

Instructions for use

MEDeHelp

Clinical decision support

for drug therapy

in emergency situations

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1 General information

The instructions for use contain detailed information on how to use the MEDeHelp smartphone application.

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3 Copyright

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4 Use specification

4.1 Intended use

The smartphone application MEDeHelp is intended to support healthcare professionals in emergency situations by providing patient-specific dosage, preparation and administration information for all age groups. Further information in emergency situations, for example physiological norm values, equipment specifications and treatment guidelines, are also provided.

MEDeHelp requires data which are maintained in the PEDeDose database. Patient-specific data such as dosage, preparation and administration information in MEDeHelp are provided by the PEDeDose medical device via web service. The application MEDeHelp is not intended to make calculations with this data but allows a simple and fast selection of the patient-specific drug information.

The final decision on the medication remains with the attending healthcare professional.

4.2 Indication

MEDeHelp enables a quick selection of dosage, preparation and administration information by body weight, age or height for drugs typically used in emergency situations for indications such as (but not limited to) resuscitation, anaphylactic shock, asthma, seizures etc. along with the display of for example physiological norm values, equipment specifications and treatment guidelines.

4.3 Patient target group

MEDeHelp can be used for paediatric patients such as newborns (term and premature babies), infants, toddlers, children, adolescents and adults.

4.4 Intended users

MEDeHelp is intended exclusively for use by healthcare professionals (e.g. physicians, paramedics, nurses, pharmacists).

4.5 Use environment

MEDeHelp is intended to be used in different environments with different light, noise, vibration and stress conditions: e.g. in the shock room of a hospital, on the way in an ambulance or helicopter or outside at the site of an emergency as well as in an office setting at the hospital, for example.

4.6 Technical description

MEDeHelp is a smartphone application that runs on iOS and Android operating systems and can be used both online and offline. The data content is updated via the internet. The use is guaranteed by a one-time registration of the user.

All calculated dosages and preparation information come from the medical device PEDeDose (class IIa) from PEDeus and are generated using algorithms. The data content is maintained by PEDeus using a specific content management system and the PEDeDose interface.

5 Language

MEDeHelp is available in German, French and English.

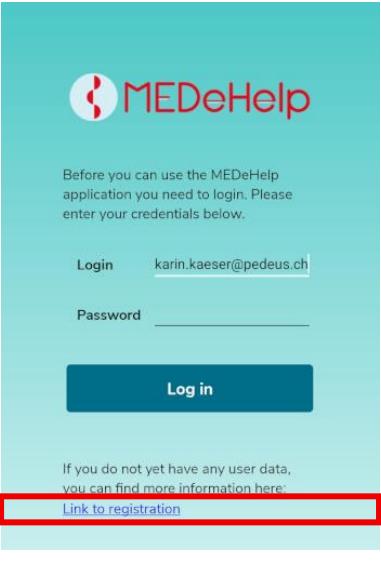
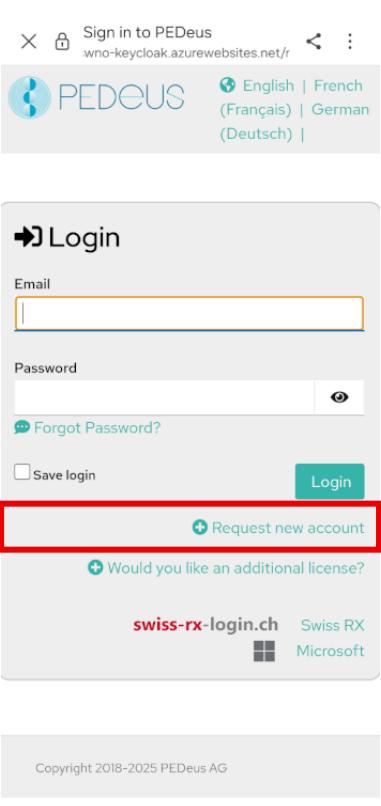
The application uses the language setting of the smartphone. If MEDeHelp does not support the selected language setting of the smartphone, MEDeHelp is automatically displayed in English.

The language can be selected by the user under the smartphone settings in the "General settings". In order for the data content to be displayed in the newly selected language, MEDeHelp must be closed and reopened on Android smartphones after the language change.

6 System requirements

6.1 Registration

MEDeHelp can only be used by registered users. This requires a PEDEUS login with user name and password and a current MEDeHelp licence.

 <p>The online registration page can be accessed via the "Link to registration" on the login page.</p>	
 <p>Under "Request new account" the user can register with PEDEUS by following the instructions in the online form.</p>	

6.2 Smartphones

MEDeHelp is supported by smartphones (64-bit) with iOS and Android operating systems. MEDeHelp runs on the current and previous versions of the iOS and Android operating systems. A free memory space of ≥ 250 MB should be available.

6.2.1 Performance

Various factors can influence or impair the performance of MEDeHelp, including the age and model of the smartphone, a low memory capacity, applications running in the background, a low battery level, an active energy-saving mode, strong heating/cooling of the smartphone or an old version of the operating system.

6.3 Installation

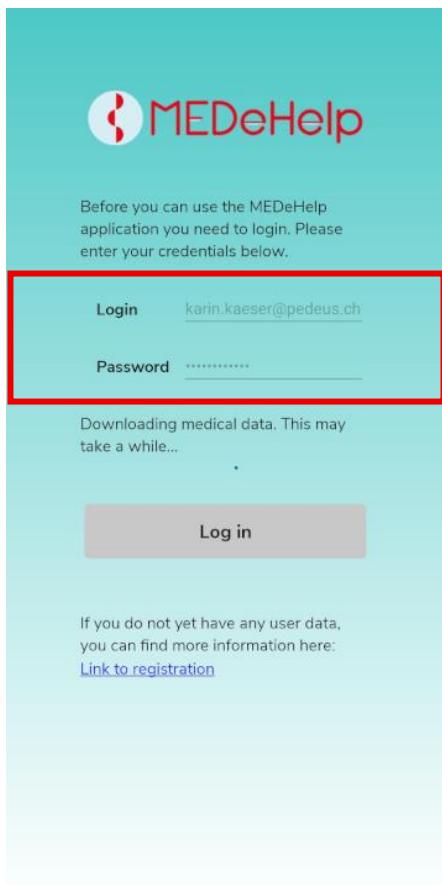
MEDeHelp can be downloaded and updated from the Google Play Store or the Apple App Store.

7 Use of MEDeHelp

7.1 Login

To use MEDeHelp, you need to log in first with your user name (email address) and password (see chapter 6.1.). After that, it is usually no longer necessary to log in.

When logging in, the smartphone must be connected to the internet.



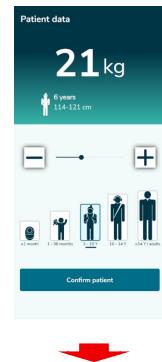
A forgotten password can be reset via "Link to registration".

7.2 Overview

You can access MEDeHelp by selecting the patient data. After confirming the patient data, you can navigate to the Emergency page (1). The navigation at the bottom of the screen takes the user to two further main pages with patient-specific information: the Medicines page (2) and the Guidelines page (3).



The fourth main page contains the settings.



1. Emergency page

- up to 10 emergency indications with patient-specific dosage and preparation information
- patient-specific reference values
- patient-specific defibrillator / equipment information



2. Medicines page

- patient-specific, alphabetical list of medications with dosage information; can be filtered by
 - product favourites
 - type of administration
 - indication



3. Guidelines page

- patient-specific emergency schemes (PDF documents or web links)
 - organisation filter
 - age filter
 - indication filter

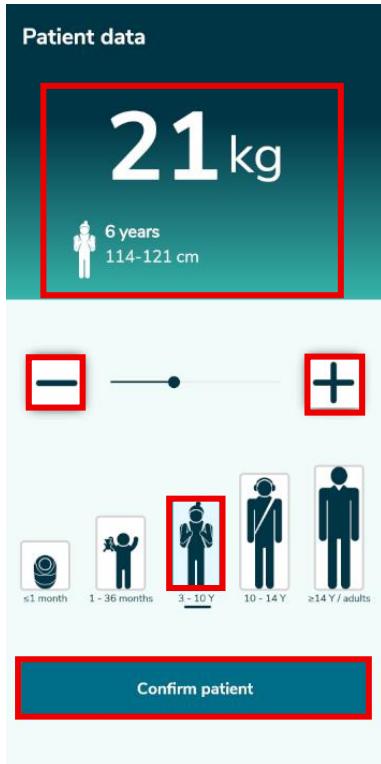


4. Settings

The "Settings" page allows users to set their favourites for products and organisations (publishers of guidelines), install data packages and view various information about MEDeHelp.

7.3 Patient data

7.3.1 Entering patient data



The (estimated) body weight of a patient can be set by clicking on the corresponding age group and making further adjustments using the "+" and "-" symbols.

- By clicking on one of the 5 age groups, the average value of the corresponding age group is displayed.
- The body weight can also be estimated using the corresponding age or body height^{1,2}.

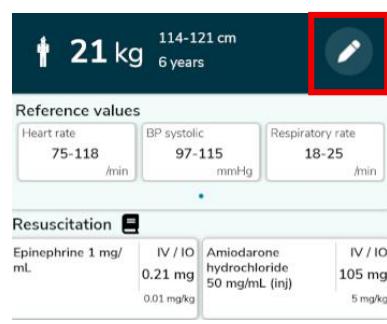
Click on "Confirm patient" to adopt the weight for display on the Emergency page, the Medicines page and the Guidelines page.

- After confirming the patient data, the user is always taken to the Emergency page.
- A confirmed patient weight remains stored for 60 minutes when the application is open, unless it is changed.

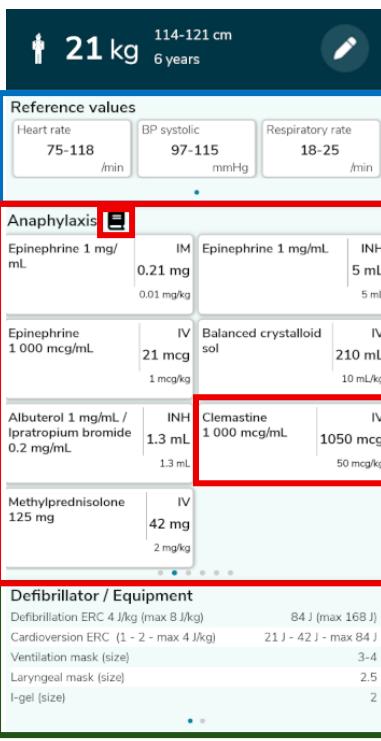
¹ Braegger C et al. New growth curves for Switzerland. *Paediatrica* 2011; 22(1): 9-11.

² Sha B et al. Comparison of Ideal Body Weight Equations and Published Height-Weight Tables with Body Mass Index Tables for Healthy Adults in the United States. *Nutrition in Clinical Practice* 2006; 21: 312-19.

7.3.2 Changing the patient data

 <p>Reference values</p> <table border="1"> <tr> <td>Heart rate 75-118 /min</td> <td>BP systolic 97-115 mmHg</td> <td>Respiratory rate 18-25 /min</td> </tr> </table> <p>Resuscitation</p> <table border="1"> <tr> <td>Epinephrine 1 mg/ mL 0.01 mg/kg</td> <td>IV / IO 0.21 mg</td> <td>Amiodarone hydrochloride 50 mg/mL (inj) 0.01 mg/kg</td> <td>IV / IO 105 mg 5 mg/kg</td> </tr> </table>	Heart rate 75-118 /min	BP systolic 97-115 mmHg	Respiratory rate 18-25 /min	Epinephrine 1 mg/ mL 0.01 mg/kg	IV / IO 0.21 mg	Amiodarone hydrochloride 50 mg/mL (inj) 0.01 mg/kg	IV / IO 105 mg 5 mg/kg	<p>The patient weight can be adjusted at any time by clicking on the pen.</p> <ul style="list-style-type: none"> • Patient data can be changed on all pages with patient-specific drug information (Emergency page, Medicines page, Preparation page, Guidelines page). • After confirming the changed patient data, the user is always taken to the Emergency page.
Heart rate 75-118 /min	BP systolic 97-115 mmHg	Respiratory rate 18-25 /min						
Epinephrine 1 mg/ mL 0.01 mg/kg	IV / IO 0.21 mg	Amiodarone hydrochloride 50 mg/mL (inj) 0.01 mg/kg	IV / IO 105 mg 5 mg/kg					
 <p>Patient data</p> <p>21 kg</p> <p>6 years 114-121 cm</p> <p>— +</p> <p>1 month 1 - 36 months 3 - 10 Y 10 - 14 Y ≥14 Y/adults</p>	<p>If no changes are made to the patient data, the page can be exited again by clicking on "x".</p> <ul style="list-style-type: none"> • The originally confirmed patient data remain saved. • The user returns to the previous page. 							

7.4 Emergency page



The Emergency page shows the user patient-specific information on drug dosages organised by indication (red frame), including reference values in the upper part (blue frame) and information on defibrillator energies and equipment in the lower part of the application (green frame).

- Additional pages on **reference values**, **indications** and **defibrillator/equipment** can be displayed by swiping. The individual number of pages (max. 10) is visualised with dots.
- If product favourites are defined in the settings, these products are displayed to the user by default (see chapter 7.8.1).
- By clicking on a medication tile (e.g. Clemastine 1000 mcg/mL), the **individual preparation and administration information** can be viewed (see chapter 7.5).
- Clicking on the **book symbol** next to the indication designation takes the user directly to the Guidelines page (see chapter 7.7).

7.5 Preparation and administration information



23 kg 119-126 cm 7 years

Nalbuphine hydrochloride 10 mg/mL Analgesia

Dose IV 3.5 mg dose range: 0.1-0.2 mg/kg 0.15 mg/kg

Preparation

Intermediate dilution

withdraw 1 mL from Nalbuphine hydrochloride 10 mg/mL add in 9 mL NACL 0.9% Concentration: 1 mg/mL Volume: 10 mL

Volume

administer 3.5 mL

Administration

IV injection

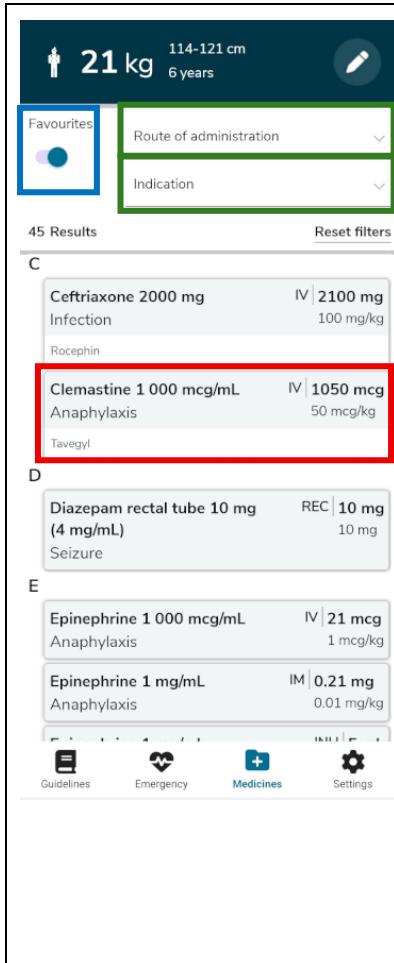
Further information

Onset of action: after 2-3 min; duration of action: 3-6 h

The Preparation page guides the user step by step through the preparation of the selected medication and provides information on administration and other details.

- The Preparation page can be accessed from the Emergency page (see 7.4) as well as from the Medicines page (7.6) by clicking on a medication tile.
- Click on "x" to close the Preparation page.
- The detailed page of the preparation and administration information can be accessed via the Emergency page and the Medicines page.

7.6 Medicines page



The Medicines page displays a list of 45 results for a patient aged 21 kg, 6 years. The results are organized into sections C, D, and E. Section C includes Ceftriaxone 2000 mg (Infection, Rocephin) and Clemastine 1000 mcg/mL (Anaphylaxis, Tavegyl). Section D includes Diazepam rectal tube 10 mg (Seizure). Section E includes Epinephrine 1000 mcg/mL and Epinephrine 1 mg/mL (both for Anaphylaxis). A red box highlights the Clemastine 1000 mcg/mL entry. The page includes a 'Favourites' button, 'Route of administration' and 'Indication' dropdowns, and a 'Reset filters' button. At the bottom are links for Guidelines, Emergency, Medicines (which is active), and Settings.

The Medicines page contains all the dosages of medications contained in MEDeHelp in alphabetical order.

The following **filter options** are available for a quicker search:

- by product favourites: toggle, see blue frame
- by type of administration: dropdown, see green frame
- by indication: dropdown, see green frame

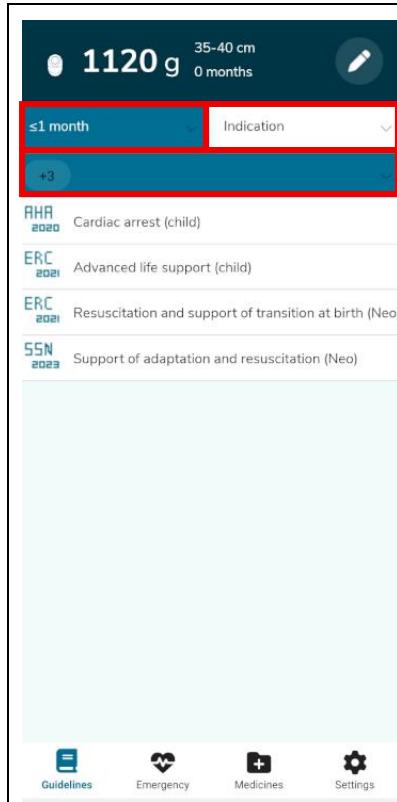
A blue dot (under favourites) indicates that the list of medications only shows the product favourites (see chapter 7.8.1).

By clicking on the blue dot, the restriction to favourites can be removed and all medications available in MEDeHelp for the selected patient data are displayed.

Filter settings made on the Medicines page remain in place until new patient data are confirmed.

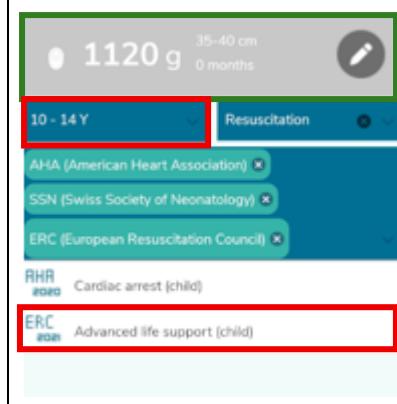
By clicking on a medication tile (e.g. Clemastine 1000 mcg/mL), the **patient-specific preparation and administration information** can be viewed (see chapter 7.5).

7.7 Guidelines page

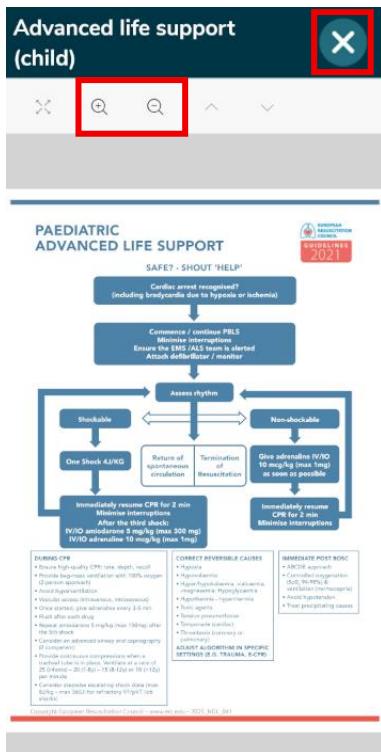


On the Guidelines page, emergency schemes are listed according to the confirmed patient data, which are stored as PDF documents or can be accessed via web links.

- The emergency schemes can be filtered by **age group**, **indication** and/or **organisation** using the drop-down menu (see red frame).
- If a user goes from the Emergency page to the Guidelines page by clicking on the book symbol, the indication filter is preset accordingly (see chapter 7.4).
- The organisation filter takes into account the favourite organisations defined in the settings. However, the list can be adjusted by the user if necessary, by adding or deleting an organisation.
- Filter settings made on the Guidelines page remain in place until new patient data are confirmed.



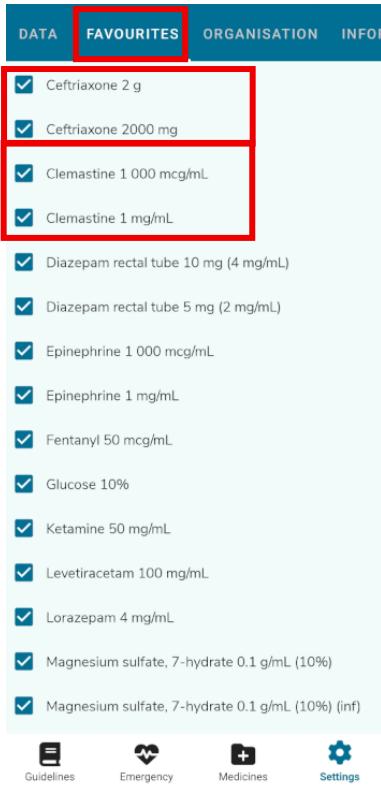
- If the age group is changed by the user (e.g. from ≤ 1 month to 10-14 Y.), the new patient data shown in grey indicate that the listed emergency schemes no longer relate exclusively to the originally selected patient data.
- By clicking on an emergency scheme, the **content** can be viewed **in detail**.



- The size of the PDF document can be adjusted to the user's requirements using the "zoom in" or "zoom out" magnifying glass or by moving two fingers on the screen.
- Click on "x" to close the PDF view of the emergency scheme.
- Emergency schemes that are called up as web links cannot be viewed in offline mode.

7.8 Settings

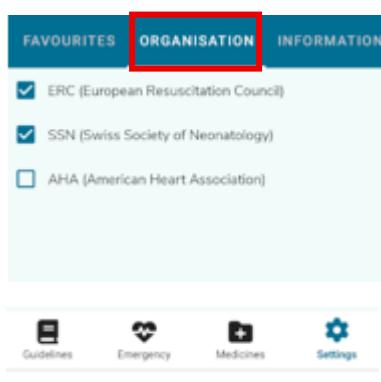
7.8.1 Product favourites



On the Settings page under the "Favourites" tab, the user can select the medication products used in their institution.

- If a product is listed several times with different units, all products should be marked as favourites, as the dosage is in different units depending on the age group.
- As soon as product favourites have been defined, only the product favourites are displayed on the Emergency page and on the Medicines page by default.
- On the Medicines page (but not on the Emergency page), the user has the option of removing the filter for the favourites (see chapter 7.6).
- If new product dosages are downloaded with a data package in MEDeHelp, the user can expand the list of product favourites accordingly.

7.8.2 Organisation favourites



On the Settings page under the "Organisation" tab, users can select the organisations relevant to their institution.

- As soon as the user has defined organisation favourites, only the emergency schemes of the defined organisations are displayed on the Guidelines page by default.
- If necessary, the user can adjust the organisation filter at any time (see chapter 7.7).

7.8.3 Information

7.8.3.1 General information about MEDeHelp

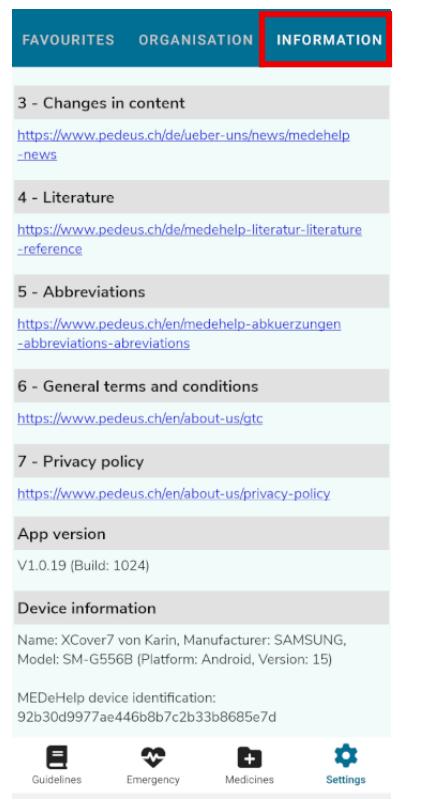
FAVOURITES	ORGANISATION	INFORMATION
1 - Contact		
PEDEus AG Technoparkstrasse 1, 8005 Zurich, Switzerland Email: info@pedeus.ch https://www.pedeus.ch/en/		
2 - Instructions for use		
https://www.pedeus.ch/de/medehelp-gebrauchsanweisung-instructions-for-use-mode-demploy		
3 - Changes in content		
https://www.pedeus.ch/de/ueber-uns/news/medehelp-news		
4 - Literature		
https://www.pedeus.ch/de/medehelp-literatur-literature-reference		
5 - Abbreviations		
https://www.pedeus.ch/en/medehelp-abkuerzungen-abbreviations-abreviations		
6 - General terms and conditions		
https://www.pedeus.ch/en/about-us/gtc		
7 - Privacy policy		
https://www.pedeus.ch/en/about-us/privacy-policy		
	 Guidelines	 Emergency
	 Medicines	 Settings

On the Settings page under the "Information" tab, the user can view information about MEDeHelp or access it via the corresponding web links.

- Instructions for use
- Changes in content
- Literature
- Abbreviations
- General terms and conditions
- Privacy policy

Web links can only be used in online mode.

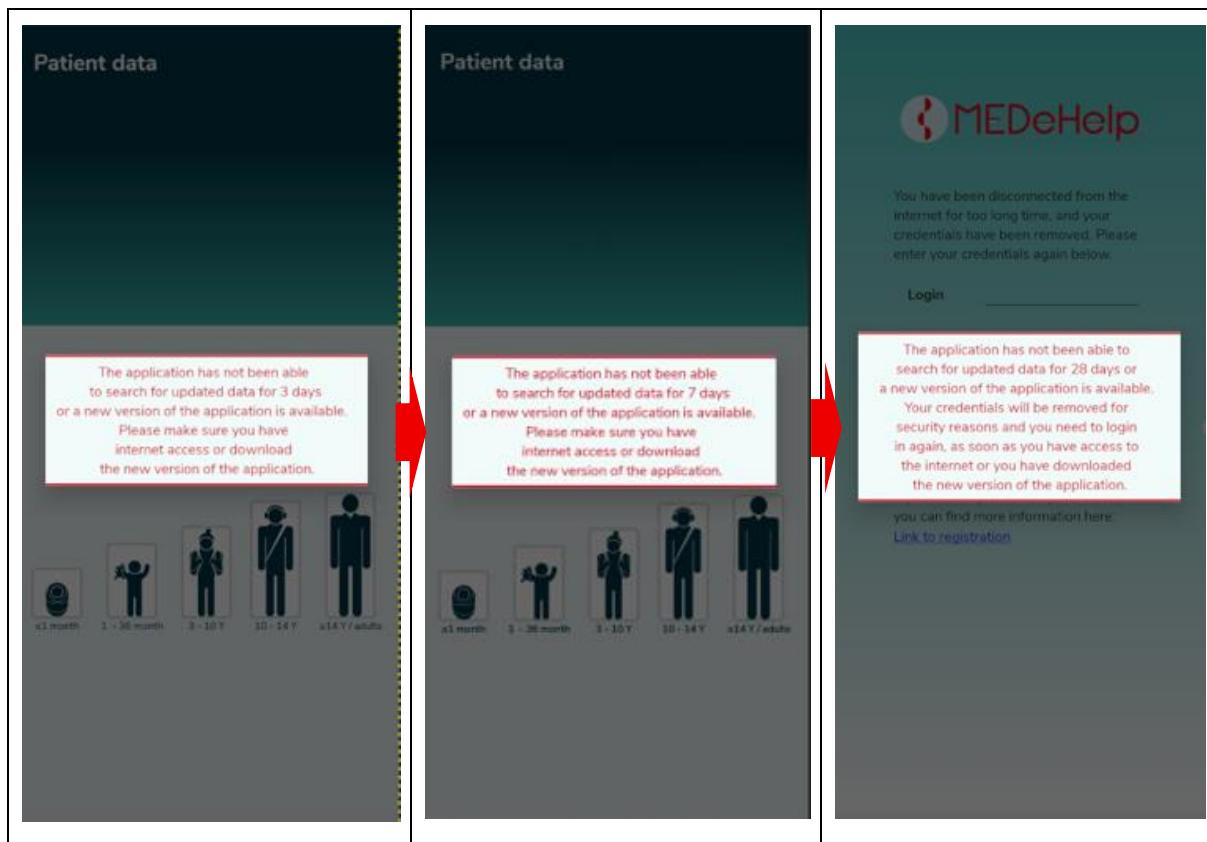
7.8.3.2 App version and device information

	<p>The app version (MEDeHelp version number) can be seen at the bottom of the Settings page under the "Information" tab (scroll down).</p> <p>The device information is displayed immediately below.</p> <p>The MEDeHelp device number is a unique number that is important for traceability in the event of troubleshooting.</p>
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7.9 Offline mode

MEDeHelp can also be used in offline mode. This ensures that MEDeHelp functions independently of internet access in emergency operation. Where internet access is available, use in online mode is preferable. To ensure that the information is always up-to-date, the application should be connected to the internet regularly (at least every 72 hours).

If MEDeHelp has been in offline mode for more than 3 days, a warning message is shown to the user. A corresponding message also appears after 7 and 28 days in offline mode, if no connection to the internet has been established in the meantime. After 28 days in offline mode, the user is logged out of MEDeHelp and must log in again with their user name and password (see chapter 7.1).



7.10 Data update

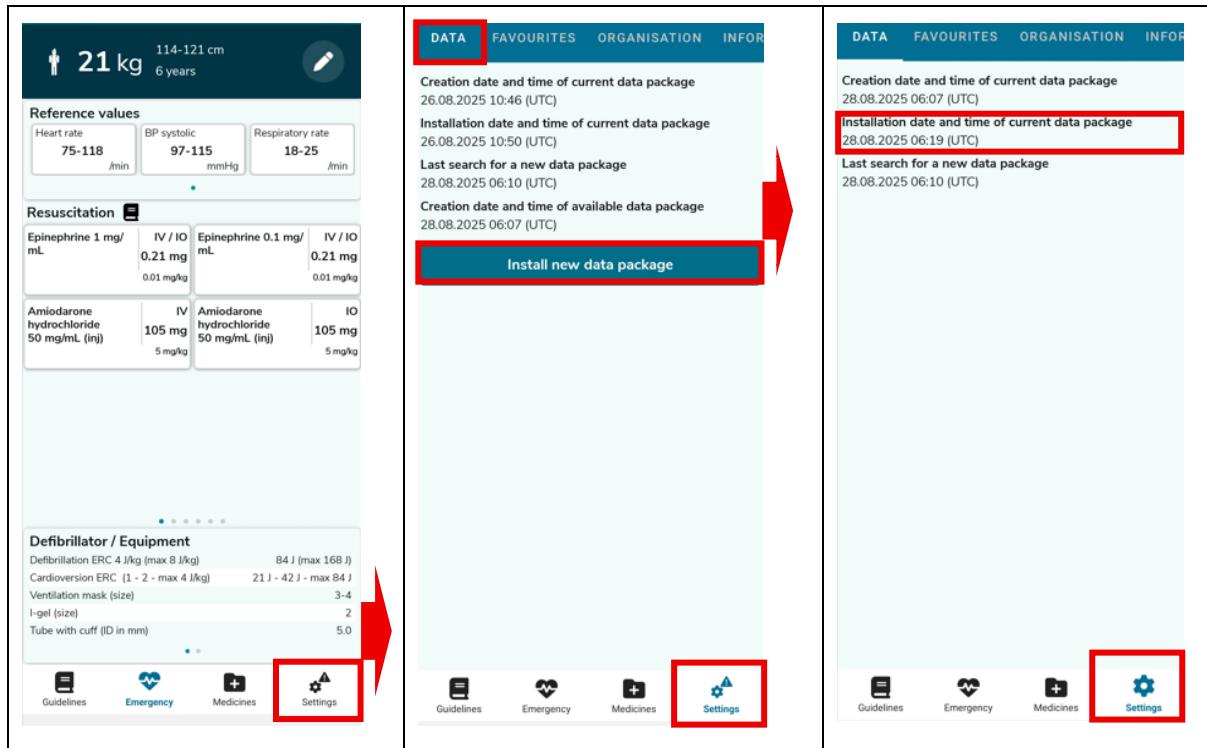
The MEDeHelp data is continuously updated by PEDeus. MEDeHelp searches for new data every 5 minutes, provided the smartphone is connected to the internet.

As soon as a new data packet has been found, an exclamation mark is displayed in the navigation bar next to the "Settings" icon.

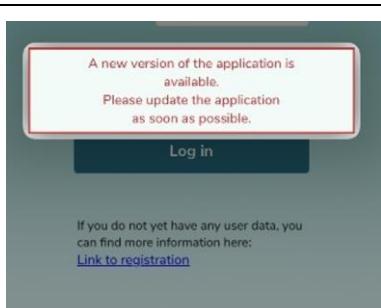
The user is required to install a data package as soon as possible.

Click on "Settings" and then click on "Install new data package" under the "Data" tab to download the new data. The process takes a few seconds.

Under the "Data" tab, you can view the creation and installation time of the current data package as well as the time of the last search for a new data package. The times are given in coordinated universal time (UTC).



7.11 Version update



As soon as a new MEDeHelp version is available, the request to update the version is displayed in MEDeHelp. In addition, a version update is announced in advance by PEDEus by e-mail.

- The new version must be updated as soon as possible via the App Store (see chapter 6.3).
- The existing settings for the product and organisation favourites are automatically transferred from the old version to the new one.
- As long as the version is not updated, no new data packages can be installed.
- If the new version is not installed, further warning messages appear after 3 and 7 days. The user will be logged out of the old version after 28 days (see the warning messages at 7.9).

7.12 Literature

The data in MEDeHelp is based on the current international guidelines for emergency medicine. The literature used can be viewed [here](https://www.pedeus.ch/de/medehelp-literatur-literature-reference) (<https://www.pedeus.ch/de/medehelp-literatur-literature-reference>) or in MEDeHelp under "Settings" > "Information" (see chapter 7.8.3.1).

7.13 Abbreviations

The abbreviations used in MEDeHelp can be viewed here via a [link](https://www.pedeus.ch/de/medehelp-abkuerzungen-abbreviations-abreviations) (<https://www.pedeus.ch/de/medehelp-abkuerzungen-abbreviations-abreviations>) or in MEDeHelp under "Settings" > "Information" (see chapter 7.8.3.1).

7.14 Support and instructions

In addition to the instructions for use, a [tutorial](https://www.pedeus.ch/en/services/medehelp) (<https://www.pedeus.ch/en/services/medehelp>) is available on the PEDEUS website.

8 Security

8.1 Warnings and residual risks

MEDeHelp users must observe the following warnings and precautions:

- MEDeHelp is intended exclusively for use in emergency situations due to the simplified (estimated) patient information and the scope of the drug dosages it contains.
- The patient data (weight, age, height) refer to standard values (see also chapter 7.3.1). Individual characteristics are not taken into account, e.g. if a patient is too heavy or too light for their age.
- Confirmation of incorrect patient data can lead to incorrect information being displayed.
- The equipment specifications may vary depending on the manufacturer.
- Some information (instructions for use, individual guidelines, abbreviations) cannot be displayed in offline mode.
- As MEDeHelp is an IT application, its performance may be affected by cybercrime.

All residual risks associated with MEDeHelp have been minimised as far as possible by taking appropriate measures. The benefits of MEDeHelp clearly outweigh the residual risks.

8.2 Feedback and complaints

Feedback on the functionality or content of MEDeHelp is welcome and can be sent by e-mail to info@pedeus.ch.

Technical and content errors in MEDeHelp that are noticed by users must be reported to PEDEUS by e-mail (info@pedeus.ch) immediately after their discovery, but within 48 hours at the latest. If an error occurs, MEDeHelp may no longer be used.