v. 2023-06-en

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

Recording Software instructions are enclosed as a separate document.

All instructions are available from the website.

KNOW YOUR DEVICE

The microCam XS (model reference MCCX) is a FullHD medical camera designed for multi-mounting to loupes or headbands. It offers handsfree operation with the USB foot pedal, and video or image capture at FullHD or HD resolution. The microCam XS is available with interchangeable and manually focused lenses of sizes 8mm wide-angle, 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.

| 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 |
|-------------------------|--|
| | 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 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. 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 |
| CAUTION - PROHIBITED | the threads are not damaged.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. |
| | Protect the device from fluids, heat and electric fields. |
| | Keep cables protected to prevent damage or tripping. |
| CAUTION | Cover the lens with the cap when not installed. Make give that the camera is attached firmly to the |
| | loupes, headband or overhead light with no wiggling. |
| | Wiggling will cause video to be shaky. |
| | • Check cables from time to time. If the surface of the cable |
| | is damaged, stop using and contact the nearest local dealer |
| NOTE | or manufacturer. |
| | environment. |

SYMBOLS





X

•••

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).

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:

| 5°C- | | |
|------|---|--|
| [| # | |

UDI

•

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 AND INSTALLATION KIT CONTENTS



| ltem # | QTY | Description | Spare Part? | Detac hable? |
|----------|-----|---|----------------|-----------------|
| MCCY | 1 | #1: Camera and installation kit with | | |
| IVICCX | 1 | installation parts containing: | | |
| CONSDT6 | 1 | #2: Torx T6 Screwdriver | Х | |
| CASEBL | 1 | #3: Camera Case (see next image) | | |
| | 1 | #4: USB foot control pedal, 1.2m cable, | v | Yes |
| ACCPDL01 | | black | ^ | |
| ACCUSB01 | 2 | #5: 5m active USB extension cables, | ~ | Yes |
| | | white, 4mm diameter | ^ | |
| ACCC1101 | 25 | #6: Extension cable clips, flat surfaces, | v | |
| ACCCLIOI | | for 4mm diameter cable | ^ | |
| 1 Mu | | Multi-language setup quick guide | | |
| IFU | 1 | Instructions for use | | |
| | | NMI Recording Software (RS) for | | |
| RS | 1 | Windows, Mac or Android with 5 | | |
| | | licenses | | |

CAMERA CASE CONTENTS



| ltem # | QTY | Description | Spare Part? | Detac hable? |
|----------|-----|---|----------------|-----------------|
| CASEBL | 1 | #1: Camera case with zipper, black, containing: | х | |
| PRINTFC | | #2: Focus assistant card | Х | |
| мссх | 1 | #3: microCam XS with selected lens installed (16mm lens default option). | | Yes |
| FUTULIAK | 1 | #4: Futulight attachment on camera | х | |
| FUTULAK | 1 | #5: Loupe attachment mounted on camera | х | |
| CONLOUC1 | 1 | #6: Universal loupes clip | Х | |
| | 1 | #7: Cable guide with clothing clip | Х | |
| CONCSA | 1 | #8: Spiral cable guide for securing the camera cable to loupe arm | х | |

TECHNICAL SPECIFICATION

| Cable, Ports and Signals | 1 x Permanently installed camera USB 2.0 Hi-Speed (480Mbit/s) with USB-A connection. 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 | Loupe mount (universal clip or loupe specific mounts) Headband |
| 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 Does not contain a battery. |
| Power System | Power is provided via the camera cable from the computer, Android device or USB hub. If used with a USB hub, the computer must also be ON. Do not use the computer's power save mode when recording. |
| 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. | | |
| | • Keep the device in the temperature between 5° to 50°C | | |
| Transportation | (41°F to 122°F). | | |
| and Storago | Allow the camera to reach room temperature before | | |
| and Storage | use. Temperature change may cause condensation on | | |
| | the sensor or lens. | | |
| | Class I EU MDR / FDA Class I Exempt / CE Marked / | | |
| Compliance | RoHS compliant. | | |
| Compliance | 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 | 14mm wide x 17mm long x 27mm high | | |
| Size and weight | Weight: 11grams without lens | | |
| | Aluminium / PA / Nylon | | |
| Materials | Electronics in camera and foot pedal | | |
| | Cardboard / plastic packaging | | |
| Recommended | NMI Recording Software for Windows, Mac or Android. 5 | | |
| software | software licenses included per device. | | |
| | Omnivision 2735 sensor with video capture of 30fps | | |
| | (frames per second) in secure h.264 mp4 format. | | |
| Imago quality | Video/image resolution of: | | |
| inage quality | FullHD 1080p (pixels) | | |
| | • HD 720p | | |
| | Exchangeable UHD manual focus lenses: | | |
| Ontics | ACCL1602 - 16mm default | | |
| Optics | ACCL2502 - 25mm close-up | | |
| | ACCL0801 - 8mm wide angle | | |
| Recording | 1 hour of recording in FullHD mode is approximately 3G. | | |
| memory size | 1 image is 2MP (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

NOTE The contrast between task lighting and ambient light should be as low as possible for best quality images:



High contrast is caused by bright task lighting and low ambient light. High contrast results in poor image quality.

How to fix: Add ambient light or zoom-in on the bright area.



Low contrast is bright and even over the entire image. The camera can easily focus and image quality is good.

COMPUTER REQUIREMENTS

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

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

Finding Windows System Information

- 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.
 - o Expand the Universal Serial Bus Controllers option and check the USB type.
 - Expand Display Adapters to check the Intel graphics card type.

Finding MacOS System Information

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

For All Computer Systems

Check the CPU rating of the computer using the website: CPUBenchmark.net

| | Basic Computer Functionality | | | |
|---------------------------------------|---|---|--|--|
| | 16GB RAM or higher | | | |
| | USB2 or USB3 port for the camera | | | |
| All Computer | Additional USB2 or USB3 p | ort for foot control pedal | | |
| Systems: | Network / internet capabil | ity | | |
| | CPU Benchmark.net rating | of 3000 or higher | | |
| | IEC 60601-1 compliant | | | |
| Windows | Windows 10 or later opera | ting system | | |
| Requirement: | NET Framework 4.5 | | | |
| MacOS | OS X version 10.15.7 (Cata | lina) or newer | | |
| Requirement: | MacBook Air/Pro 2015 or r | newer | | |
| Video quality | HD (720p) | Full HD (1080p) | | |
| Windows PC Minimum requirements | Screen resolution of 1024x768 or higher. CPU rating over 3000. | Hardware encoding (QuickSync technology) Intel graphics card 16GB RAM minimum Screen resolution of 1920x1080 or higher. CPU rating over 5000. | | |
| 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 or higher. CPU rating over 5000. | | |

ANDROID DEVICE REQUIREMENTS

Check the CPU rating of the Android device by following the instructions on the website: androidbenchmark.net

| Android OS | Android 11 or higher with the Android recording software | | | |
|----------------------------------|--|-------------------------------------|--|--|
| Requirement | available on the Google Play store. | | | |
| Android | The phone must support on-the-go (OTG) function. | | | |
| Connectivity | NOTE The user must | buy an OTG adaptor cable to connect | | |
| connectivity | the microCam cable to the Android device. | | | |
| HD (720p) | | Full HD (1080p) | | |
| CPU rating over 5000. | | CPU rating over 5000. | | |
| Screen resolution of 1024×768 or | | Screen resolution of 1920×1080 or | | |
| higher. | | higher. | | |
| 64bit CPU | | 64bit CPU | | |
| 4 GB RAM or higher | | 8 GB RAM or higher | | |



INSTALL THE RECORDING SOFTWARE

Recording software instructions are enclosed separately.

Recording software must be downloaded and installed on the computer or Android device.

INSTALL THE FOOT PEDAL

NOTE The foot pedeal is not used for Android camera control.

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

INSTALL TO LOUPES OR HEADBAND

The camera backplate comes installed with the loupe clip for attachment to loupes or headbands.



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 camera cable to the computer. 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 long cables neatly in place.

Or, connect the an OTG cable to the Android device for mobile use. Use the clothing clip to hold the cable in place.

STARTING THE CAMERA IN LIVE VIEW MODE

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

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:

| AIM THE CAMERA Put this card at your normal working distance. Look at the center of this card through your loupes. Align your camera to the center as well. | | | 2. FOCUS THE CAMERA -Rotate the lens to focus the image. -Try to get the thin lines as sharp as possible. |
|--|---|---|---|
| | Ħ | ŧ | |
| | | | |

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.
- \circ $\;$ 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 check colour and lighting.

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.



4

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 |
| | Taka a still photo | 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 or fullHD) | ↑ Up-key / Down-key ↓ | ↑ Up-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 is a USB powered device that turns off when:

- Closes the recording software. ٠
- Closes any other video problem using the camera.
- Disconnects the USB cable. •
- Turns the computer off.
- Turns the USB hub 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 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:

- Flicker: Rapid changes in image brightness. 1.
- Tearing: Image seems to consist of different parts, 2. 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.
 - 0 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 0 cable as a spare part.
- Graphics card is not Intel.
 - The camera may not work consistently with 0 graphics cards other than AMD.

#2 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 graphics cards other than AMD.
- Graphic driver is out of date.

#3 Camera is not detected in Windows after installing software and clicking the camera refresh button In the recording software:

 Go to Settings and select the camera from the camera dropdown list to activate the camera. You might need to close and re-start the Recording Software.

If this does not work:

- Go to "Control panel" -> " Device Manager" or search "Device Manager" by clicking on the "camera" button.
- Open the device list and right click on the camera name (microCam XS).
- Choose "uninstall" and then re-plug in the camera to ٠ re-install. .
- Open the Recording Software and press the camera refresh button.

If the camera still cannot be detected, try with a different camera cable and USB port. If this does not help, contact your local distributor or NMI 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 low light, high contrast light or an unfocused lenses. Check that:

- the total task light intensity is over 32,000lux with strong ٠ ambient light to create low contrast.
- a color spectrum of light (CRI) of over 90) is used. ٠
- the camera is correctly focused and clean.
- no halogen lights are used. •

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

See the 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 advanced camera settings.
- Do not use with halogen lights.
- Try another lens.

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.

See full details on the website: https://www.futudent.com/contact/about/privacy-policy

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. An example consent form 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.

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 P | ort (Table 8, IEC 6 | 50601-1-2:2014) | | |
| 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. The up-to-date EULA is made available on https://www.futudent.com/contact/about/termsof-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 Medical Innovations or (iii) the Product and/or Accessory is not purchased from an authorized Novocam Medical Innovations 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.

CONTACT US

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 lists are on the www.futudent.com and www.novocam.com websites.

Contact Novocam Medical Innovations

Contact information and Technical Support contact are available on the www.futudent.com and www.novocam.com websites.

Postal mail, product returns, billing and invoices should use the NMI 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, please send a report to support@futudent.com OR support@novocam.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.



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