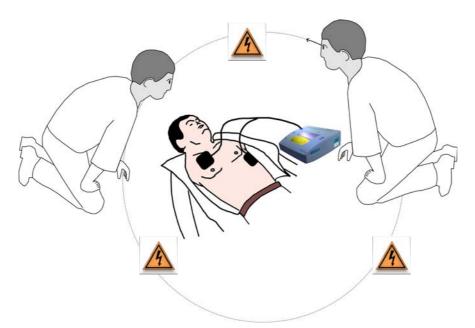
## Automatic shock delivery

As soon as the energy charge is completed, the device automatically delivers the shock, without user intervention. A countdown is displayed on the screen and the orange button  $\frac{1}{5}$  blinks until the shock is delivered.



Shock hazard!

- ▲ Do not, under any circumstances, touch the patient during shock delivery.
- Make sure that the patient does not touch any conducting objects.



After the shock delivery, proceed with Step 4 Performing cardiopulmonary resuscitation.

Step 4

## Performing cardiopulmonary resuscitation

- 5. Perform a CPR cycle. According to the configuration of the device, a CPR cycle consists of:
  - performing chest compressions for the period of time configured, or
  - performing alternatively 30 chest compressions and 2 breathes during the period of time configured.

After the CPR cycle, the device proceeds with Step 2 Automatic ECG analysis.

# Finishing the therapy

See 4.8 Finishing the therapy.

4.6 Manual Defibrillation (option)

The option to switchover to manual mode is only available for the semi-automatic version of **FRED easy**®.

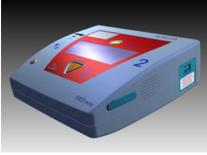
The **FRED** easy® with manual mode is indicated by a red foil on the casing. If the user does **not** activate the manual mode after switchon, the unit remains in semi-automatic mode. The defibrillation will then be carried out as described in section 4.4.

Even though non physicians are legally authorised to use semi-automatic defibrillators, the **FRED easy®** must not be used by non physicians when it is in manual mode.

In some countries, however, the option to switch from semi-automatic mode to manual mode is made available to EMTs and medical personnel (non physicians). In this situation, individual protocols must be determined in cooperation with the EMTs. These protocols must be based on AHA or ERC protocols or on the regulations of the country in question. Furthermore, the emergency service is required to ensure that the procedures established are observed and that the staff is trained accordingly.

- \_ . . . . . . .
  - The device cannot be turned on directly in manual mode.
    It is not possible to switch to manual mode while the device is powering on. Therefore, do not press the orange button while the device is powering on.
  - It is not possible to switch the defibrillator to manual mode while a defibrillation procedure is in progress (analysis, charging, shock delivery).
  - The patient's ECG signal is automatically displayed when the **FRED easy**® is switched to manual mode.





SCHILLER

**FRED** easy

i

Ĭ

Fig. 4.11 FRED easy® semi-automatic with manual option

#### 4.6.1 Manual defibrillation - description

The user is informed of each step by a voice prompt as well as text instructions on the display.

Press the green button () to switch on the device.

Wait until the device has fully started up and is prompting you to connect and apply the electrodes.

Simultaneously press the green and orange button (1) + **4**. You are prompted to press the buttons a second time to confirm switchover to manual mode. You need to confirm this within 5 seconds.

Connect the electrode cable and apply the electrodes to the patient's chest (see section 4.3 Applying the adhesive electrodes).

The patient's ECG signal is automatically displayed when the FRED easy® is switched to manual mode.

In manual defibrillation, the energy values of the first 3 shocks are those defined for the semi-automatic mode. For all subsequent shocks, the energy level of the 3rd shock is used.

The device prompts the user to press the green button (1) to charge the energy. The charging progress is displayed on the screen.

As soon as the set energy is charged, the orange button  $\mathbf{V}$  is lit and the user is prompted to deliver the shock (by voice prompt as well as written instructions).

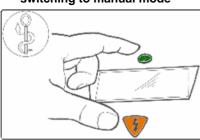
Once the shock is delivered, the device repeats the prompt to charge the energy for the following shock.

switching to manual mode

> Turning on the device and

> Shock delivery

> Defibrillator charging

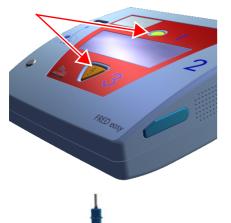




#### 4.6.2 Manual defibrillation procedure

	Patient hazard — Only a physician is allowed to enable manual mode. Observe the instructions given in section 4.1 Instructions and Safety Notes.

## Step 1



**A**CAUTION

## Switching on and preparing the device

- 1. Briefly press the green button (max. 1 second) (1) to switch on the device.
- 2. Switch to manual mode by simultaneously pressing the green and orange buttons + \frac{1}{7}. Confirm the switching by simultaneously pressing these same buttons a second time.

- Connect the electrode cable to the device. 3.
- Apply the electrodes on the patient's upper body (see 4.3 Applying the adhesive 4. electrodes).

Step 2

### Charging the energy

Briefly press the green button (max. 1 second). 5.

Patient hazard — Press the green button ( only briefly (max. 1 second) to start the energy charging. If you press the button for too long, the device is switched off.

## Step 3



Fig. 4.12 Button to deliver the shock

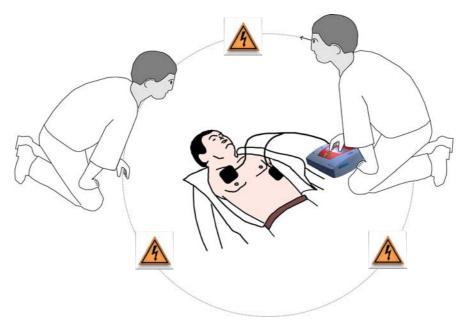
### Shock delivery

As soon as the energy is charged, the device prompts the user to deliver the shock by pressing the orange button  $\checkmark$ . The orange button  $\checkmark$  remains lit until the shock is delivered.



#### Shock hazard!

- Only deliver a shock when a shockable heart rhythm is present.
- ▲ Do not, under any circumstances, touch the patient during shock delivery.
- ▲ Make sure that the patient does not touch any conducting objects.



Deliver the shock by pressing the button V.
 After the shock delivery, proceed with Step 2 Charging the energy.

# Finishing the therapy

See 4.8 Finishing the therapy.

#### 4.6.3 Switching to semi-automatic operational mode

To return to semi-automatic mode, turn off the **FRED easy**® and leave it turned off for at least 5 minutes before switching it on again.

## 4.7 Internal safety discharge

## 

i

**FRED** easy

SCHILLER

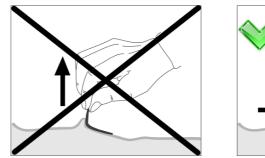
If the device's behaviour differs from the description given in this user guide, the device is defective and must be repaired.

An internal safety discharge ensures that the stored energy is discharged within the device every time a defibrillation shock was not delivered correctly. An internal discharge is performed if:

- after the defibrillation energy has been charged, the heart rate changes into a non shockable rhythm
- the shock has not been delivered within the 20 seconds following the end of defibrillation energy charging
- an electrode error is detected
- the battery voltage is insufficient
- the device is defective
- the device is switched off before the shock is delivered.

## 4.8 Finishing the therapy

- Switch off the device once the therapy has been completed (press and hold the green button for approx. 3 seconds).
- · Disconnect the electrode cable.
- Carefully peel the pads off the patient's skin (see Fig. 4.13 Removing the adhesive pads).
- Recycle the disposable pads immediately after use to keep them from being reused by mistake (hospital waste).



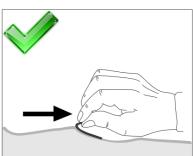


Fig. 4.13 Removing the adhesive pads

- 5 minutes after the device has been switched off, the number of shocks delivered as well as the time elapsed since the device was turned on, are reset to zero.
- If the device is turned off for less than 5 minutes, all data is stored (even if the battery is removed), and the device continues to count the number of shocks delivered, to measure the time elapsed since the device was turned on, and to store intervention events from the point at which the device was turned off.

## **5** Versions

## 5.1 SD card version

i

#### Equipment damage hazard —

- ▲ The memory card slot must always be covered with the rubber cover. This is to prevent moisture penetrating the device.
- ▲ Always turn off the device before inserting or removing the SD card.
- ▲ Do not insert the Ethernet adapter into the SD card slot.

#### Malfunction hazard —

- ▲ The SD card must only be used in one single device. Before being used in another device, the SD card must be reformated with the Schiller data viewing software; otherwise, the recorded information will be incorrect.
- Only use SD cards supplied by SCHILLER.

#### **Operating principle**

This version records all defibrillation-related events on a removable SD card.

The SD card is able to record:

- 2 hours of ECG signal,
- 2 hours of sound recording (if this parameter has been activated using FRED-CO® and unless ambient noises are too loud).
- 500 events concerning the intervention (see table below).

#### Overview of recorded events, with date and time:

#### Power on

- Movement detection (beginning and end)
- Operating mode
- · Start of analysis
- Analysis result
- Defibrillator charging
- Defibrillation shock
- Defibrillation shock cancelled
- Internal discharge<sup>a</sup>
- Electrode alarm
- "Battery low" alarm
- Critical error
- · Power off

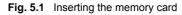
a. This event is only recorded when the defibrillator has switched to "limited mode" due to a technical problem.



#### 5.1.1 Inserting the SD card

- 1. Make sure that the SD card is not write-protected.
- 2. Switch off the device before inserting the card.
- Insert the card as shown in Fig. 5.2 SD card inserted (text facing up, in the direction indicated by the arrow). Otherwise, the device will not recognise the card and the symbol 
  is displayed.



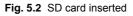


4. Once the card is inserted, close the rubber cover of the card slot.

If the symbol is not displayed even though the card has been inserted, check that the card has been recommended by SCHILLER for the use in this type of device.

Inserting the SD card automatically activates the memory function and the symbol  $\downarrow_{\downarrow\downarrow}$  is displayed (see Fig. 5.2 SD card inserted).





The symbol  $\bigcup_{UV}$  starts blinking when the SD card is full. No further data is stored; however, previously recorded data remains stored on the card.

SD cards can be read on a PC using the Schiller data viewing and "LifeDataNet®" software.



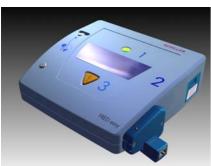


Fig. 5.3 Ethernet version

i

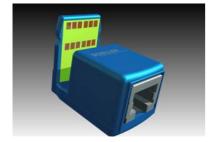


Fig. 5.4 Ethernet adapter

## 5.2 Ethernet version

#### Operating principle

This version is able to send intervention data (stored on the internal memory) as well as detailed device configuration data to the **LifeDataNet**® web server.

The data is transmitted via a network infrastructure.

The internal memory is able to record:

- 2 hours of ECG signal,
- 2 hours of ambient noise (if the sound recording parameter is activated using FREDCO®),
- 500 events concerning the intervention.

Once the internal memory (SD card) is full, the  $\Box$  symbol starts blinking and no more data can be stored. Stored data will be cleared once it has been transmitted. Transmitted data can be viewed using **LifeDataNet**®.

- The memory card cannot be removed for the **FRED easy®** Ethernet version.
- All events transmitted by the device are listed on page 48.
- In order to protect other electrical devices from interference during data transmission, a ferrite core must be placed on the Ethernet cable in close proximity to the Ethernet adapter (see 5.2.3 Installing the ferrite core).

To ensure correct data transmission:

- 1. the "Network" and "Online" sections of the device settings must first be configured using the **FREDCO**® software program (see 5.2.1 Connecting the Ethernet adapter and 5.4.2 Configuring the "Online" Tab),
- 2. the Ethernet adapter must be connected to the network hosting the LifeDataNet® web server, via an Ethernet cable,
- 3. the Ethernet adapter must be inserted in the Ethernet interface of the device (see 5.2.1 Connecting the Ethernet adapter).

#### 5.2.1 Connecting the Ethernet adapter

The Ethernet adapter needs to be inserted in the Ethernet interface (see Fig. 5.5 Inserting the Ethernet adapter in the Ethernet interface).

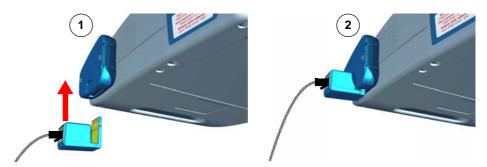


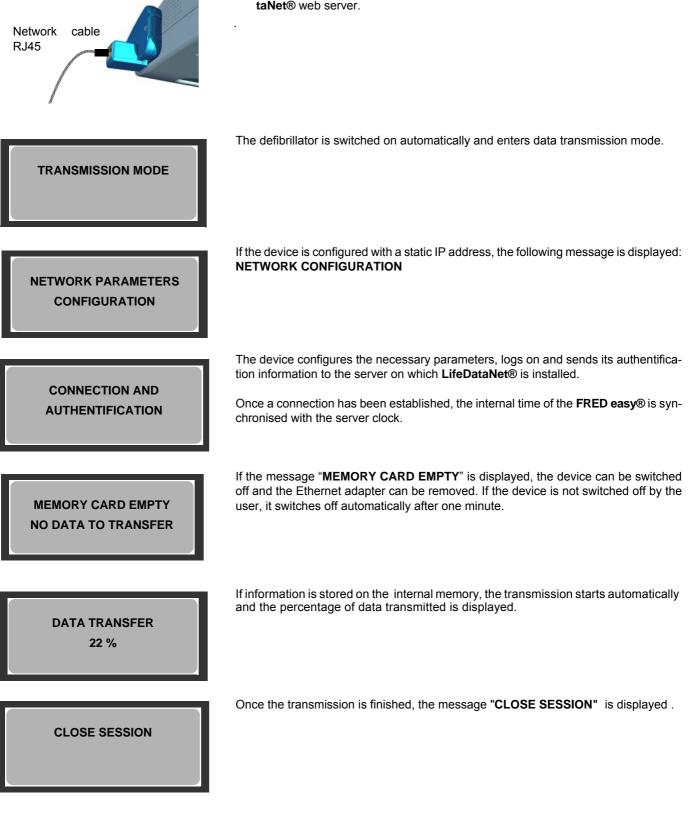
Fig. 5.5 Inserting the Ethernet adapter in the Ethernet interface



Art. no.: 0-48-0013 Rev. m

#### 5.2.2 Data transmission procedure

- 1. Switch off the device and disconnect the electrode cable.
- 2. Connect the FRED easy to a network to establish a connection to the LifeDataNet® web server.



Page 51

MEMORY ERASING 25 %	After transmission, the data is deleted from the internal memory. The percentage of data removed is indicated.
i	The data stored on the internal memory is deleted once the transfer of the entire data record is completed. If the transfer is interrupted, data remains stored on the internal memory and the transfer can be restarted.
TRANSMISSION COMPLETE	At the end of the transmission procedure, the following message is displayed: You can switch off the device and remove the Ethernet adapter.
i	FRED easy automatically aborts the connection 5 minutes after the data transfer has been completed, or if the Ethernet connection is interrupted.



#### 5.2.3 Installing the ferrite core



Fig. 5.6 Installing the cable within the ferrite core



Fig. 5.7 Reducing the loop

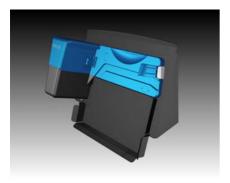


Fig. 5.8 Correctly installed ferrite core

#### FRED easy® Ethernet accessories

Part No.	Description
1-58-5303	Ethernet adapter
5-30-0003	Ethernet cable (3 m, category 5)
4-33-0002	Ferrite core
0-05-0026	Ethernet cable (3 m, with ferrite core)

- 1. Form a loop and route the Ethernet cable through the open ferrite core (see Fig. 5.6 Installing the cable within the ferrite core).
- 2. Shut the ferrite core without closing it completely and check the cable position.
- 3. Reduce the size of the loop to place the ferrite core as closely as possible to the Ethernet plug. To do so, pull the long end of the cable (see Fig. 5.7 Reducing the loop).
- 4. Close the ferrite core (see Fig. 5.8 Correctly installed ferrite core).



## 5.3 Online version

#### **Operating principle**

This version is intended to ensure communication between the device and the LifeDataNet® web server.

Just as with the Ethernet version, this version is able to send intervention data (stored on the internal memory) as well as detailed device configuration data to the LifeDataNet® web server. It also allows a total remote control of the FRED easy® using Life-DataNet® (see table below).

Communication takes place via a network infrastructure using the SNMP (Simple Network Management Protocol) communication protocol.

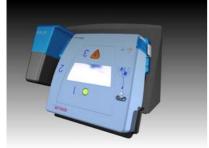


Fig. 5.9 Online version with docking station

i

- The SD card is not removable in the FRED easy® Online version.
- All events transmitted by the device are listed on page 48.

#### Overview of actions that may be performed remotely, using LifeDataNet®:

- Monitoring of battery capacity and self-test result
- · Update of device's software
- · Modification of device configuration
- Modification of device language
- Triggering of audible alarms or visual indications on the devices
- Viewing the device status
- Geographic location of devices (Google Maps)

The internal memory is able to record:

- 2 hours of ECG signal,
- 2 hours of ambient noise (if the sound recording parameter is activated using FREDCO®),
- 500 events concerning the intervention.

Once the internal memory is full, the  $\bigcup_{\mu\nu}$  symbol starts blinking and no more data can be stored. Stored data will be cleared once it has been transmitted.

#### 5.3.1 Ensuring data transmission



i

The user and installation handbook for the docking station (part no. 0-48-0156) provides further information on the use of the docking station and configuration of the **FRED easy®** Online.

- The "Network" and "Online" sections of the device settings must be configured using the **FREDCO**® software program,
- The **FRED easy®** Online needs to be inserted in the docking station (see section 5.3.2 page 56).
- Only use lithium batteries with the Online version. Do not use rechargeable NiCd batteries.
- Do not remove the battery from the device while the device is inserted in the docking station.
- Turn off the device before inserting it in the docking station. Otherwise, no data will be transmitted.

#### 5.3.2 Placing the FRED easy® in the docking station

- 1. Switch off device.
- 2. Position the device as shown in illustration (1).
- 3. Push the device into the docking station (2) until it clicks into place (3).



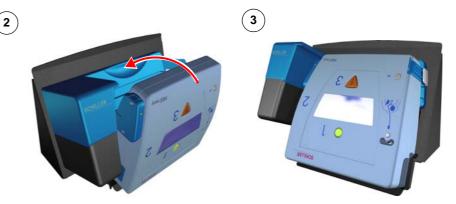


Fig. 5.10 Inserting the device into the docking station

- The device switches on and starts transmitting the data from its internal memory in the same way as the Ethernet version (see 5.2.2 Data transmission procedure).
- The indicator (see Fig. 5.11 Communication indicator) is blinking when the device is able to communicate with the data network.
- The same screens are displayed as during data transmission with the Ethernet version (see 5.2.2 Data transmission procedure).

Once all data has been transmitted, the display illumination switches off and the message "FREDeasy Online READY" is displayed. This message is displayed whenever the device is able to communicate with the data network. In addition, the indicator is blinking (see Fig. 5.11 Communication indicator).



Fig. 5.11 Communication indicator

If communication is interrupted, the message " **NO SERVER**" is displayed and the indicator remains lit.

You can read and edit the transmitted data using the LifeDataNet® web server.

SCHILLER

FRED easy

#### 5.3.3 Activating the maintenance mode

While inserted in the docking station, the device can be switched to maintenance mode.

To do so, simultaneously press the buttons **()** and **V**. The message **"MAINTE-NANCE IN PROGRESS"** is displayed.

While in maintenance mode, the device can be removed from the docking station for service purposes. In this case, the server recognises that the device was not removed for defibrillation purposes and does not generate any alarms.

After the device has been returned to the docking station, maintenance mode must be switched off by again simultaneously pressing both buttons.

Ĭ

## 5.4 Configuration Ethernet/Online using FRECO

A password provided by SCHILLER must be entered to access the network parameters.

#### 5.4.1 Configuring the "Network" tab

• Start the FREDCO® software program and select the "Network" tab (1).

	Series Configuration Menu : FRED_EASY_2G	
	Configuration Tools Help	
1	Option P2 Battery Auto Test Results Flash Card Network OnLine Disconnect	
2	IP Configuration	
3	Dynamic (DHCP) 💿 Static MAC Address 00:00:00:00:00	8
4	IP Address 192.168.16.0	
5	Network mask 0.0.0.0 Server IP address	9
6	Gateway 0.0.0.0 Login fredeasy	10
7	DNS 0.0.0 Password schiller	11
	Network Options	
	Encryption Software update ECG transmission	
	📕 Binary mode 👘 Periodic test connect. 🛒 Sound transmission	
	Embedded config.  Clock synchronisation Z transmission	
	Update	12

Fig. 5.12 Network configuration ("Network" tab)

- (1) "Network" tab in FREDCO®
- (2) IP address configuration section
- (3) Selection of IP address configuration mode: dynamic or static
- (4) IP address of the FRED easy® Ethernet version
- (5) IP address of the network mask (depends on the network infrastructure)
- (6) IP address of the network gateway (depends on the network infrastructure)
- (7) IP address of the domain name system (depends on the network infrastructure)
- (8) MAC address of the **FRED easy**® Ethernet version (located on the label on the underside of the device)
- (9) IP address of the server's network interface, used by **FRED easy®** to connect and transmit data
- (10) Login of a user with access to the server on which LifeDataNet® is installed
- (11) User password
- (12) Confirmation of "Network" tab configuration
- The parameters of the "IP Configuration" section (2) depend on the network infrastructure:
  - in "Static" mode (3), your network administrator will provide this information and you are required to fill in (4), (5), (6), and (7).
  - In "Dynamic" mode (3), the 4 parameters are automatically configured (see Fig. 5.13 Configuring the dynamic mode).
- Check that the "MAC Address" (8) displayed on the screen is identical to the address indicated on the underside of the device.

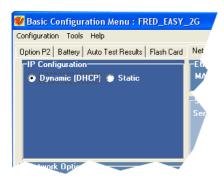


Fig. 5.13 Configuring the dynamic mode



- Fill in the Server IP address field (9).
- Enter a login (10).
- Enter the password (11).
- Click the "Update" button (12) to apply any changes.
- i
- Login (10) and password (11) can be freely changed but they must be the same as those specified in the "SNMP Parameters" tab of LifeDataNet® (see user manuel of LifeDataBox/LifeDataNet® (0-48-0117)). By default, the login is "fredeasy" and the password is "schiller".
- To apply any changes to the parameters, click the "Update" button (12).
- Once the battery is inserted, **FRED easy**® Ethernet offers the option to manually configure the IP addresses without using **FREDCO**®, if configured so.

i

#### 5.4.2 Configuring the "Online" Tab

#### • Start the FREDCO® software program and select the "Online" tab (1).

A password provided by SCHILLER must be entered to access the network parameters.

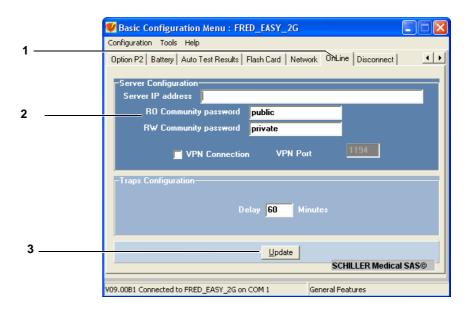


Fig. 5.14 Network configuration ("Online" tab)

- (1) "Online" tab in FREDCO®.
- (2) "RO and RW Community" password.
- (3) Confirmation of "Online" tab configuration.
- Enter the "RO and the RW Community" password (2). You can choose any password, but it must be identical to the password entered in the "FREDeasy®" section of the "SNMP Parameters" tab in LifeDataNet® (see Fig. 5.15 SNMP parameter in LifeDataNet®).

CAL SCHILL					
admin A Déconnexi	20	Configur	ration LifeDa	taNet 🕐	
Liste des appareils Action(s) Config.LifeDataNet					
Gestionnaire des utilisateurs     Gestionnaire des groupes	Home > Config Paramétres	Paramétres d'alarme	Paramétres SNMP	Logiciel FRED easy@	Configuration PDI

Fig. 5.15 SNMP parameter in LifeDataNet®

• Click the "Update" button (3) to apply any changes.



## 5.4.3 Configuring the date and time as well as IP addresses without using FREDCO®

- Date and time setting can also be done on non Ethernet/Online devices if the parameter has been activated in FREDCO.
- When the battery has been inserted, a self-test is performed. If no errors are detected during this self-test, the date and time as well as IP address for the Ethernet/ Online version can be set, if configured so.
- If the green button is not pressed within a couple of seconds, the message disappears automatically and the device status indicator starts blinking. (For the Online and Ethernet version, the device first recommends configuring the IP address before the message disappears).

This is only available if the parameter "Setting date and time" and/or "IP Address" has been activated in FREDCO®.

- 1. Insert the battery and wait for the prompt to set the date and time and/or to configure the IP address.
- 2. Press the green button (). Three fields are displayed: date, time, summer/winter and/or 3 IP address fields.
- 3. Press the orange button **F** to change the value.
- 4. Press the green key () to jump to the next value.
- 5. Press the green button to jump to "Apply" and press the orange button  $\frac{1}{5}$  to confirm and apply the changes.

When you have confirmed the values, the menu disappears and the device can be switched on.

Setting the date/time and/or IP address for Ethernet/Online versions

i

## 6 Options

## 6.1 ECG display

When the "ECG Display" option is activated, the ECG signal obtained by the electrodes is displayed on the screen (see Fig. 6.1 ECG display).

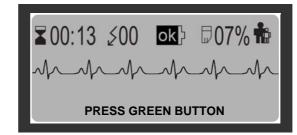


Fig. 6.1ECG display

- The "ECG Display" option is only available for the **FRED easy®** semi-automatic.
- This option is automatically activated when the **FRED easy®** is switched to manual mode.
- When the ECG signal is displayed, messages are only displayed on one single line.

## 6.2 Metronome

i

When the "Metronome" is enabled, the device sets the rhythm for chest compressions during CPR at 100 bpm.

The FREDCO® software program allows you to:

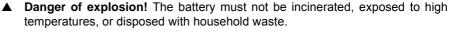
- set the metronome frequency to a value between 80 and 150 bpm (in steps of 5 bpm).
- the metronome can be set to signal to the user to give 2 rescue breaths (the metronome is stopped for 8 seconds after 30 chest compressions).



## 6.3 Rechargeable NiCd battery

The battery must remained packed in its original plastic packaging (blister) during the whole storage time. The plastic packaging must only be removed when the battery is used.





- ▲ Do not expose the battery to chemicals that could dissolve ABS, polypropylene, polyvinyl chloride, nickel, mylar, or steel.
- ▲ Do not short-circuit, cut, destroy or incinerate the battery.

Fig. 6.2 NiCd battery charging unit

As an alternative, a rechargeable NiCd battery (12 V, 650 mAh) is available for the defibrillator. The capacity of a new, fully charged battery is sufficient for:

- 45 shocks at maximum energy, or
- 40 minutes operating

Like the lithium battery, the device warns the user when the NiCd battery has reached the "low" battery threshold. The device will still allow the user to perform defibrillation, but the battery must be recharged/replaced as soon as possible.

The **FRED easy®** also detects when the NiCd battery is "depleted". In this case, the device does not allow the user to perform defibrillation and instead prompts him or her to perform CPR. The battery must be recharged/replaced immediately.

For further details, see 3.1 Inserting the battery.

i

i

- This option is only available for the FRED easy® SD Card and Ethernet versions.
- This option is only available for **FRED easy**® devices that have a 2nd generation CPU board.

These devices can be recognised by their 12-digit serial number.

When charging NiCd batteries, make sure to observe the values 100 - 240 V, 50 - 60 Hz (see 9.1 Order Information). The charging time is max. 1 hour.

When the device is equipped with a NiCd battery, it runs a daily self-test.

Battery service life — Unused batteries (whether or not inserted in the device) should be charged at least every 2 months.



## 6.4 Silent mode

The FRED easy with silent mode option is intended for locations where a quick transferral to a hospital cannot be guaranteed. If in Silent mode a change in the cardiac rhythm is detected the device reactivates the AED mode and the user will be prompt to check the patient.

In silent mode, operating time is approx. 6.5 hours if no analysis or defibrillation is performed.

#### 6.4.1 Silent mode

If a patient has been successfully defibrillated or if the device does not detect a shockable rhythm, the device can be switched to silent mode in order to detect changes of the patient's cardiac rhythm without the user or patient being disturbed by the AED's repeated voice prompts.

If the device detects a change in the cardiac rhythm or if the green button is pressed, silent mode is abandoned and voice prompts instruct the user about the next steps to be taken.

Moreover, the heart rhythm is recorded and can be transmitted via network with the FRED easy Ethernet/Online (see 5.2.2 Data transmission procedure).

	<ul> <li>Even though the device issues voice prompts if a change in rhythm occurs, this is not a substitute for the regular checking of the patient's vital functions.</li> <li>Silent mode must only be activated if the device does not detect a shockable rhythm and if the patient is responsive.</li> </ul>
i	<ul> <li>The silent mode must not be carried out while the device is starting up.</li> <li>The silent mode must not be carried out during an analysis or defibrillation.</li> </ul>

2 x

#### 6.4.2 Switching to silent mode

Defibrillation is performed according to the safety notes in section 4.1 Instructions and Safety Notes and the procedure in section 4.4 Semi-automatic defibrillation. Switchover to silent mode can be done at the earliest after Step 2, as long as no shockable rhythm has been detected, or after a successful defibrillation (Step 3) followed by a "normal" cardiac rhythm. After Step 2, or 3, respectively, simultaneously press the green button and the orange button **W** until the message **"Confirm Silent Mode"** is displayed. Immediately release both buttons and press shortly them again to confirm the silent mode. Procedure for semi-automatic defibrillation Step 1 Switching on 
and preparing the device See section 4.4 Semi-automatic defibrillation. Step 2 ECG analysis Press the green button for max. 1 second. - If the device detects ventricular fibrillation or ventricular tachycardia with a heart rate exceeding 150 bpm, Step 3 Shock delivery follows. If the device does not detect a shockable rhythm, the user is prompted to continue with cardiopulmonary resuscitation. 2 x In this case, the device can be switched to silent mode if the patient is responsive. Step 3 Shock delivery



Once the shock has been delivered, the user is prompted to continue with cardiopulmonary resuscitation.

- If the therapy has been successful and if the patient is responsive, the device can ÷ be switched to silent mode.
- Even though the device issues voice prompts if a change in rhythm occurs, this is not a substitute for the regular checking of the patient's vital functions.

#### 6.4.3 Deactivating silent mode

## 

▲ If the patient is no longer responsive (i.e. loses consciousness), immediately press the green button (max. 1 second) to deactivate the **silent mode** and again start an analysis (Step 2).

#### 6.4.4 Erasing the memory card

The function "Erasing memory" without transferring the data is only available in silent mode.

In silent mode, since the heart rhythm is recorded over a prolonged period of time, the message "Not enough memory" might be displayed. To ensure further recording of the ECG signal, the data can be transmitted via Ethernet (see page 51); the data is automatically deleted after transmission.

Alternatively, you can erase the memory during recording in silent mode as follows:

Simultaneously press the green button and the orange button **until the message "Erase memory?"** is displayed. Immediately release both buttons and press them again to erase the memory.





i

# FRED easy

## 6.5 Special operating conditions

The device may be approved for special operating conditions in consultation with the manufacturer and/or the inspecting authority, as long as all guidelines and regulations are observed (e.g. for the maritime sector).

#### 6.5.1 Maritime use

The following device is approved for maritime use:

- · FRED easy with silent mode
- Basic wall mounting without mains connection
- Sufficient spare batteries
- LAN cable for the transmission of the ECG

Accessory that is not included in the scope of delivery and needs to be provided by the owner:

· Insulating mat for defibrillation on conducting surfaces.

The device needs to be stored before use (incl. inserted battery, electrodes and spare batteries) according to the technical data.

#### Ambient conditions for storage before use

In order to guarantee operational readiness of the device and accessories, the device preferably needs to be stored in a climatised room below deck, in the following climatic conditions:

- **Temperature 15...25 °C** Ensures operational readiness as well as maximum battery life.
- **Temperature -5...40 °C** Ensures operational readiness but reduces battery life. (This is compensated by spare batteries).

#### Ambient conditions for operation

**Temperature -5...40 °C** Operation is guaranteed if the storage conditions listed above are met for the storage before use.

If higher or lower temperatures prevail during use, a limited operation time of up to one hour is possible if the device incl. electrodes has been stored at a temperature of 15...25 °C. It is recommended to store spare batteries and spare electrodes at a temperature of 15...20 °C.

#### Operating conditions on deck

- For the defibrillation, the patient needs to be placed on a dry and non conducting surface to prevent leakage currents that could endanger the rescuers. Therefore, the patient needs to be placed on an insulating mat.
- If the patient's skin is wet, it needs to be dried completely with a cloth so as not to reduce the shock's efficiency.
- In extreme weather conditions such as rain and wind, the patient must not be treated on deck.

#### **Operating conditions below deck**

In addition to the operating conditions on deck, the following regulations apply:

- If the patient is lying on a conducting surface (e.g. metal floor in the engine or storage room), the patient needs to be positioned on an insulating mat prior to defibrillation.
- Make sure that even the patient's arms and legs are positioned on the insulating mat.

## 7 Maintenance

## 7.1 Maintenance Intervals

i

CHILLER

**FRED** easy

- **FRED easy®** is an emergency device that must always be in proper working order. The device must be serviced on a regular basis. The test results must be recorded and compared to the values in the accompanying documents (see 9.5 Inspection report).
- These checks and replacements can be performed within the framework of a maintenance contract by SCHILLER technical department or an authorised distributor.
- The following table indicates the intervals and competence of the maintenance work required.

Interval	Maintenance - replacement	Responsible
Before each use	<ul> <li>Visual inspection of the device and accessories, see 7.1.1 Visual in- spection of the device and accessories.</li> </ul>	- ≻ User
	Check that the green indicator is blinking, see 7.1.2 Green indicator	
Once a Week/Month	<ul> <li>Visual inspection of the device and accessories.</li> </ul>	> User
	Check that the green indicator is blinking, see 7.1.2 Green indicator	
Every 3 years	<ul> <li>Technical safety inspections according to SCHILLER documenta- tion (available for technical departments authorised by SCHILLER) see 7.1.3 Functional check.</li> </ul>	
Every 6 years	Replacement of internal backup battery.	<ul> <li>Service staff authorised by SCHILLER</li> </ul>

#### 7.1.1 Visual inspection of the device and accessories

Before each use, inspect visually the device and the cables in order to detect possible mechanical damages.

Check that he important safety labels are legible. The lacking or illegible ones must be replaced.

If you observe damages or dysfunctions which can endanger the safety of the patient or user, only use the device once it has been serviced.

Points to inspect:

- Check that the green indicator is blinking, see 7.1.2 Green indicator
  Device casing undamaged?
- Cables not twisted, without wear signs due to friction or deterioration?
- No excessive clogging or damage?
- All the signal inputs in perfect condition?
- Legible nameplate at the rear of the device?
- · Legible inscriptions on the front face of th device?
- Expiration date of the accessories elapsed?
- ▲ Electrodes past their expiration date must be replaced immediately.
- ▲ Defective units or damaged cables must be replaced immediately.

Fig. 7.1

If the device is defective or if problems have been detected by the device during the self-test (green indicator not blinking), the device must be repaired before use.

#### 7.1.2 **Green indicator**



Blinking green indicator

#### **Functional check** 7.1.3

	Patient hazard — If the device's behaviour differs from the description given in this user guide, the device is defective and must be repaired.
	<ul> <li>In case of intensive use of the device, SCHILLER recommends that these inspections be performed at shorter interval.</li> <li>The regulations in force in each country regarding inspection frequency must be observed (if shorter intervals than those recommended by SCHILLER are imposed).</li> </ul>
Points to inspect:	<ul> <li>Visually inspect the device and the accessories (see 7.1.1 Visual inspection of the device and accessories).</li> <li>Check for proper functioning.</li> <li>Measure the leakage current.</li> <li>Measure the energy delivered at 50 Ohms.</li> </ul>
7.1.4	Internal backup battery
	The internal backup battery must be replaced at least every 6 years by SCHILLER technical support department or an authorised distributor.
i	The old battery must be recycled in accordance with local regulations.

#### FRED easy

**A** DANGER

SCHILLER

## 7.2 Cleaning and disinfection

Shock hazard — Remove the battery before cleaning the device. This ensures that the device will not be turned on inadvertently while you are cleaning it. Risk of death! Disconnect the defibrillation pads before cleaning the device.

Risk of shock, equipment damage — Liquids must not enter the device. If a liquid has penetrated the device, it must not be reused until it has been checked by a service technician.

i	<b>Equipment damage!</b> Do not clean the surface of the device with phenol-based disinfectants or peroxide compounds.	
Device casing	→ Wipe the device with dampened cloth; make sure no liquid enters the device. All cleaning or disinfection products commonly used in hospitals and containing al-cohol (maximum 70 %) are appropriate. If liquids enter the device, it can only be re-operated after it has been checked by the technical support department.	
Cables, electrodes	→ Discard the disposable electrodes immediately after use to prevent their reuse (hospital waste).	

## 7.3 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 easy**<sup>®</sup>. A full list of all SCHILLER representatives can be found on the SCHIL-LER website (<u>www.schiller.ch</u>). In case of difficulty, contact our head office in Switzerland. Our staff will be pleased to help process your order or to provide details for all SCHILLER products.

## 7.4 Disposal information

#### 7.4.1 Battery Disposal

### A 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 SCHILLER AG.

#### 7.4.2 Disposal of accessories that come into contact with the patient



Disposable articles (e.g. pads, etc.) must be disposed of as hospital waste.

#### 7.4.3 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.



Art. no.: 0-48-0013 Rev. m

## 7.5 Trouble Shooting



- If it is not possible to get the device back into operating condition within a reasonable period of time, continue cardiopulmonary resuscitation until the rescue service arrives.
- If the device switches to Limited mode (CPR) due to an error, the alarm messages may differ.

#### Forced shutdown procedure

• If the device cannot be switched off via normal OFF procedure (press and hold the green button for approx. 3 seconds), remove the battery and inserting again.

#### 7.5.1 Error messages

•

Error message	Possible cause	Remedy
TEST FAILURE XXX	<ul> <li>Technical errors that may occur during function tests:</li> </ul>	Switch the unit off and then on again to con- firm. If the message still appears, the device must be repaired immediately.
<ul> <li>ADC</li> <li>EEPROM</li> <li>RTC</li> <li>LCD</li> <li>OKI</li> <li>DSP</li> <li>SHOCK BUTTON</li> <li>CHARGE DEFIBRILLATOR</li> <li>COMMUNICATION DEFIBRILLATOR</li> <li>5 WEEKS CHARGE 150J</li> </ul>		
Error INFO: XXX	<ul> <li>Technical problems that can oc- cur during defibrillation</li> </ul>	Switch the unit off and then on again to con- firm. If the message still appears, the device must be repaired immediately. Continue cardiopulmonary resuscitation until the res- cue service arrives.
<ul> <li>XXX =</li> <li>CPU DEFI</li> <li>CRC DEFI</li> <li>SAFETY DEFI</li> <li>REF VOLTAGE DEFI</li> <li>ADC DEFI</li> <li>DEFI DISCHARGE</li> <li>DEFI EPROM</li> <li>DEFI SHOCK KEY</li> </ul>		

7.5 Trouble Shooting

SCHILLER FRED easy

Error message	Possible cause	Remedy
Error INFO: FREDEASY ONLINE Error	<ul> <li>Technical problem         <ul> <li>The device has detected an error after having been placed in the docking station.</li> </ul> </li> </ul>	
Error TIME AND DATE RESET TO 01/01/98 >REINSERT BATTERY	Wrong date	Turn device off and reconfigure. (see page 60)
REPLACE BATTERY 30 COMPRESSIONS THEN 2 BREATHS	Battery depleted during use	→ Turn device off and insert a new battery (see page 26).
EMPTY BATTERY >REPLACE BATTERY	Battery depleted	Turn device off and insert a new battery.
CONFIGURATION LOST RESTORE DEFAULT CONF >REINSERT BATTERY	Battery problem	→ Turn device off and insert a new battery.
CRITICAL ERROR PLEASE SWITCH OFF	Technical problem	→ Switch the unit off and then on again to con- firm. If the message still appears, the device must be repaired.
MANUEL MODE FORBBIDEN AT START, RELEASE SHOCK BUTTON	<ul> <li>The device was switching on while the orange  and green button  have been pressed.</li> </ul>	
-!!LIMITED MODE!!-	<ul> <li>The device has detected a charge transistor error</li> </ul>	→ Switch the unit off and then on again to con- firm. If the message still appears, the device must be repaired.

#### 7.5.2 Transmission error Ethernet/Online FRED easy®

If the connection to the network fails, an error message is issued. Potential error messages include the following:

Error message	Cause	Remedy
TRANSMISSION FAILURE ERROR CODE : 001 SD CARD READING	Error reading SD card	Disconnect and reconnect the device to confirm. If the message still appears, the de- vice must be repaired.
TRANSMISSION FAILURE ERROR CODE : 002 NOT ENOUGH MEMORY	<ul> <li>Technical problem</li> </ul>	Disconnect and reconnect the device to confirm. If the message still appears, the de- vice must be repaired.
TRANSMISSION FAILURE ERROR CODE : 003 NETWORK CONFIGURATION	<ul> <li>Incorrect network IP configura- tion or DHCP server not availa- ble</li> </ul>	
TRANSMISSION FAILURE ERROR CODE : 004 ADAPTER DISCONNECTED	<ul> <li>Ethernet adapter not inserted in the Ethernet interface case</li> </ul>	Turn device off and connect the Ethernet adapter; if the message is still displayed, re- place the Ethernet adapter. If the message still appears, the device must be repaired.
TRANSMISSION FAILURE ERROR CODE : 005 PATIENT DETECTED	<ul> <li>The pads are connected to the device and are placed to the pa tient</li> </ul>	
TRANSMISSION FAILURE ERROR CODE : 006 BATTERY LEVEL	<ul> <li>Battery is empty</li> </ul>	<ul> <li>Insert a new battery.</li> </ul>
TRANSMISSION FAILURE ERROR CODE : 007 TIME OUT INACTIVITY	<ul> <li>Device not used for more than 3 minutes</li> </ul>	Disconnect and reconnect the device to confirm. If the message still appears, the de- vice must be repaired.
TRANSMISSION FAILURE ERROR CODE : 008 SESSION OPENING	<ul> <li>The device is not able to con- nect to the server</li> </ul>	Check the connection to the server and the network configuration, then restart data transmission; if the message is still dis- played, the device must be repaired.

#### 7.5 Trouble Shooting

SCHILLER FRED easy

Error message	Cause	Remedy
TRANSMISSION FAILURE ERROR CODE : 009 SESSION OPENING	The device is not able to con- nect to the server	Check the connection to the server, the net- work configuration and check that the device is added in the "Device Manager" of LifeDa- taNet®; if the message is still displayed, the device must be repaired.
TRANSMISSION FAILURE ERROR CODE : 010 SESSION OPENING	The device is not able to con- nect to the server	Check the connection to the server and the network configuration, then restart data transmission; if the message is still dis- played, the device must be repaired.
TRANSMISSION FAILURE ERROR CODE : 011 SESSION CLOSING	The device is not able to con- nect to the server	Check the connection to the server and the network configuration, then restart data transmission; if the message is still dis- played, the device must be repaired.
TRANSMISSION FAILURE ERROR CODE : 012 SESSION CLOSING	The device is not able to con- nect to the server	Check the connection to the server, the net- work configuration and check that the device is added in the "Device Manager" of LifeDa- taNet®; if the message is still displayed, the device must be repaired.
TRANSMISSION FAILURE ERROR CODE : 013 DATA TRANSMISSION	Erroneous data transmission	Check the connection to the server and the network configuration, then restart data transmission; if the message is still dis- played, the device must be repaired.
TRANSMISSION FAILURE ERROR CODE : 014 DATA TRANSMISSION	<ul> <li>Erroneous data transmission</li> </ul>	Check the connection to the server, the net- work configuration, and the LifeDataNet® configuration, then restart data transmis- sion; if the message is still displayed, the de- vice must be repaired.
TRANSMISSION FAILURE ERROR CODE : 015 DATA TRANSMISSION	<ul> <li>Erroneous data transmission</li> </ul>	Check the connection to the server, the net- work configuration, and the LifeDataNet® configuration, then restart data transmis- sion; if the message is still displayed, the de- vice must be repaired.
TRANSMISSION FAILURE ERROR CODE : 017 DATA ERASING	<ul> <li>Erroneous erasing of the SD card</li> </ul>	Disconnect and reconnect the device to con- firm. If the message still appears, the device must be repaired.



User Guide

i

Error message	Cause	Remedy
TRANSMISSION FAILURE ERROR CODE : 021 SUPERVISION START REQ	<ul> <li>The device is not able to con- nect to the server</li> </ul>	Check the connection to the server, the net- work configuration, and the LifeDataNet® configuration, then restart data transmis- sion; if the message is still displayed, the de- vice must be repaired.
TRANSMISSION FAILURE ERROR CODE : 022 SUPERVISION START ACK	<ul> <li>The device is not able to con- nect to the server</li> </ul>	Check the connection to the server, the net- work configuration, and the LifeDataNet® configuration, then restart data transmis- sion; if the message is still displayed, the de- vice must be repaired.
TRANSMISSION FAILURE ERROR CODE : 023 SUPERVISION STOP REQ	<ul> <li>The device is not able to con- nect to the server</li> </ul>	Check the connection to the server, the net- work configuration, and the LifeDataNet® configuration, then restart data transmis- sion; if the message is still displayed, the de- vice must be repaired.
TRANSMISSION FAILURE ERROR CODE : 024 SUPERVISION STOP ACK	The device is not able to con- nect to the server	Check the connection to the server, the net- work configuration, and the LifeDataNet® configuration, then restart data transmis- sion; if the message is still displayed, the de- vice must be repaired.

- These errors are not applicable for the **FRED easy®** SD Card version.
  - Error 004 (ADAPTER DISCONNECTED) only applies to the **FRED easy**® Ethernet version.
  - Errors 023 and 024 (SUPERVISION STOP REQ and SUPERVISION STOP ACK) only apply to the FRED easy® Online version.

#### 7.5.3 Trouble Shooting

# i

#### Forced shutdown procedure

If the device cannot be switched off via normal OFF procedure (press and hold the green button for approx. 3 seconds), remove the battery and inserting again.

Problem	Possible causes	Remedy
The green "OK" standby indi-	<b>,</b>	→ Replace the battery.
cator does not blink and/or the device cannot be turned	<ul> <li>No battery inserted, or battery not correctly inserted.</li> </ul>	→ Insert the battery correctly.
on.	Device defective.	→ Have the device repaired.
electrode connector does not	• The pads are past their expiration date.	→ Use new electrodes.
go out.	<ul> <li>Dry contact agent.</li> </ul>	→ Use new electrodes.
	<ul> <li>High contact impedance between the pads and the skin.</li> </ul>	→ Apply the pads exactly as described. Shave the electrode application area.
	Device defective.	→ Have the device repaired.
The device prompts the user		→ Apply the pads exactly as described.
to check that the electrodes	<ul> <li>Poor pad contact.</li> </ul>	→ Firmly press down on the pads.
are properly applied and con- nected.	• The pads are past their expiration date.	→ Use new electrodes.
	<ul> <li>Dry contact agent.</li> </ul>	→ Use new electrodes.
	Device defective.	→ Have the device repaired.
The device cannot be turned off.	On/Off button was pressed less than 3 seconds.	→ Hold down the on/off button for at least 3 seconds.
	Software hangs	→ Remove battery and inserting again
	Device defective.	→ Have the device repaired.
Incorrect analysis result (e.g.	0 1 3	→ Repeat chest compressions.
the device does not detect a shockable rhythm, even though the patient exhibits	<ul> <li>Electromagnetic waves disturb the ECG signal.</li> </ul>	→ Turn off the source of interference (e.g. radio transmitter, cellular telephone). Position the patient outside the range of interference.
ventricular fibrillation).	<ul> <li>Patient moved during analysis.</li> </ul>	→ Do not move patient during the analysis.
	<ul> <li>Device defective.</li> </ul>	→ Have the device repaired.
Defibrillation shock cannot be	, ,	→ Replace the battery.
delivered.	CPR caused a pad error.	→ Re-apply the pads.
	<ul><li>Cardiac rhythm has changed.</li><li>Device defective.</li></ul>	→ Repeat the analysis.
		→ Have the device repaired.
The alarm tone does not	Battery defect.	→ Replace the battery.
stop.	Device defective.	→ Have the device repaired.
Message "ERROR xxx".	Device defective.	→ Have the device repaired.
Battery capacity indicator blinks.	Battery almost depleted.	→ Replace the battery.
No data recorded on the SD	Card defect.	→ Replace the card.
card.	Device defective.	→ Have the device repaired.



Problem	Possible causes	Remedy
The SD card symbol $\prod_{III}$ is no	• No SD card is inserted.	→ Switch the device off and insert the card the right way around.
displayed, or the symbol C is displayed.	• The card is inserted the wrong way.	→ Switch the device off and insert the card the right way around.
	• The card was inserted with the device turned on.	→ Switch the device off and then on again.
	• SD card write-protected.	→ Turn off the device, remove the SD card, unlock the write protection, and re-insert the card. Then, restart the device.
	Device defective.	→ Have the device repaired.
Incorrect date and time stored on SD card.	• Internal clock error.	→ Have the system parameters updated by an authorised person using the configuration/downloading kit.
	Device defective.	→ Have the device repaired.



i

ĭ

i

#### 7.5.4 Measures to prevent electromagnetic interferences

The user can help avoid electromagnetic disturbances by keeping the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the **FRED easy®**. The distance depends on the output performance of the communication device as indicated below.

HF source	Transmitter fre- quency [MHz]	Power P [W]	Distance d [m]
Radio telephone (microcellular) CT1+, CT2, CT3	885-887	0.010	0.23
Cordless DECT telephone, WLAN, UMTS phone	1880-2500	0.25	1.17
Mobile phone USA	850/1900	0.6	1.8
Mobile phone - GSM900, - GSM850, NMT900, DCS 1800	900 850,900,1800	2 1	3.3 2.3
Walkie-talkie (rescue service, police, fire bri- gade, service)	81-470	5	2.6
Mobile telephone system (rescue service, po- lice, fire brigade)	81-470	100	11.7

It can be deducted from the table that **portable** HF telecommunication devices must not be used within a radius of 3 m from the **FRED easy®** and its cables.

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.

For more detailed information, please refer to page 85.

If the devices are used in the vicinity of power networks operating at a frequency of 16.7 Hz (railway systems in some countries), the 16.7 Hz filter must be activated via the configuration software before use. The filter is by default activated.

CHILLER

**FRED** easy

ĭ

# 8 Technical Data

Unless otherwise stated, all specifications are valid at a temperature of 25 °C.

System Specifications 8.1 Manufactured by SCHILLER MEDICAL **Device name** FRED easy® Dimensions 70 x 230 x 220 mm (h x l x w) SD card version 70 x 237 x 220 mm (h x l x w) Ethernet/Online Versions Weight Approx. 1.5 kg Protection class of the device IP54 (protection against dust and splashing water) housing **Recorded data** ECG signal recording (2 hours) Ambient noise recording (2 hours) Event recording (500 events) Internal power supply, suitable for continuous operation with intermittent loading Power supply Lithium/MnO<sub>2</sub> 12 V, 2.8 Ah Standard battery type Battery life 180 shocks at maximum energy, or 3.75 hours of operating (alternately 30 minutes ON and 30 minutes OFF) Several years in standby (standby duration corresponding to laboratory tests at 25°C: 5 years with weekly self-tests) **Optional battery type** NiCd 12 V, 650 mAh, rechargeable Battery life 45 shocks at maximum energy, or operating for 1 h 20 min. Environmental conditions<sup>a</sup> Device -5...40 °C at a relative humidity of 30 to 95% (no condensation) Operation -5...40 °C with the battery inserted and incl. electrodes at a relative humidity of 30 Storage befor use to 95 % (no condensation) but resulting in a reduced battery life; optimal conditions: 15...25 °C to ensure maximum battery life. Atmospheric pressure 700 to 1060 hPa -20 ... 50 °C at a relative humidity of 0 to 95% (no condensation) Storage and transport Atmospheric pressure 500 to 1060 hPa **Battery and Electrodes** Storage and Transport temper- 0 ... 60 °C (48h max. between 0...15 °C and 25°...60°C) ature battery LiMnO<sub>2</sub> Storage and transport temper-• 0 ... 50 °C ature electrode pads

a. For additional information about operating and storage conditions see page 67 Chapter 6.5 Special operating conditions.

no.: 0-48-0013 Rev. m

Αr.

ĭ

Display

Туре

Dimensions

SCHILLER FRED easy

**Classification and safety standards** 8.2 Standards FRED easy® complies with IEC standard 60601-2-4. According to IEC standard 60601-2-4, FRED easy® is a device for frequent use. EMC See 8 Technical Data. Compliance FRED easy® bears the ( 6 0459 (Notified Body LNE/G-MED) mark indicating its ٠ compliance with the provisions of the Directive 93/42/EEC (modified by the Directive 2007/47/EEC) regarding medical devices and fulfils the essential requirements of Annex I of this directive. FRED easy® is a class IIb device. **Patient Protection** BF type, resistant to defibrillation shocks. **Explosions protection** FRED easy® is not designed to be used in the presence of flammable mixtures of anaesthetic agents with air or oxygen.

100 x 37 mm

The SCHILLER quality management system complies in full with the international standards ISO 9001 and ISO 13485.

High-resolution LCD screen, electroluminescent backlighting, text and symbol display



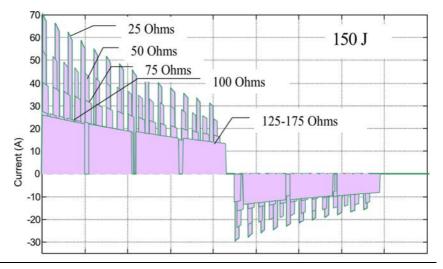
## 8.3 Defibrillation pulse

Form

SCHILLER

**FRED** easy

- Biphasic pulsed defibrillation pulse with approximately constant phases for optimal physiological compatibility.
- Maintains the energy delivered to the patient at an approximately constant level with regard to patient resistance by applying pulse-pause modulation that varies according to measured patient resistance.



#### Accuracy at 50 $\Omega$ : ± 3 J or ± 15 % (the higher value is assumed)

SCHILLER's customer service department can change the default energy levels to the following values:

1 - 2 - 4 - 6 - 8 - 15 - 30 - 50 - 70 - 90 - 110 - 130 - 150 J (adults) 1 - 2 - 4 - 6 - 8 - 15 - 30 - 50 - 70 J (children)(automatic adaptation when paediatric pads are connected)

(Maximum time between start of the analysis and shock availability, in semi-automatic mode)

< 11 seconds

After 15 discharges with max.

Cycle time: switch-on of the device – shock availability (in semi-automatic mode)

Cycle time: rhythm analysis -

shock availability (in semi-auto-

With full battery:

Patient impedance at which shock delivery is possible

**Default energy settings** 

matic mode)

energy:

Indication when ready to shock

< 11 second

< 11 seconds

(Maximum time between the switch-on of the device and the shock availability, in semi-automatic mode)

< 22 seconds

30 to 250  $\Omega$  (Impedance is compensated up to 175  $\Omega)$ 

The orange button 😽 is lit

8.3 Defibrillation pulse



2

1395

Specificity > 95 %

99.86 %

Shock delivery	With the orange button      (in semi-auton	natic or manual m	ode)	
	<ul> <li>Via disposable pads applied to the patien or-posterior position</li> </ul>	it in an anterior-an	nterolateral or anteri-	
Safety discharge when:	<ul> <li>A non shockable rhythm has been detected</li> <li>The shock is not delivered within the 20 seconds after charging</li> <li>An electrode problem is detected</li> <li>Battery voltage is insufficient</li> <li>The device is defective</li> <li>The device is turned off.</li> </ul>			
Defibrillation pad connection	BF type			
Defibrillation electrodes	Electrode cable, 2 m in length			
Adult pads Paediatric pad	<ul> <li>80 cm<sup>2</sup> active surface</li> <li>42 cm<sup>2</sup> active surface</li> </ul>			
VF/VT detection	VF/VT detection is based only on the ECG signal.			
Conditions for ECG analysis	Minimum amplitude for signals suitable for analysis > 0.15 mV, signals < 0.15 mV are considered asystole.			
Shock recommendation	For VF and VT (VT > 150 B/min).			
	VF	VT	Non shockable rhythms NSR/N/Asystole	

148

2

Sensitivity > 90 %

98.67 %

100

2

Sensitivity > 75 %

98.04 %

Shock

No Shock

Performance criteria

Observed performance



## 8.4 Electromagnetic interferences

The **FRED easy®** is intended to be used in the electromagnetic environments listed in the following tables. The owner or user of the **FRED easy®** has to ensure that the device is operated in an adequate environment.

#### 8.4.1 Electromagnetic emissions

Emission measurement	Compliance with the regula- tions	Electromagnetic environment - explanations
HF emissions CISPR 11	Group 1	<b>FRED easy</b> ® only uses HF energy for internal functions. Therefore, HF emissions are very low and interferences with electronic devices nearby are unlikely.
HF emissions CISPR 11		FRED easy® is suitable for use in all establishments, including do-
Harmonics IEC 61000-3-2		mestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for
Voltage fluctuations IEC 61000-3-3	Not applicable	domestic purposes.

#### 8.4.2 Electromagnetic immunity

Interference testing	IEC 60601 test level	Conformity level	Electromagnetic environment - explanations
Electrostatic dis- charge IEC 61000-4-2	± 6 kV contact ± 8 kV air	IEC 60601-1 conformity	Floors should be made of wood, concrete or ceramic tiles. If floors are covered with synthetic material, relative humidity should be at least 30%.
Electrical fast tran- sient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable	
Surge IEC 61000-4-5	± 1 kV between conductors ± 2 kV conductor-earth	Not applicable	
terruptions and volt- age variations on power supply input	40 % $U_{T}$ (60 % dip in $U_{T}$ ) for 5 cy-		
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	3 A/m	IEC 60601-1 conformity	Power frequency magnetic fields should be that of a typical com- mercial and/or hospital environment.
Note: U <sub>T</sub> indicates the AC voltage of the mains before the test level.			

#### 8.4 Electromagnetic interferences

Interference testing	IEC 60601 test level	Conformity level	Electromagnetic environment - explanations
			<b>Recommended minimum distances</b> Portable and mobile HF telecommunication devices must keep the recommended minimum distance from the <b>FRED easy®</b> and all its components, incl. cables; the recom- mended minimum distance is calculated based on the trans- mitter's frequency.
Conducted HF IEC 61000-4-6	3 Veff between 150 kHz and 80 MHz outside of the ISM fre- quency bands <sup>a</sup>	Not applicable	
	10 Veff between 150 kHz and 80 MHz in ISM frequency bands <sup>a</sup>	Not applicable	
Radiated HF IEC 61000-4-3	10 V/m Batterie 80 MHz to 2.5 GHz	10 V/m	

 Note 1
 For 80 MHz to 800 MHz, the higher frequency range applies.

 Note 2
 These guidelines might not always be applicable. Electromagnetic radiation is influenced by absorption and reflection on structures, objects and people.

- a. The ISM frequency bands (ISM = industrial, scientific, medical) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
- b. The conformity levels within the ISM frequency bands between 150 kHz and 80 MHz and between 80 MHz and 2.5 GHz serve to minimise the probability of interferences caused by mobile/portable communication equipment that accidentally happens to be in the patient environment. The formula for the calculation of the recommended distance has been adapted by the factor 10/3 for transmitters in this frequency range.
- c. The field strength of stationary transmitters, e.g. base stations for radio telephones (mobile or cordless) and portable radio equipment, amateur radios, AM and FM radios and TV signals cannot be predicted accurately in a theoretical way. In order to analyse electromagnetic environments caused by stationary HF transmitters, an electromagnetic analysis on site should be considered. If the measured field strength exceeds the HF conformity level, it needs to be checked whether the **FRED easy®** can be used in this environment. If an abnormal behaviour is detected, additional measures need to be taken, e.g. reorientation or change of location of the **FRED easy®**.
- d. For the frequency range between 150 kHz and 80 MHz, the field strength must be lower than 3 V/m.

HILLER

FRED easy

SCHILLER

**FRED** easy

#### 8.4.3 Recommended minimum distances

The **FRED easy®** is intended to be used in electromagnetic environments in which it is possible to control radiated HF interferences. The user of the **FRED easy®** can prevent electromagnetic interferences by always keeping a minimum distance between portable/mobile HF communication devices (transmitters) and the **FRED easy®**. The recommended minimum distances are listed in the following table according to the transmitters' max. transmitting power.

	Distances according to the	ne transmitter's freque	ency (m)	
Max. transmitting power of the transmitter (W)		$d = \frac{12}{10} \times \sqrt{P}$ between 150 kHz and 80 MHz within the ISM frequency band	$d = \frac{12}{10} \times \sqrt{P}$ between 80 MHz and 800 MHz	$d = \frac{23}{10} \times \sqrt{P}$ between 800 MHz and 2.5 GHz
0,01			0,12	0,23
0,1			0,38	0,73
1	Net surlissing	Natauslisable	1,2	2,3
10	Not applicable	Not applicable	3,79	7,27
100			12	23

For transmitters with a max. transmitting power that is not listed in the above table, the recommended minimum distance d in metres (m) can be calculated using a formula based on the transmitter's frequency, where P is the max. transmitting power of the transmitter in Watts (W) (according to manufacturer data).

Note 1 These guidelines might not always be applicable. Electromagnetic radiation is influenced by absorption and reflection on structures, objects and people.

Note 2 To calculate the recommended minimum distance of transmitters in the ISM frequency bands between 150 kHz and 80M Hz and in the frequency band between 80 MHz and 2.5 GHz, the additional factor 10/3 is used to minimise the probability of interferences caused by mobile/portable communication equipment that accidentally happens to be in the patient environment.

# 9 Appendix

### 9.1 Order Information

Devices

Accessories
-------------

Part No.	Description
1-58-9913	FRED easy® SD Card, semi-automatic
1-58-9100	FRED easy® SD Card, automatic
1-58-9301	FRED easy® Ethernet/Online, semi-automatic
1-58-9401	FRED easy® Ethernet/Online, automatic
EASY T2	FRED easy® TRAINER

Part No.	Description
1-58-5303	Ethernet adapter
0-80-0013	Accessory bag for Online version
5-30-0003	Ethernet cable (3 m, category 5)
4-33-0002	Ferrite core
0-05-0026	Ethernet cable (3 m, with ferrite core)
EASY ELEC	1 pair of disposable adhesive defibrillation pads for adults, 80 cm <sup>2</sup>
0-21-0000	1 pair of disposable adhesive defibrillation pads for children, 42 cm <sup>2</sup>
0-21-0020	1 pair of disposable adhesive defibrillation pads for adults, 80 cm <sup>2</sup> , "pre-connected"
0-21-0021	1 pair of disposable adhesive defibrillation pads for children, 42 cm <sup>2</sup> , "pre-connected"
0-48-0013	User Guide, English
EASY BAT	Disposable lithium battery
0-02-0003	Rechargeable NiCd battery
3-55-0030	Battery charger, 100 – 240 V, 50 – 60 Hz, UE
3-55-0033	Battery charger, 100 – 240 V, 50 – 60 Hz, UK
3-55-0034	Battery charger, 100 – 240 V, 50 – 60 Hz, US
EASY S	Instrument bag
0-80-0008	Instrument bag, reinforced
EASY CARD	Formatted SD card
5-35-0037	Formatted SD card (for <b>FRED easy</b> ® with software version ≥ 06.00)

# 9.2 Required accessories

- User Guide
- One pair of adhesive pads
- 1 lithium batteries
- One SD card (only for the SD Card version)

SCHILLER

FRED easy

### 9.3 Literature

European Resuscitation Council (2010)	European Resuscitation Council Guidelines for Resuscitation 2010 (doi:10.1016/j.re-suscitation.2010.08.021).
American Heart Association (2010)	International Consensus on Cardiopulmonary Resuscitation and Emergency Cardi- ovascular Care Science With Treatment Recommendations (DOI: 10.1161/CIRCU- LATIONAHA.110.971010).
Cansell A.	Effectiveness and Safety of New Transthoracic Cardiac Defibrillation Waveforms – Bi- phasic Pulses In "La Revue des SAMU 20": 280 - 294. 2000.

## 9.4 Glossary

ABCD The primary ABCD

- A = Airways (check if airways are free)
- B = Breathing (artificial respiration)
- C = Circulation (circulatory signs or cardiac massage)
- D = Defibrillation
- AED Automated external defibrillator. This term is also used for semi-automatic defibrillators
- **BLS** Basic Life Support (artificial respiration and cardiac massage) CPR is frequently used synonymously
- **CPR** Cardiopulmonary resuscitation
  - VT Ventricular tachycardia
  - VF Ventricular fibrillation

# 9.5 Inspection report

The user guide must be read before the inspection.

Serial number:

i

Checks - before each use					
→ Visual inspection of the device and accessories		1			
→ Device casing undamaged?					
→ Cables not twisted, without wear signs due to friction or deteriorati	on?				
→ No excessive clogging or damage?					
→ All the signal inputs in perfect condition?					
→ Legible nameplate at the rear of the device?					
→ Legible inscriptions on the front face of th device?					
→ Expiration date of the accessories elapsed?					
Da	ate:				
Performed	by:				
Checks - once a Week/once a Month					
Visual inspection of the device and accessories					
(see previous table)					
The green indicator	ate:				
Performed	by:				
Checks - every 3 years					
Visual inspection of the device and accessories					
(see previous table) Functional test					
→ Check for proper functioning.	_	_	_	_	_
<ul> <li>→ Measure the leakage current.</li> </ul>					
<ul> <li>→ Measure the energy delivered at 50 ohms.</li> </ul>					
	ate:				
Performed	by:				
Replacement - every 6 years					
Internal backup battery replacement.					
Da	ate:				
Performed					

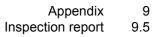
In case of problems, please notify your Biomedical Department  $\Box$ , your local SCHILLER distributor  $\Box$ , or the authorized Customer Service for your area  $\Box$ :

Name: .....

Tel.: .....

**SCHILLER** 

FRED easy



# 10 Index

#### **Numerics**

16.7 Hz filter 17	7
-------------------	---

#### Α

Accessories	53, 88
AED	13, 27
Appendix	
Glossary	89
Inspection Report	90
Literature	89
Order information	88
Required accessories	88

#### В

-	
Battery	
Battery Disposal	72
Battery is empty	26
Inserting the battery	22
Low battery	25
Sufficient battery capacity	24
Biocompatibility	13

### С

•	
Cleaning 7	71
Configurable parameters	
16.7 Hz filter 1	7
Energy levels 1	7
Connection error7	'5
Controls and indicators	
-Display 2	21
Ethernet interface case 2	20
Green button 2	
Green indicator 2	20
Orange button 2	20
Port for adhesive pads 2	20
SD card slot 2	20
SD card version 2	20
Yellow indicator 2	20

#### D

-
Danger of electric shock!7
Danger of explosion7, 22
Defibrillation
Automatic defibrillation 40
Biphasic pulsed defibrillation impulse 14
Cardiopulmonary resuscitation
Defibrillation procedure
Defibrillator application guidelines 27
Finishing the therapy 47
Internal safety discharge 47
Manual defibrillation
Switching to semi-automatic
operational mode46
Safety notes for AED use
Semi-automatic Defibrillation
Shockable condition
Ventricular fibrillation
Ventricular tachycardia

Design Disinfection	
Display Symbols/Indicators	
in this User Guide	10
on the display	11
on the electrode packaging	12
used on the battery	11
used on the device	10
Disposal information	
Accessories into contact with patien	ts72
At the end of useful life	72
Battery	72

#### Ε

ECG	62
Electrodes	
Adult and paediatric electrodes	36
Applying the pads	35
Checking the electrodes	37
Insert connector into device	35
Open the electrode packaging	35
Pre-connected pads	35
Electromagnetic interferences	81
Events stored on the memory card	48

### F

FRED easy® Ethernet	
"Network" tab configuration	50
"Online" tab configuration	60
Connecting the Ethernet Adapter	50
Data transmission	51
Dynamic IP addressing	58
Ethernet interface case	20
Ferrite core	50
Installing the ferrite core	53
MAC address	58
Operating principle	50
Read Community configuration	60
Static IP addressing	58
FRED easy® Online	
Ethernet interface case	20
Inserting in the Docking station	56
Maintenance mode	57
Operating principle	54
SNMP protocol	54
FRED easy® SD Card	
Controls and indicators	20
Inserting the Memory Card	49
Operating principle	
FREDCO®	17, 50
Function	16

### L

LifeDataNet®	5	54
--------------	---	----

#### Μ

Maintenance	
Green indicator	70
Internal backup battery	70

Maintenance Intervals	69
Test	70
Visual inspection	69
Memory card	14, 48
Metronome	62
Motion detection	31

### R

Rechargeable NiCd battery63
-----------------------------

#### S

Safety Notes	5
Self-test	

#### Т

-	
Technical Data	
Defibrillation impulse	83
Dimensions	81
Energy levels	83
Environmental conditions	81
Patient impedance	83
Patient Protection	
Power supply	81
Protection class	81
Standards	
Weight	81
Terms of Warranty	9
Trouble Shooting	73