MRSJ

SOFTWARE

Regulatory References	Version
EN ISO 13485:2016	4.2.3
EN ISO 20417:2021	All
IEC EN 82304-1:2016	All

Instructions for Use of RescueCard

Version: 1.1   Date: 23.06.2023

Street 1, 1111 NotReal, Austria   Email: test@technikum-wien.at

Website: https://rescuecard.at

CE 0000

AT000000000

MRSJ Software

RescueCard is a class IIb medical device in accordance with 93/42/EEC (for MDD) // Regulation (EU) 2017/745 (for MDR). The product is class C according to IEC 62304, as a serious injury could potentially occur. UMDNS Code: 17-222

This manual provides a basic understanding of the RescueCard software and how to use it. The software is designed to offer a quick and secure way to access emergency medical data. When using the software, it is required to follow the instructions as described in the manual. Any images used in the manual are representative of the software and its use. In accordance with our program of continued product development, designs and specifications are subject to change without notice.

Product Description

Intended Medical Use

The Intended Use of the product is to provide critical patient information, especially in the case of a sudden medical emergency, e.g. a serious traffic accident. This information consists of administrative as well as medical information about the patient, and possible contact persons, and may be provided to emergency doctors, medical staff and first responders.

Function

The intended use of this product is to import, extract and store medical data in accordance with ELGA and EU regulations to create a Digital Emergency Patient Summary (DEPS). Users log into a web app, authenticate themselves, and the data is processed from ELGA according to CDA and FHIR standards. The system updates the data and generates a DEPS. A web app displays the DEPS and, if necessary, provides a QR code for detailed access.

To properly display the necessary medical information in an up-to-date fashion, the patient's data must be part of the Austrian Electronic Health Record ELGA or manually entered, in order to be retrievable by the product.

Materials

A link for the RescueCard Homepage will be sent
Instruction for use
QR-code Sticker or PDF

Contraindication

The product is intended to be used by the patient themself, as well as doctors, medical staff or people with justified interests such as first responders. No others are allowed to use the product without the patient's direct consent. The product shall only be used in accordance with the law and regulations.

The product should not be consulted when software misbehavior is apparent, or the displayed information is obviously incorrect or not up to date.

Patient Target Group

The target patient group includes all patients in emergency situations who require quick assistance. This is e.g. important for patients with allergies, pre-existing conditions, or special needs, as they often require special attention and specific medical measures.

Intended users

The target audience for this product includes primarily first responders, medical personnel and emergency doctors.

Clinical Benefits

A quick and accurate summary of all emergency medical data can enable faster and safer treatment. This can speed up decision-making in emergency situations and increase treatment efficiency. Regular updates of ELGA data ensure improved data accuracy and completeness, reducing the risk of medical malpractice due to incomplete or outdated information.

By providing relevant medical data, including medication lists and allergies, the software reduces the risk of medication errors. This is especially crucial in emergency situations where there is often no time for a thorough review.

Providing a QR code to a login page for quick access to the DEPS facilitates communication between different medical professionals and ensures that all parties have the same accurate information.

The implementation of a secure authentication system ensures that only authorized personnel have access to sensitive medical data, protecting patient privacy and meeting high data protection standards.

The software ensures that the data complies with EU guidelines for patient summaries and ELGA standards, facilitating cross-border healthcare and ensuring that the information is understandable and usable throughout the EU.

Exclusions

The product must not be used for data queries without a valid reason. It is to be used exclusively in emergency situations. Unauthorized individuals must not have access to the emergency pass. This includes individuals without proper authentication and those who are not medical professionals. The product requires a stable connection and should not be used with poor internet connectivity, as data queries may take a very long time. Users who are not familiar with this software or do not own it themselves must not have access to the emergency pass, except for trained medical personnel.

Language

The following languages are available for the product: German, English

System Requirements

Hardware

The device used must have a processor that is equal to or better than an Apple A9 chip or a Samsung Exynos 7 Octa 7870 64-bit processor. When using a computer, a processor that is at least as powerful as an Intel i3-8100 should be used. To access the emergency pass, the device must have a minimum download bandwidth of 30 Mbps.

Software

To use the software, the latest version of any internet browser must be installed. IOS 11 or Android 8.0 or newer must be used. Supported Operating Systems include Windows 11 & 10 and MacOS 10, IOS 10.

Safety and Maintenance

The following safety precautions must be strictly adhered to by all users and administrators of the software to ensure the safety and protection of patient data as well as the proper functioning of the software.

Product Handling information
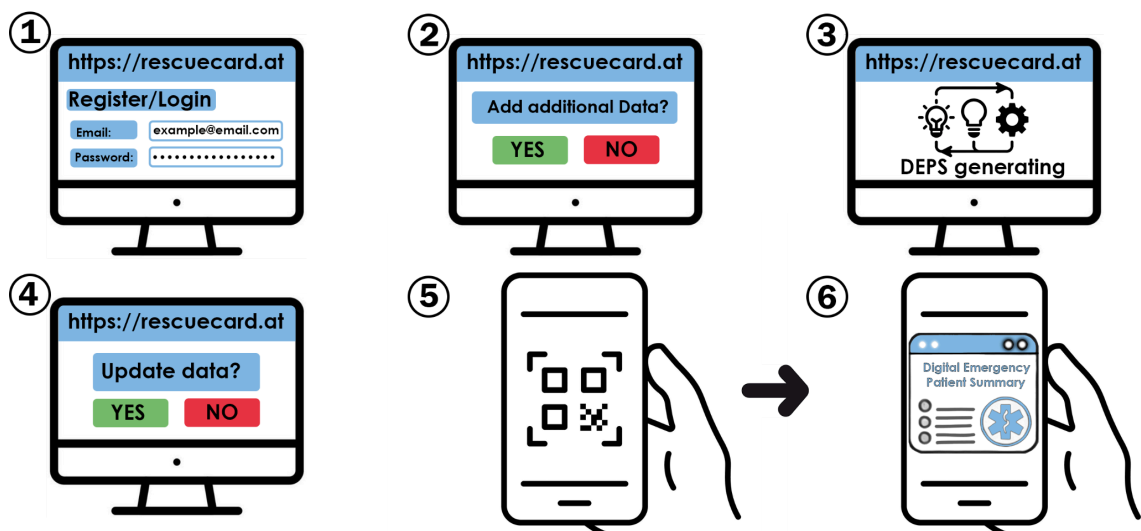
1. Register or log in on the website: https://rescuecard.at
2. Add additional data if necessary.
3. The Digital Emergency Patient Summary will be created. When creating a DEPS, you will have the option to receive a QR code sticker to affix to the back of your smartphone. Alternatively, you can use the QR code as your lock screen.
4. If data changes or additional data is added, press update. If not, please ignore this step.
5. In a medical emergency, a QR code should be visible on either the back of the person's smartphone or on their lock screen. This has to be scanned. Authentication must be completed to obtain further information about the patient.
6. A website will appear asking for login credentials. The DEPS data varies based on user specifics verified within the login process. Doctors and medical staff receive more information than first responders.

Warning and precautions

The software must be used in accordance with the European General Data Protection Regulation (GDPR). Information about individuals processed through this software must comply with these regulations.

The usage of the software is strictly limited for emergency situations only. Misuse of this product may lead to exclusion.

Ensure the information displayed is up to date and factual. Whenever possible, make sure to check critical information with other medical sources.

Compatible devices and operating systems must be used to ensure that no erroneous information is displayed.

The software requires a stable and secure internet connection to ensure successful data output. A stable internet connection should have a minimum download bandwidth of 30 Mbps.

All users must ensure that the software is always up-to-date to close potential security gaps and improve functionality.

All professional users of the software must be adequately trained to ensure they can use the software correctly and safely. This includes knowledge of functionalities and security protocols.

All security incidents or suspected security breaches must be reported immediately and investigated according to established procedures.

To keep sensitive information secure, it is recommended to have security measures active on the used device. Use strong passwords and enable biometric authentication if available, to restrict unauthorized access. Do not share login credentials with other people.

The product is intended to supply critical information in cases of medical emergency. However, it is advised not to rely on it as the sole source of the patient's data.

Residual risks and Undesirable side-effects

There may be technical errors such as bugs that can lead to malfunctions in the software that were not detected during testing. If the recommended minimum requirements for hardware or internet are not met, the performance of the software may be impaired. Despite security measures, there is a residual risk of data breaches and cyberattacks. There is a chance of data loss or data corruption due to unexpected system errors. Incorrect diagnoses or data may occur due to software errors or faulty data analysis. Overreliance on the software can distort medical judgment or lead to the

neglect of additional diagnostic tests. Slow system responses or crashes can slow down the medical workflow.

Product Problem Reporting/Troubleshooting

Problem: The authentication wasn't successful.

Approach: Verify the used device has a stable connection to the internet. Be sure to have validated your identity with the certified authentication entity beforehand.

Problem: No information was retrieved.

Approach: Verify the used device has a stable connection to the internet. Be sure to not have opted out of ELGA for your information to be retrievable.

Problem: An error message is displayed.

Approach: If possible, follow the instructions of the message and retry the desired process. If unsuccessful, note down the error message and contact support.

If the provided quick solutions did not help in solving your problem or you have specific questions, please phone our 24/7 support team under +43/123 456 7890 or reach out at support@rescuecard.at.

Software

Since DEPS is a web app, the software is updated automatically. Because of this feature, the user does not need to update the software manually. However, it is still advisable to check if the latest version is being used.

Special facilities, or special training, or particular qualifications of the product user and/or other persons

When setting up the product, instructions will be displayed in a step by step fashion to ensure proper functioning. If further assistance is required, the technical support team may be consulted.

Users will not be needing special instructions on how to use the product, as the design should be intuitive enough. When provided with the patient's critical information by the product, those in a position to make potentially severe decisions must be of appropriate education to the degree of the severity of their action and its consequences.

Symbology

Safety Information

Information

SN   Serial number

UDI   Unique Device Identification

MD   Medical device

Manufacturer