Novocam Medical Innovations Oy smartCam Instructions for Use

v. 2023-03





Thank you for purchasing this Novocam Medical Innovations Oy product. The instructions must be read and understood before using the device.

The brands "futudent", "novocam" and "vetcam" are used by the manufacturer Novocam Medical Innovations Oy (NMI).

KNOW YOUR DEVICE

The smartCam (model reference SMCS) is an autofocus 4K medical camera designed for multi-mounting to overhead lights or flexible arms (goosenecks). It offers handsfree operation with the USB foot pedal, and video or image capture at 4K, FullHD or HD resolution. The smartCam is available with two non-removable lenses of sizes 16mm or 25mm.

Intended Use

These devices are intended to be used by qualified healthcare professionals to capture videos and pictures during dental and medical treatments for the purpose of documentation, providing additional information for diagnosis, following and evaluating changes of medical conditions, and for educational purposes in dental and medical fields.

The device may not be used for any other purpose.

General Liability Note

This instruction and the accompanying documents should be thoroughly read and understood before using the device. Novocam Medical Innovations Oy is not responsible for any injury, damage or malfunction arising from the use of the device, or inability to use any information, apparatus, method or process disclosed in this document.

IMPORTANT INFORMATION

Ignoring warnings and prohibitions may result in harm to the patient, user, product or use environment.

Cautions and Notes are provided to ensure the best use experience.

Download software, login and find more information at: www.futudent.com

Further help guides are available at: https://www.futudent.com/support/user-guide/how-to

Accessories and spare parts may be purchased from NMI at: https://www.futudent.com/shop

WARNINGS	 Do not use if the camera overheats (over 50°C/120°F). If overheating occurs, disconnect it and allow it to cool for one hour. If the device becomes hot again in a relatively short period (1-5min), do not use it and contact the seller or manufacturer. Keep the cables away from high temperatures (over 70°C/158°F). Connect the camera USB cable only to IEC 60601-1 or IEC 60950 computers in the clinic. The camera may gather static during use. Do not touch the camera during treatment. If the camera stops working for any reason during the treatment, continue the treatment as you would do and
	disregard the camera.
CAUTION - PROHIBITED	 No modification of this equipment is allowed. Modifying the equipment can cause the equipment to fail and will void the warranty. Do not connect to life-supporting or critical devices. Do not service the device while it is in use with a patient. Detachable parts may fall on to the patient. Do not rotate the lens – it will break the autofocus motor and void the warranty. Do not place the device under hot clinic lights. The sensor and plastic parts will be damaged. Do not spray the device with water/detergent or submerge the device in any liquid. The sensor will be damaged. Do not point at direct sunlight. The sensor will be damaged. Do not use in environmental conditions with dust, salt, magnetic fields, chemicals, gases, radiation, electrostatic discharge, acceleration, thermal ignition sources. The optics will be damaged. The device is not compatible with other types of
	devices that are not mentioned in this document.
CAUTION	 Protect the device from fluids, heat and electric fields. Keep cables protected to prevent damage or tripping. Cover the lens with the cap when not installed. Make sure that the camera is attached firmly with no wiggling. Wiggling will cause video to be shaky.
NOTE	 Check cables from time to time. If the surface of the cable is damaged, stop using and contact the nearest local dealer or manufacturer. This device is suitable for use within the patient environment.

SYMBOLS

Symbols on the camera and cables:

SN

Serial Number (ISO 15223-1:2021 - 5.1.7)

 $\prod_{\mathbf{i}}$

Consult operator's manual; operating instructions (ISO 15223-1:2021 - 5.4.3)

Do not dispose in normal household waste (Directive 2002/96/EC - WEEE).

MD

Medical Device (ISO 15223-1:2021 - 5.7.7)

•••

Manufacturer (ISO 15223-1:2021 - 5.1.1).

CE

European Community mark.

•

USB connection from cable

Additionally on the packaging:

Temperature limit for storage, transportation and use (ISO 15223-1:2021 - 5.3.7).

#

Product Model Number (ISO 15223-1:2021 – 5.1.10)

UDI

Unique Device Identifier (ISO 15223-1:2021 – 5.7.10): (01) the ID assigned to the product model

(21) the serial number for the specific camera

INSTALLATION KIT CONTENTS



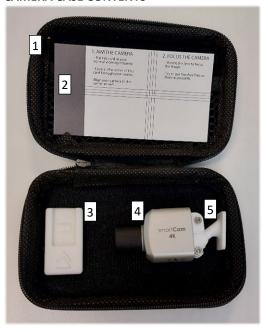
Item #	QTY	Description	Spare Part?	Detac hable?
ACCKIT01	1	Installation kit containing (#1)		
ACCUSB03	1	microUSB to USB-A camera cable 5m, white (#3)	х	Yes
ACCPDL01	1	USB foot control pedal, 1.2m cable, black (#2)	х	Yes
ACCUSB01	2	5m active USB extension cables, white, 4mm diameter (#4)	х	Yes
ACCCLI02	15	Extension cable clips, curved surfaces, for 4mm diameter cable (#5)	х	
ACCCLI01	25	Extension cable clips, flat surfaces, for 4mm diameter cable (#6)	х	
ACCOHL03	1	Universal overhead light attachment with screws (#7)	х	

CAMERA KIT CONTENTS



Item #	QTY	Description	Spare Part?	Detac hable?
ACCUSB05	1	microUSB to USB-A camera cable 1.5m, black	х	Yes
CONSDT6	1	Torx T6 Screwdriver	Х	
	1	Camera Case (see below)		
	1	Multi-language setup quick guide		
IFU	1	Instructions for use		
FRS	1	Futudent Recording Software (FRS) with 5 licenses		

CAMERA CASE CONTENTS



Item#	QTY	Description	Spare Part?	Detac hable?
CASEBL	1	Camera case (#1) with zipper, black, containing:	X	
PRINTFC		Focus assistant card (#2)	Х	
ACCOHL04	I	Overhead light adhesive mount (#3)	Х	
SMCS	I	smartCam (#4) with permanently installed lens	X	Yes
ACCOHL03	I	Ball-joint for overhead light attachment installed on backplate (#5)	X	

TECHNICAL SPECIFICATION

TECHNICAL SPEC	CIFICATION	
	• 1 x Camera USB 2.0 Hi-Speed (480Mbit/s) for USB A to microUSB connector (1.5m or 5m)	
Cable, Ports and Signals	1 x Foot pedal USB 2.0 for the USB A to foot pedal cable.	
	USB cables may be connected and disconnected as per standard plug-and-play USB.	
Cable lengths	Active USB extensions cables up to 10m.	
Connection Requirements	Connect to an IEC 60601-1 or IEC 60950 compliant computer via USB.	
Restriction on network/data couplings	This USB device may be connected to any clinic computer USB socket with electrical isolation. Failure to connect to an electrically isolated USB socket may result in signal interruption in the case of electromagnetic interference.	
USB Isolation	If electrocautery/surgery devices are used or if the computer used is not IEC rated for a medical environment, a USB isolator of 5kVrms protection must be used to ensure electromagnetic conformity.	
Mechanical connection	Overhead light Gooseneck / flexible arm	
IEC 60601-1	Class I. This device is not intended to contact the patient and has no applied parts.	
IEC 60601-1-2	CISPR 11 Group 1 Class B classification	
Rated power	5 V d.c. / 100mA nominal / 150mA maximum Power via USB cable. Does not contain a battery.	
Mode of Operation	Continuous operation as a USB device when PC is ON. OFF when USB port is disabled or PC is off.	
Use environment	 For inside use only, in clinics with temperatures under 30°C/86°F and relative humidity is under 85%. Not for use in oxygen rich environments (over 25% oxygen content). Do not use in conjunction with flammable liquids. Do not use in close conjunction with anaesthetic gas. 	
Transportation and Storage	Keep the device in the temperature between 5° to 50°C (41°F to 122°F). Allow the camera to reach room temperature before use. Temperature change may cause condensation on the sensor or lens.	
Compliance	 Class I EU MDR / FDA Class I Exempt / CE Marked / RoHS compliant. Conformity to IEC 60601-1 and IEC 60601-1-2 No applied parts; not for patient contact. 	
Sterility	Not provided sterile or intended for sterilization.	
Size and weight	22mm wide x 27.5mm long x 28.6mm high Weight: 50grams with lens	
Materials	Aluminium / PA / Nylon Electronics in camera and foot pedal Cardboard / plastic packaging	
Recommended	Futudent recording software for Windows, Mac or	
software	Android. 5 software licenses included per device. Sony IMX 415 sensor with video capture of 30fps (frames per second) in secure h.264 mp4 format. Video/image resolution of: 4K 2160p (pixels) FullHD 1080p HD 720p	
Optics	Permanently installed autofocus UHD lenses: SMCS2501 - 25mm XL. Identify the lens by the smooth sleeve. SMCS1601 - 16mm XL. Identify the lens by the 1 raised ring. smartCam 4K	
Recording memory size	1 hour of recording video at 4K resolution is approximately 10GB. 1 hour of recording in FullHD mode is approximately 3G.	

COMPUTER REQUIREMENTS

NOTE It is possible to connect a laptop to an external 4K screen even the laptop screen is not 4K resolution. You can record 4K even if your screen does not support 4K.

The camera and foot pedal connec as plug-and-play USB devices. It requires 2 USB ports.

The Futudent Recording Software (FRS) allows for image and video capture and secure sharing. Before installing the FRS, we recommend you check that your computer operating system and applications are up to date, and your computer has the technical requirements for 4K video recording.

For Windows

- Check the CPU rating of the computer using the website: CPUBenchmark.net
- Find Windows system information by right-clicking the Start Menu and selecting System.
 - In the System menu, click on Display to check and change the screen resolution.
- Find Windows device information by right-clicking the Start Menu and selecting Device Manager.
 - Expand the Universal Serial Bus Controllers option and check the USB type.
 - Expand Display Adapters to check the Intel graphics card type.

For MacOS

Find MacOS system information by clicking About This Mac from the Apple Menu.

For All Systems

	Basic Functionality				
	8GB RAM or higher				
	USB2 or USB3 port for the camera				
All Systems:	Additional USB2 or USB3 port for foot control pedal				
All Systems.	Network / internet	capability			
	CPUBenchmark.ne	t rating of 3000 or hig	her		
	IEC 60601-1 compl	iant			
Windows	Windows 7 or late	r operating system			
Requirement:	NET Framework 4.	5			
MacOS	OS X version 10.13	(High Sierra) or newe	r		
Requirement:	MacBook Air/Pro 2	2013 or newer			
Android OS	Android 11 or high	er with the Android fu	itudent recording		
Alluloid O3	software available	on the Google Play st	ore.		
Video quality	HD (720p)	Full HD (1080p)	4K (2160p)		
Windows PC Minimum requirements	Screen resolution of 1024x768 or higher. CPU rating over 3000.	Hardware encoding (QuickSync technology) Intel graphics card 8GB RAM minimum Screen resolution of 1920x1080 min. CPU rating over 5000.	Windows 10 OS Intel graphics card 16GB RAM Screen resolution of 3840x2160 min. CPU rating over 10000.		
MacOS Minimum Requirements	MacBook Pro/Air, iMac or Mac-mini from 2015 or newer. Screen resolution of 1024x768 min. CPU rating over 3000.	MacBook Pro/Air, iMac, Mac-mini from 2017 or newer. Screen resolution of 1920x1080 min. CPU rating over 5000.	MacBook Pro, iMac, Mac-mini from 2018 or newer. 16GB RAM. Screen resolution of 3840x2160 min. CPU rating over 10000.		

1 image is 8MP (megapixel).



LIGHTING REQUIREMENTS

For best quality images, the clinic and task lighting are recommended to have at least the following:

- Ambient Light Illumination Intensity: 10,000lux in the clinic room area
- Task Light Illumination Intensity: 30,000lux or higher, depending on ambient lighting.
- Colour Temperature: Adjustable, average of 5,500 Kelvin
- CRI: 95 or higher

INSTALL THE FUTUDENT RECORDING SOFTWARE (FRS)

To download the Futudent recording software on to the clinic computer:

- Go to the website: https://www.futudent.com/services/software
- Log in or create a futudent account to access the download page.
- Download and run the installation file:
 - Windows OS can downloaded and install directly from the website.
 - o MacOS downloads and installs via the Apple Store.

Photos and videos are saved locally on your computer in predefined folders. The folder location can be changed in the FRS settings:

Photos are saved in a folder on your desktop.

NOTE Connect the camera before loading the FRS software so the camera is automatically detected.

INSTALL FRS TO AN ANDROID DEVICE

FRS for Android OS can be downloaded and installed from the Google Play store.

- Connect the camera to your mobile device with the 1.5m microUSB cable and an OTG (on-the-go) adapter.
- Start the FRS app on your phone and grant all required permissions (only required first time app is run).
- Live feed from camera should now be visible if not visible, disconnect camera and reconnect after a few seconds.
- Use the phone's screen to control the camera.

NOTE The foot pedeal is not used for a mobile camera control.

INSTALL THE FOOT PEDAL

The foot pedal is a plug-and-play USB device. Plug it in to an available USB port on your computer.

INSTALL ON OVERHEAD LIGHT

The smartCam is delivered with the ball-joint attachment (ACCOHL03) for overhead light or flexible arm installation.



WARNING Do not allow the camera or cables to be in direct or indirect contact with the lamp.

CAUTION The overhead light adhesive attachment clip is designed for temperatures up to 80C. If the overhead lamp surfaces reach over 80C, the adhesive may fail.

NOTE Clean the overhead light surfaces with isopropyl alcohol

to remove and residues.

For best results, center the light and the camera so they align on the same treatment point.

Do not block light sensors.

Press the overhead light adhesive attachment clips (ACCOHL04) on to the light in a central location.

Slide the balljoint clip in to the light attachment clip.

Connect the 5m microUSB camera cable (white) to the camera. If this cable is not long enough to reach the computer, use the 2 x 5m active USB cables.





Use the flat or curved cable clips to hold the cables neatly in place.

INSTALL CAMERA ON A GOOSENECK / FLEXIBLE ARM

Screw the flexible arm on to the c-clamp.

Slide the c-clamp on to a table and tighten in place.

Check that the ball joint clip is on the camera. The friction of the ball-joint can be tightened with the screwdriver.

Slide the balljoint clip in to the gooseneck mount.

Connect the 1.5m microUSB camera cable (black) to the camera. If this cable is not long enough to reach the computer,



use the 5m long microUSB camera cable or the 2 x 5m active USB cables.

Use the cable spirals and flat or curved cable clips to hold the cables neatly in place.



STARTING THE CAMERA IN LIVE VIEW MODE

With the camera and foot pedal installed, open the futudent recording software (FRS).

The camera and foot pedal will detect as USB devices and the screen will show video in live view mode.

MICROPHONE USE

NOTE The computer microphone is on by default and will record audio when recording videos.

The microphone can be muted/unmuted by clicking the microphone icon in the software. Any connected PC microphone may be used for audio recording. A microphone is not integrated in to the camera.

CHECK AND ADJUST WORKING DISTANCE

WARNING

Do not rotate the autofocus lens cover to focus! The lens cover may be gently turned ¼ turn at a time to move the working distance.

The pre-set working distance for autofocus is between 50-120cm from the camera.

If your working distance range is less than 50cm or more than 120cm, bring it in to the focus range as follows:

Put the camera in a normal working position.

Find the small notch on the front of the autofocus lens,



Rotate the sleeve gently to adjust:

Further away (right turn)



Closer (left turn)

- If your working distance is closer than 50cm, rotate the lens sleeve ¼ turn counter clockwise (left) to bring the focus range closer by 15-20cm.
- If your working distance is further than 120cm, rotate the lens sleeve ¼ turn clockwise (right) to move the focus range away by 15-20cm.

The camera is now set to your working distance and ready to use.

USING THE CAMERA – QUICK START

NOTE Test video recording prior treatment for best results.

To Start / Stop Video Recording

- On-screen click the camera icon to start or stop.
- Foot pedal press the pedal for 3 seconds to start or stop.
- Keyboard press the F6 key for 3 seconds, or press Fn and F6 at the same time for 3 seconds to start or stop.

To Set a Bookmark During Video Recording

- On-screen click the bookmark icon to set a bookmark.
- Foot pedal press the pedal briefly to set a bookmark.
- Keyboard press the F6 key briefly, or press Fn and F6 at the same time.

When a bookmark is set, the bookmark symbol will appear below the time bar.

To Take a Still Photo

- On-screen click the camera icon to take a photo
- Foot pedal press the pedal briefly to take a photo
- Keyboard press the F6 key briefly to take a photo or press
 Fn and F6 at the same time.

Keyboard Shortcuts

	Description	Windows	macOS
	Description	Command	Command
	Talana atili abada	F6 / Fn+F6	F6
	Take a still photo	Short press	Short press
	Start / Stop Video	F6 or (Fn + F6)	F6
While in	Recording	3 second press	3 second press
Recording	Set a Bookmark while	F6 / Fn+F6	F6
Mode	Video Recording	Short press	Short press
	Digital Zoom (only in HD	↑ Up-key /	↑ Up-key /
	or fullHD)	Down-key ↓	Down-key ↓
	Minimize / Maximize Gallery	F5 or (Fn + F5)	F5
	Open / Exit Full-Screen	F11 or (Fn+F11)	F11
While in Gallery / Playback	Pause / Play Video Playback	Space key	Space key
	Forward / Reverse in 5	← Left-key /	← Left-key /
	second intervals	Right-key →	Right-key →
	Move between saved	↑ Up-key /	↑ Up-key /
	bookmarks in video	Down-key ↓	Down-key ↓

TURNING THE CAMERA OFF

The camera turns off when the user:

- Closes the futudent recording software.
- Closes any other video problem using the camera.
- Disconnect the USB cable.
- Turns the computer off.

CLEANING AND MAINTENANCE

Cleaning

The external parts of the camera can be cleaned and disinfected as follows:

- Use a soft, lint-free wipe to clean dust and debris off the device.
- Disinfecting can be done using low-alcohol or alcohol-free medical disinfectant.
- Squeeze excess fluid out of the cloth/wipe before cleaning the device.
- The lens must be cleaned only with camera lens cleaner.

CAUTION Do not directly spray liquid on to or submerge the device in a liquid. Do not use an autoclave for the device; not intended to be sterilized.

If dust has entered the housing, the inside of the camera may be cleaned with dry compressed air.

Regular Maintenance Checks

It is recommended to check the camera and accessories daily before use and weekly to:

- Check the cables are not worn or damaged.
- Replace cables with signs of damage such as broken
- Check that all parts are attached, in particular mounting clips and attachments.
- Restore positioning by tightening mounting joints with the screwdriver provided.
- Replace mounts and attachments if they do not firmly hold the camera in position after tightening the joints.
- Make sure Instructions for Use are available for all users.

Annual Maintenance check

It is recommended to make annual check for cameras as follows:

- Check that your computer has all operating system updates installed.
- Check that you have the latest futudent recording software version installed.

Disposal Instructions

The expected service life of this device is 5 years. If maintained and kept safe from mechanical, chemical and electrical damage, the camera has no features that expire or limit its service life.

Dispose of the camera and accessories according to the rules defined in your country. The camera and foot pedal must be taken to official electronic waste disposal sites. The device may also be sent back to the seller or manufacturer.

TROUBLESHOOTING

The vocabulary NMI uses to explain different digital signal effects that may be seen in the video:

- 1. Flicker: Rapid changes in image brightness.
- 2. Tearing: Image seems to consist of different parts, like tiles of video that form a jigsaw or mosaic.

Banding: There are (typically horizontal) bands of color, white or black in the image. The bands might be static or moving.

Common Problems

#1 Camera stops functioning

- Electrocautery or electrosurgery device is taken in use while the camera is attached to the loupes.
 - A USB isolator of 5kVrms protection must be taken in use between the camera and the computer.
- Cable is unplugged or broken.
 - Stop using the camera and order a replacement cable as a spare part.
- Graphics card is not Intel.
 - The camera may not work consistently with other graphics cards.

#2 Futudent recording software cannot open or is frozen frequently

- Check your computer software and hardware requirements.
- Update your PC software and operating system.
- Graphics card is not Intel. The camera may not work consistently with other graphics cards.

#3 Camera is not detected after installing software and clicking the camera refresh button

In Windows:

- Go to "Control panel" -> " Device Manager" or search "Device Manager" by clicking on the "camera" button.
- Right click on the camera name (proCam XS) to uninstall and install again.
- After that, try camera refresh button in the FRS.

If the camera cannot be found in " Device manager -> Camera" list, please test the USB port with other available devices (ie, a mouse or keyboard).

If the camera still cannot be detected, test it with a different camera cable. If this does not help, contact your local distributor or the manufacturer for support.

#4 Camera signal is not stable and recording cannot continue.

- Check that all of the USB cables are securely connected.
- Test the USB port condition by gently wiggling the
- Try connecting the 1.5m camera cable directly to the

USB signals require active extension cables when the distance is over 2m. Use only the provided active USB cables. Over 10m is not recommended. Long distances can cause image tearing.

#5 Camera image quality is low

This is often due to insufficient light or unfocused lenses.

- Ensure the total task light intensity is over 32,000lux.
- Ensure a color spectrum of light (CRI) of over 90) is used.

INSTRUCTIONS FOR USE smart Cam

Ensure the camera is correctly focused and clean.

#6 The camera's color representation looks different than it does from your human perception

See the Futudent Recording Software Instructions for full explanations of colour and image adjustment settings:

- Use a reference color palette for comparison and colour
- Adjust your monitor or screen colour settings.
- Adjust the camera settings.

DATA PROTECTION AND PATIENT PRIVACY

Novocam Medical Innovations is an EU company and governed by the requirements of the EU General Data Protection Regulation. All cloud services are located in the EU.

End User Responsibility: The end user of the camera is a Data Controller who is responsible for deciding what information to collect and how to use it according to their local data privacy laws.

- The end user must inform the patient of why the data is being collected and where it will be used; a consent form is recommended. A consent form template is available on the futudent.com website:
 - https://www.futudent.com/contact/about/privacy-policy
- End user camera images may be stored locally, on a Cloud or not stored at all.
- Information such as patient and treatment details are added at the discretion of the end user and according to their local data privacy laws.

NMI Responsibility: NMI acts as data controller and data processor of end user data, including contact information, purchase information, voluntarily given data and images stored on the Cloud services.

- NMI does not require patient healthcare identifiable data in order to use the system.
- See full details on the website: https://www.futudent.com/contact/about/privacy-policy

EMC GUIDANCE

CAUTION Strong ESD (electro-static discharge) can cause the camera's signals to become confused. The video quality may be degraded or the video be stopped. If this occurs, the software may re-load the camera. If the camera does not come back online, either press the software camera refresh button or unplug the USB cable and plug it in again before restarting the software and video.

NOTE The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). It is also used in a residential environment for which CISPR 11 class B is normally required. For CISPR 11 Class B, this equipment might not offer adequate protection to radiofrequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment. Contact NMI for support if needed.

Technical requirements to minimize EMC Interference

NMI does not provide separate EMC protective equipment with its system. The end user is responsible to check that the following equipment is IEC 60601-1 compliant and rated for use in a professional healthcare facility: computers, monitors, mains power supplies.

If the end-user does not have an IEC 60601-1 compliant computer or monitor, they may purchase a hi-speed USB isolator with the following technical specification:

- USB 2.0 Hi-Speed (480 MBit/s)
- 500mA (internal DC/DC)
- ESD protection (20kV)
- Isolation withstands 5kV_{RMS}

EMC Characteristics

The following cables and accessories are likely to affect compliance of the NMI system with the requirements of electromagnetic emissions and immunity. The end user is responsible to check these parts with the functionality of the camera system:

Supplier	Description	Length	Reasoning
NMI	Active USB extension cable (shielded)	10m max.	Emissions from electro surgical
NMI	Camera USB cable (shielded)	1.5m max.	equipment can
End- User	Cables from surrounding computer equipment bundled with the Novocam cables. Signal and power cables bundled together.	Varies	interfere with video signals. This does not cause a hazardous situation. Refresh
End- User	Electro-surgical knife and tools	Varies	the camera to restore.

Emission interference can be checked by the end-user by watching the image for signs of:

- Horizontal lines in the image
- Flicker in the image
- Frozen video

EMC Compliance

Compliance of NMI products is tested according to the following electromagnetic emissions and immunity standards, in the electromagnetic environment specified below. The end user of the equipment should assure that it is used in such an environment.

Enclosure Ports (Table 4, IEC 60601-1-2:2014)				
Phenomenon (immunity)	EMC standard or test method	Immunity test levels – professional healthcare facility environment		
Electrostatic discharge (ESD)	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air		
Radiated RF EM fields	IEC 61000-4-3	3 V/m / 80 MHz – 2,7 GHz 80% AM at 1kHz		
Proximity fields from RF wireless communications equipment	IEC 61000-4-3 / IEC 60601- 1-2 Table 9			
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m / 50 Hz		
Signal input/output Parts Port (Table 8, IEC 60601-1-2:2014)				
Phenomenon (immunity)	EMC standard or test method	Immunity test levels – professional healthcare facility environment		
Electrostatic discharge (ESD)	IEC 61000-4-2	± 8 kV contact		

		± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Electrical fast burst transients / bursts	IEC 61000-4-4	± 1 kV, 100kHz repetition frequency
Surges – Line-to-ground	IEC 61000-4-5	± 2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V / 0,15 MHz – 80 MHz 80% AM at 1kHz

WARRANTY

Standard limited warranty: 2 years from the date of purchase for camera products, 1 year for accessories (foot pedal, attachments, etc.). The warranty period starts when the product is delivered and/or given to the Buyer.

Extended warranty: 2 or 3 years extension is available. The extended warranty begins from the last day of the standard limited warranty. Please contact your local dealer or Novocam Medical Innovations Oy.

What is included in the limited warranty: This limited warranty covers defects in materials and workmanship in the Products and Accessories.

Software End User license Agreement: Software incorporated in the Products is covered by End User License Agreement (EULA) and its warranty terms. Up-to date EULA is made available https://www.futudent.com/contact/about/terms-of- service and EULA must be accepted prior or during Software installation.

What is not covered by the limited warranty: This limited warranty does not cover any damage, deterioration or malfunction resulting from any alteration, modification, improper or unreasonable use or maintenance, misuse, abuse, accident, neglect, exposure to excess moisture, fire, lightning, power surges, or other acts of nature. This limited warranty does not cover any damage, deterioration or malfunction resulting from any unauthorized tampering with the Product or Accessory, any repairs attempted by anyone not authorized by Novocam Medical Innovations Oy to make such repairs, or any other cause which does not relate directly to a defect in materials and/or workmanship of the Product or Accessory.

Operator may not be held liable for defects or dysfunction of the Software and/or the Service due to (i) lack of qualification and competence on the part of the persons using it, and/or (ii) changes made by the Licensee, a third party other than Operator or not previously certified in writing by Operator, and/or (iii) software and/or equipment is not supplied and installed by Operator or its authorized distributor.

The warranty is void in these situations: This limited warranty is void if (i) the label bearing the serial number of the Product and/or Accessory has been removed or defaced, (ii) the Product and/or Accessory is not distributed by Novocam or (iii) the Product and/or Accessory is not purchased from an authorized Novocam distributor. Your rights under the limited warranty are not diminished if you do not complete and return the product registration form or complete and submit the online product registration form.

Warranty Claim Remedies

NMI will at, at its sole discretion, provide one of the following remedies to the extent it shall deem necessary to satisfy a claim under this limited warranty:

- 1. **Repair** any defective part within a reasonable period of time, free of any charge for needed parts and labor to complete the repair and to restore the product to its proper operating condition. Novocam will also pay the shipping costs necessary to return the products and accessory to the customer once the repair is complete.
- Replace the product with a direct replacement or with a similar product deemed by NMI to perform substantially the same function as the original product.
- **Refund** the original purchase price less depreciation to be determined based on the age of the product at the time the claim is made under limited warranty.

HOW TO MAKE A WARRANTY CLAIM

Who may return products for repair: Anyone with a camera may ask for support and repair, even for products not in warranty.

Who may make a warranty claim: Authorized distributors, authorized NMI repair technicians, and buyers / owners of the camera. An original purchase receipt is required for warranty claims.

Make the Claim Request: The returner shall contact NMI through Support. Include the following information:

- the camera serial number
- what is broken
- any information to help diagnose the problem (what happened?)
- where it was purchased (distributor, directly from NMI, etc.)
- evidence of the purchase from NMI or a distributor in the form of the original dated receipt.

Receive a Return Authorization from NMI: If the product is accepted under limited warranty, the returner shall be given a Return Authorization. The Return Authorization will indicate where to send the product for repair: Novocam Medical Innovations Oy or an authorized repair-distributor.

Package the Product: Please use a cardboard box with padding to return the products. Include inside the package:

- Name
- Address
- Return authorization number / support ticket number

Return deliveries must be insured: Returned products must be insured during shipment, with the insurance and shipping cost pre-paid by the product owner. If the product is returned uninsured, the product owner assumes all risks of loss or damage during shipment.

INSTRUCTIONS FOR USE smart Cam

SUPPORT AND CONTACT

Contact local Distributors

Our devices are distributed by our global network of distributors. If you purchased your camera from a local distributor, first contact them for fastest support. The partner list is on the website at:

https://www.futudent.com/contact/partners

Contact Novocam Medical Innovations

General contact information is online at https://www.futudent.com/contact or by e-mail info@futudent.com.

Technical support contact can be made on www.futudent.com/support or by e-mail support@futudent.com.

Postal mail, product returns, billing and invoices should use

the company address:

Novocam Medical Innovations Oy Pasilanraitio 5B, 00240 Helsinki Finland

Phone: +358 50 388 008

Incident Reporting

In case of an incident involving a Novocam Medical Innovations product, send a report to info@futudent.com with the subject: ATTN: Incident Report. In the report, please include:

- Camera serial number
- Describe what happened before, during and after the incident
- Describe any injuries or near-misses
- Describe any immediate actions taken.