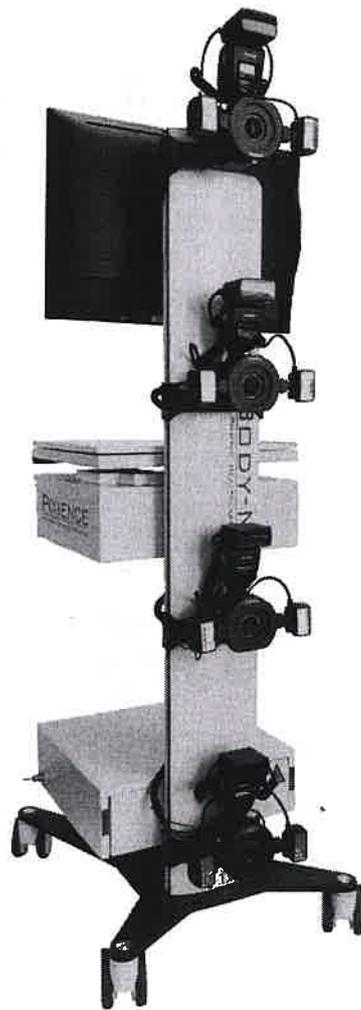


User Guide – Body-Mapper

BODY-MAPPER

BY PIXIENCE HEALTHCARE TECHNOLOGY SOLUTIONS

USER GUIDE BODY-MAPPER



PIXIENCE

HEALTHCARE TECHNOLOGY SOLUTIONS

Pixience SAS, société au capital de 50 200 €
751 108 739 RCS Toulouse – TVA FR30 751 108 739
12, rue Louis Courtois de Viçose - Les Arches, bâtiment 3 - 31100 Toulouse
Reproduction interdite

Version 2.0.2023

User Guide – Body-Mapper

In the event of a device failure, please contact the supplier immediately:

Pixience
 12 rue Louis Courtois de Viçose
 31100 Toulouse
 France
 Tél. +33(0)5 81 31 42 74
 E-Mail: support@pixience.com



PIXIENCE

12 RUE LOUIS COURTOIS DE
 VICOSE, LES ARCHES, BAT.3
 31100 TOULOUSE, FRANCE

2.5. TECHNICAL SECURITY CONTROLS

Before each use, the condition of the appliance should be checked thoroughly. Pay particular attention to possible damage to the power cord.

2.6. TECHNICAL SPECIFICATIONS

2.6.1. BODY-MAPPER E4

GENERAL INDICATIONS

Trade name:	Body-Mapper E4
Version:	1.0
Product Type:	Automatic Full-Body Photography System
Accessories:	
1.1.3. Polarized flash	Included
Computer	Included

TECHNICAL INDICATIONS

1.1.2.2. Camera reference :	Canon EOS 5DSR
Camera Resolution:	50.6 MPx <i>T1</i>
Lens:	SIGMA 1.4 50mm f1/4
Working Distance:	1.10 m
Power supply:	Power supply 220V – 50Hz

3. EQUIPMENT DESCRIPTION

3.1. AREAS OF APPLICATION OF BODY-MAPPER TECHNOLOGY

The Body-Mapper device allows:

1.1.1.

- A so-called "clinical" photograph, implying of the patient's body.
- Import the photographs into the C-Cube Edition Dermatology software.
- To map the lesions to be imaged in dermoscopy on the photographs taken in the C-Cube Edition Dermatology software.
- Compare the images acquired during the follow-up of consultations.

3.2. OVERVIEW OF THE BODY-MAPPER

3.2.1. BODY-MAPPER E4

The Body-Mapper device consists of the following components:

- 4 cameras paired with a 50mm f1/4 lens. (1) 1.1.2.1.
- An all-in-one touchscreen computer. (2) 1.1.4.
- A handle allowing the mobility of the trolley. (3) 1.1.5.
- A storage drawer. (4)
- An electrical compartment integrating the connection of all the integrated elements to the Body-Mapper system. (5)
- Casters with brakes ensuring the stability and safety of the trolley. (6)

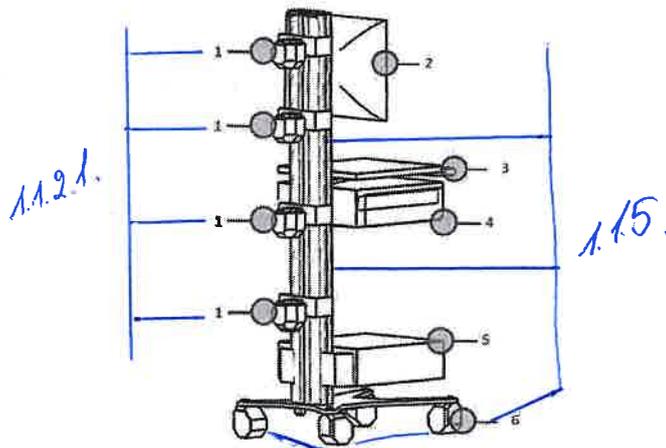


Figure 1: Technical description of Body-Mapper E4

3.2.1.1

CAMERAS

These cameras are specifically dedicated to taking pictures of the body.



Important: This camera should not be disconnected from its USB transmission or power supply. Opening the camera's power compartment is completely prohibited.

User Guide – Body-Mapper

1.13. Lighting Type:	Individual polarized flashes
Lifespan:	5 years

2.6.2. COMMON FEATURES

COMPUTER INDICATIONS

Reference:	DELL OptiPlex All-in-One
Operating system:	Windows 11
Processor:	Intel Core i7
RAM:	32 Go
Hard disk:	512 Go SSD + 4 To SSD
1.14. Screen Size:	23.8"
Screen Type:	Touch-screen multipoints
Guarantee:	Dell pro-support – 2 years

MEDICAL TROLLEY INDICATIONS

Reference:	JANSEN MEDICARS FLEXX ONE
------------	---------------------------

OPERATIONAL AND STORAGE CONDITIONS OF USE

Operational :	
Operating temperature	+10 °C - +40 °C
Humidity	10% - 90% HR
Pressure	80 – 106 kPa
Storage:	
Operating temperature	-25 °C - +50 °C
Humidity	10% - 90% HR
Pressure	80 – 106 kPa

2.7. STANDARD-COMPLIANT SYSTEM CONTROL

The system is installed in accordance with the rules if:

- The safety indications relating to the place and the environment are respected.
- The Body-Mapper is connected to an electrical installation that complies with NF C 15-100 standards.

2.8. CONTRAINDICATIONS BEFORE SYSTEM COMMISSIONING

- Do not open the lower electrical compartment.

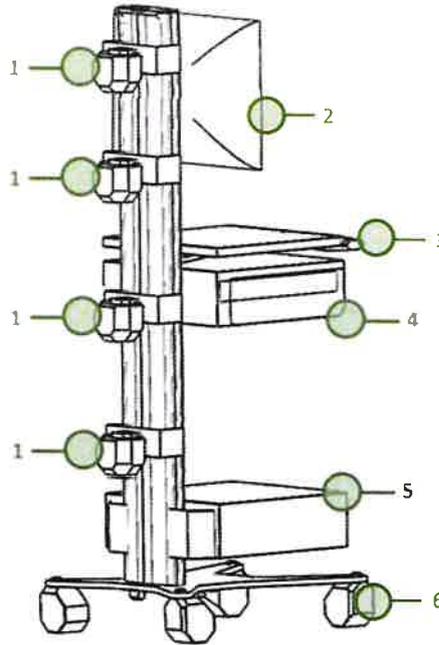
The Body-Mapper device allows to take so-called "clinical" photographs of the patient's body. 1.1.2.
1.1.2.

1.1. BODY-MAPPER E4

The Body-Mapper E4 allows you to photograph your patient's body using 4 cameras (1) attached to a medical trolley that also supports the computer (2). This medical trolley is itself composed of:

- (3) a handle allowing mobility of the trolley.
- (4) a gear storage drawer,
- (5) a compartment of electrical connections.
- (6) four castors, two of which have brakes to ensure the stability and safety of the trolley.

1.1.5.



Thanks to the use of camera synchronization, it is possible to easily image the patient's entire body in 4 preset poses (front, back, right profile, left profile). 1.1.2.

2. SAFETY INSTRUCTIONS

2.1. FOREWORD

The Body-Mapper hardware comes fully configured for use in daily dermatology practice. No hardware modifications need to be made by the user, especially within the electrical connection compartment (5).

2.2. ELECTRICAL SAFETY INSTRUCTIONS

Pixience explicitly states:

- That the user of the appliance assumes responsibility for the electrical installation of the equipment.

User Guide – Body-Mapper

During a patient's first consultation, it is possible to adjust the distance between the Body-Mapper and the subject. Once the Body-Mapper is positioned at the desired distance, the ruler below the adjustment interface can be used to shift the horizontal red line and align it with that of the mat.



The distance used will be memorized for the patient in question, and the red lines can be used in subsequent consultations to position the Body-Mapper at the same distance.

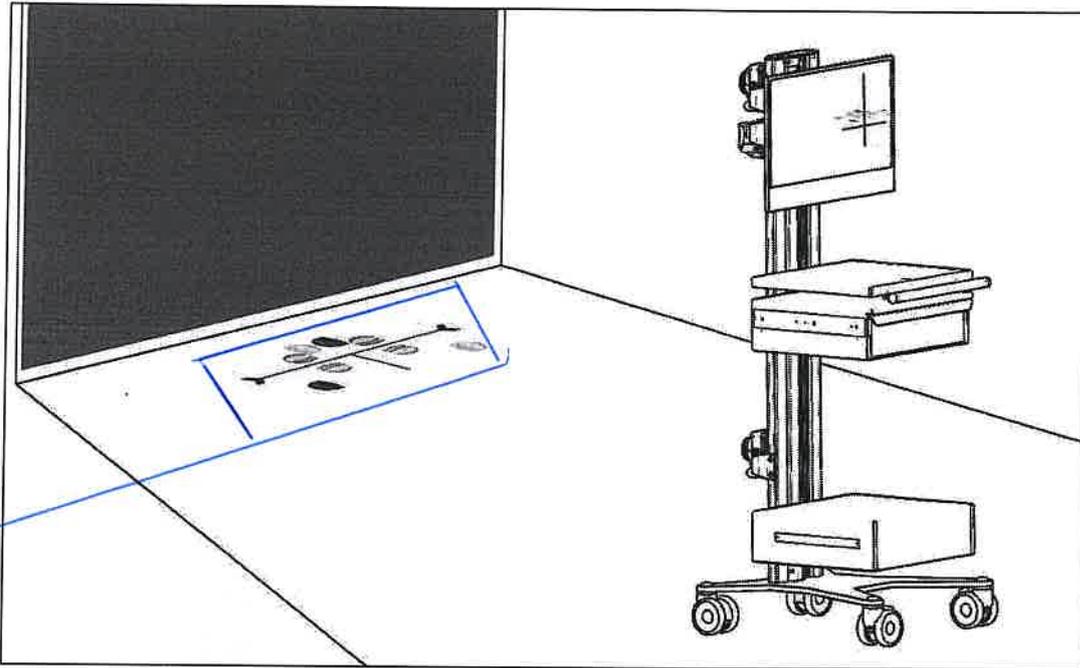


Figure 6: Adjusting the shooting distance and position.

8.3. FIRST CONSULTATION

When conducting the first consultation:

1. Position the Body-Mapper so that the red line on the screen overlaps with the red line on the carpet and click OK.
2. Then position the subject on zone 1 with the heels in the markings provided.
3. Indicate the pose of arms to be taken for the photograph.
4. Click on the *Interface Acquisition* button. Only devices selected in area 5 of the interface will be used.
5. The cameras are set automatically.
6. Validate the photo taking if it suits you.



7. Move on to the next poses using the same process.

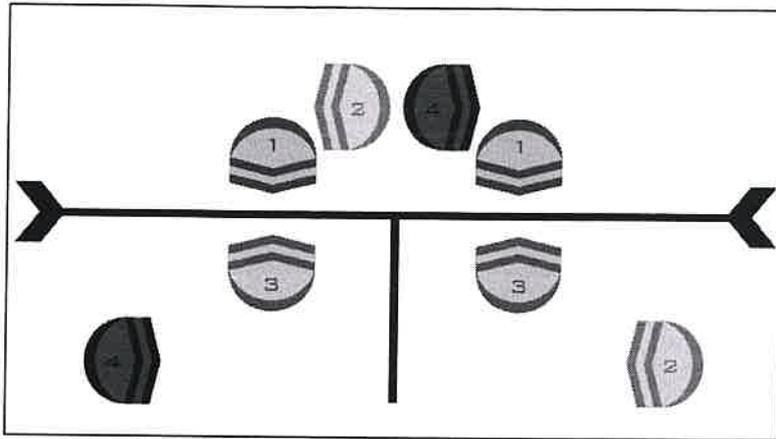
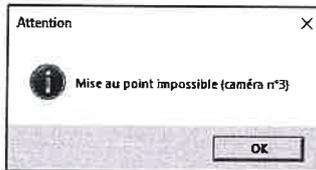


Figure 7: Positioning mat.



Important: If one of the cameras fails to complete its pre-photo setting, an error message appears. In this case, please refer to the *Figure 8: Mode GhostView®*.

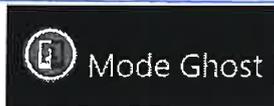


Important: It is recommended to ask the patient to close the eyelids during the photograph in order to avoid any possible glare phenomenon.

8.4. SUBSEQUENT CONSULTATIONS

In order to ensure optimal repositioning of the subject from one consultation to the next, the Body-Mapper system has an exclusive GhostView® interface. It makes it possible to place the subject in transparency during the previous consultation in order to guide it.

T₃



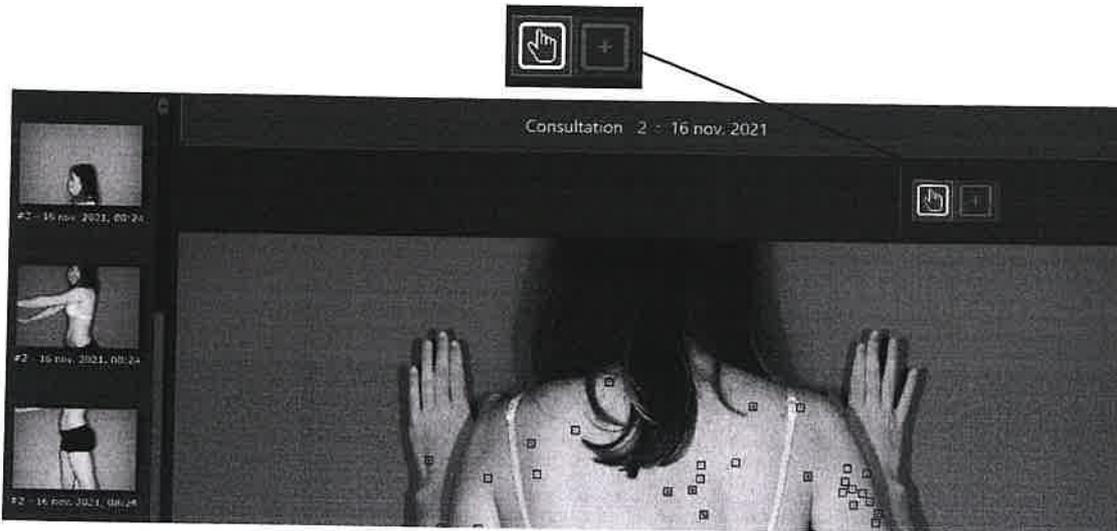
1.1.10.5.

In order to enable GhostView® mode, select Ghost Mode in Zone 2 of the Body-Mapper acquisition interface (see Figure 13). Then instruct the patient to position themselves in the same way as in the previous consultation.

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	Product Photo	Article	Product Description			
P A C K B O D Y M A P P E R E 4		BODY-MAPPER TOWER E4 (50 Mpix)	<p><u>Medical Cart</u> 4 x CANON Cameras (50 Megapixels) 4 x Full Frame Lenses 4 x Professional Ring LED Lights 4 x 90° Cross-Polarized Filters Positioning Aid Mats and Posters Articulated Screen Support 4 x Anti-shock Mounts 24" Touchscreen All-in-one Computer</p> <p><u>Windows 11 Professional</u> 3-Year Dell Pro On-site Warranty 16GB DDR4 Memory 2TB SSD Hard Drive Windows Configuration Software Installation Software Configuration</p> <p><u>Body-Mapper Software Module</u> Instantaneous acquisition of each side (4 acquisitions for 16 shots of your patient) Integrated Ghost function for perfect repositioning during follow-up Lesion detection + sorting by area and size New lesion detection</p>			
		Professional Edition Software	<p><u>Professional Edition Software (1 User License + 1 Viewer License)</u> Patient Management Module (Includes Vital Reader) Lesion Mapping Module on Mannequin and Clinical Images Dermoscopic Image Management Module Clinical Image Management Module Automated Weekly Backup Management for your C-Cube System Statistical Tools Module Non C-Cube Image Management Module Expert Management Module Automatic Registration + Intelligent Zoom</p>			
		Dermoscope C-Cube 3	<p>C-Cube (Resolution: 55Lpmm, Acquisition Area +- 14.5mm*19.5mm) Transport Case C-Cube Table Stand Standard C-Cube cap Precision C-Cube cap Video Dermoscope C-Cube 3 Warranty: 2 years</p>			
		Smartphone Access	Smartphone Access (Android Version >= 5.1 and iOS Version >= 6)			
		Aesthetic Module	<p>*Pigmented Spots Analysis *Tattoo Analysis / Removal *Redness / Irritation Analysis *Report Editing</p>			
P A C K C - C U B E D E R M A T		Dermoscope C-Cube 3	<p>C-Cube (Resolution: 55Lpmm, Acquisition Area +- 14.5mm*19.5mm) Transport Case C-Cube Table Stand Standard C-Cube cap Precision C-Cube cap Video Dermoscope C-Cube 3 Warranty: 2 years</p>			
		Professional Edition Software	<p><u>Professional Edition Software (1 User License + 1 Viewer License)</u> Patient Management Module (Includes Vital Reader) Lesion Mapping Module on Mannequin and Clinical Images Dermoscopic Image Management Module Clinical Image Management Module Automated Weekly Backup Management for your C-Cube System Statistical Tools Module Non C-Cube Image Management Module Expert Management Module Automatic Registration + Intelligent Zoom</p>			
		Smartphone Access	Smartphone Access (Android Version >= 5.1 and iOS Version >= 6)			
		Aesthetic Module	<p>*Pigmented Spots Analysis *Tattoo Analysis / Removal *Redness / Irritation Analysis *Report Editing</p>			



The detection interface allows you to add or select a detection box on the selected photograph. By clicking on the entire image of zone 2 of the interface, a new box will be created and positioned at the point if you choose the Add function (Plus icon) otherwise it selects the pointed box ("Main" icon).

9.5. COMPARISON OF DETECTIONS OVER TIME

Comparison over time of clinical photographs is available when the "History" tab is selected in area 4 of the interface. The right half of the interface then makes it possible to visualize, for each photograph of the current consultation, its equivalent in a past consultation. The bar in zone 5 of the interface allows you to choose this consultation.

1.1.10.1.



The "History" tab also allows you to start a detection on the selected past consultation (see Section 9.2. [Interface Description](#)).

1.1.9.

The zoom functionality is synchronized between the photograph of the current consultation and the photograph of the previous consultation, so pointing at a lesion on one of the two images makes it possible to visualize the evolution of this lesion between the two consultations. If markers are located in the pointed area, they will be indicated by arrows accompanied by the number of the corresponding marker.

1.1.10.2.



9.6. LIST AND DISPLAY OF DETECTED LESIONS

9.



9.2. INTERFACE DESCRIPTION

1.1.10.5

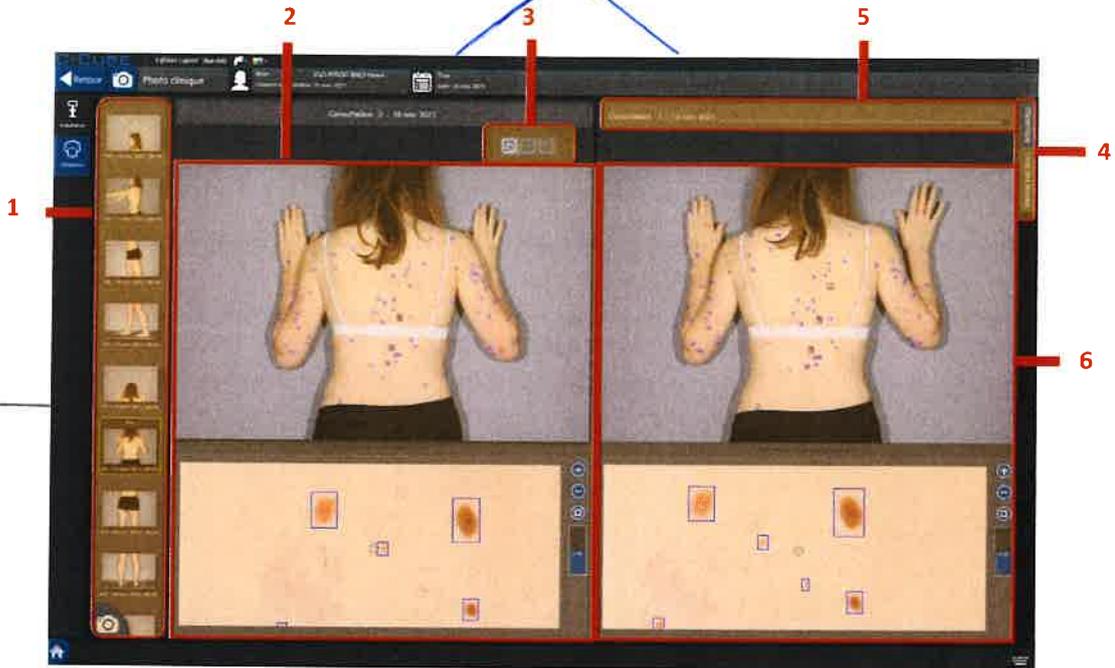


Figure 14: Detection Interface (History Tab)

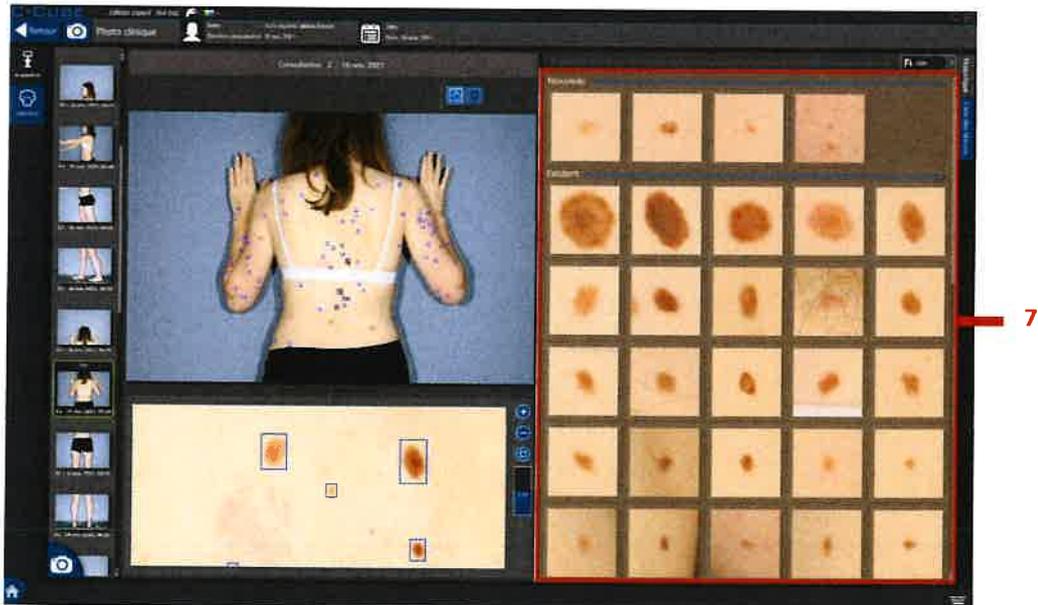


Figure 15: Detection interface (lesion list tab).

10.

User Guide – Body-Mapper

The interface is divided into several areas that allow you to manipulate one or more photographs of the consultation.

1. Selection of a photograph of the current consultation that can be manipulated from other areas of the interface.
2. High-resolution display of the selected photograph with its zoom as well as the boxes of the associated detected lesions. *A.1.9.*
3. Management of detection boxes for the selected photograph (Selection / Add)
4. Choice of the feature displayed on the right half of the interface ("History" or "Lesion List").

Historical

5. Selection of a previous consultation of the patient, to which the clinical photographs of the current consultation are compared.
6. Display of the photograph in the selected past view of the same body part as the selected photograph in the current view.

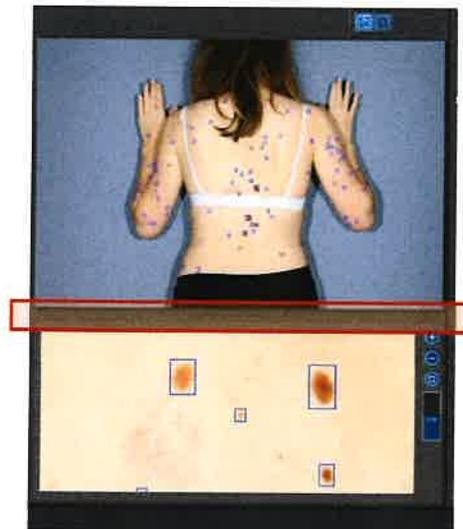
List of lesions

7. Display a set of thumbnails from the selected photograph, one for each lesion detected.

9.3. DETECTION

The detection interface makes it possible to automatically identify certain lesions on the photographs of the current consultation. *A.1.No.3.*

Once the analysis of a photograph is complete, the results are displayed on top of it (area 2 of the interface) when it is selected.

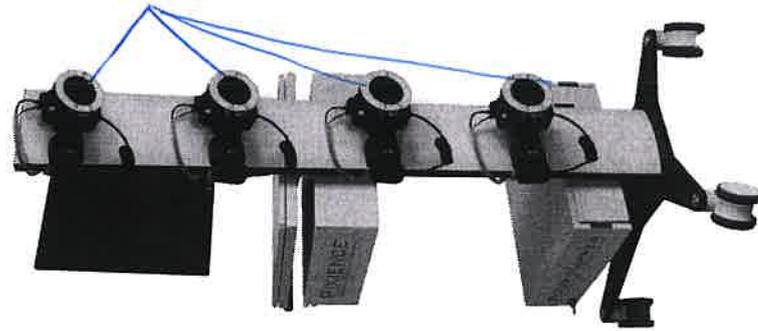


A.1.9. The display of clinical photography is divided into two sections. The first part displays the entire image; The second part is zooming in on the section of the image pointed by the mouse over the entire photograph. It is possible to adjust the size of these two elements by clicking and dragging the resize bar between them.

9.4. MANAGEMENT OF DETECTION BOXES ON A CLINICAL PHOTO

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Dermatology - BodyMapper E4



Save time on acquisition

Why 4 fixed devices? *A.A.G.*

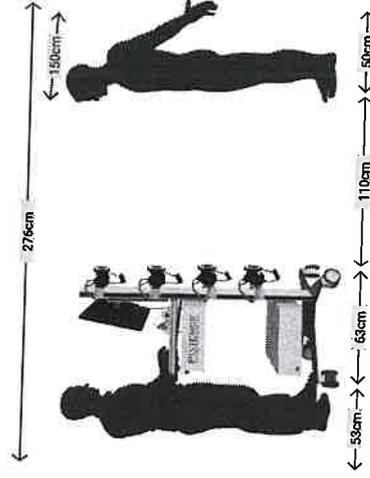
- Acquisition 4 times faster than all other systems on the market! *A.A.G.*
- Removes patient movement issues by making 4 simultaneous acquisitions per plan. *A.A.G.*

Mastering the changes Before / After

Side-by-side and transparent display of the different planes to detect the evolution of lesions or identify new ones. Automatic and unadjusted shooting with standardized framing for accurate later comparisons. *A.A.G.*

High definition total body photography in polarized light

- 90° cross-polarized optics/flash *A.A.G.*
- 4 x 50Mp cameras *T1*
- Standardized background, carpet and repositioning aid poster *A.A.G.*
- Compatible with C-Cube 3 dermoscope video *A.A.G.*



1-1-8.

User Guide – Body-Mapper

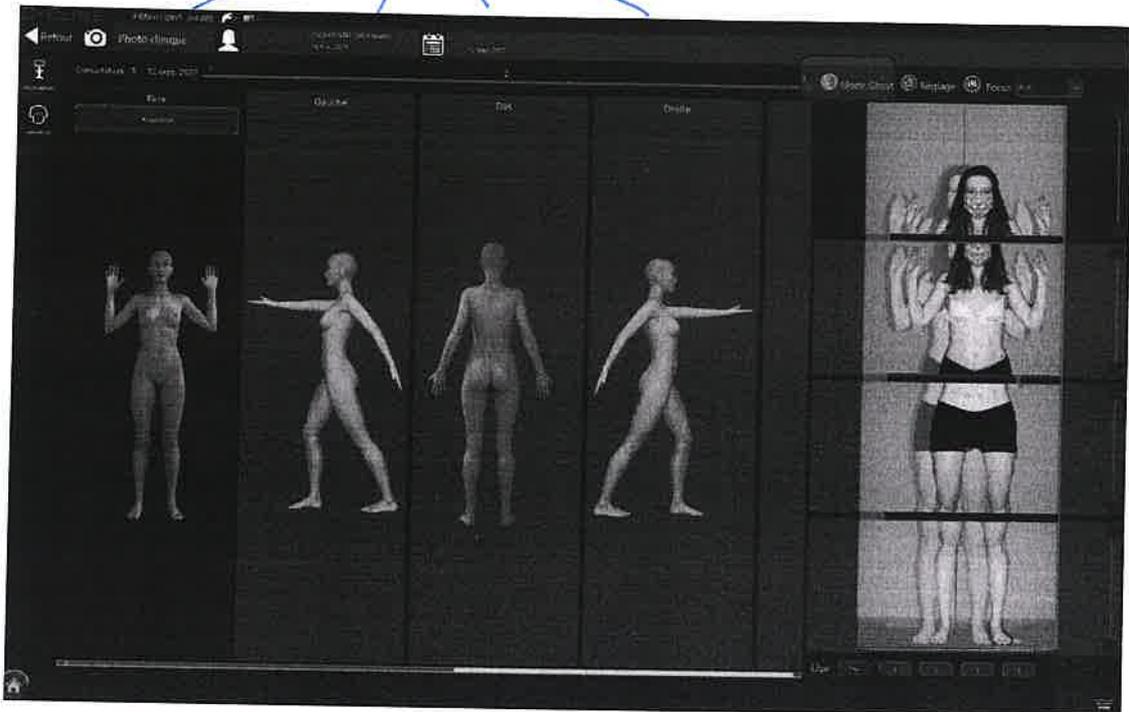
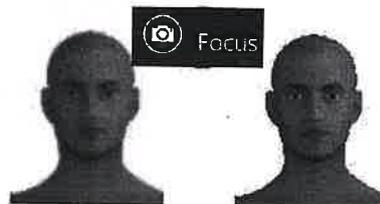


Figure 8: Mode GhostView®.

8.5. FOCUS ADJUSTMENT.

To focus the cameras, click the *Focus* option in Zone 2 of the Body-Mapper acquisition interface (see Figure 13).

The cameras then adjust automatically and simultaneously to ensure optimal sharpness of the photographs.



Important: If the message "Unable to focus" appears, please check that the Body-Mapper is correctly positioned in relation to the subject (see Section 0), and that the lighting in the room is sufficient while respecting the recommendations of the Section 8.2.3.

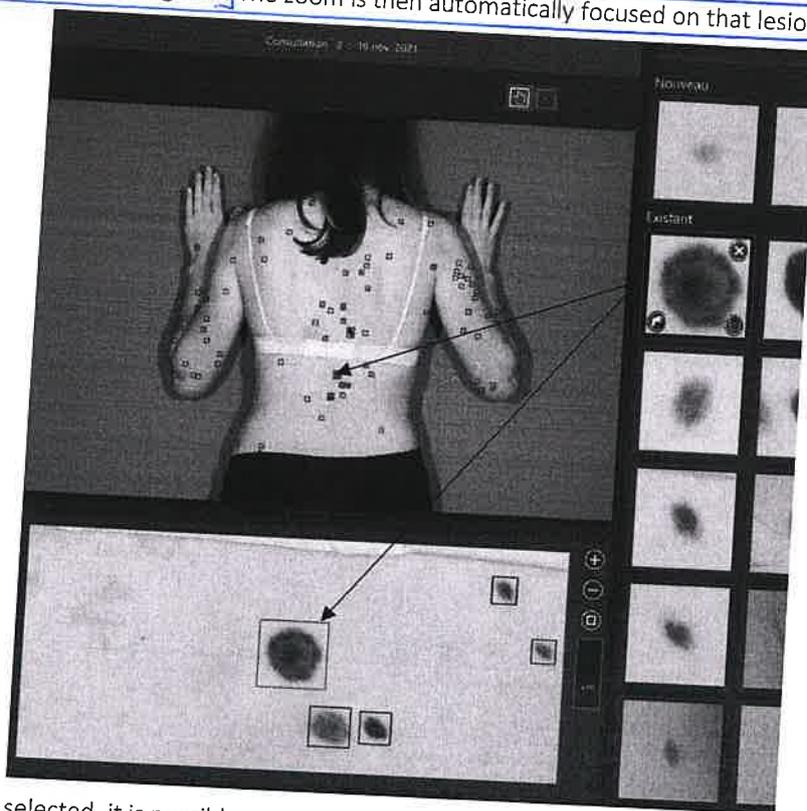
There are two focus modes. This can be done automatically (automatic mode), or on repositionable fireplaces (manual mode). To change modes, click on the drop-down menu in zone 2 of the interface.

User Guide – Body-Mapper

The list of detected lesions is available when the "Lesion List" tab is selected in area 4 of the interface. The right half of the interface then presents a mosaic, each of which is a piece of the image (called a "thumbnail") where a lesion has been detected.

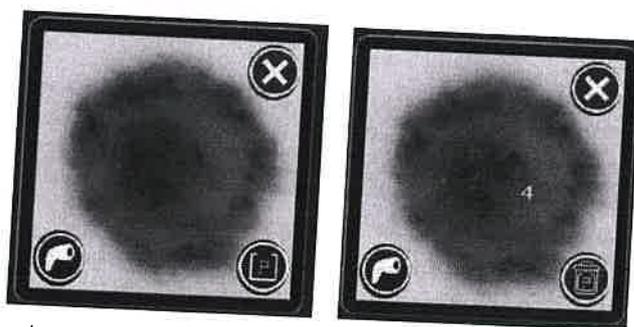
1.1.10.4.

Clicking on a lesion in the mosaic dataset selects it, and the corresponding indicator on the clinical photograph is displayed in green. The zoom is then automatically focused on that lesion.



When a lesion is selected, it is possible to place a marker where it is located. To do this, click on the add button  at the bottom right of the corresponding tile.

If a marker has already been placed at the location of the lesion, it can be removed by clicking the button  at the bottom right of the thumbnail  again.



When a marker is in the thumbnail, it is represented by an arrow with its number. This arrow is colored red if the associated marker does not have a dermoscopic photograph in the current consultation, or colored green if it does.

1.1.10.4.

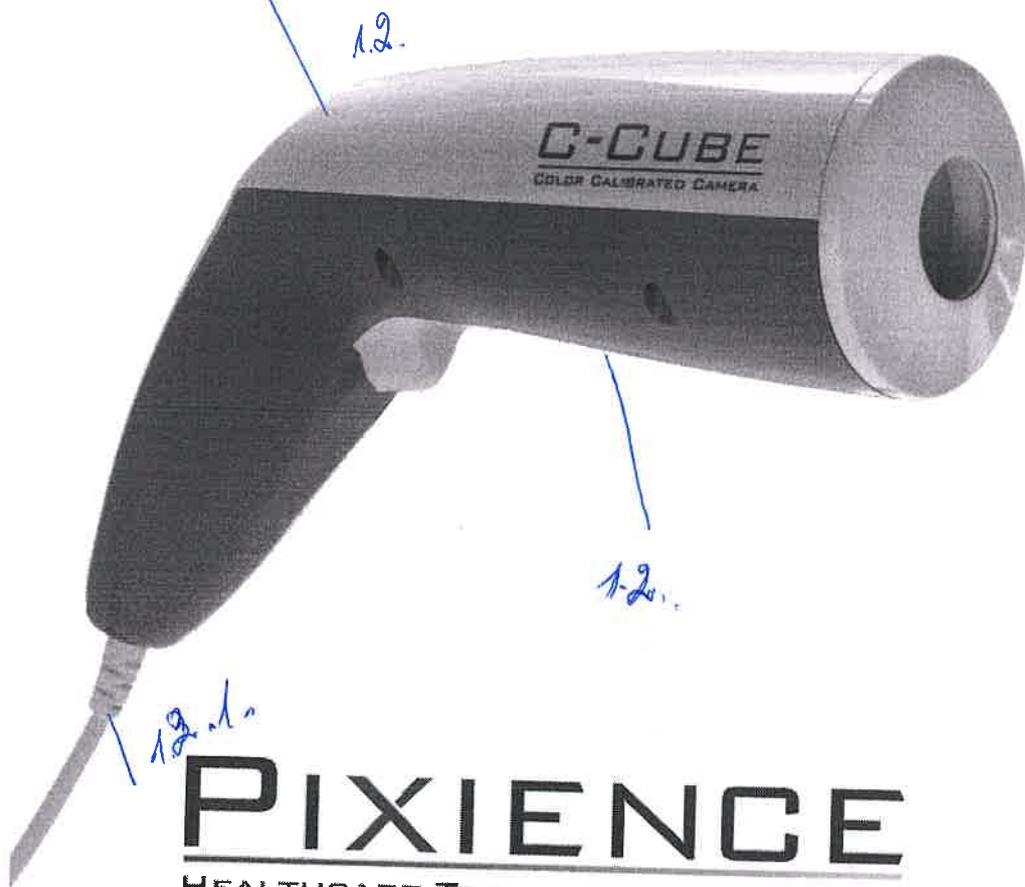
14.

User manual – C-Cube Dermoscope 3 Dermatology Edition

C-CUBE

COLOR CALIBRATED CAMERA

USER MANUAL – C-CUBE DERMOSCOPE 3 DERMATOLOGY EDITION



PIXIEN
HEALTHCARE TECHNOLOGY SOLUTIONS

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V1.2

26/08/2022

1.5.

4.5. TECHNICAL SAFETY INSPECTION

Please check the condition of the appliance carefully before each use. Pay particular attention to any damage to the communication cords and to the glass on the cap.



Important: The system must be checked regularly according to the accepted code of practice. You are advised to have the system checked every 12 months.

4.6. TECHNICAL CHARACTERISTICS FOR MEDICAL DEVICES

GENERAL DETAILS

<i>Commercial name:</i>	C-Cube 3
<i>Version:</i>	3.0
<i>MD class:</i>	Class I
<i>Product type:</i>	Digital dermoscope for a dermatological application
<u>Accessories:</u>	
<i>Camera</i>	Options
<i>C-Cube 3 bracket</i>	Supplied
<i>Standard cap</i>	Supplied
<i>Precision cap</i>	Supplied
<i>Cap characteristics</i>	Glass, interior anti-reflective coating, magnetised
<i>Weight with the standard cap</i>	410g

1.2.5.

TECHNICAL DETAILS OF THE C-CUBE 3 DERMOSCOPE

<i>Image capture technology:</i>	CMOS
<i>Image capture device:</i>	1/2.3" or 1/1.8"
1.2.5. <i>Resolution:</i>	4912 x 3684 pixels or 4000 x 3000
<i>Number of pixels:</i>	18 Mpx or 12 Mpx
<i>Acquisition time:</i>	1 second
1.2.8. <i>Acquisition surface area:</i>	12 x 16 mm ² or 15 x 19 mm ²
<i>Smallest structure visible:</i>	9 µm (Lpmm >= 50)
<i>Archiving and viewing image format:</i>	DICOM
<i>Document export image format:</i>	jpeg, png
<i>Power supply:</i>	USB 3.0 (5V, 2A)
<u>Lighting:</u>	
<i>Type of lighting:</i>	Group 0 LED (16 LEDs) 1.2.2.
<i>Lighting technology:</i>	Backscatter lighting without glare (patented)
<u>Lens:</u>	
<i>Enlargement:</i>	80x or 60x
<i>Focal length:</i>	25 mm
<i>Lifetime</i>	5 years

SOFTWARE TECHNICAL DETAILS

<i>Commercial name:</i>	C-Cube 3 Dermoscope
<u>Minimum PC characteristics:</u>	
<i>Operating system:</i>	Windows 10 or higher
<i>Processor:</i>	Intel Core i5 6th generation or higher (OpenCL compatible GPU)
<i>RAM:</i>	8 GB
<i>Hard drive:</i>	250 GB
<u>Functionality:</u>	Dermoscopic image capture

5. DESCRIPTION OF THE EQUIPMENT

5.1. APPLICATIONS OF THE C-CUBE 3 DERMOSCOPE AND THE DIGITAL CAMERA

No set-up is necessary. Your C-Cube 3 is ready to use.

C-Cube 3 digital dermoscope:

The digital dermoscope is essential for the daily work of a busy practice. This alone makes it possible to create both a quick observation using **4K live** and dermoscopic image archiving at the same time. Only the **C-Cube 3** offers ultra-high resolution combined with unparalleled image stability, reliability and standardisation. We therefore recommend working with the digital dermoscope alone and only using the digital camera to capture images used to map dermoscopies for monitoring purposes.

The digital camera (optional):

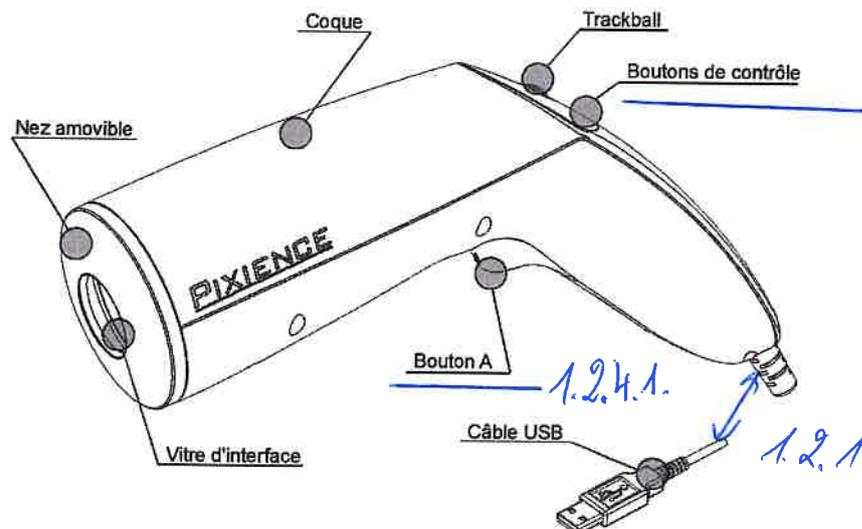
This digital camera can be used to supplement the digital dermoscope with high resolution photos to document the development of skin diseases or treatment in cosmetic medicine.

The digital camera is managed by the Pixience software. Images have a resolution of several million pixels enabling you to zoom in for extremely precise comparison and mapping of dermoscopies for monitoring purposes.

5.2. OVERVIEW OF THE C-CUBE 3 DIGITAL DERMOSCOPE

The C-Cube 3 digital dermoscope is composed of the following elements:

- The shell, specially designed for daily use.
- Two removable caps which can be adapted based on your needs.
- An interface glass.
- A trackball system to move the mouse on the screen.
- Three control buttons to navigate or acquire images.
- A USB cable to connect the C-Cube 3 dermoscope to your computer.



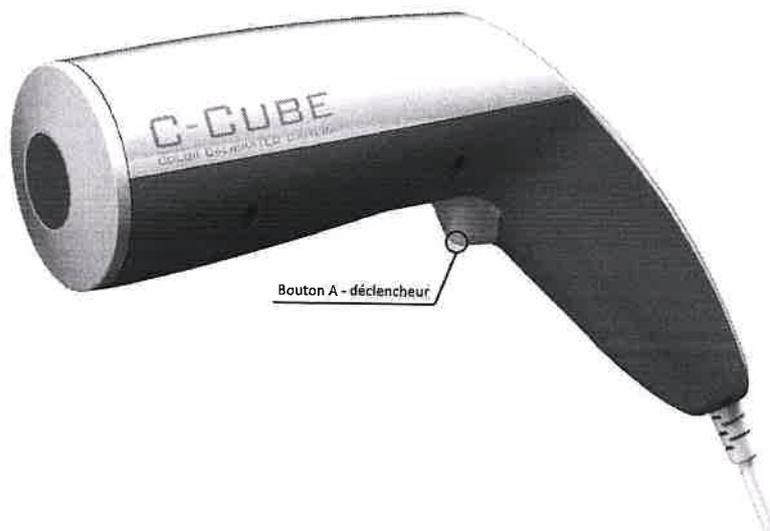


Figure3: Position of Button A

- Button A: Used to validate, acquire an image, validate it or move on to the next operation.

A.L.H.I.

5.2.4. USB CABLE

The USB cable connects the C-Cube 3 dermoscope to your computer. Please refer to the installation section for further information.



Important: Do not bend the cable and avoid crushing it with objects or by walking on it.

5.2.5. REMOVABLE CAPS

Different caps can be used, depending on usage (e.g. narrow cap for hard-to-reach areas).



Important: The cap uses class N45 magnets. It is, therefore, a risk for patients fitted with pacemakers. We draw your attention to the fact that the C-Cube 3 cap must not be brought closer than 43 mm to the patient's pacemaker.

Do not pull on the cap to remove it. Twist it.

5.2.6. INTERFACE GLASS

The interface glass must be disinfected to ensure the examination is harmless to the patient.

If your glass is damaged, an additional cap must be ordered by contacting the Pixience sales department.

We draw your attention to the fact that using a dirty or damaged glass may affect image quality. A cap with broken glass must not be used on a patient to avoid any risk of injury.

5.3. CONNECTING THE C-CUBE 3 DERMOSCOPE

Ensure that your C-Cube 3 dermoscope is correctly connected to your computer.

18.

Figure1: Technical description.

5.2.1. SHELL

The C-Cube 3 dermoscope shell is specially designed for optimum grip and to reduce user fatigue.



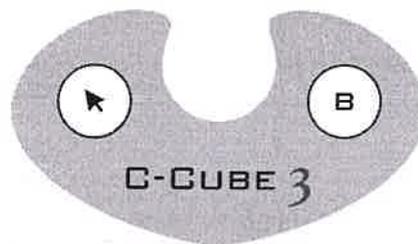
Important: The shell must not be opened under any circumstances. Doing so will invalidate the equipment warranty.

5.2.2. TRACKBALL (EMBEDDED MOUSE)

The trackball can be used to control your computer remotely during consultations. The pointer moves on the screen exactly like a standard mouse. This avoids numerous back-and-forth trips between the patient and the computer.

5.2.3. CONTROL BUTTONS

Buttons A and B and the “pointer” can be used to facilitate navigation in the software.



- **“Pointer” button:** Operates in exactly the same way as left-clicking using a mouse. Combined with the trackball, you can access all the software functions remotely.
- **Button B:** Cancels or changes an action. *1.2.4.2*

Figure2: Control panel

PIXIENCE



Model	Pixience C-Cube	FotoFinder medicam 1000
Connection	Directly on USB 3 port	Need Docking Station
Weight (without cable)	approx. 390 g	approx. 897 g
Weight with cable (Really Weight during examen)	approx. 410 g	approx. 1496 g
Optical distortion	No	Yes
Blurred effect	No	Yes
Vignetting effect	No	Yes
Color calibration	Yes	No
Standardisation	Yes	Option cap
Field of view	19.5x14.5 mm	12.5x7 mm
Magnification	80x to 140x	20x to 140x
Option Optical magnification 400X	No	Option cap
Mobility	Yes	No
Resolution Live	4K (4*HD)	HD
Medical labeling	Class I	Class I
Manufacturing country	France	Germany
Price € Excluding tax	15 000	20 000
BODYMAPPER option	35 000	50 000

1.2.4.

PIXIENCE

HEALTHCARE TECHNOLOGY SOLUTIONS

Subject: Confirmation of Products Specifications

Dear Algis Bakutis,

I am writing to confirm the following specifications of the products discussed.

For the Body Mapper:

- The monitor is a 24" touchscreen with full HD resolution (1920x1080). 1.1.4.

For the C-Cube:

- The USB cable length connecting the C-Cube with the PC is 3 meters. 1.2.10
- The integrated LED in the C-Cube provides a luminous flux (LUX) of 12000 Lux. 1.2.3.
- The optical zoom capability of the C-Cube is X60 1.2.6.
- The digital zoom capability of the C-Cube is X140 1.2.7.

Please consider this letter as confirmation of the accuracy of the aforementioned specifications.

Thank you for your attention to this matter.

Best regards,

Sébastien Mangeruca

CEO

