

Funktion:Sår

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Product: Funktion:Sår

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Product: Funktion:Sår Reference Card

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USER GUIDE (IFU) - ENGLISH

Contents

1.	Introduction	3
2.	Product description	3
3.	Intended use	4
3.1	Intended Purpose Funktion:Sår.....	4
3.2	Intended Purpose Funktion:Sår Reference Card	4
4.	Performance Characteristics.....	4
5.	Limitations	5
6.	Indication for use and operating environment	5
7.	Intended users	5
8.	Conta-indications for use.....	5
9.	Technical specifications for the use of Funktion:Sår	6
9.1	General specifications	6
9.2	Obtaining Funktion:Sår Reference Card	6
10.	Risk assessment.....	7
10.1	Risks, Warnings, and Precautions	7
10.2	Residual risks	7
11.	How Funktion:Sår is used.....	8
12.	Clinical benefits.....	9
13.	Performance & Security.....	9
14.	Troubleshooting or complications	9
15.	Updating the application	9
16.	Access to user guide/user manual	9
17.	Reporting.....	10
17.1	Foreseeable medical emergency situations	10
18.	IT and Information Security.....	10
19.	Contact information for the manufacturer.....	10
20.	Explanation of symbols displayed in the application.....	11
20.1	Labelling in Funktion:Sår	12
21.	Appendix 1 - IT and Network Configurations	12

1. Introduction

The instruction for use (IFU) covers the mobile application "Funktion:Sår" and the accessory "Funktion:Sår Reference Card", both medical devices are part of this document as the accessory can only be used in conjunction with the mobile application.

Please read this manual before use, the contents include important information about how to use the software safely and correctly.

Note: For retrieving older versions and/or physical copies of the manual, please send an email to karl@sebermedical.com for delivery within 7 calendar days without additional cost. To ensure that eIFU is available for all users, DermaCut AB encourages all users to download the manual locally on their preferred device/computer in case of server downtime of www.sebermedical.com/howto.

2. Product description

Funktion:Sår is a digital wound documentation and follow-up solution intended to support structured documentation of images and wound related information. The solution enables healthcare professionals to document wound-related information and visualize wound progression over time using image-based documentation.

Funktion:Sår includes AI-supported image analysis functionality intended to assist healthcare professionals in documentation and follow-up of wound characteristics. The application may provide visual documentation, wound measurements and aggregated overview information at care unit or organizational level to support structured wound documentation and follow-up.

Funktion:Sår is not intended for diagnose wounds, recommend or evaluate treatment, prioritize patients, triage patients, or replace healthcare professionals' clinical assessment.

The software supports both automated and manual wound documentation workflows. Documentation output is images (png or jpg) or PDF with measurements displayed in metric system.

Optional: The Funktion:Sår Reference Card is an optional accessory intended to be used together with the medical device software Funktion:Sår. The accessory consists of a physical reference card containing a predefined reference area of known dimensions. The Funktion:Sår Reference Card is used to provide a known size reference within images captured using Funktion:Sår. When the reference area is visible in an image, Funktion:Sår can determine the real-world size represented by individual image pixels. This information is subsequently used by Funktion:Sår to perform image-based measurements. The Funktion:Sår Reference Card does not contain software, electronics, or active components and performs no calculations, image analysis, or medical functions independently. Its sole purpose is to provide a physical reference of known dimensions for use during image acquisition. The Funktion:Sår Reference Card should be held adjacent to the wound during image acquisition and should not be in contact with the patient's skin. Use of the Funktion:Sår Reference Card is optional and depends on the selected image acquisition method. The optional accessory is intended for use by healthcare professionals trained in the use of Funktion:Sår.

3. Intended use

3.1 Intended Purpose Funktion:Sår

Funktion:Sår is a software application intended to be used by healthcare professionals to capture, document and follow-up wound images and wound-related information over time. The application may provide visual documentation, wound measurements and aggregated overview information at care unit or organizational level to support structured wound documentation and follow-up.

Funktion:Sår is not intended to diagnose wounds, recommend or evaluate treatment, prioritize patients, triage patients, or replace healthcare professionals' clinical assessment

3.2 Intended Purpose Funktion:Sår Reference Card

The Funktion:Sår Reference Card is an accessory intended to be used together with the medical device software Funktion:Sår. The accessory provides a predefined physical reference area of known dimensions within images captured using Funktion:Sår, enabling the software to determine the real-world size represented by image pixels and perform image-based measurements. The Funktion:Sår Reference Card should be held adjacent to the wound during image acquisition and should not be in contact with the patient's skin.

The Funktion:Sår Reference Card is an accessory to Funktion:Sår and does not have an independent medical purpose, indication, diagnosis, monitoring, treatment, or therapeutic function. The accessory is intended solely to provide a physical reference of known dimensions to support image-based measurements performed by Funktion:Sår.

4. Performance Characteristics

Funktion:Sår have the following core features, functionalities and corresponding performance attributes:

Feature / Functionality	Performance attributes
Reliable and secure wound documentation for text and images	Complete and 100% fulfilled system and penetration tests and cyber security analysis
Wound surface area measurement	Accuracy: 91.88% Precision: 88.29% Coefficient of variation: 0,049 Mean absolute error: 0,39cm ²
Non-invasive Wound depth (3D) measurement	Accuracy: 87.24% Precision: 90.00% Coefficient of variation: 0,056 Mean absolute error: 0.42mm
Proportion of slough in wound bed	Accuracy: 80.30% Precision: 64.86% Coefficient of variation: 0,042 Mean absolute error: 6.73%
Proportion of necrosis in wound bed	Accuracy: 84.73% Precision: 82.35% Coefficient of variation: 0,083 Mean absolute error: 2.05%

5. Limitations

- Funktion:Sår should not and cannot be used by mobile devices with specifications not included in the Technical Specifications.
- For use without optional reference card (iOS devices equipped with LIDAR):
 - Funktion:Sår images cannot be captured outside the optimal distance of 31-34 cm
 - Funktion:Sår does not yield reliable estimates of wound depth for wounds with edges steeper than 40 degrees.

6. Indication for use and operating environment

Funktion:Sår supports structured wound documentation and follow-up by enabling healthcare professionals to capture wound images, document wound-related information and display wound measurements over time. Funktion:Sår is intended to be used in healthcare settings where wound documentation and follow-up are performed, including specialist clinics, primary care and municipal care such as home healthcare and nursing homes. Funktion:Sår is intended to be used by all healthcare professionals that are involved in wound documentation and follow-up.

7. Intended users

Funktion:Sår is intended to be used by all healthcare professionals that are involved in wound documentation and follow-up.

8. Contra-indications for use

- Wounds with deep passages not visible for the camera.
- Funktion:Sår results are not to be used for debridement recommendations.
- Funktion:Sår cannot indicate specific location for either necrosis or slough.
- There are no known contraindications associated with the Funktion:Sår Reference Card when used in accordance with this Instructions for Use. The accessory is intended solely to provide a physical reference of known dimensions during image acquisition and does **not** come into contact with the wound bed or the patient's skin, perform any medical function, or interact directly with the patient.

9. Technical specifications for the use of Funktion:Sår

9.1 General specifications

Funktion:Sår is standalone medical device software (SaMD) designed for use on compatible mobile platforms. The software captures and processes wound images with a target image resolution of 512 × 512 pixels. Minimum device requirements for Funktion:Sår are:

- Image resolution: minimum 13 MP camera
- Processing power: minimum 1.6 GHz CPU and 2 GB RAM
- User interface: minimum screen resolution of 1280 × 720
- Operating system: iOS version 10 to iOS version 18 and Android version 11 to Android version 14

Approved devices for use without the optional reference card are iPhone 12 Pro, iPhone 13 Pro, and iPhone 14 Pro with iOS version 14 to iOS version 18.

If an MDM tool is used to manage mobile devices, access and installation of applications may be affected. In case of challenges regarding download/installation of Funktion:Sår, please contact your mobile management unit, often IT department, to allow Funktion:Sår as a possible application for your user group.

9.2 Obtaining Funktion:Sår Reference Card

Funktion:Sår Reference Card is an optional reference card for devices meeting the general specifications. It is obtained by contacting DermaCut AB. Each reference card has its unique ID that is used to identify the individual card. Contact details are found at the end of this document. If questions arise related to new or used reference cards, please reach out to DermaCut AB.

10. Risk assessment



10.1 Risks, Warnings, and Precautions

- Improper handling during image capture can negatively impact documentation and measurements. The user is responsible for capturing images correctly and for verifying the documentation output generated by the application, including contours and measurements.
- New users are encouraged to take multiple images per wound during the induction period to learn how to operate the application.
- The user verifies that images taken using Funktion:Sår are stored in the device's memory before use on a patient and continuously during use. Follow local guidelines regarding manual removal of images from the device.
- Funktion:Sår is not intended for long-term storage of images.
- The user is responsible for keeping the username and password in a secure place.
- Check the battery level before using the application.
- Make sure you have an internet connection before use.
- The user is responsible for documenting the results on the right patient.
- For use of optional reference card: Automatic image capture does not guarantee optimal documentation. It is important that images are captured correctly, with sharpness and that the reference frame appears equilateral when the image is taken, to generate reliable documentation. Disinfecting the reference card and device itself before and after use, infections from the reference card can lead to prolonged healing time. If the reference card square is not intact, contact DermaCut AB.

10.2 Residual risks

Software hazards should be assessed with an assumption of failure. The hazards were overestimated in terms of probability and had varying degrees of severity levels. Control measures were implemented, decreasing the probability of occurrence and thereby the overall residual risk. All identified risks, including risks initially considered acceptable, have been reduced as far as possible without adversely affecting the benefit-risk ratio.

Identified risks were related to wrong information on wound dimensions and characteristics leading to delayed healing or poor documentation, patient integrity and data privacy, manual error during device use, unauthorized access to the device and AI and data management. All risks have been mitigated as far as possible without adversely affecting the safety and performance of the device.

11. How Funktion:Sår is used

Note: New users should complete these three steps to ensure that Funktion:Sår is properly installed and can perform safely.

Step One: Install Software

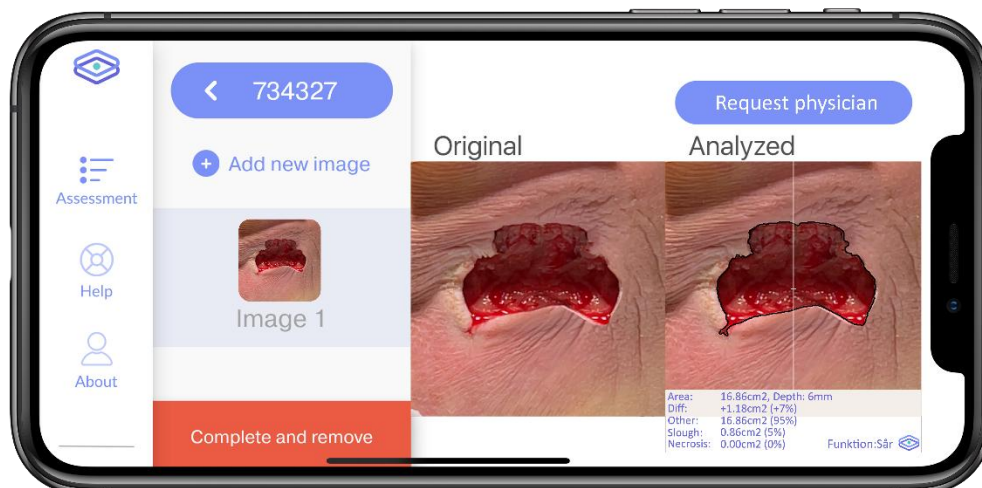
- Funktion:Sår can be installed via AppStore or Google Play.
- DermaCut AB shares username and password for login.

Step Two: Check warnings

- Check warnings on page 4.

Step Three: Perform Analysis and Get Decision Support

- Launch the Funktion:Sår app on your mobile device
- Creating a new patient
- Place the reference card equilaterally with the wound and capture image (**optional**)
- Capture an image of the desired wound
- For usage of iOS devices equipped with LiDAR: *Optimal distance for measurements of 31cm-33cm between device and wound, therefore the user can only capture image within this threshold (when camera button is green).*
- Check and possibly adjust wound area, wound depth and tissue proportions including topology map
- Add additional documentation manually (optional)
- Repeat until all images are captured (note - the patient's needs come first)
- Check potential dressing category for training or dialogue purposes
- Transfer images from the mobile device to the patient's medical record



12. Clinical benefits

Funktion:Sår supports structured wound documentation and follow-up by enabling healthcare professionals to capture wound images, document wound-related information and display wound measurements over time.

13. Performance & Security

Funktion:Sår is an interactive tool with high reliability and reproducibility. Funktion:Sår has been shown, to have high reproducibility and precision in measurements of wound area, depth and tissue proportions. Funktion:Sår fits into existing workflows in clinical documentation and thus does not impose new knowledge requirements from healthcare professionals or entail additional risks that may harm patients. Healthcare professionals always have the final decision regarding wound documentation when using Funktion:Sår.

14. Troubleshooting or complications

In case of any errors or complications, please contact DermaCut AB via the information available under the ABOUT page of the application. Or directly via:

E-mail: Karl@sebermedical.com,

Telephone: +4672- 211 13 37

15. Updating the application

To ensure that the correct version is installed, the user should regularly check for new software updates on the App Store or Google Play. It is recommended to be checked at regular intervals, about 4-6 months.

16. Access to user guide/user manual

The latest version of the user manual for Funktion:Sår (this document) is always available via DermaCut AB / Seber Medical's website, www.sebermedical.com/howto. If you would like further instructions or manuals, please contact karl@sebermedical.com. The hardware and software requirements for displaying user manual and other appropriate device information is; if downloaded locally on a computer a PDF reader, and if accessed through DermaCut AB / Seber Medical's website a stable internet connection, standard web browser (Chrome, Safari, Edge) and a PDF reader.

The user is recommended to always use the latest available version for correct and safe use.

17. Reporting

Serious incidents or undesirable events that occur in connection with the use of Funktion:Sår should be reported as soon as possible to both DermaCut AB and the Medical Device Agency/Competent Authority of the Member state in which the user or patient is established. If you are unsure whether a specific event is covered by the reporting requirements, you should still inform DermaCut AB about the event as soon as possible. Please report incidents to DermaCut AB via karl@sebermedical.com and to the Medical Device Agency/Competent Authority of the Member state in which the user or patient is established via their e-service.

17.1 Foreseeable medical emergency situations

All medical emergency situations shall be reported to DermaCut AB via Karl@sebermedical.com. Foreseeable medical emergency situations include incorrect wound assessment without ability to manually change the result, system failure leading to lack of wound progression data and loss of patient information. If in doubt, always report situations to DermaCut AB.

18. IT and Information Security

Funktion:Sår has a high level of IT and information security, and all processing of data and images is managed locally on the device. Internet connection is needed to be granted access to Funktion:Sår and to being logged in. As limited data connected to user identification is transferred during use, there are no requirements on IT network speed. If you would like further information regarding DermaCut AB's data management and privacy policy, please visit DermaCut AB Privacy Policy on the website <https://www.sebermedical.com/sv/privacy-notice>. For further information, please contact zacharias@sebermedical.com.

19. Contact information for the manufacturer

Manufacturer: DermaCut AB

Address: Norr Mälarstrand 60, 6tr, 112 35 Stockholm

Website: www.sebermedical.com

Email: Karl@sebermedical.com

Telephone number: + 4672-211 13 37

20. Explanation of symbols displayed in the application

Warnings

Informs about warnings necessary for safe use



Electronic Instruction Manual

User guide/User manual is available in electronic format

User Manual: www.sebermedical.com/howto



Manufacturing date

2025-06-10



Legal Manufacturer

DermaCut AB

Norr Mälarstrand 60, 6tr, 112 35 Stockholm, Sweden



Medical technology product

Medicinal software in class I

UDI-DI: (01)4262423150014

UDI: 4262423150014(8012)2.0.0



CE – labelling

Medical Device in EU MDR 2017/745



Optional: Funktion:Sår Reference Card

Medical technology product

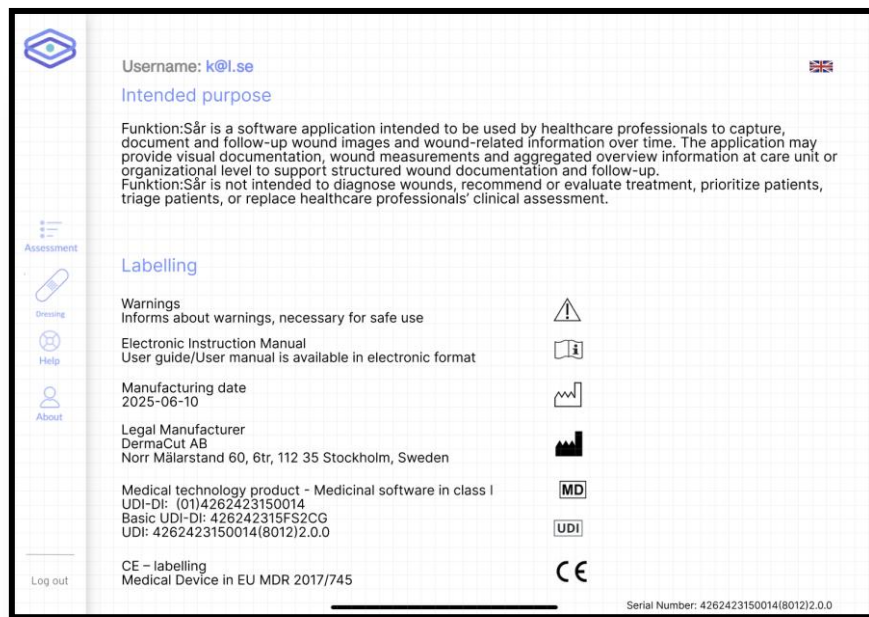
Medicinal Accessory in class I

Basic UDI-DI: 426242315FSRC83

UDI: 04262423150021



20.1 Labelling in Funktion:Sår



21. Appendix 1 - IT and Network Configurations

IT Department Responsible for MDM-tool: The application is designed for use on mobile devices within a secure IT environment. Since the IT network is outside the control of the manufacturer, we require deployment through a Mobile Device Management (MDM) tool to enforce security policies, application control, and network protection. This ensures protection against unauthorized access, secure updates, and controlled execution of the software. To ensure a secure system, the latest update of the software should always be installed.

MDM Solution: Required for secure installation and enforcement of security policies.

Network Requirements: Wi-Fi Connection: Secure WPA2/WPA3-protected network (No public or open Wi-Fi). Stable internet connection (Minimum 2 Mbps)

Security Requirements: SSL/TLS 1.2 or higher for all authentication requests, No proxy or VPN blocking device usage.

Authentication Methods Requirements for traffic: Authentication: Email & Password, authentication tokens, Operating system: Android, Google, Apple iOS

Note: There is a risk that execution of the software on IT network could result in previously unidentified risks to patients, users or third parties, the responsible organization is advised to identify, analyses, evaluate and control risks, subsequent changes to the IT network could introduce new risks and require analysis and changes to IT network include: changes to IT network configuration, addition of items, removal of items, update of hardware and or software, upgrade of hard ware and or software.