Video Console ^{2}

MD RX Only

User Manual (EN)

Part Number: CCU-0200
Part of 3NT-3000

LBL-0030 Rev03.3, Jun 2024

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Table of Contents

1 Important Information

Caution: Federal U.S. law restricts this medical device to sale by or on the order of a physician.
These user instructions are applicable to the 3NT Video Console (item number CCU-0200), which is also interchangeably referred to in this document as Video Console [2], Video Console or Console, and is part of 3NT Endoscopy System.
The user instructions may be updated from time to time without further notice.
Please be aware that these instructions do not explain or discuss clinical procedures. The instructions describe only precautions and functions related to the operation of the 3NT Video Console [2].
Read this manual thoroughly prior to using the 3NT Medical Video Console and ensure its proper use and care are well understood.
The images in this document are provided for illustration purposes only.
In case of any serious incident that has occurred in relation to 3NT Endoscopy System report to 3NT Medical and to the local authorities.

Contact 3NT Medical for any questions or comments:
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The following terms and definitions are used in this manual:
WARNING - Alerts the user of situations which, if not avoided, could result in death or serious injury.
CAUTION - Alerts the user of situations which, if not avoided, could result in moderate or minor injury to the user or patient. It is also used to alert the user of conditions and actions that could cause equipment damage.
NOTE - Indicates additional helpful information.

2 Intended Use

3NT Endoscopy System is intended to visualize the internal cavities of the ear, airways, nose and sinus cavities during diagnostic and therapeutic endoscope procedures.

3 Patient Population

Patients in whom endoscopic evaluation is required; For further information regarding patient population please refer to the IFU of the compatible endoscope in use: for Colibri refer to LBL-0020; for Peregrine refer to LBL-0003.

4 Contraindications

None.

5 Warnings

1. **Do not use this equipment in the presence of a flammable anesthetic mixture containing air, oxygen or nitrous oxide. There is a possibility of fire or explosion.**
2. 3NT endoscopy system should only be used by or under the supervision of a physician trained in endoscopy procedures at professional healthcare facilities.
3. 3NT Video Console should be handled with care. Do not use the 3NT Video Console if it is damaged in any way.
4. Do not connect to 3NT Video Console endoscopes which are not specified in Table 2 of this manual as approved models. Using incompatible equipment can result in patient or user injury, or damage to the Video Console.
5. Do not use accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment. Using incompatible equipment could result in patient or user injury, increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
6. The provided Console power cord is equipped with a three-wire grounding plug (a plug that has a third grounding pin). Always connect the power cord to a grounded power outlet to avoid risk of electric shock.
7. Special care must be taken when connecting accessory equipment to the Console isolated HDMI port and isolated USB port. Verify that equipment connected to these ports complies with the respectively nationally harmonized IEC standards (i.e., IEC 60950 for data processing equipment, IEC 60065 for video equipment and IEC 60601-1 for medical equipment.) and that the configuration complies with 3NT Endoscopy System safety standard IEC 60601-1.
8. 3NT Video Console provides VESA mounting interface. Always use standard VESA mounting elements which are compatible with the Console size and weight as specified in Table 3. Console mechanical installation should be carried out by a professional technician. 3NT medical is not responsible, nor is it liable for the proper mounting of the Video Console. Improper installation of the 3NT Video Console can result in user or patient injury.
9. Do not continue operation in a case of no image, frozen image or unclear image and remove scope from patient body.
10. Remove the endoscope from the patient's body before viewing recorded images or video files to prevent injury.
11. Use of this equipment adjacent to or stacked with other electrical equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
12. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the 3NT Video Console, including cables specified by the manufacturer. This could result in equipment performance degradation.
13. The 3NT Video Console images must not be used as an independent diagnosis of any pathology. Physicians must interpret and substantiate any finding by other means in light of the patient's clinical characteristics.

6 Cautions

1. Store 3NT Video Console according to the storage conditions provided in section 8.
2. Always connect 3NT Video Console to power outlet during use. The Console internal backup battery will provide operating time of several minutes only to enable automatic shutdown in case of power loss.
3. Position the Console power cord where it is unlikely to be stepped on. Do not place any objects on the power cord.
4. The Console is not a sterile device. Be careful not to breach the scope or patient area sterility during operation by touching the screen.
5. 3NT Video Console is defined as a 'waste electrical and electronic equipment' (WEEE) and should be collected, disposed of or recycled according to state policies and regulations.

7 System Description

The 3NT Video Console is a non-sterile, reusable device (multiple patient multiple use) intended to display the video image received from 3NT Medical endoscopes (see
Table 2 – Compatible Scopes). 3NT Video Console includes a system power source, a video processor and a touch screen. It displays the video images received from the endoscope and powers the illumination LED located at the tip of the endoscope. In addition, the video Console allows the user to rotate the image by 90° increments and save still images and videos.
The system is a stand-alone system which is not connected to any external network / other IT system.
The system does not store identifiable patient / user information.

The 3NT Video Console package includes the following components:

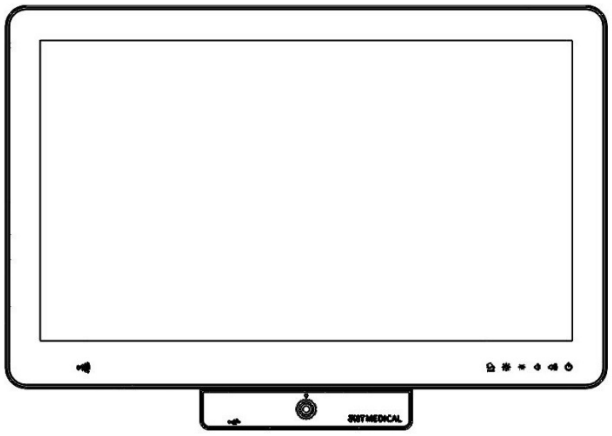
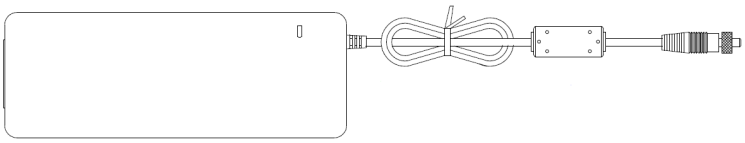
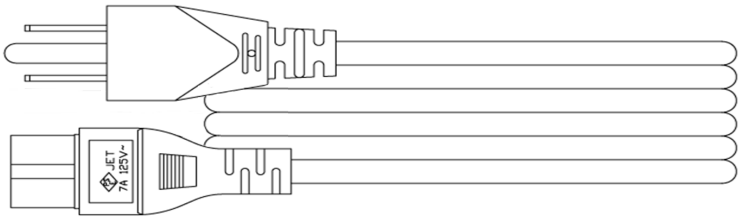
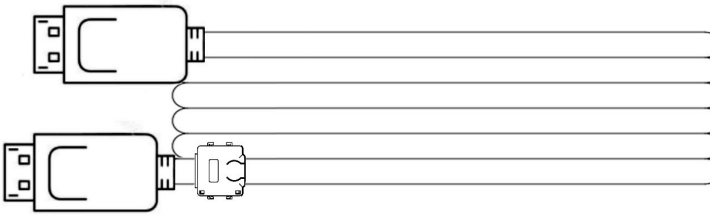
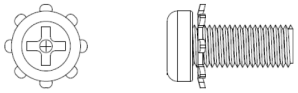
Part	Picture
3NT Video Console	
Medical Power Adapter (19Vdc, 4.7A)	
US Power cord (three-wire grounding plug)	
HDMI cable (4m) with Ferrite Bead	
4 x mounting screws (M4 x 6mm)	

Table 1 – 3NT Video Console Components

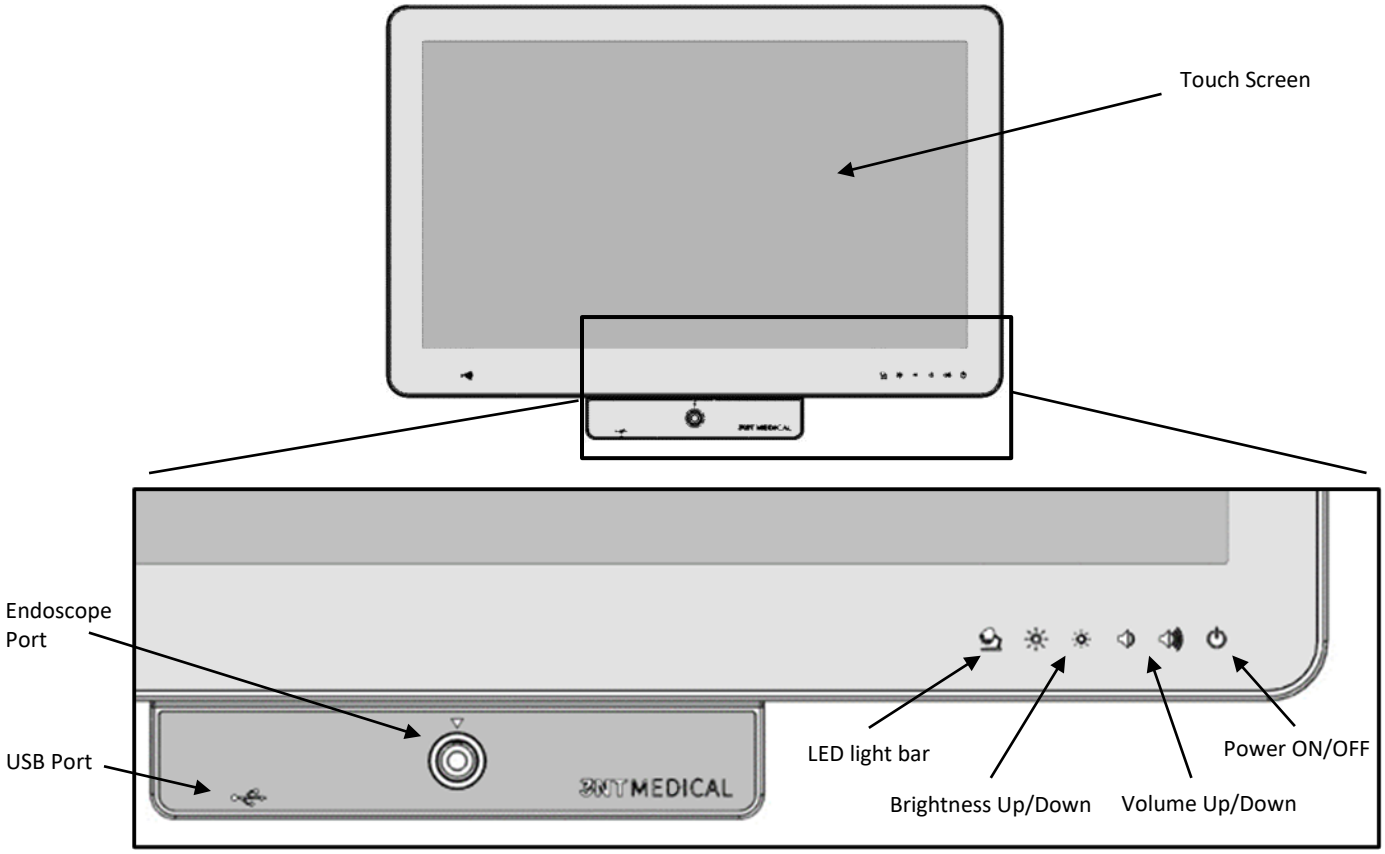


Figure 1 - Console Front Panel

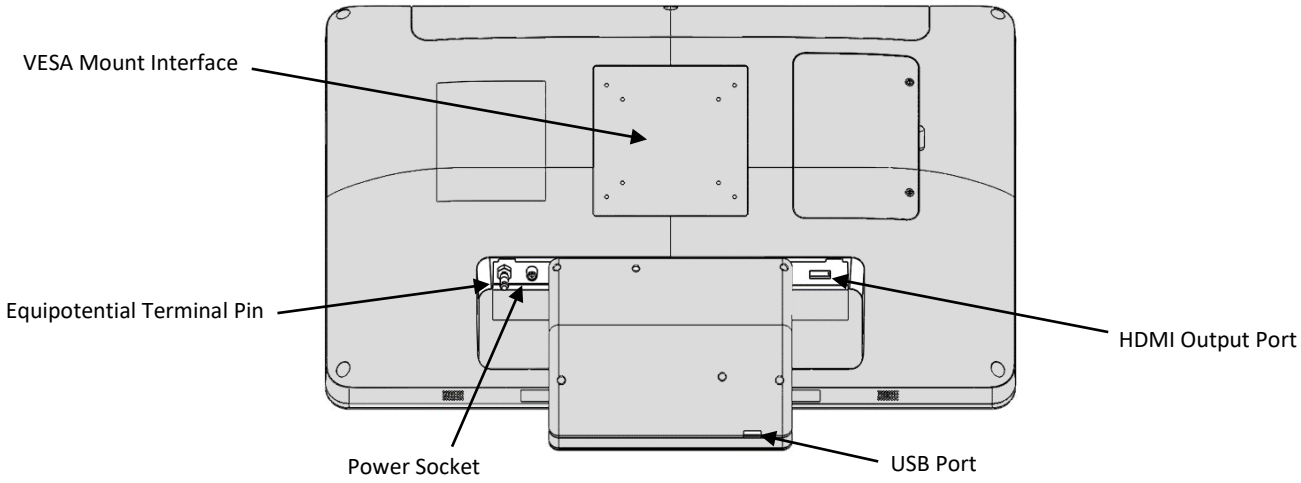


Figure 2 - Console Rear Panel

The 3NT Video Console can be connected only to the following 3NT endoscopes:

Compatible Device	Catalog Number
Colibri™ Micro ENT Scope / Angled Colibri	ERW-0100 / ERW-0200
Peregrine™ Drivable ENT Scope	SWY-0100

Table 2 – Compatible Scopes

Only one device can be connected to 3NT Video Console at a time. Refer to each device Instruction for Use for specific information.

8 Specifications

Specification	Details
Touch Screen	21.5” PCAP multi touch
Screen Resolution	1920 x 1080
Display Type	LCD
Interfaces	Standard HDMI x 1 USB A x 1
Color Gamut	72% NTSC
Operating Environment Temperature	32° to 104° F (0° to 40° C)
Storage Environment Temperature	14° to 131° F (-10° to +55° C)
Relative Humidity	10% - 90% RH
Atmospheric Pressure	70 - 106 kPa
Power Requirement	19V 4.7A DC input
Backup Battery	14.4V / 1150 mAh
Power Adapter Requirements	100-240 VAC, 50-60 Hz, 2.0-1.0 A
Maximal Power Consumption	90 W
Electrical & Thermal Safety	IEC 60601-1, IEC 60601-2-18
Electromagnetic Compatibility	IEC 60601-1-2
Degree of Protection Against Electrical Shock	Class I equipment
Console dimensions	539.6 x 342.6 x 45.5 mm
Console weight	14.55 lb. (6.6 kg)

Table 3 – Specifications

9 Preparation and Inspection

1. Visually examine 3NT Video Console and its accessory components for any damage.
   Warning: Do not use the equipment if any defects are detected.
2. Mount 3NT Video Console using the provided standard VESA 75/100 mounting interface and secure it in place with four provided M4 x 6mm screws. Console mechanical installation should be carried out by a professional technician. 3NT medical is not responsible, nor is it liable for proper mounting of the Video Console.
   Warning: Always use standard VESA mounting elements which are compatible with the Console size and weight. Make sure to secure the screws of the mounting tightly to avoid impact which can result in user or patient injury and can compromise the functionality and/or safety of the equipment.
   Caution: Do not block the VESA mount rear metal area by any soft material as this metal area functions as a cooling surface that transfers heat from the Console to outside air.
   Warning: Avoid the risk of electric shock by locating the Video Console and the power adapter in a dry place and avoiding contact with liquids.
   Warning: The Console location must not contain explosive or flammable gases.
   Caution: The Video Console shall be located out of the sterile area, if exists.
   Note: Position the Video Console at a sufficient distance from the patient allowing the user to operate the scope and its cable freely.
3. Connect the power adapter cable to the Console. Plug the supplied power cord into the power adapter and to the power outlet.
   Note: An equipotential terminal pin is provided to optionally connect to a hospital ground/earth system.
   Warning: Do not overload the power outlet by connecting the Video Console to a multiple socket-outlets or an extension cords as this may result in fire or electric shock.
   Caution: The power cord should be routed so that it is not likely to be stepped on. Do not place any objects on the power cord.
   Caution: The Video Console is equipped with internal backup battery to allow continuous operation in case of power disconnection. When power disconnection occurs a message prompt the user to connect the power back appears on the screen. In case the external power is not restored, automatic shutdown will be initiated.
4. To output the video stream to an external monitor, connect the provided HDMI cable, with the Ferrite Bead side (Table 1) to the Console HDMI isolated output port and follow the instructions in Figure 12.
5. Switch on the Console by firmly pressing the power ON/OFF button. The power ON/OFF LED will turn green and the application software will upload automatically (Figure 3).

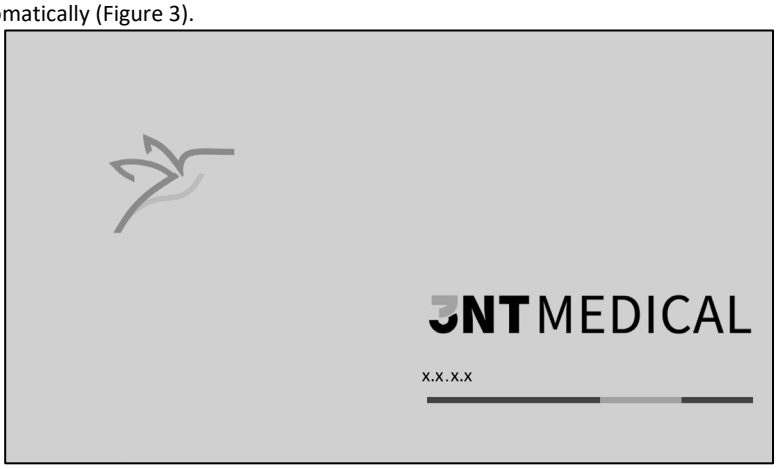


Figure 3 - Login Screen

10 System Operation

1. Unpack and prepare a compatible endoscope for operation (for scope operating instructions refer to the specific scope instruction for use).
2. Connect the connector of the endoscope to the designated endoscope port on the front panel of the Console (Figure 4).

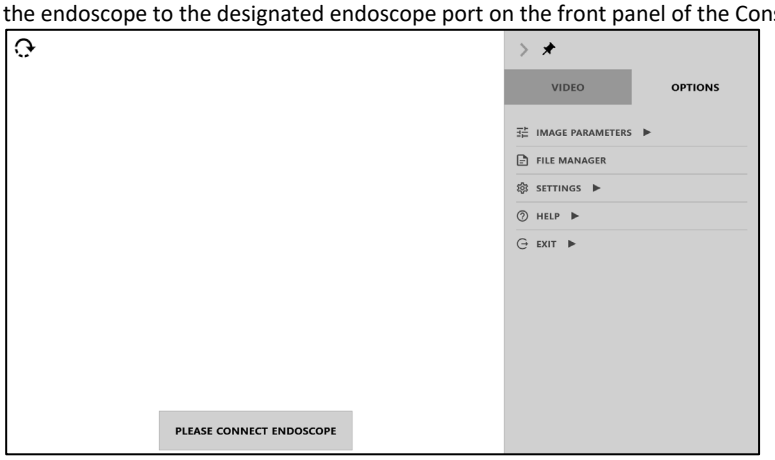


Figure 4 - Endoscope Connection Screen

3. Ensure a live video image appears on the screen.
   If an image does not appear, press on INITIATE CAMERA button in the VIDEO screen (Figure 5).

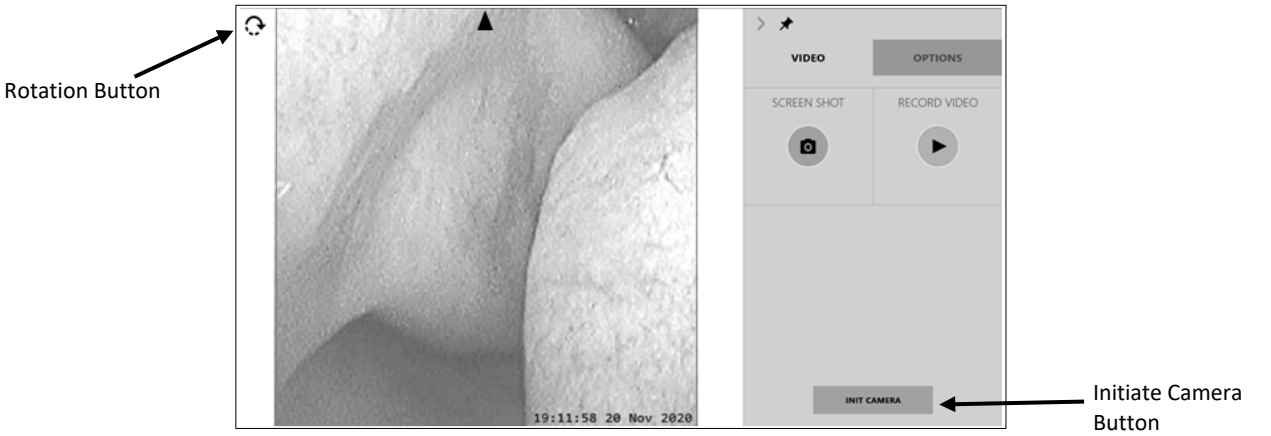


Figure 5 - VIDEO Screen

4. If necessary, press the Rotation Button located on the upper left corner of the screen (Figure 5) to cyclically rotate the image by 90˚ increments until the desired orientation is reached.
5. Introduce the endoscope into the patient.
6. For saving a screen shot press the corresponding button on the screen (Figure 5). Verify a screen shot was taken by looking for the "IMAGE SAVED" message below the SCREEN SHOT button or on the bottom left corner of the live video.
7. For recording a video stream press the corresponding button on the screen (Figure 5). Verify a video is recording by looking for the square recording symbol (replacing the play symbol) and the recording clock under the RECORD VIDEO button. To stop recording, press on the square recording symbol button.
   Note: System storage is limited. When the system storage is running low a warning message will appear prompting to delete unnecessary files from file manager.
8. At the end of the procedure, withdraw the endoscope from the patient body and disconnect it from 3NT Video Console. Dispose of the endoscope according to the instruction for use of the specific device.
9. Turn off the Video Console by pressing the SHUT DOWN button in the OPTIONS→ EXIT Screen (Figure 6).
   Note: The system has a session time-out feature. If the system was not in use for four hours, it will shut down automatically.

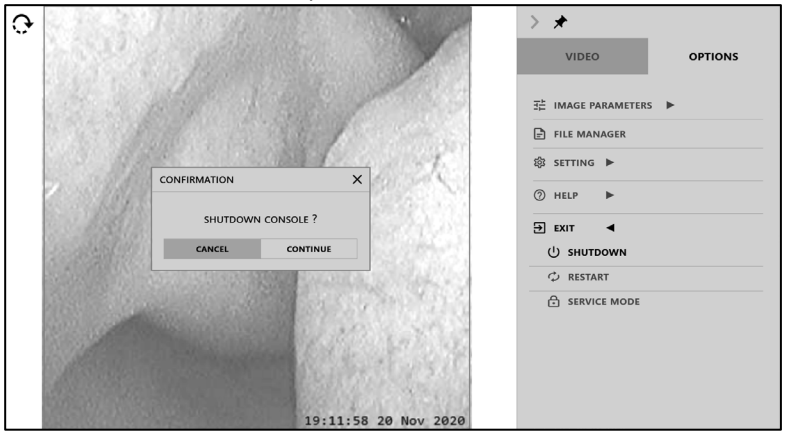


Figure 6 - Shut Down Screen

10. Clean and disinfect 3NT Video Console according to the instructions in section 12.

11 Advanced Options

1. Advanced options such as image parameters, files manager, video out and clock setting can be adjusted in the OPTIONS screen (Figure 7).

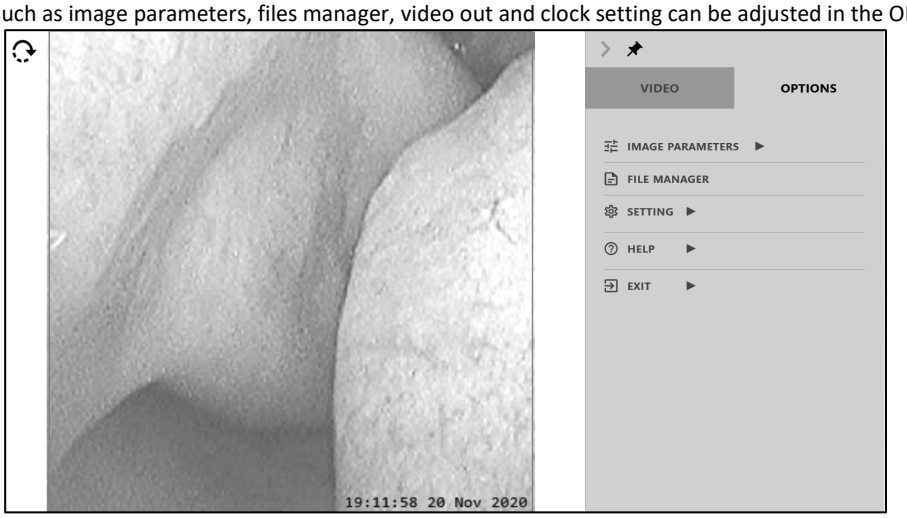


Figure 7 - OPTIONS Screen

2. IMAGE PARAMETERS:
   2.1. IMAGE PARAMETERS menu enables the user to calibrate and adjust the image brightness and RGB gains (Figure 8).
   2.2. BRIGHTNESS presets can be selected to control the level of image brightness.

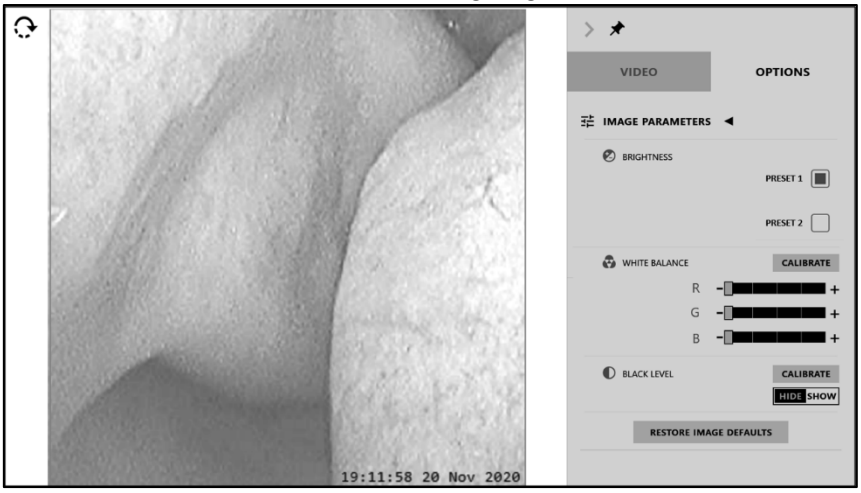


Figure 8 - IMAGE PARAMETERS Screen

   2.3. By default, white balance is calibrated to fit the LED located at the tip of the compatible endoscopes. If white balance is still required, Press on WHITE BALANCE Calibration button and follow the displayed instructions (Figure 9).
      2.3.1. Aim the endoscope tip to white or gray surface and press CONTINUE.
      2.3.2. Wait until the process bar disappears.

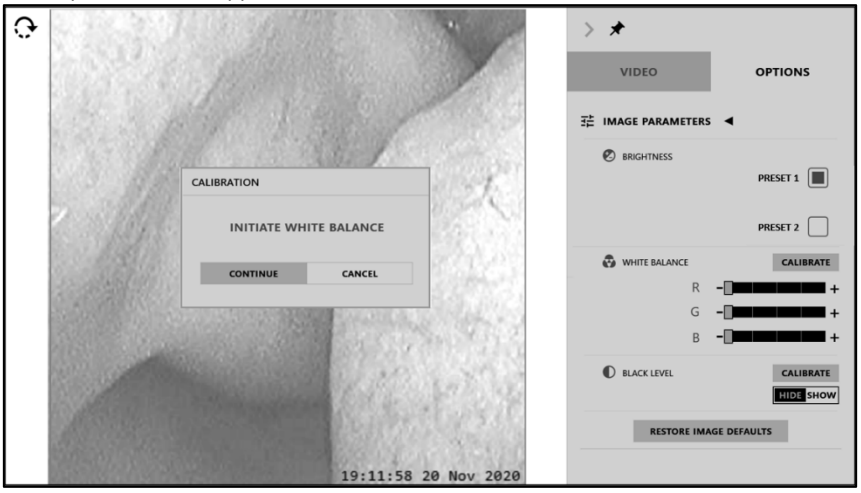


Figure 9 - White Balance Screen

2.4. If black level calibration is required, press on BLACK LEVEL Calibration button and follow the displayed instructions (Figure 10).
  2.4.1. Cover endoscope tip using a sterile, blackout cloth and press CONTINUE.
  2.4.2. Wait until the process bar disappears and remove the cloth.
  2.4.3. If you wish to keep the new calibration, select SHOW. If you wish to remain without calibration, select HIDE (Figure 10).

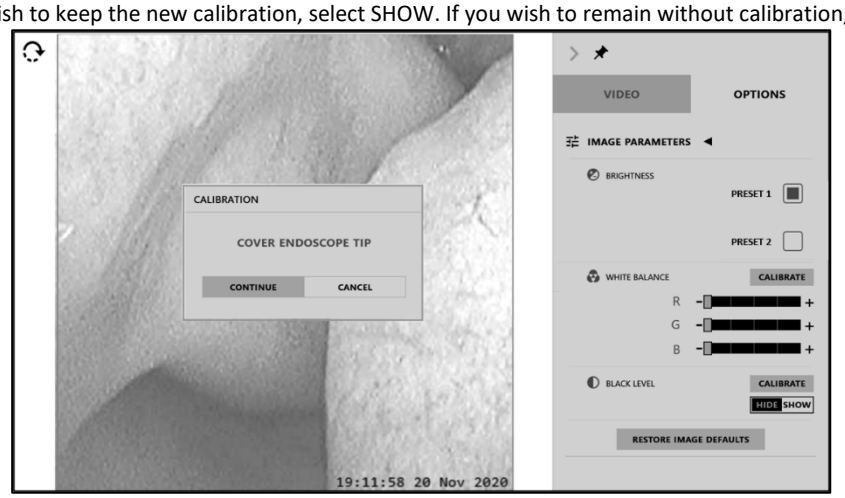


Figure 10 – Black Level Screen

2.5. In order to restore image parameters to default press RESTORE IMAGE DEFAULTS button (Figure 8).

3. FILE MANAGER:

Note: The file manager is protected by a password. The initial password is 3333, please make sure to change it in the first login.

3.1. By default, the file manager includes folders sorted by dates and files are sorted by time (Figure 11).

3.2. File manager screen enables deleting and exporting files.

3.3. File manager also enables viewing recorded videos and saved images.

Caution: Remove the endoscope from the patient body before viewing recorded images or video files.

3.4. In order to export a file, you must insert an external USB storage device to the video Console USB port.

Note: The file manager has a session time out protection feature and will automatically switch to VIDEO screen in case no interaction is made.

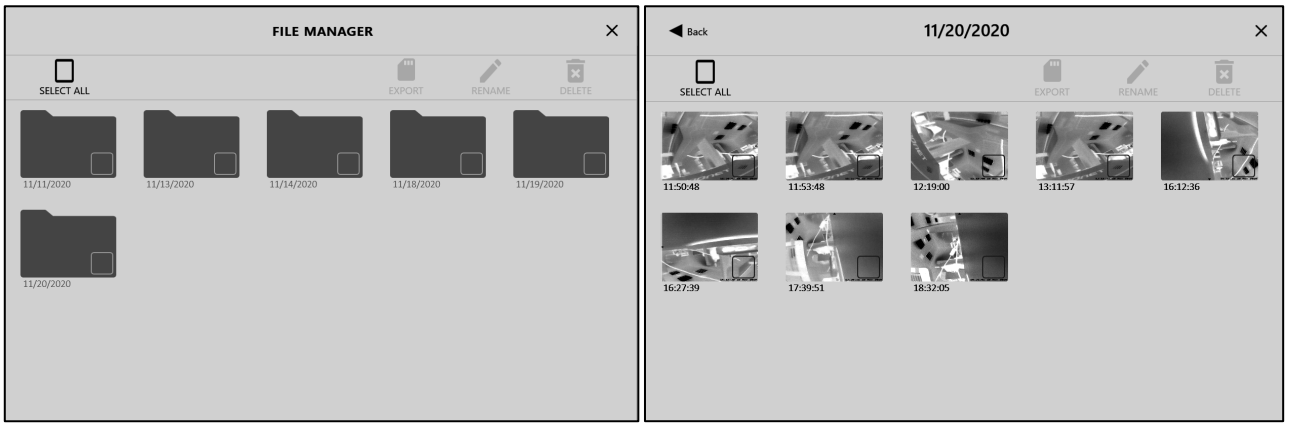


Figure 11 - File Manager Screens

4. SETTING:

4.1. VIDEO OUTPUT window allows the user to configure external monitor settings (Figure 12). Verify the displayed test pattern fully appears on the external monitor and that the image is not distorted.

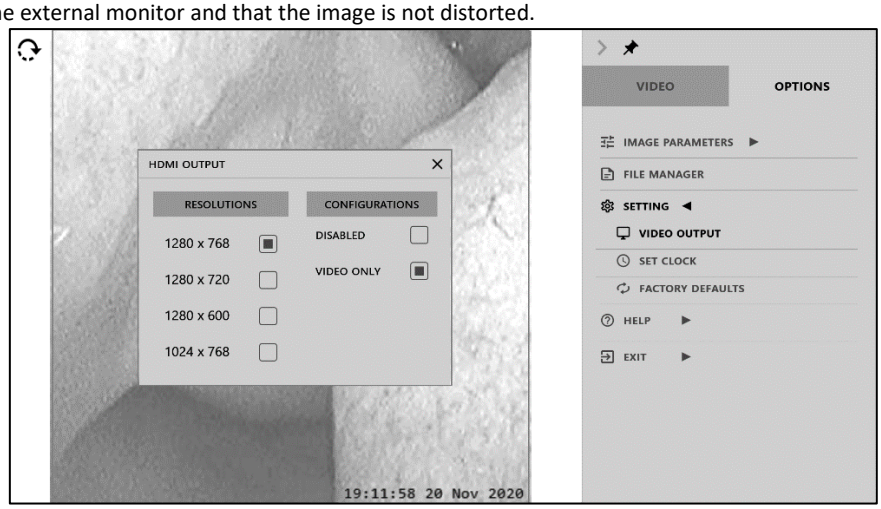


Figure 12 - Video Output Screen

4.2. SET CLOCK window (Figure 13) enable to set the date and time.

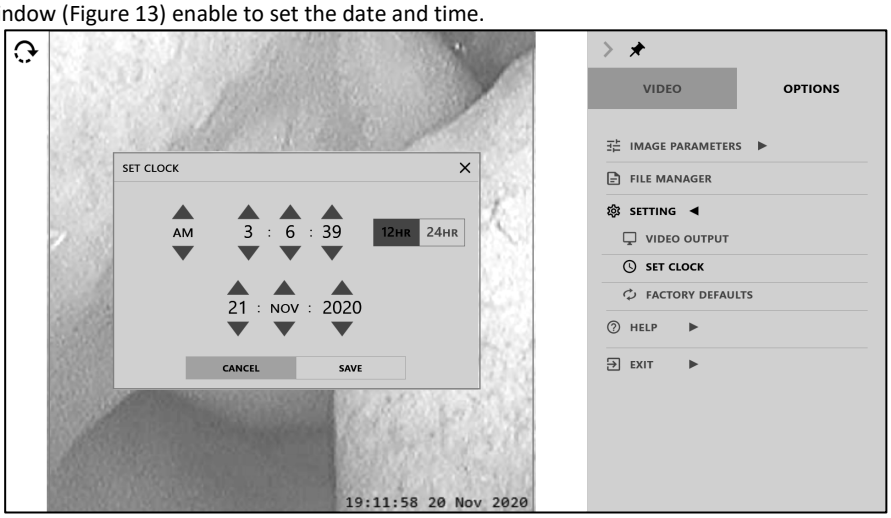


Figure 13 – Clock Setting Screen

4.3. FACTORY DEFAULT window allows the user to restore all system settings back to default (Figure 14).

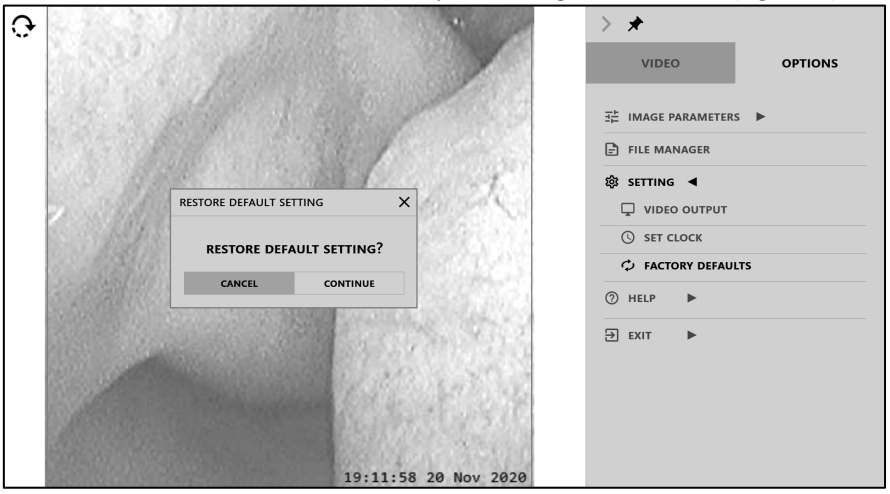


Figure 14 - Factory Default Screen

5. HELP:
   5.1. The TRAINING screen enable the user to watch how to use the system.
   5.2. ABOUT screen provides details on the Video Console serial number and software version (Figure 15).

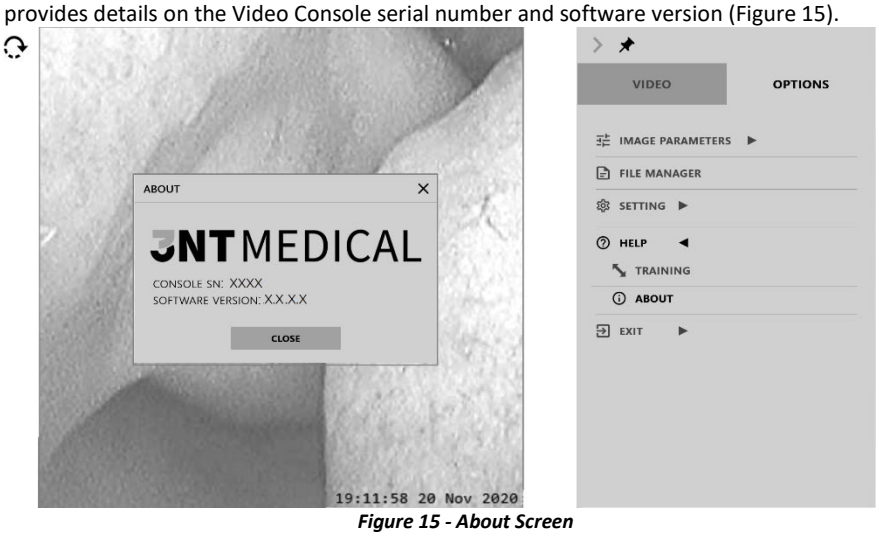


Figure 15 - About Screen

6. EXIT:
   6.1. EXIT screen enables the user to shut down or restart the Video Console.
   6.2. SERVICE MODE screen is restricted for use by 3NT technical support personnel only and requires an admin password (Figure 16).

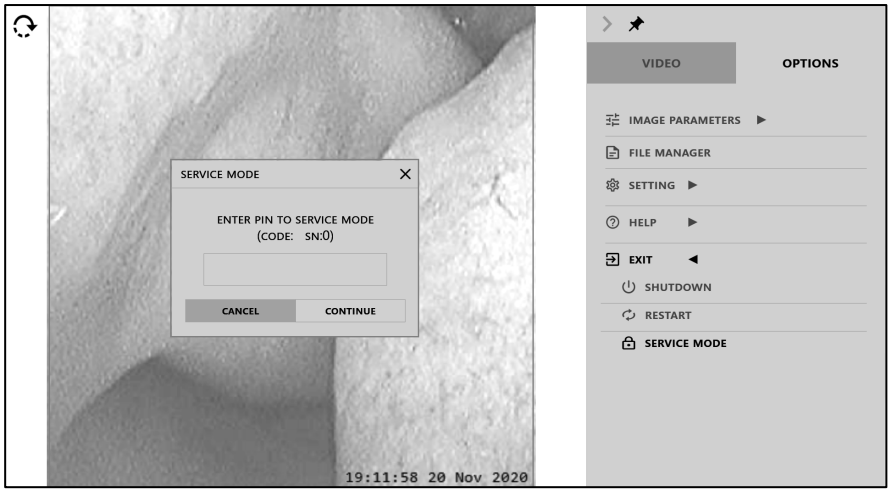


Figure 16 – Service Mode Screen

12 Cleaning and Disinfection

The 3NT Video Console should be cleaned and disinfected before and after each use according to good medical practice.

Caution: Do not use liquid or spray detergents for Console cleaning in order to avoid damage to internal components of the Console.

1. Turn off the Video Console and disconnect it from any accessories and mains power supply before cleaning and disinfection**.**

Caution: Verify the power adapter and the endoscope are not connected to the Console and that the Console is turned off completely when performing cleaning and/or disinfection actions.

2. **Cleaning** –
   - 2.1. Wet a soft, lint-free or microfiber cloth with cleaning agent per manufacturer's instructions or hospital protocol (see recommended cleaning agents/wipes below).
   - 2.2. Wipe the Console surface in a gentle motion to remove dust, fingerprint smudges and heavy soil such as blood or body fluids.
3. **Disinfecting –**
   - 3.1. Use a clean wipe (see recommended wipes below) to thoroughly wet the Console surface and make sure it remains wet for required disinfection duration.
   - 3.2. Wipe any moisture excess with a dry lint-free cloth to finish cleaning before turning the Console back on.
4. Let the Console dry.

Cleaning agents/wipes:

It is recommended to use the following commercial clean and disinfection wipes which were tested by 3NT Medical and to refer to the wipe's instruction for use for detailed use explanation.

1. Super Sani-Cloth® Germicidal Disposable Wipes manufactured by PDI, for two (2) minutes disinfection duration.
2. Sani-Cloth® Bleach Germicidal Disposable Wipes manufactured by PDI, for four (4) minutes disinfection duration.
3. Alcohol 70% wipes.

13 Storage and Maintenance

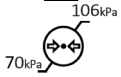
1. The 3NT Video Console and its components should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes. For storage conditions refer to Table 3.
2. The Video Console contains no user-serviceable parts; never attempt to modify or repair them. Doing so may cause further equipment damage and/or compromise patient safety if the Console is subsequently used in a procedure. In case of need contact 3NT Medical representative for service provision.
3. At the end of the product life dispose of the Video Console and components in accordance with applicable state policies and regulations relating to batteries and electronic equipment waste.

14 Troubleshooting

PROBLEM	SUGGESTED ACTION
System does not turn on	• Verify the power cord is well connected to the power outlet and power adapter. • Verify the power adapter is well connected to the Console power socket. • Turn on the Console by firmly pressing the power ON/OFF button. • If problem continues, contact 3NT Medical representative for further instructions.
"Internal hardware failure" message is presented	• Restart the Console. • If problem continues, contact 3NT Medical representative for further instructions.
Live video is not displayed or "Please connect endoscope" message is presented	• If the video signal is lost during a procedure and cannot be restored, slowly withdraw the scope from the patient. • Press on INITIATE CAMERA button (see Figure 5 - VIDEO Screen). • Make sure a scope is well connected to the Video Console. • If the problem is still not resolved replace scope. • If problem continues, contact 3NT Medical representative for further instructions.
Presented image is not clear, poor image quality	• Wipe the Video Console screen with a clean cloth. • Verify the endoscope tip is clean. • Press on INITIATE CAMERA button (see Figure 5 - VIDEO Screen). • Restore to image default settings. • Perform Black Level (see Figure 10 – Black Level Screen) or White Balance (see Figure 9 - White Balance Screen). • If the problem is still not resolved replace scope. • If problem continues, contact 3NT Medical representative for further instructions.
Low battery level	• Connect the Video Console to external power adapter. • If problem continues, contact 3NT Medical representative for further instructions.
Video is not displayed on an external monitor or display resolution is non optimal	• Verify HDMI cable is well connected to the Console HDMI output and external monitor. • Verify HDMI cable is connected with the Ferrite Bead side (Table 1) to the Console HDMI isolated output port. • Verify external monitor is turned ON and correct video input source is selected. • Verify Console video output is enabled (OPTIONS → SETTING → VIDEO OUTPUT). • Verify the correct resolution is selected. • If problem continues, contact 3NT Medical representative for further instructions.
Exporting files to USB storage device is not working	• Verify FAT32 or NTFS formatted USB device is well connected to the console USB port. • Replace USB storage device. • Restart the Console. • If problem continues, contact 3NT Medical representative for further instructions.
Touch screen is too dark	• Increase the display brightness by pressing the Brightness UP button (Figure 1 - Console Front Panel). • If problem continues, contact 3NT Medical representative for further instructions.
Touch screen is not working	• Press the LED light bar button (Figure 1 - Console Front Panel) for 4 seconds to turn on the touch function. • Restart the Console. • If problem continues, contact 3NT Medical representative for further instructions.

15 Symbols

The symbols listed below can be found on 3NT Video Console or its package.

	Type BF applied part (Safety degree specified by IEC 60601-1)
	Consult instructions for use
	Warning
	Power on / off / stand-by
	Equipotential
	Serial number
	RoHS compliant
	Manufactured by
	Catalog number
	Prescription Use Only
	Manufacturing date
	Keep dry
	WEEE - follow the national requirements for disposal of equipment
	Atmospheric pressure limitation
	Humidity limitation
	Temperature limit
	Fragile, handle with care
	HDMI out
	USB port
	Medical Device symbol
	Consult electronic instructions for use

16 Limited Warranty

THE WARRANTY PERIOD OF 3NT VIDEO CONSOLE IS ONE YEAR FROM THE DATE SHIPPED TO THE CUSTOMER. IN CASE OF MATERIAL DEFECTS OR A DAMAGED DEVICE, 3NT MEDICAL SHALL, AT ITS OPTION, REPAIR OR REPLACE THE CONSOLE.

3NT MEDICAL LTD. WARRANTS THAT REASONABLE CARE HAS BEEN USED IN THE DESIGN AND MANUFACTURE OF THIS DEVICE. 3NT DISCLAIMS ALL OTHER WARRANTIES, REPRESENTATIONS, TERMS AND CONDITIONS (STATUTORY, EXPRESS, IMPLIED OR OTHERWISE) AS TO QUALITY, CONDITION, DESCRIPTION, MERCHANTABILITY, FITNESS FOR PURPOSE AND NON-INFRINGEMENT, AND ANY WARRANTY REGARDING RESULTS OBTAINED THROUGH THE USE OF THE PRODUCTS INCLUDING, WITHOUT LIMITATION, ANY CLAIM OF INACCURATE, INVALID, OR INCOMPLETE RESULTS, SINCE HANDLING AND STORAGE AS WELL AS OTHER FACTORS RELATING TO THE PATIENT, DIAGNOSIS, TREATMENT, MEDICAL PROCEDURES, AND OTHER MATTERS BEYOND 3NT MEDICAL'S CONTROL, DIRECTLY AFFECT THE DEVICE AND THE RESULTS OBTAINED FROM ITS USE. 3NT MEDICAL SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM THE USE OF THIS DEVICE. 3NT MEDICAL NEITHER ASSUMES, NOR AUTHORIZES ANY OTHER PERSON TO ASSUME FOR IT, ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THIS DEVICE.

APPENDIX - ELECTROMAGNETIC COMPATIBILITY (EMC) DECLARATIONS

The 3NT Video Console is intended to be use at professional healthcare facilities.
The following properties are essential for safe use of the 3NT Endoscopy System:
1. Live video display
2. Scene illumination
3. Image orientation
Exposure of the system to electromagnetic environment beyond specified in the appendix can lead to degradation of mentioned before properties.

The emissions characteristics of 3NT Video Console make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it used in a residential environment (for which CISPR 11 class B is normally required) 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.

The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.

3NT Video Console has not been tested for known sources of electromagnetic interference such as Magnetic Resonance Imaging (MRI), Computerized Tomography (CT), diathermy, radio frequency identification (RFID) systems, and electromagnetic security systems such as metal detectors, and should not be used in conjunction with or in proximity to such technology.

Guidance and manufacturer's declaration – electromagnetic emissions		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1 Class A	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class A	The system is suitable for use in all establishments, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage Fluctuations and Flicker IEC 61000-3-3:2013	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2, 4, 8, 15 kV air	8 kV contact 2, 4, 8, 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	2 kV for power supply lines 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/output) to earth	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/output) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or by the built-in rechargeable battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 (A/m)	30 (A/m)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
Immunity test	**IEC 60601 TEST LEVEL**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3V, 6V	3Vrms, 6V	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{12}{V_2}]\sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m	3V/m	$d = [\frac{12}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{23}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz
	3V/m from 0.15 to 80MHz 6V/m from 0.15 to 80MHz and 80% AM at 1kHz	3V/m from 0.15 to 80MHz 6V/m from 0.15 to 80MHz and 80% AM at 1kHz	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. D Interference may occur in the vicinity of equipment marked with the following symbol: 
	10V/m from 80MHz to 2.7GHz	10V/m from 80MHz to 2.7GHz	
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Recommended separation distances between portable and mobile RF communications equipment and the system				
The System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System as recommended below, according to the maximum output power of the communications equipment.				
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**			
	150 kHz to 80 MHz outside ISM bands $d = [\frac{3,5}{V_1}]\sqrt{P}$	**150 kHz to 80 MHz in ISM bands** $d = [\frac{12}{V_2}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{12}{E_1}]\sqrt{P}$	**800 MHz to 2,5 GHz** $d = [\frac{23}{E_1}]\sqrt{P}$
0.01	0.12	0.2	0.4	1
0.1	0.37	0.64	1.3	2.6
1	1.17	2	4	8
10	3.7	6.4	13	26
100	11.7	20	40	80

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment							
Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum Power (W)	Distance (m)	Immunity test level (V/m)	Compliance level (V/m)
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28	28
870							
930							
1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28	28
1845							
1970							
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28	28
5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9	9
5500							
5785							
NOTE: If necessary, to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the system may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.							
[a] For some services, only the uplink frequencies are included. [b] The carrier shall be modulated using a 50 % duty cycle square wave signal. [c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.							