Wheels Bridge



TiVi9000Dental User Manual

User Manual 1.1 March 2018

PIONEERS IN TISSUE VIABILITY IMAGING

Dear Valued Customer!

Welcome to the WheelsBridge TiVi9000Dental microcirculation analyzer intended for automatic and user-independent analysis of intraoral tissue as well as investigation of microvascular events in the skin and other tissues.

The Wheelsbridge TiVi9000Dental microcirculation analyzer utilizes a hand-held camera equipped with polarization filters to capture photos and video clips of tissue microcirculation which are analysed using the integrated TiVi9000Dental software.

Among the many useful features of the TiVi9000Dental microcirculation analyzer software, the following are of particular interest:

- Monitoring tissue microcirculation in real time.
- *Capturing, displaying and storing photos and images of tissue microcirculation.*
- Uploading photos for quantification of tissue erythema and blanching.
- Threshold settings for selective analysis of low or high microcirculation activity.
- Using Regions Of Interests (ROIs) for analysis of local microvascular events.
- Automatic calculation of erythema intensity and erythema area.
- Displaying up to four photos and images simultaneously for comparison.
- All results exportable to Excel® document for further processing.
- Main results exportable in report form to Word® for further editing and print-out.

We are convinced that the TiVi9000Dental microcirculation analyser will be a productive tool in the validation process in development of vaso-active reaction of tissue following application of pharmaceuticals and dental care products in general.

Thank you for choosing the WheelsBridge TiVi9000Dental analyzer.

WheelsBridge AB

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Wheelsbridge products are covered by patents: EU pat: 1737339, Jap. pat: 5062961, US pat: 8.208.997.

1. INTRODUCTION

The intended use of the Tissue Viability Imager *TiVi9000Dental* microcirculation analyzer is rapid screening and quantification or erythema and blanching in intraoral cavity tissue irritation grading, assessment of microvascular effects of vaso-active substances topically applied to the tissue and in the validation of dental care products as well as pharmaceuticals with respect to safety and efficacy. Its use in not restricted to investigation of intraoral cavity tissue - it is useful in tissue microvascular research in general.

TiVi9000Dental is truly portable and can be used for point-of-sale imaging of tissue microcirculation in retail shops and in the home environment as well as for rapid screening in dental, cosmetic and personal care product studies.

TiVi9000Dental is further suitable for the study of small animal tissue microcirculation, because the recorded images are not affected by movement artefacts.

Although the *TiVi9000Dental* device is not yet cleared for diagnosis and treatment of disease it may still be used in medical research applications where the use of bulky equipment is not feasible.

After having captured photos by the *TiVi9000Dental* microcirculation analyzer these photos can be analyzed using a PC or tablet host computer and the *TiVi9000Dental* system software or exported to the *TiVi700 Tissue Viability Imaging* system for more in-depth analysis. The *TiVi9000Dental* runs on computers with the operating systems Windows 7, 8 and 10.

2. OPERATING PRINCIPLE

TiVi9000Dental is an emerging technology intended for mapping the tissue microcirculation [O'DOHERTY, J., HENRICSON, J., ANDERSON, C., LEAHY, M, NILSSON, G and SJOBERG, F. Sub-epidermal Imaging using Polarized Light Spectroscopy for Assessment of Skin Microcirculation. Skin Research and Technology 2007, 13; 472-484].



Operating Principle of the TiVi9000Dental.

In *TiVi9000Dental*, linearly polarized white light from a ring of white light emitting diodes (LEDs) – embedded in a hand-held probe - illuminates the tissue surface under investigation. An integrated digital camera equipped with polarizing filters captures individual photos or video clips. The light illuminating the skin is partially reflected both in the tissue surface, as well as partially scattered in a diffuse manner into the deeper tissue layers where the microvascular network resides. The light directly reflected from both the surface and near-surface layers of the tissue preserves its linear polarization, while the light diffusely scattered in the deeper layers quickly becomes randomly polarized. The directly reflected light approaching the camera is effectively blocked by a polarizing filter with a polarization direction in a plane perpendicular to that of the linearly polarized light produced by the LEDs Illuminator. A portion of the diffuse, randomly polarized light is backscattered from within the deeper tissue layers, passes through the filter and finally reaches the detector. The resulting "sub-epidermal" image gives the impression that the camera can "see beneath" the top layer of the tissue and probe the microvascular network. The polarizing filters on the camera lens and LED light source are set in cross-polarized mode.

The green component of the backscattered randomly polarized light reaching the camera detector array is attenuated to an extent determined by the relative presence of red blood cells in the scattering volume, while the red component of the light is virtually unaffected due to its low absorption rate in red blood cells. In contrast to what is the case with the red blood cells in the tissue microvascular network, the surrounding tissue absorbs both green and red light to approximately the same extent. After capturing a colour photo (or a frame in a video clip), the

TiVi9000Dental system software divides the image into discreet red, blue, and green matrices. A software algorithm subtracts the colour value of each picture element within the normalized green colour matrix from the colour value of the corresponding picture element within the red colour matrix. These calculations result in the generation of a pseudo-colour output matrix (*TiVi*-image) which is displayed on a PC monitor or a tablet computer screen, effectively mapping the local red blood cell concentration. In contrast to what is the case with methods based on the detection of time-variable phase factors (*Laser Doppler Imaging* and the *Laser Speckle* devices), *TiVi9000Dental* is not affected by movement artefacts. It is therefore also well suited for assessment of the microcirculation in moving tissues.

3. SYSTEM DESCRIPTION

TiVi9000Dental camera parts

The *TiVi9000Dental* system comprises a miniature camera with integrated LEDs for illumination of the tissue. This camera probe is hold by hand during measurement. A set of easily exchangeable light shields can be attached to the camera probe front end to eliminate the adverse effect of ambient light. The *TiVi9000Dental* software is pre-installed in the computer (if this is ordered with the system) or stored on a memory stick for installation on a PC or tablet computer.





Handheld camera probe (left: side view, right; top view).





Left: Front end of probe with 6 light emitting diodes and camera in centre. Right : Front end with Light Shield attached.

The *TiVi9000* probe is delivered with two Light Shields with a camera-to-tissue distance of 5 and 8 mm respectively.

TiVi9000Dental runs on PC and tablet computers with or without touch screen under Windows 7, 8 or 10.

Always use a light shield when capturing photos with the TiVi9000Dental system. The light shield eliminates the adverse effect of ambient light on the photo and also defines the distance to the object. When capturing photos, the light shield should be in contact with the object or positioned closed to the object.

Installing the TiVi9000Dental software.

- 1. Drag the *TiVi9000Dental INSTALL* folder in the memory-stick to the target desktop computer.
- 2. Open the folder and click the setup icon to start the installation. Follow the instructions on the screen.
- 3. With the camera-probe connected to the computer, click the *TiVi9000Dental* icon on the desktop to start the program. The start-up page of the software is the **Camera Page** and the camera starts operating momentarily displaying the photo and the TiVi video.

4. SYSTEM SOFTWARE OVERVIEW

The *TiVi9000Dental* system software comprises the following three main pages:

Camera Page:

In the *Camera Page* the photo video and the associated TiVi-image video of the object in the field of view are continuously displayed in real-time in the left panel. By clicking the *Capture* button photos and TiVi-images are extracted from the video and displayed in the right panel. If a filename has been inserted in the text-box after clicking the *Save As* button, the photo is also saved to the hard-desk. Continuously clicking the Capture button causes consecutive photos to be saved (naming convention: MyFile-0001, Myfile-0002 etc.). Compensation for different background colours is made by clicking any of the elements in the *Background Discrimination* panel. The color scale of the TiVi-images are changed by clicking any of the elements under *Color* in each of the upper panels.



Layout of the Camera Page.

Analyze Page:

In the *Analyze Page* captured photos are uploaded for display and comparison. The left picture box can for instance hold the first photo in a sequence while the right picture box holds the last (for comparison). While moving the mouse over the photo or the TiVi-image, the local TiVi-value is displayed next to the photos.

⅔ TiVi9000 SN0251				-	
Camera Page Analyze Page	e Library Page Camera Setup Language About Factory Setting:	License Manual			_
				TiVI: 0	
		Cator O O O O		Color O O O	
Load Photo 1	File Name: DEA-0111 Date: 2018:03:13 10:02:05	Background Discrimination	Load Photo 2 File Name: DEA 0155 Date: 2018:03:13 10:02:08	Clear Al	

Layout of the Analyze Page.

Library Page:

In the *Library Page*, up to four photos and the associated TiVi-images can be displayed. While moving the mouse over a photo or TiVi-image, the local TiVi-value is displayed in the rightmost panel.



Layout of *Library Page*.

Selecting *Lower* and *Upper Threshold* by clicking the elements of the *Lower Threshold* and *Upper Threshold* panels eliminates pixels of low and high TiVi-values from the TiVi-images and in the calculation of the average TiVi-values and Area.



Displaying only the lower TiVi-values by reducing the Upper Threshold.



Displaying only the higher TiVi-values by increasing the Lower Threshold.

Threshold settings can be combined with creating a Region Of Interest (ROI) in the photo or TiVi-image to display only pixels within the threshold settings and boundaries of the ROI area.



Creating a ROI in the second photo and/or TiVi-image displays only pixels within the threshold settings and ROI boundaries.

A ROI can be drawn in a photo or TiVi-image by first moving the mouse pointer to the start point (upper left corner of the ROI), pressing the right mouse button, dragging the mouse to the lower Right ROI corner and then releasing the mouse button.

By checking different colors in the rightmost panel, the color scale of the displayed pixels can be altered. Such color scale alterations do not affect calculated average TiVi-values and areas.

Clicking the Subject Data button open the Subject Data window displaying test subject data.

🐕 Subject Data		- 🗆 X
Filename :		
ID DJ	Gender O Female Male	
First Name David	Family Name Jones	Bithday
Phone 0708 123456	E-mail djones@gmail.com	YearMonthDay561213
Address 12 Unity Road	Comment test subject	Save Data

By clicking the *Export* button the caluclated data and displayed photos and TiVi-images can be exported to an MS Excel® spreadsheet (provided MS Excel® is installed).

By clicking the *Print* button the caluclated data, displayed photos and TiVi-images can be exported to an MS Word® document (provided MS Word® is installed).

5. DETAILED DESCRIPTION

A. Menus

Camera Page – click to select *Camera Page*.

Analyze Page – click to select Analyze Page.

Library Page – click to select *Library Page*.

Camera Setup – click to start the camera 'calibration procedure.

Language – click to select language (Chinese, English, French, German, Japanese or Swedish).

About – click to display the TiVi9000Dental About window.

Factory Settings – select to revert to parameter factory settings.

License – click to display the *License Agreement*.

Manual – click to display this online TiVi9000Micro manual as a printable pdf-document.



B. Camera Page

When the *Camera Page* is selected, the system is automatically set to continuous video mode.

Left panel:

Upper Picture box – displays the video.

Lower Picture box – displays TiVi in video mode.

Color – select to alter the color scale of the TiVi video.

Right panel:

Upper Picture box – displays the photo captured by clicking the Capture button or the button on the probe.

Lower Picture box – displays the TiVi image associated with the captured photo.

Color – select to alter the color scale of the TiVi image captured.

Lower Panel:

Save As: Click to navigate to the folder in which a captured photo is to be saved and select a filename. The file number is automatically added by the software. The filename is displayed in the text-box. Successive photos will be saved under the same name and an updated file number. If no filename is selected (empty text-box) a captured photo and TiVi image will be displayed, but no photo is saved.

Capture - click to capture a new photo. A new photo can alternatively be captured by pressing the button on the probe.

Background Discrimination - Click an element to adjust the offset of the TiVi image (to compensate for alternating background colors).

C. Analyze Page



Left panel:

Upper Picture box – displays the first photo uploaded from file.

Lower Picture box – displays the first TiVi image associated with the first photo.

Color – select to alter the color scale of the first TiVi image displayed.

Right panel:

Upper Picture box – displays the second photo uploaded from file.

Lower Picture box – displays the second TiVi image associated with the second photo.

Color – select to alter the color scale of the second TiVi image displayed.

Lower panel:

Load Photo 1- Click to navigate to and upload the first photo.

Filename: Displays the name of photo 1.

Date: Displays the date and time at which the first photo was captured.

Load Photo 2 - Click to navigate to and upload the second photo.

Filename: Displays the name of photo 2.

Date: Displays the date and time at which the second photo was captured.

Background Discrimination - Click an element to adjust the offset of the TiVi image (to compensate for alternating background colors).

Clear All: Click to clear all four picture boxes.

D. Library Page

5 TW9500 DN0001 -					
	up Language About Factory Settings Licence IV				
File New: - OuCaRCorkEg 001	Fie Name: CwcGallCov/teEg 005	Filerane:	Florance	Cater O O	
Date: 2018:01:11 10:36:04	Date: 2018:01:11 10:36:04	Date:	Date:	0	
TiVI-value: 187	TiVi-value: 183	TiVi-Value:	TiVi-Value:		
Area: 20200	Nets: 202723	Area:	Load Photo 4	Export	
Lower Threshold	Upper Threshold		Background Discrimination	Clear All	

Four Upper Left panels:

Upper Picture box – displays the photo uploaded from file.

Lower Picture box – displays the TiVi image associated with the photo.

Filename: Displays the name of the photo.

Date: Displays the date and time at which the photo was captured.

TiVi-Value: Displays the average TiVi value (in between set thresholds):

Area: Displays the number of pixels displayed.

Lower panel:

Lower Threshold - to select the lower threshold.

Upper Threshold - to select the upper threshold.

Background Discrimination - Click an element to adjust the offset of the TiVi images (to compensate for alternating background colors).

Right panel:

Color – select to alter the color scale of the TiVi images displayed.

Export – Click to export the result to an MS Excel® spreadsheet (assumes that MS Excel® is installed).

Print – Click to print the result to a printable MS Word ® document (assumes that MS Word® is installed.

Clear All: Click to clear all eight picture boxes.

To draw a region of interest (ROI) in a photo or TiVi image: 1) position the mouse pointer at the upper left corner of the ROI to be drawn. 2) press the left mouse button and drag the mouse pointer to the lower right corner of the ROI to be drawn. 3) Release the mouse button. The ROI will now be drawn in the photo. In the TiVi-image only TiVi-values within the ROI boundary are displayed and accounted for in the average TiVi-value and area calculations.

6. CAMERA SETUP

Each TiVi9000 probe is carefully calibrated for maximum performance in the manufacturing process, and generally no additional calibration is needed unless the probe is exchanged. The probe serial number (on the body of the probe) and the serial number in the top panel of the TiVi9000 software have to match for optimal performance with respect to especially uniform sensitivity over the entire image surface. If these numbers do not match proceed with the calibration procedure below.

To equalize the spatial sensitivity, the algorithm utilized is based on a compensating mechanism for the possible non-uniformity of the individual camera sensitivity. This compensation mechanism forms an integral part of the software package fine-tuned to the specific probe in use.

If the probe is replaced correction of this compensation mechanism in the software may be necessary to preserve a uniform sensitivity over the TiVi-image surface. This correction process is performed through the following steps.

Select *Camera Setup* in the pull-down e menu.

Follow the instruction on the screen. While the calibration process is in progress the **Save As** textbox flashes red and green.



Probe placed in calibration position above the "white" calibration box.

7. DISINFECTION OF PROBE HEAD

Remove the Light Shield from the probe and immerse it in disinfectant liquid. Clean the front end of the probe by a cloth soaked with disinfectant liquid. Wipe off any liquid on the probe before using it for measurements again. Do not immerse the probe head in disinfection liquid.

Cidex® or any other disinfectant liquid may be used for disinfection.

8. SPECIFICATION

Image size	640 x 480 pixels		
Field of View (standard Light Shield)	About 11 x 8.2 mm (about 0.017 mm /pixel)		
Field of View (shallow Light Shield)	About 8.2 x 6.1 mm (about 0.012 mm /pixel)		
Minimal camera – object distance	About 5 mm		
Operating temperature	+ 10 to + 40 degrees centigrade		
Computer processor	Core i5 or Core i7		
Operating system	Windows 7, 8 or 10		