

# Novocam Medical Innovations Oy

## proCam XS 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 proCam XS (model reference PRCX) is a 4K medical camera designed for multi-mounting to loupes, overhead lights or headbands. It offers handsfree operation with the USB foot pedal, and video or image capture at 4K, FullHD or HD resolution. The proCam XS is available with interchangeable and manually focused lenses of sizes 8mm wide-angle, 16mm, 25mm or 35mm high magnification.

### 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](http://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>




<b>WARNINGS</b>	<ul style="list-style-type: none"> <li>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.</li> <li>Keep the cables away from high temperatures (over 70°C/158°F).</li> <li>Connect the camera USB cable only to IEC 60601-1 or IEC 60950 computers in the clinic.</li> <li>The camera may gather static during use. Do not touch the camera during treatment.</li> <li>If the camera <b>stops working</b> for any reason during the treatment, continue the treatment as you would do and disregard the camera.</li> </ul>
<b>CAUTION - PROHIBITED</b>	<ul style="list-style-type: none"> <li>No modification of this equipment is allowed. Modifying the equipment can cause the equipment to fail and will void the warranty.</li> <li>Do not connect to life-supporting or critical devices.</li> <li>Do not service the device while it is in use with a patient. Detachable parts may fall on to the patient.</li> <li>Do not change lenses near patients. If lens needs to be adjusted make sure the camera is not above the patient due to the risk of the lens dropping.</li> <li>Do not turn lens too much because it might fall out. The camera will be completely out of focus well before the lens detaches. If the lens is detached, insert it carefully so that the threads are not damaged.</li> <li>Do not place the device under hot clinic lights. The sensor and plastic parts can be damaged.</li> <li>Do not spray the device with water/detergent or submerge the device in any liquid. The image sensor will be damaged.</li> <li>Do not point at direct sunlight. The sensor will be damaged.</li> <li>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.</li> <li>The device is not compatible with other types of devices that are not mentioned in this document.</li> </ul>
<b>CAUTION</b>	<ul style="list-style-type: none"> <li>Protect the device from fluids, heat and electric fields.</li> <li>Keep cables protected to prevent damage or tripping.</li> <li>Cover the lens with the cap when not installed.</li> <li>Make sure that the camera is attached firmly to the loupes, headband or overhead light with no wiggling. Wiggling will cause video to be shaky.</li> </ul>
<b>NOTE</b>	<ul style="list-style-type: none"> <li>Check cables from time to time. If the surface of the cable is damaged, stop using and contact the nearest local dealer or manufacturer.</li> <li>This device is suitable for use within the patient environment.</li> </ul>

## SYMBOLS

Symbols on the camera and cables:

-  Serial Number (ISO 15223-1:2021 – 5.1.7)
-  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).
-  Medical Device (ISO 15223-1:2021 – 5.7.7)
-  Manufacturer (ISO 15223-1:2021 – 5.1.1).
-  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)
-  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

## CAMERA KIT CONTENTS



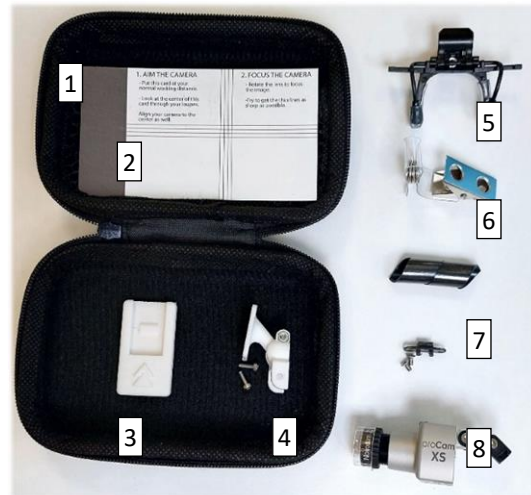
Item #	QTY	Description	Spare Part?	Detachable?
ACCUSB05	1	microUSB to USB-A camera cable 1.5m, black	X	Yes
CONSDT6	1	Torx T6 Screwdriver	X	
	1	Camera Case (see below)		
	1	Multi-language setup quick guide		
IFU	1	Instructions for use		
FRS	1	Futudent Recording Software (FRS) with 5 licenses		

## INSTALLATION KIT CONTENTS



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

## CAMERA CASE CONTENTS



Item #	QTY	Description	Spare Part?	Detachable?
CASEBL	1	Camera case (#1) with zipper, black, containing:	X	
PRINTFC		Focus assistant card (#2)	X	
ACCOHL04	1	Overhead light adhesive mount (#3)	X	
ACCOHL03	1	Ball-joint for overhead light attachment installed on backplate (#4)	X	
CONLOUC1	1	Universal loupes clip (#5)	X	Yes
	1	Cable guide with clothing clip (#6)	X	Yes
CONCSA	1	Spiral cable guide for securing the camera cable to loupe arm (#7)	X	Yes
FUTULIAK	1	Futulight attachment with 2 x 4mm screws in a bag (#8 on camera)	X	
PRCX	1	ProCam XS (#9) with selected lens installed (16mm lens default option)	X	Yes
FUTULAK	1	Loupe attachment and 2 screws attached to the camera (#10)		
FRS		Futudent recording software		

## TECHNICAL SPECIFICATION

Cable, Ports and Signals	<ul style="list-style-type: none"> <li>1 x Camera USB 2.0 Hi-Speed (480Mbit/s) for USB A to microUSB connector (1.5m or 5m)</li> <li>1 x Foot pedal USB 2.0 for the USB A to foot pedal cable.</li> <li>USB cables may be connected and disconnected as per standard plug-and-play USB.</li> </ul>
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	Loupe mount (universal clip or loupe specific mounts) Overhead light or headband 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	<ul style="list-style-type: none"> <li>For inside use only, in clinics with temperatures under 30°C/86°F and relative humidity is under 85%.</li> <li>Not for use in oxygen rich environments (over 25% oxygen content).</li> <li>Do not use in conjunction with flammable liquids.</li> <li>Do not use in close conjunction with anaesthetic gas.</li> </ul>
Transportation and Storage	<ul style="list-style-type: none"> <li>Keep the device in the temperature between 5° to 50°C (41°F to 122°F).</li> <li>Allow the camera to reach room temperature before use. Temperature change may cause condensation on the sensor or lens.</li> </ul>
Compliance	<ul style="list-style-type: none"> <li>Class I EU MDR / FDA Class I Exempt / CE Marked / RoHS compliant.</li> <li>Conformity to IEC 60601-1 and IEC 60601-1-2</li> <li>No applied parts; not for patient contact.</li> </ul>
Sterility	Not provided sterile or intended for sterilization.
Size and weight	30mm wide x 20mm long x 20mm high Weight: 14grams without lens
Materials	Aluminium / PA / Nylon Electronics in camera and foot pedal Cardboard / plastic packaging
Recommended software	Futudent recording software for Windows, Mac or Android. 5 software licenses included per device.
Image quality	Sony IMX 415 sensor with video capture of 30fps (frames per second) in secure h.264 mp4 format. Video/image resolution of: <ul style="list-style-type: none"> <li>4K 2160p (pixels)</li> <li>FullHD 1080p</li> <li>HD 720p</li> </ul>
Optics	Exchangeable UHD lenses: <ul style="list-style-type: none"> <li>8mm wide angle</li> <li>16mm</li> <li>25mm default</li> <li>35mm close-up</li> </ul>
Recording memory size	1 hour of recording video at 4K resolution is approximately 10GB. 1 hour of recording in FullHD mode is approximately 3GB. 1 image is 8MP (megapixel).

## 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 connect 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 fulfils 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		
All Systems:	8GB RAM or higher USB2 or USB3 port for the camera Additional USB2 or USB3 port for foot control pedal Network / internet capability CPUBenchmark.net rating of 3000 or higher IEC 60601-1 compliant		
Windows Requirement:	Windows 7 or later operating system NET Framework 4.5		
MacOS Requirement:	OS X version 10.13 (High Sierra) or newer MacBook Air/Pro 2013 or newer		
Android OS	Android 11 or higher with the Android futudent recording software available on the Google Play store.		
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.

## 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 download and install directly from the website.
  - 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 pedal 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 TO LOUPES OR HEADBAND

The camera backplate comes pre-installed with the attachment for loupes or headband use.

Slide the camera with loupe attachment on to the matching clip on:

- The futudent headband
- OEM loupes, using a brand-specific adapter from the NMI attachment library or the loupe manufacturer.

The friction of the attachment can be tightened with the screwdriver.

Slide the cable spiral on the the loupe arm and put the cable inside.

Clip the clothing clip around the cable. Clip this to your coat to prevent the cable from pulling as you work.

Connect the 1.5m microUSB camera cable (black) 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 ON OVERHEAD LIGHT

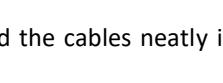
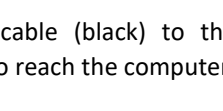
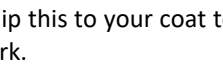
Replace the loupe attachment with the ball-joint attachment:

- Use the Torx T6 screw driver to unscrew the loupe attachment from the camera backplate.
- Use the same screw driver to install the ball joint attachment (ACCOHL03) to the backplate.
- Store the loupe attachment in the plastic bag in the camera case for later use.

**WARNING** Do not allow the camera or cables to be in direct or indirect contact with the lamp's hot parts or beam.

**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 adhesive light mount.

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.



## HOW TO INSTALL A HEADLIGHT MOUNT

LED Headlights are an accessory to the camera. The futulight adapter is delivered with your camera. Check with NMI for other brand adapters.

Remove the hole cover from the top of the camera.

Take the camera mount and 2 screws from their bag.

Screw firmly on to the top. Do not over tighten because this can crack the mount.

The camera can now be attached to the top of the camera.

Aim the LED light and camera at the same focus spot for best results.



## 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

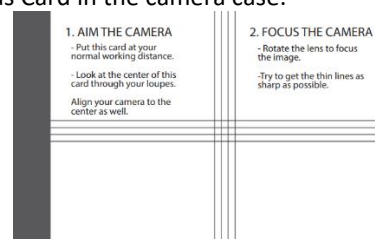
**NOTE** The computer microphone is on by default and will record audio when recording videos.

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 FOCUS

When installing the camera, the camera lens needs to be focused based on the user's working distance.

Find the Focus Card in the camera case:



Attach your camera to its working position on loupes, headband or overhead light.

Place the focus card at your normal working distance and location.

Aim the camera at the centre of the focus card where the lines cross. Check the aim on the computer screen.

If using loupes, look at the center of the focus card through your loupes while aiming the camera to the centre of the focus card. Check the aim on the computer screen.

Now focus the camera while looking at the computer screen:

- Rotate the camera lens left or right to focus the image.
- Try to get the focus card lines as sharp as possible.



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

### WARNING

Do not adjust the lens while the camera is in use with the patient. The lens is detachable by unscrewing it fully out from the camera housing.

### USING THE CAMERA – QUICK START

**NOTE** It is recommended to test video recording prior treatment to ensure colors are acceptable for use.

#### 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 Command	macOS Command
While in Recording Mode	Take a still photo	F6 / Fn+F6 Short press	F6 Short press
	Start / Stop Video Recording	F6 or (Fn + F6) 3 second press	F6 3 second press
	Set a Bookmark while Video Recording	F6 / Fn+F6 Short press	F6 Short press
	Digital Zoom (only in HD or fullHD)	↑ Up-key / Down-key ↓	↑ Up-key / Down-key ↓
While in Gallery / Playback	Minimize / Maximize Gallery	F5 or (Fn + F5)	F5
	Open / Exit Full-Screen	F11 or (Fn+F11)	F11
	Pause / Play Video Playback	Space key	Space key
	Forward / Reverse in 5 second intervals	← Left-key / Right-key →	← Left-key / Right-key →
	Move between saved bookmarks in video	↑ Up-key / Down-key ↓	↑ Up-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 insulation.
- 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 distributor 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.
3. **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 cable.
- Try connecting the 1.5m camera cable directly to the PC.

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.
- 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 accuracy.
- 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 re-starting 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 radio-frequency 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<sub>RMS</sub>

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

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.
2. **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.
3. **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.

**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](mailto:info@futudent.com).

**Technical support** contact can be made on

[www.futudent.com/support](http://www.futudent.com/support) or by e-mail [support@futudent.com](mailto:support@futudent.com).

**Postal mail, product returns, billing and invoices** should use the company address:

Novocam Medical Innovations Oy  
Pasilanraito 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](mailto: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.