

TIVITA® Wound System

» High Performance Hyperspectral Imaging

VIS/NIR Hyperspectral Camera System to support
wound diagnosis and treatment



» Data sheet

NON-INVASIVE DETECTION OF IMPORTANT TISSUE PARAMETERS TO ASSESS THE CONDITION OF THE WOUND, THE HEALING PROCESS, AND THE POSSIBILITY OF OBJECTIVE WOUND DOCUMENTATION.

The innovative **TIVITA® Wound System** is a highly integrated, hyperspectral camera system **with integrated wound documentation software**. The basic function is an imaging tissue oximeter. For the first time, it enables the non-invasive acquisition of the following parameters for perfusion evaluation - in real time and over a large area:

- Tissue Oxygenation (StO_2)
- Near Infrared (NIR) Perfusion Index
- Tissue Hemoglobin Index (THI)
- Tissue Water Index (TWI)

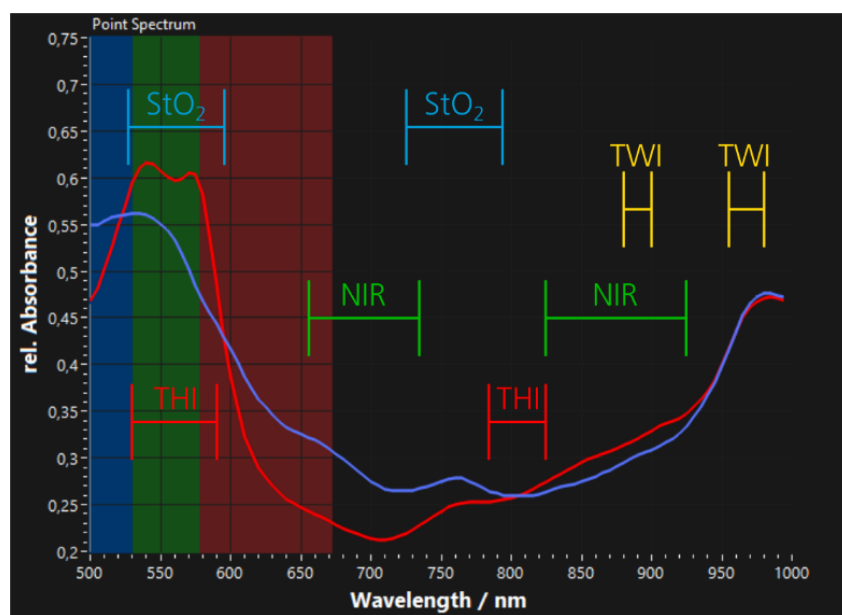


Fig. 1: Spectra of the parameters StO_2 , NIR Perfusion, THI, and TWI, recorded by the TIVITA® Wound

The full spectroscopic data from the integrated absorption spectra in the range from 500 to 1000 nm is acquired within a few seconds.

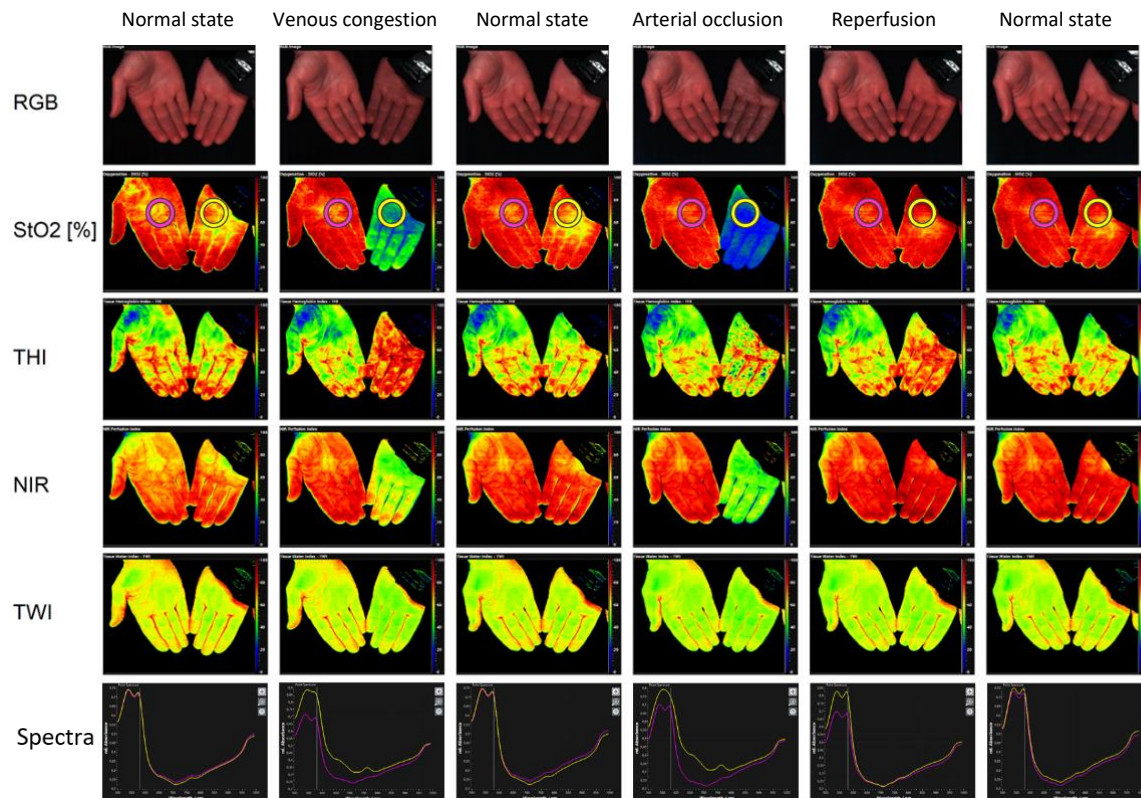


Fig. 2: Example images from an occlusion test in which measurements were taken under normal conditions, during artificially generated venous congestion, as well as during arterial occlusion and reperfusion. The TIVITA® Wound works as an imaging tissue oximeter.

These parameters allow an objective assessment of the tissue condition in a wound. With the help of the assessment of the wound condition, an optimisation of the therapy approaches is possible and professional treatment within the framework of the guidelines for wound treatment is simplified.

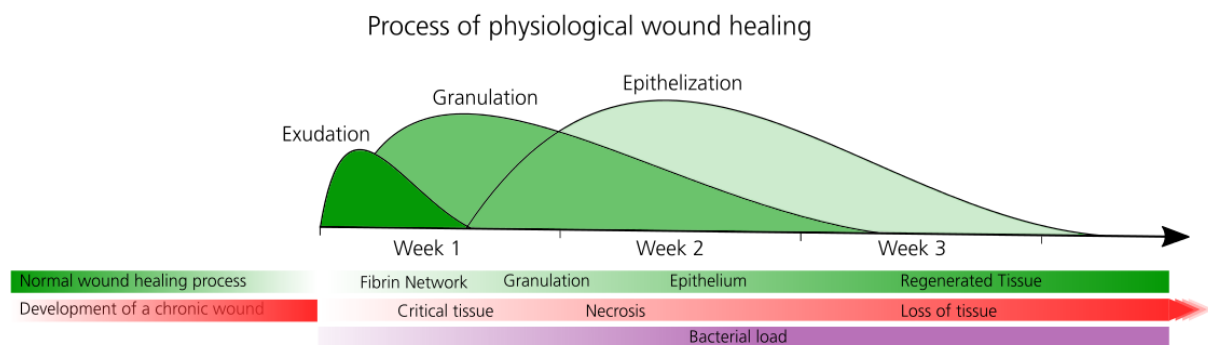


Fig. 3: Representation of the physiological processes of a wound.

In addition to information on oxygenation and perfusion of the wound tissue, the TIVITA® Wound System also contains important information on the **water content of the tissue**, which is an important factor in assessing the patient and wound status. In addition, an **expert system is integrated** which contains a chemometric classification of wound tissue and thus provides information on specific wound areas.

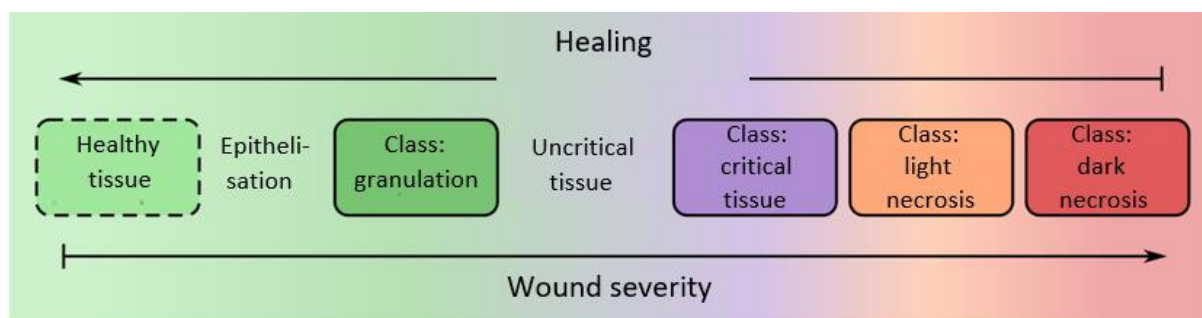


Fig. 4: Important tissue classes in a wound.

THE TIVITA® WOUND PRODUCT LINE

Product line TIVITA® Wound	Item No.	Description
TIVITA® Wound Camera with illumination unit (TWC)	40-05-02-0320	Comprising: <ul style="list-style-type: none"> • Hyperspectral camera VIS/NIR • Connection cable and power supply • Lens • Illumination unit • Incl. TIVITA® Suite Wound software
TIVITA® Wound System (TWS)	40-05-02-0321	Comprising: <ul style="list-style-type: none"> • Hyperspectral camera VIS/NIR • Illumination unit • Lens • Connection cable and power supply • Box pc • Medical cart • Incl. TIVITA® Suite Wound software
TIVITA® Wound System USV (TWS-USV)	40-05-02-0322	Comprising: <ul style="list-style-type: none"> • Hyperspectral camera VIS/NIR • Illumination unit • Lens • Connection cable and power supply • Box pc • Medical cart with uninterruptible power supply • Incl. TIVITA® Suite Wound software

TIVITA® SUITE WOUND – THE BASIC SOFTWARE

The TIVITA® Wound camera is controlled by the special software TIVITA® Suite Wound, included in the delivery.

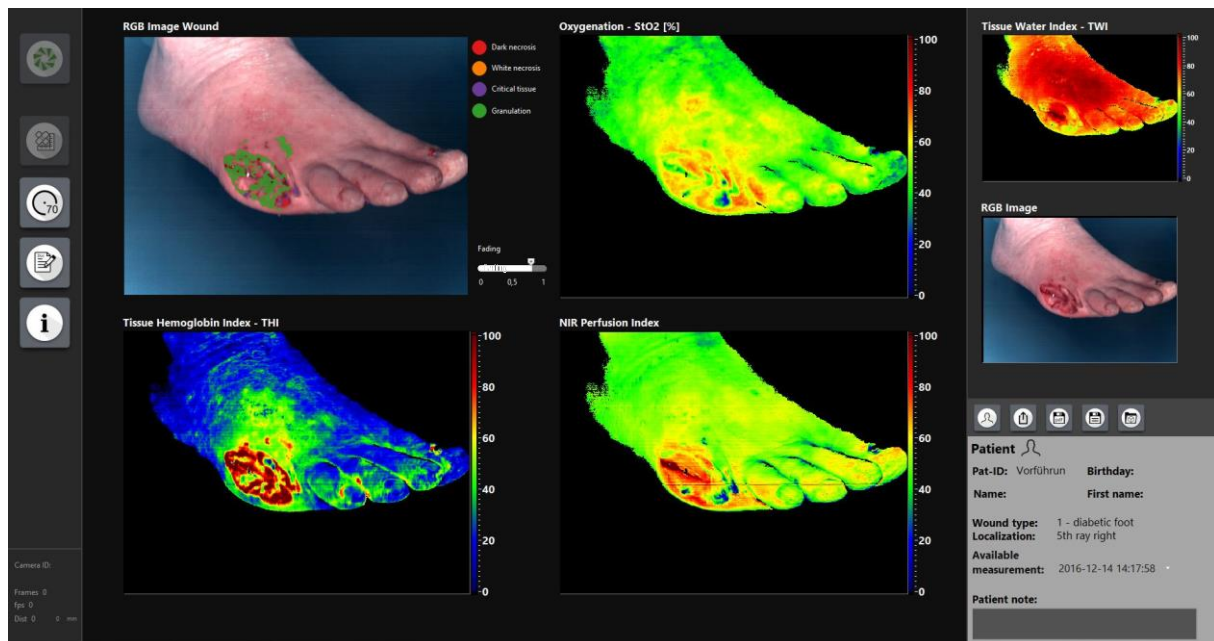


Fig. 5: Screenshot of the user interface of TIVITA® Suite Wound. Top left: Control panel of the software with the buttons i.a. "Recording", "Documentation tool" and "Information". Center: Wrong colour images of the parameters Oxygenation, THI and NIR Perfusion and the calculated RGB image, which corresponds to a normal colour image photograph, calculated by the camera. This image is superimposed on the wound tissue classification of the expert system. Top right: further available parameters TWI (shiftable into the middle field by drag & drop) and RGB colour image without fading. Down right: Field for patient information with data entry via the documentation tool.

TIVITA® WOUND CAMERA – SYSTEM PERFORMANCE OVERVIEW

Parameter	Description	Measuring area
RGB colour image	The red-green-blue colour image is a standardized colour image extracted from the recorded data..	-
Tissue oxygen saturation; StO ₂ [%]	The parameter describes the relative oxygen saturation of the blood in the microcirculatory system in superficial tissue layers. The penetration depth is approximately 1 mm.	1 – 100 [%]
Tissue hemoglobin index; THI	The THI describes the existing hemoglobin distribution in the microcirculatory system of the considered tissue area. This is an index value and not an absolute value.	1 – 100
Near infrared perfusion index NIR	This parameter describes the relative oxygen saturation of the blood in the microcirculatory system in deeper tissue layers. The penetration depth can be 4 - 6 mm.	1 – 100
Tissue water index TWI	The TWI describes the existing water distribution in the considered tissue area. This is an index value and not an absolute value..	1 – 100

Sophisticated and compact: The set-up of the TIVITA® Wound.

The technology of TIVITA® Wound is based on the principle of imaging spectroscopy – thus, it corresponds to an imaging tissue oximeter. It uses visible and near-infrared spectroscopy (VLS / NIRS) to detect the light reflected by the object under investigation and determines its chemical composition on the basis of the recorded wavelengths.

Both, visible light and part of the near-infrared region of the light (the latter not being visible to the human eye) are recorded by the TIVITA® Wound.

The visible area is used to generate the colour image provided by the software (this image is calculated from standardized data sets and therefore always looks the same). On the other hand, the visible spectrum of light is evaluated to obtain information about the melanin and hemoglobin content of the tissue near the tissue surface. The light from the NIR area is reflected from deeper tissue layers, enabling to gather information about the deeper composition of the tissue, such as haemoglobin, water, or fat content.

Quick and easy: The measuring process

For the measuring process, the TIVITA® Wound is positioned at a distance of approx. 50 cm from the wound. The hardware includes an LED-based pointer system which indicates the user the centre of the image area and the distance of the object from the camera. The pointer system is based on the triangulation principle: at a working distance of 50 cm, the two pointer spots overlap perfectly to one point.

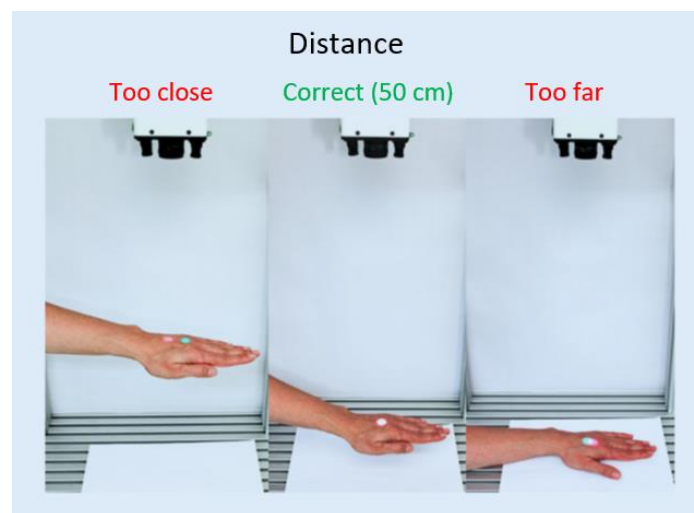


Fig. 6: Pointer system with integrated triangulation distance measurement

The pointer system is also used by the camera to measure the distance of the object using the triangulation measurement. With the known distance, the actual image area is scaled and a wound area measurement can be carried out within the image. This is used for manual selection of the wound area by the user and the software generates the size of the wound area for documentation purposes. In addition, a complete wound documentation system for modern wound care is included.

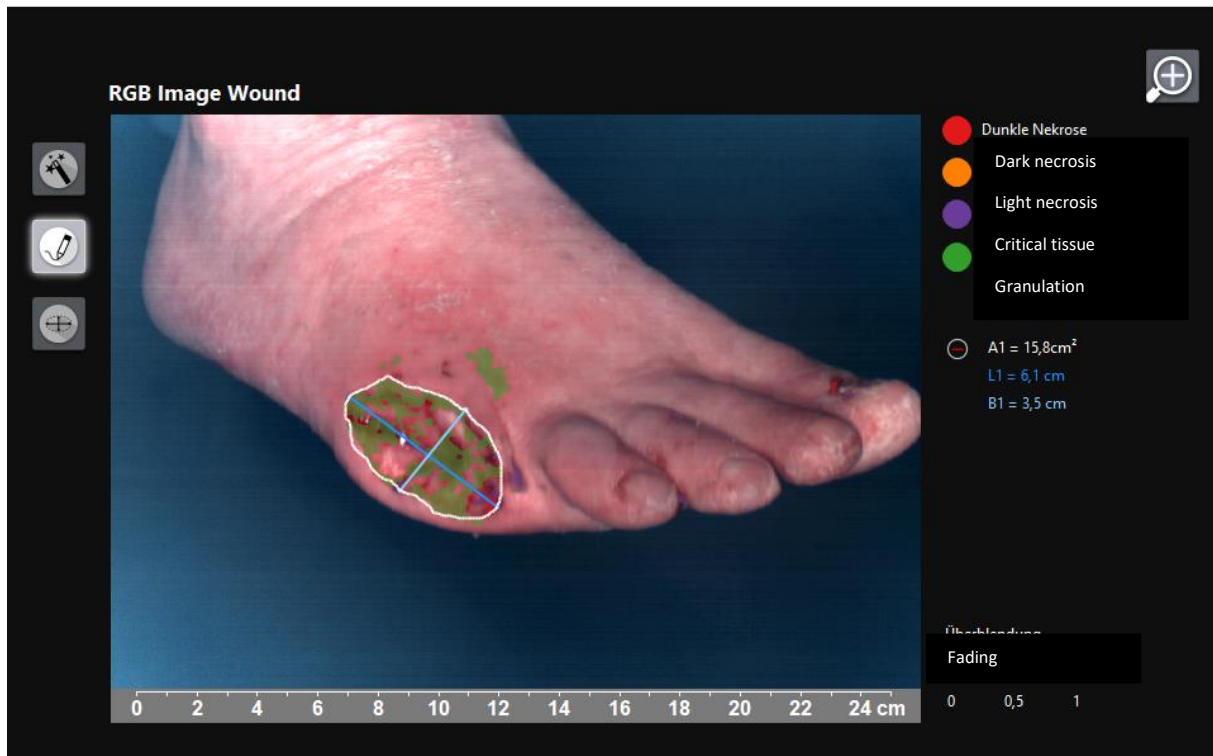


Fig. 7: Software tool for determining the size of the wound surfaces

The expert system for classifying wound tissue enables the software-supported determination of wound tissue types on the basis of an expert system. These suggestions can be helpful to the user because they are based on spectroscopic differences in tissue areas that are not visible to the human eye in most cases, because they are based on the spectral resolution of the system and information from the NIR part of the light spectrum. **Neither part of the information is accessible to the human eye.**



Fig. 8: Expert system for classification of wound tissue

In addition, a complete wound documentation system for modern wound care is included:

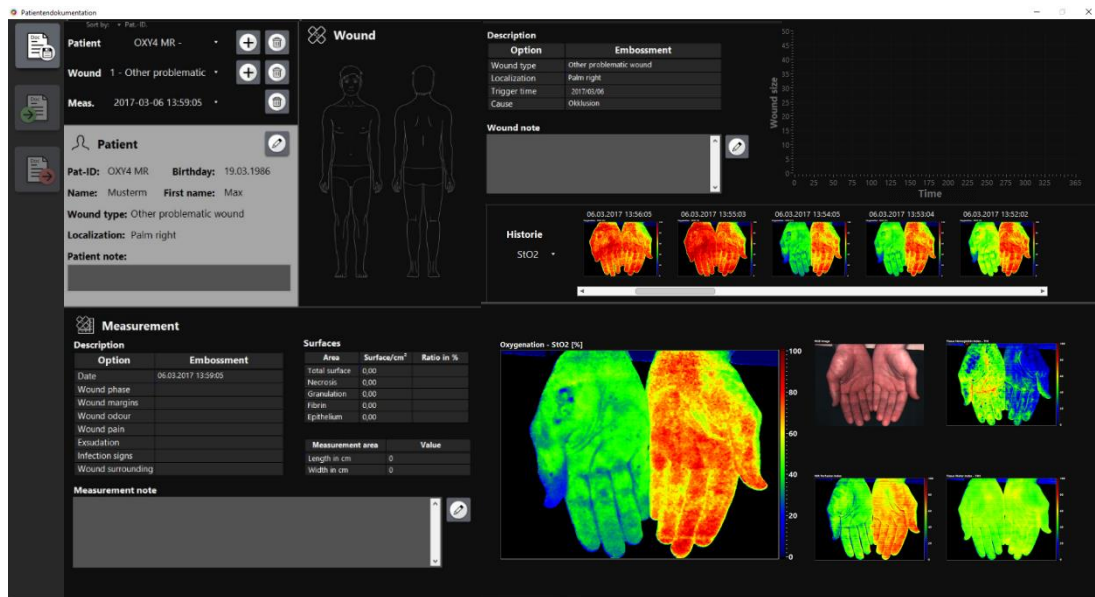


Fig. 9: User interface for documentation of wound treatment

A measurement with standard image resolution takes approx. 6 seconds. The data recorded by the camera is visually processed by the supplied software and made available in false colour images. The entire evaluation takes about 15 seconds.

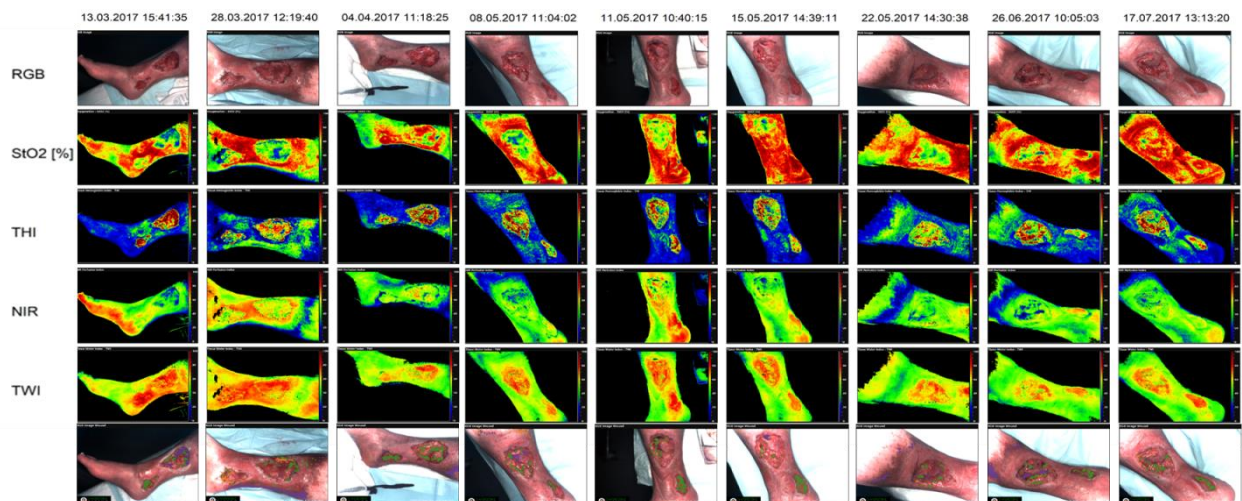


Fig. 10: Example of a clinical course of treatment of a long-term wound situation. The results of perfusion improvement, oedema management by compression and progressive epithelisation are clearly visible. But also the deterioration of the wound condition during a treatment pause is given in this example.

TIVITA® WOUND CAMERA – OVERVIEW OF SYSTEM COMPONENTES

Spectrograph

Spectral range	500 – 1000 nm
----------------	---------------

Camera

Sensor	CMOS image sensor
--------	-------------------

Supply and connections

Power supply	External power supply
Supply voltage	24 V
Power connector	DC plug connector 2,5 mm round, screw type
Network connection	GigE, RJ45

Illumination unit – Halogen [optional]

Technology	Halogen floodlight, thermal floodlight
Operation	Automatic switching

Medical cart [optional]

Dimension (B x H x T)	56 x 150 x 73 cm
Weight	Appr. 25 kg
Material	Plastic / metal

Box PC [optional]

Operating system	Windows-based
Hard disk capacities	1 TB / 128 GB SSD
Main storage	DDR4 16 GB

Mechanics

Dimensions (L x B x H) [mm]	133 x 90 x 95
Housing	Aluminium
Weight	Appr. 450 g
Mount	Adapter plate

Operational range

Temperature – application	0 – 30 °C
Temperature – transport	-10 – 45 °C
Temperature – long term storage	15 – 26 °C

Interfaces and data output

The following interfaces are integrated into the program for the use of the Wound Documentation of the TIVITA® Suite Wound in medical practices and hospitals:

- Data storage of the individual images in PC-based image format (.png) and in DICOM image format;
- HL7 interface to hospital information systems (HIS) (in preparation).

Via these interfaces, the wound documentation of the TIVITA® Suite Wound uses, among other things, the patient base of the external software. For example: if you change directly from the index card of the HIS to the corresponding position of the wound documentation of the TIVITA® Suite Wound, you will automatically receive a new index entry in the external application when you return.

In addition, a patient report can be created and output in PDF format.

„Our vision is our mission: Establish Hyperspectral Imaging in medicine as standard diagnostics for physiological monitoring“

