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Instructions for Use – WoundTrack-II

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Abbreviation	Definition
ICC	Intraclasse Correlation Coefficient
MAE	Mean Absolute Error
MRE	Mean Relative Error
SD	Standard Deviation

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A. Introduction

"Please read this user's guide carefully to fully understand how the device works. If you have any further questions, encounter a problem or wish to suggest improvements, please contact PIXACARE at contact@pixacare.com or visit our website at https://pixacare.com."

WoundTrack-II enables healthcare professionals to be assisted in the dimensional and content analysis of chronic wounds. To do this, users will need to use a centimetric reference sticker affixed close to the wound, then take a photograph and launch the artificial intelligence module from an interface.

WoundTrack-II is a Class IIa medical device, following Rule 11 of Annex VIII of the European Regulation (Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning medical devices). WoundTrack-II gives no indication to healthcare professionals to establish a diagnosis, but the analyzed photos can be used as a basis for information. Indeed, Pixacare's artificial intelligence modules are designed to provide information used for therapeutic or diagnostic purposes.

B. Intended use

WoundTrack-II is a medical device which makes it possible to determine from a photograph of a chronic wound:

- The surface area of the wound in cm^2
- The proportion of granulation surface area relative to the total surface area
- The proportion of fibrin lesion surface area relative to the total surface area
- The proportion of necrotic lesion surface area relative to the total surface area

C. Contraindications

The use is contraindicated for wounds smaller than 4 cm^2 and larger than 100 cm^2.

D. Precautions for use

To make the use of the WoundTrack-II device relevant:

- the photo must contain the entire wound and the reference sticker to be eligible for analysis
- the sticker must be used in accordance with the instructions given
- The user should disinfect the skin after use if the sticker is placed on the skin
- the user must avoid blurred photos (good focus): placing the sticker in the same plane as the wound, combined with the sticker detection step carried out during analysis by WoundTrack-II, should make the analysis of blurred photos by WoundTrack-II impossible
- the user must ensure that he/she has access to an Internet connection
- the user must not touch the wound with his/her smartphone/camera. Direct contact of the smartphone with the wound could introduce potentially pathogenic organisms. These can cause infection and inflammation of the wound.

WoundTrack-II cannot replace the advice of a doctor and/or healthcare professional. WoundTrack-II provides decision-support data only.

E. Potential side effects

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No side effects have been detected by following the precautions for use.

F. Targeted patients

WoundTrack-II can be used on patients with chronic wounds with a surface area of 4 to 100 cm^2.

G. Target users

WoundTrack-II is suitable for the evaluation of a medical photograph taken by a healthcare professional.

H. Clinical benefits

The WoundTrack-II device can operate without directly contacting the wounds, thus reducing the risk of wound infection. By using a calibration marker sticker placed on the healthy skin near the wound, the device automatically focuses on the wound and improves the accuracy of wound area measurement. Additionally, the device can automatically trace the wound border, allowing clinicians to determine the wound area. Furthermore, it can automatically classify the type of wound tissue, reducing the need for tedious manual measurements and subjective assessments.

I. System performance

	Definition of the performance	Results
• **Clinical performance 1**	• Measurement (or automatic calculation) of the **area** of a wound requiring healing in cm2 based on a picture	• MRE (WoundTrack-II versus the planimetry): 28.3% (SD: 18.6) • MRE (expert's visual assessment versus the planimetry): 34.7% (SD: 21.3) • ICC (WoundTrack-II versus planimetry): 0.956 CI95 [0.917;0.977]
• **Clinical performance 2**	• Automatic calculation of the proportion of the **granulation** surface area relative to the total surface area of a wound requiring healing process based on a picture.	• MAE (WoundTrack-II versus the photo measurement): 23.49% (SD: 18.70) • MAE (expert's visual assessment versus the photo measurement): 24.91% (SD: 20.56)
• **Clinical performance 3**	• Automatic calculation of the proportion of the **fibrin** surface area relative to the total surface area of a wound requiring healing process based on a picture.	• MAE (WoundTrack-II versus the photo measurement): 24.49% (SD: 19.20) • MAE (expert's visual assessment versus the photo measurement): 26.10% (SD: 19.99)

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• **Clinical performance 4**	• Automatic calculation of the proportion of the **necrosis** surface area relative to the total surface area of a wound requiring healing process based on a picture.	• MAE (WoundTrack-II versus the photo measurement): 6.28% (SD: 11.65) • MAE (expert's visual assessment versus the photo measurement): 6.49% (SD: 13.04)

J. User manual

WoundTrack-II works by using a centimetric standardization sticker, which is affixed close to the wound.

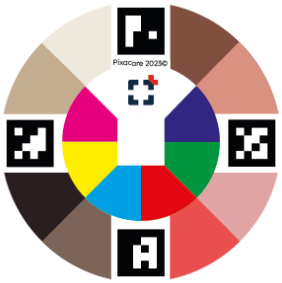


Figure 1 : WoundTrack sticker

How to use the centimetric reference sticker:

- The sticker is a single-use device: do not use the same sticker more than once.
- The sticker must be placed close to the wound: do not place the sticker directly on the wound.
- The sticker must be placed in the same plane as the wound to fully fulfill its function as a centimetric reference.
- The photo should be taken parallel to the wound.
- Care should be taken to avoid the presence of foreign tissue or objects obscuring the wound in the photo
- If it is not possible to place the sticker on a flat skin surface in the same plane as the wound, we recommend that you place it on a tongue depressor and hold it in the same plane as the wound for the photo.
- The sticker must not contain any light reflection.

The photo must not be too blurred (good focus) to enable WoundTrack-II operation, too blurred photos will be automatically discarded.

The photo must contain only one wound. The software is not able to correctly analyze photos that include multiple wounds. If your patient has multiple wounds, you must analyze each wound individually.

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Figure 2 : Photo quality required



Figure 3 : Photo quality not usable

How to use WoundTrack-II from my photo:

The WoundTrack-II device is accessible through an interface which general characteristics are described in the **DEV-F-17_Technical_Description_WoundTrack-II**. The automatic analysis of the photograph will take just a few seconds. The 'test' interface is available through a browser at the following address: https://pxc-ai-demo.azurewebsites.net/predict.

Step 1: Authentication:
Enter the provided password to access the device.

Step 2: Upload the photo:
Upload or submit the photo of the wound to be analyzed.

Step 3: Wound contouring and surface area calculation:
WoundTrack-II automatically calculates the wound surface area based on the contouring performed. The contouring done is displayed, and it is possible to refuse to continue the analysis if the contouring is not satisfactory. In this case, you should take a new photo, ensuring that you follow the recommendations for using the centimeter reference sticker, and then proceed to Step 2.

Step 4: Wound content analysis:
WoundTrack-II determines the percentage of tissue present in the wound:

- % of granulation tissue
- % of fibrin
- % of necrosis

Comparing the original photo with the AI-processed photo allows you to confirm or reject the analysis.

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K. Protection and security of personal data

When PIXACARE processes personal health data, the patient is informed and must expressly consent to the processing of said data, in accordance with Article 9.2.a of Regulation 2016/679. Otherwise, PIXACARE will not be able to carry out the analysis.

Please note that the data processed by WoundTrack-II is not hosted; it is hosted by the interface that retrieves the data.

L. Labeling



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