

C-CUBE

COLOR CALIBRATED CAMERA

09/02/2017

USER MANUAL C-CUBE DERMOSCOPE 2 DERMATOLOGY EDITION



PIXIENCE

HEALTHCARE TECHNOLOGY SOLUTIONS

User manual – C-Cube 2 Dermoscope Dermatology Edition

Pixience C-Cube 2 Ultra HD

The world's leading video microscopy system using indirect light and standardised digital photography for dermatology.

User manual



Please read this user manual carefully.

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1. THE C-CUBE 2 DERMOSCOPE CONCEPT

The C-Cube 2 dermoscope, the new standard in digital dermatology, is the product of 10 years of skin engineering R&D, designed to combine technology, style and accuracy in a system which will reduce your consultation time.



The C-Cube 2 is a digital dermoscope used to capture images of skin lesions in Ultra High Definition. The structural details of the skin can then be easily explored. The patented lighting technology provides image capture without glare with uniform lighting. Its metric calibration makes monitoring lesions easier and ensures accurate, precise measurement. Thanks to the colour calibration process, capture standardised images of unparalleled realism which can be used to calculate lesion characterisation criteria and for discussion between colleagues.

The C-Cube 2 is an indispensable tool for your practice to fight skin cancer and increase the reliability of your diagnoses. By recording your standardised images, regular checks on pigmented lesions have never been more reliable.

The related C-Cube 2 Dermatology software and its user-friendly interface allow you to:

- manage consultations,
- capture images using several acquisition modes,
- monitor lesions,
- generate consultation reports,
- export your images or reports to other C-Cube 2 licence holders,
- guarantee the security of your patients' data.




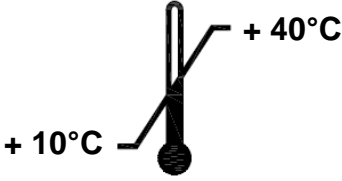
2. SAFETY INSTRUCTIONS








2.1. ELECTRICAL SAFETY INSTRUCTIONS

Pixience explicitly states that:

- the appliance must be directly connected to the USB port of a PC.
- in compliance with standard 60601-1 the appliance is equipped with an earth connection at the back of the computer.
- patients are not authorised or intended to be in contact with the PC.
- the user of the appliance is responsible for the electrical system where the equipment is installed.
- The appliance conforms to standard 60601-1-2 with regard to electromagnetic compatibility.

2.2. SYMBOLS KEY

Manufacture	
 <p>PIXIENCE 12 RUE LOUIS COURTOIS DE VICOSE, LES ARCHES, BAT.3 31100 TOULOUSE, FRANCE YYYY-MM</p>	<p>Name and address of the manufacturer of the medical device and date on which the device was manufactured YYYY (year) – MM (month)</p>
 <p>C-CUBE 2</p>	<p>C-Cube 2 dermoscope catalogue reference</p>
 <p>YYWWVPPXX</p>	<p>Product serial number (12 figures) → Symbol which must be adjacent to the previous symbol relative to the product catalogue reference YY: Year of batch manufacture WW: Week of batch manufacture VV: Equipment version number (here 01) PP: Product number (here 02) XXXX: Number in the batch</p>
Storage	
	<p>Temperature range in which the device can be safely used</p>
Using the device safely	

	<p>Read the user manual</p>
<p>Regulatory symbols according to the WEEE and RoHS directives</p>	
	<p>Do not dispose of used devices in household waste.</p> <p>Selective sorting of electrical and electronic devices.</p> <p>Take to municipal collection points</p>
	<p>Symbol certifying product compliance with the RoHS directive (Reduction of Hazardous Substances)</p>
<p>Regulatory symbols according to standard NF EN 60601-1</p>	
	<p>Type BF applied part</p>
<p>DC INPUT: +5 V  2A</p>	<p>Indicates the standard supply voltage and current according to standard USB 3.0</p>
<p>Accessories</p>	
 VVPP	<p>Standard cap catalogue reference VV → version number: 01 PP → Standard cap code: 03</p>
 VVPP	<p>Precision cap Catalogue reference VV → version number: 01 PP → Standard cap code: 04</p>
<p>Other markings</p>	

Made in France	Voluntary mark affixed by the manufacturer of the manufactured product
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2.3. ESSENTIAL INSTRUCTIONS

Please take note of the following instructions:

- The appliance must only be used by trained, specialised personnel.
- **It is absolutely essential that this instruction manual is read in its entirety before starting up the C-Cube 2 system.**
- The safety instructions must be followed.
- Before cleaning or servicing the appliance, it must be disconnected from the PC.

As far as possible, the system must not be used in the following cases:

- The communication cord and/or appliance are visibly damaged,
- The C-Cube 2 has fallen to the ground.

The appliance must only be used in its original configuration. Any modification to this configuration must obtain the prior consent of the manufacturer. Failure to do so will invalidate the warranty in case of damage or malfunction.

The components of the appliance must only be opened by the manufacturer or by personnel approved by the manufacturer. Infringement of this condition will invalidate the warranty and EC protection.

The system must not be exposed to damp!

Do not use the appliance in an MRI environment or near gas (e.g. anaesthetic gases).

The manufacturer shall accept no liability in the event of improper use of the system or incorrect operation.

Do not place the appliance near a heat source such as a radiator or in a very dusty environment. Do not expose to sunlight, vibrations or impacts.

Do not place the appliance near other appliances which generate a strong magnetic field such as a current converter or a high voltage line.

If you want to move the appliance, first disconnect it from the PC.

In the event of malfunction, please contact the manufacturer immediately:

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



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2.4. 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, at least once a year.

2.5. TECHNICAL CHARACTERISTICS FOR MEDICAL DEVICES

GENERAL DETAILS

<i>Commercial name:</i>	C-Cube 2
<i>Version:</i>	2.0
<i>MD class:</i>	Class I with measuring function
<i>Product type:</i>	Digital dermoscope for a dermatological application
<u>Accessories:</u>	
<i>Camera</i>	Options
<i>C-Cube 2 holder</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

TECHNICAL DETAILS OF THE C-CUBE 2 DERMOSCOPE

<i>Image capture technology:</i>	CMOS
<i>Image capture device:</i>	1/2.3”
<i>Resolution:</i>	4912 x 3684 pixels
<i>Number of pixels:</i>	18 Mpx
<i>Acquisition time:</i>	1 second
<i>Examination surface area:</i>	12 x 16 mm ²
<i>Smallest structure visible:</i>	9 µm
<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 (20 LEDs)
<i>Lighting technology:</i>	Backscatter lighting without glare (patented)
<u>Lens:</u>	
<i>Enlargement:</i>	x 80
<i>Focal length:</i>	25 mm
<i>Lifetime</i>	5 years

SOFTWARE TECHNICAL DETAILS

<i>Commercial name:</i>	C-Cube 2 Dermoscope
<u>Minimum PC characteristics:</u>	
<i>Operating system:</i>	Windows 8.1 or higher
<i>Processor:</i>	Intel Core i5 6th generation or higher (OpenCL compatible GPU)
<i>RAM:</i>	8 GB
<i>Hard drive:</i>	500 GB
<u>Functionality:</u>	Dermoscopic image capture
	Image display and archiving
	C-Cube 2 configuration
	Dimensional measurement
	Consultation management
	Lesion monitoring
	Image export (jpeg, DICOM format) between C-Cube 2 license holders
	Creation of consultation reports (.pdf format)