

MEDICAL MULTICONSOLE



User Manual

Version 1.6 (EN | EU)

Distribution, recording and storage
for the Operating Room

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Product Overview

MEDICAL MULTICONSOLE



Figure 1: Medical Multiconsole, (Left:D1-G-24T-BI, Middle:D1-G-49T-BI, Right:D1-G-55T-BI)

Revisions

Version	Date	Author	Changes
1.0	02 APR 2014	Product Management HAB	Initial version, Medical Multiconsole
1.1	02 SEP 2015	Product Management	Modification according to new standard for MULTICONSOLE
1.2	07 APR 2016	Product Management	Editorial modification
1.3	29 JUN 2017	Product Management/ Quality Management	Description of new buttons and operating procedure, restructuring of safety information
1.4	28 JAN 2019	Product Management/ Quality Management	Modifications regarding usage & company name change
1.5	20 MAY 2019	Product Management/ Quality Management	Editorial modifications & Risk Management
1.6	10 FEB 2023	Team Lead Quality Assurance	Layout changes, Medical Multiconsole

Translations

Original user manual version is created in English language. Manual is translated into German, Spanish, French, Italian, and Turkish by:



ADAPT Localization Services GmbH
Godesberger Allee 127
53175 Bonn, Germany

English Not your language? Check the supplied USB stick!

Deutsch Nicht ihre Sprache? Überprüfen sie den mitgelieferten USB-Stick!

Français Pas votre langue? Vérifiez la clé USB fournie !

Español ¿No es su idioma? Compruebe la memoria USB suministrada.

Italiano Non è la tua lingua? Controllare la chiavetta USB in dotazione!

Türkçe Senin dilin değil mi? Verilen USB belleği kontrol edin!

Manufacturer

The manufacturer of the MEDICAL MULTICONSOLE is:

Address of the factory

Caresyntax GmbH
Komturstr. 18A
12099 Berlin
Germany

Legal Disclaimer

Although we have attempted to achieve technical accuracy in this document, we assume no responsibility for any errors that may occur. Our goal has been to provide you with the most accurate and usable documentation possible. If you discover any errors, please let us know.

The technical specifications of Caresyntax® are subject to change without notice.

Service

In case of any malfunctions and incidents with the device, you can reach our service team 24 hours per day, seven days a week at the following hotline:

Caresyntax® Service hotline:

- +49 (0) 1805 722730 (0.14 €/minute landline calls in Germany, mobile calls can be more expensive)
- +49 (0) 8005 722730 (landline calls are free of charge within Germany)

E-Mail: service@caresyntax.com

All calls will be registered and routed appropriately. With this service, Caresyntax® GmbH aims to provide a quick, linear, and well-defined process to resolve any arising issues with the device. Please note that enquiries concerning servicing must be lodged exclusively via the service hotline.

To process service enquiries, please have at hand the following information:

- Product name, article number (REF number on device label) and full serial number (SN number on device label)
- Complete description of fault with accompanying photos and videos if possible

For other service inquiries, contact us:

Europe-Middle East-Africa

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Information about this User Manual





This manual refers to all product variants named in *Features by Variant*. Depending on the equipment, some functions and options described in these operating instructions may not apply to your console.

It is intended for medical professionals such as physicians and nurses, as well as technical staff responsible for the operation and maintenance of the console. This manual is intended to familiarize personnel with the Medical Multiconsole. It also contains technical data and information on the hardware functions of the device.

Safety Symbols in this User Manual




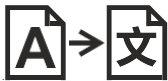
The following cautions or warnings are used in this manual.














Table 1: Safety Symbols

Symbol	Meaning
	DANGER indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury. DANGER is used only for situations that present the most serious degree of risk of injury or death.
	WARNING indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury. Hazards identified by the WARNING present a lesser degree of risk of injury or death than those identified by DANGER.
	CAUTION indicates a hazardous situation, which if not avoided, could result in minor or moderate injury.
	NOTICE addresses practices or conditions not related to personal injury.

Explanation of Symbols

Table 2: Symbols

Symbol	Description
	Indicates that the device meets the requirements of the applicable CE regulations
	Indicates that the item is a medical device
	Indicates the Unique Device Identifier
	Indicates that the original <i>medical device</i> information has undergone a translation which supplements or replaces the original information

	This symbol on the product indicates that this product must not be disposed of with other municipal waste in accordance with the European Directive 2012/19/EU on waste electrical and electronic equipment
	Observe operating instructions
	Indicates the device part number or the reference number
	Indicates the serial number of the device
	Indicates the manufacturer
	Identifies Germany as the country of manufacture of the product and the date of manufacturing
	Attention
	Main switch
	PC Power Button
	USB Port
	Ground Point, PE
	Potential Compensation, PA
	Warning: dangerous voltage

Information about the Product

Overview

The Medical Multiconsole is a wall-mounted console that can be used as an independent solution for distribution, recording and storage of video and audio signals in the digital operating room. In the small version it can also be used well as a nurse pc or Picture Archiving and Communication System (PACS) workstation.

Features by Variant

Check the variants list in *Table 3: Variants* to see what features apply to your console type.

- Integrated PC with Windows® 10 operating system
- Hardware for recording video signals
- Integrated Barco Nexxis™ decoder
- Touch screen
- On Air light
- Smart bar
- DICOM® button

Table 3: Variants

Model	Type	Internal PC	Smart Bar	On Air	Audio	DICOM®	Keyboard
D1-24	PC	x	x	x			x
	Nexxis (TC)		x	x	x		x
	Nexxis (Rack)		x	x	x		x
D1-49	Viewer					x	
	PC	x		x		x	x
	Nexxis (TC)			x		x	x
	Nexxis (Rack)			x		x	x
	Nexxis Viewer					x	
	SDI					x	
D1-55	Viewer					x	
	PC	x				x	x
	Nexxis (TC)					x	x
	Nexxis (Rack)					x	x
	Nexxis Viewer					x	
	SDI					x	



NOTICE

Depending on the product variant, CX-Prime™ and Barco Nexxis™ may need to be installed.

Scope of Delivery

- Console, depending on variant
- Mounting kit for wall mounting
- User manual (Printed)
- Mass storage medium with drivers and software used
- Silicone seal
- Medical silicone mouse (optional)



NOTICE

If you do not wish to keep their packaging, please contact the on-site installation company for proper disposal of materials.

References

CX-PRIME Manual: CX-PRIME-user-manual-v5.6_EN.pdf

Product Explanation

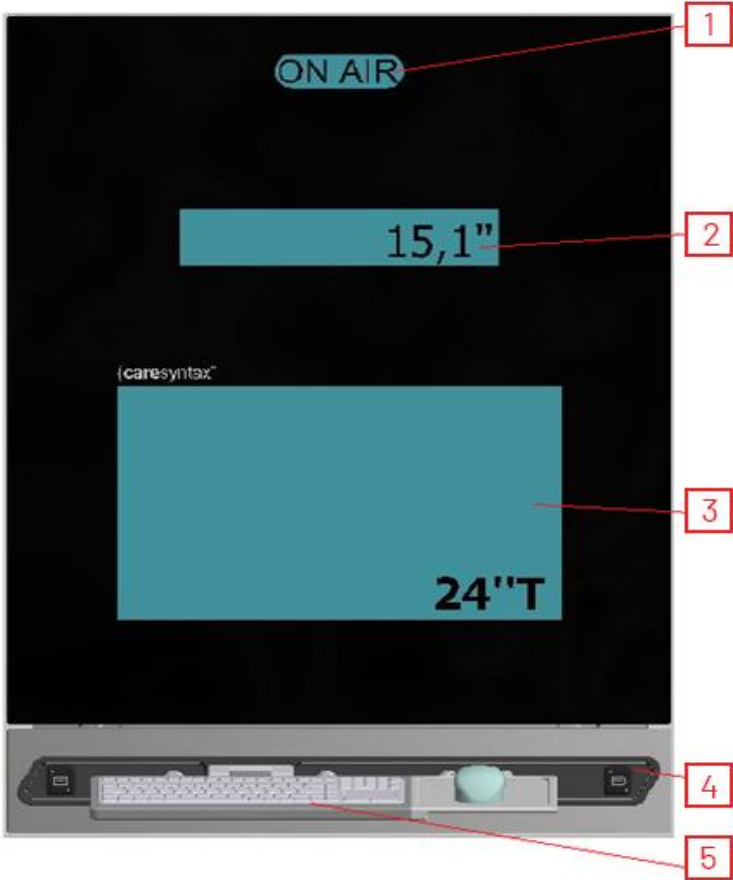


Figure 2: Medical Multiconsole, Variant D1-G-24T-BI

Table 4: Medical Multiconsole for Wall Mounting, Variant D1-G-24T-BI

Callout	Name
1	On Air Light (optional)
2	Smart Bar (optional)
3	Display
4	Dashboard
5	Keyboard with Mouse Holder

On Air Light

The On Air light indicates a transmission in progress. It works only in connection with CX-Prime™. It can be preset to a specific transmission channel and will light up when transmitting to that source.

Smart Bar

The smart bar displays time and date. You can select to display the date in either European format (DD.MM.YYYY) or ISO 8601 format (YYYY-MM-DD).

Depending on the variant purchased, the smart bar may also have a stopwatch function. To operate the stopwatch, see *Table 5* in *Dashboard*.



Figure 3: Smart bar with Time & Date (Left) and with Time, Date and Stopwatch (Right)

Dashboard

Table 5: Buttons










Name	Graphic	Description	LED Color and Status
Main Switch Console		Main switch to power on/off the console	Color: Blue On: Main Power On Off: Main Power Off
PC Switch		PC button to power on/off the computer	Color: Green On: PC On Off: PC Off
HOME		Route a preset source to the display Note: This button only works with CX-Prime running.	Color: White On: Display shows the home screen Off: Display shows the preset source
DICOM		Switches the display mode between normal mode and DICOM mode.	Color: White On: DICOM Mode Off: Normal Mode
Source		Switches display between internal PC and external video sources	No LED
Start/Resume		Start/Resume the stopwatch	No LED
Stop/Reset		Stop/Reset the stopwatch	No LED

Table 6: Inputs

Name	Graphic	Description
USB Input		USB input (can also be HID only)
Source Input		Source input (SDI/HDMI/Fiber)

Technical Specifications

Table 7: Technical Specifications

Housing color	RAL 9010
Product dimension (L x H x D) (in mm)	D1-G-24T-BI 796 x 1050 x 120 D1-G-49(T)-BI 1196 x 1050 x 120 D1-G-55(T)-BI 1396 x 1050 x 120 D1-G-24T-CF 836 x 1090 x 120 D1-G-49(T)-CF 1236 x 1090 x 120 D1-G-55(T)-CF 1436 x 1090 x 120
Packaging dimension (L x H x D) (in mm)	D1-24: 1000 x 1280 x 290 D1-49: 1400 x 1280 x 290 D1-55: 1600 x 1280 x 290
Net weight	D1-24: 55Kg D1-49: 70Kg D1-55: 85Kg
Net weight packaging	+15Kg
Assembly standard	Wall mounting
Protection class	Product Class I
Rated power	240 VAC, 50 Hz, 2 A
Power consumption	D1-24: 75-115 Watt D1-49: 170-215 Watt D1-55: 200-250 Watt
General functions	Main switch console PC Switch HOME DICOM Source Start/Resume Stop/Reset
Optional accessories	Mobile Video Source Neutrik opticalCON accessories
Accessories included	User manual Installation manual Service manual
Fuses	Main circuit: Circuit breaker 1-pole + N 10A + 5A glass fuse Secondary circuit: 10A Littelfuse 0297010 Terminal block "RKB 3" 3A Littelfuse 0297003 Terminal block "RKB 5"
Batteries	PC BIOS Battery: CR2032, LiMnO2 button cell Ø 20mm, 3V / 220mAh
Compliance with legal requirements and certifications	CE (Medical Device Class I) Security-specific: IEC 60950-1:2005 + A1:2009 – EN 60950-1:2006 + A1:2010 + A11:2009 + A12:2011 + A2:2013 – IEC 60601-1:2005 + A1:2012 – EN 60601-1:2006 + A1:2013 + A12:2014 EMI-specific: IEC 60601-1-2:2014 (4. Ausgabe) – EN 60601-1-2:2015 (4. Ausgabe)
Green conformity	WEEE

Operating temperature	0 °C to 40 °C (10 °C to 40 °C within specifications)
Storage temperature	-20 °C to 60 °C
Humidity during operation	20 % to 85 % (no condensation)
Humidity during storage	20 % to 85 % (no condensation)
Air pressure in operation	70 kPa Minimum
Air pressure during storage	50 to 106 kPa
Warranty	2 years

Safety Instructions

User Target Group

The Medical Multiconsole is intended for use by qualified medical professionals who have received extensive training on the device before using the device in the operating room/theatre.

Intended Use

The device is intended for displaying medical images from medical systems such as endoscopic and laparoscopic cameras, room and light cameras, ultrasound, image-guided therapy, and intervention, PACS, anesthesia, patient information, and other compatible medical imaging systems, and is designed to connect to Nexxis, Barco's VoIP distribution system.

Intended Use Environment

The device is primarily intended for medical use without direct patient contact (non-applied parts).

The device must not be used in combination with life support systems.

The user should not touch the device or signal inputs/outputs and the patient at the same time.

Inappropriate Use

The device and connected monitors are not designed for direct diagnosis and therapeutic interventional radiology.

Connected monitors are not designed for use as primary monitors for surgical procedures.

Do not use the device in the following areas:

- Near equipment that emits a strong magnetic field (e.g., an MRI).
- In areas where direct contact with patients is likely: diagnosis, treatment, monitoring, and during recovery from injury or disability.
- In conjunction with life support equipment.

Note for the User and/or Patient

All serious incidents that occur in connection with the product must be reported to the manufacturer and the competent authority at the user's and/or patient's place of residence.

Training

Depending on the complexity of the MEDICAL MULTICONSOLE, it is recommended to complete a basic training course before using it.

Preventive care

Regular care and inspection are required to maintain optimum condition and to ensure safe operation.

During regular care and inspection of this equipment, give safety your full attention.

General recommendations:

- Keep the product clean to extend its operating life.
- Periodically check that the sealing is not damaged or porous.
- The display undergoes an aging process and may become darker over time, check if the brightness is sufficient.

Environmental Protection Information

Please dispose of your discarded device by taking it to a designated collection point for the recycling of electrical and electronic waste. Please separate this device from other waste to avoid potential environmental and health damage from uncontrolled waste disposal. Recycle this device responsibly to promote sustainable reuse of raw materials.

For more information about recycling this product, please contact your local government or municipal waste disposal service.

WEEE-Reg.-No.: DE 52152345

Inspections

Annual inspection and maintenance of the Medical Multiconsole by authorized service personnel is recommended.

Some components contain batteries that allow the modules to function properly. These batteries should be replaced every three years by authorized service personnel.

Do not open the front flap. There are no parts inside that can be serviced by amateurs. Maintenance should be left to qualified technicians.



DANGER - Risk of Electrocutation

Do not touch any cables or terminals inside the enclosure. Failure to comply may result in severe injury or death.

Safety information

General safety requirements and conformity

The Medical Multiconsole may only be installed and connected by the manufacturer or a system integrator. Any changes to the configuration may only be made by the manufacturer.

The Medical Multiconsole is a protection class I device and complies with the necessary requirements of EN 60601-1. It is suitable for use in medical facilities, treatment rooms and medical intensive care facilities. Exceptions are such areas where there is a risk of fire or explosion.

- The Medical Multiconsole must not be used in a flammable or potentially explosive environment.
- No parts of the Medical Multiconsole are designed for internal use in the patient's body.

This device complies with the essential requirements for medical devices as defined in the European standard EN 60601-1-2. Nevertheless, a malfunction may occur caused by other devices generating high electromagnetic interference. Such a malfunction may temporarily affect the full functionality of the device but does not pose any danger to the patient or the operator. To avoid such contingencies, all sources of electromagnetic interference of any kind in the vicinity of the device should be removed whenever possible.

Safety category (flammable anesthetic mixtures)



WARNING - Risk of Explosion or Fire

Do not use this device in areas with flammable anesthetic mixtures. Do not use this device in an area where the oxygen content of the air exceeds 25%. Failure to comply may result in severe injury or death.

Not therapeutic equipment

The device is primarily intended for medical use without direct patient contact (non-applied parts).

The device must not be used in combination with life support systems.



WARNING - Risk of Electrocutation

Avoid simultaneously touching the device (or signal inputs/outputs) and the patient. Failure to comply may result in severe injury or death.

Applications without use alternatives

In applications where the monitor is of critical importance, provide a backup monitor.

Moisture condensation



NOTICE

Moisture may condense on the surface or inside of the product, or a fine mist may form inside the console. This is not a malfunction of the product but may cause damage to the product. If condensation occurs, do not turn on the product until the condensation evaporates.

Do not use the product in rapidly changing temperatures or humidity. Avoid direct contact with the cold air of the outlet of an air conditioner.

Daily Operation

Switch on

To switch on the console and the internal computer:

1. Press the main switch to start the console.
Result: The blue LED indicator of the main switch illuminates.
2. Press the PC button to start the computer.
Result: The green LED indicator of the PC button illuminates.



NOTICE

After you switch on the console and internal computer, there may be a delay of up to five minutes before the display shows content because the Nexxis™ system needs that time to initialize all devices.

Switch off

To switch off the console and the internal computer:

1. Press the PC button to shut down the computer. The LED indicator of the PC button turns off when the computer is completely shut down.
2. Press the main switch to turn off the console. The LED indicator of the main switch turns off when the console is powered off.



NOTICE

Switching off the console via the main switch before the computer has shut down properly can lead to data loss or damage the operating system!
The Medical Multiconsole is not designed to operate constantly. Completely reboot the console or rack at least once a week. For best results, shut down unused systems at the end of the workday.

Home

The home screen shows a pre-defined source, like the primary desktop of the PC with the CX-Prime software running.

If the LED is on, you are already on the home screen.

If the LED is off, press the button to return to the default home screen.



NOTICE

The **HOME** button only works if CX-Prime is already running.

Stopwatch (Smartbar)

Start: Press the "Start/Resume" button to start the stopwatch.

Stop: Press the "Stop/Reset" button to stop the stopwatch.

Resume: By pressing "Start/Resume" again, the stopwatch continues to run.

Reset: After stopping, the stopwatch can be completely reset by pressing "Stop/Reset" again.

DICOM

Press the DICOM button to change the gamma curve of the display to a characteristic DICOM gamma curve.

DICOM mode meets requirements for DICOM Part 14 GSDF (Gray Scale Display Function).

When the LED is on, DICOM is active.



NOTICE

The monitors are approved exclusively for displaying DICOM images. They are not allowed to be used for diagnostics.

Malfunctions

Under the following conditions, turn off the power at the main switch and have maintenance work performed by qualified service technicians:

- If the unit does not operate normally despite following the operating instructions. Inform your in-house technician or first level support to restore normal operation.
- If the product exhibits significant performance degradation indicating the need for service.

General Warnings

The product is not intended for sterilization.

The product has no applied parts, but the front of the product and the steel housing have been treated as an applied part, as the patient may accidentally touch them over a period of < 1 minute.

Device handling

A backup device must be scheduled at the end-user level in case a transmission device fails.

The Medical Multiconsole is not to be used for diagnostic analysis of medical image data, active monitoring of a patient's condition, or primary transmission of data used as a basis for assessing a patient's condition. It is also not suitable for use with data from which measurements are used to derive a patient's treatment.

The Medical Multiconsole may not be used to operate medical devices, except those that have been approved and installed by the manufacturer itself.

The Medical Multiconsole may be used in conjunction with other imaging equipment and software, provided, however, that it is intended solely for medical applications and complies with the previously stated purpose limitations.

All equipment connected to the Medical Multiconsole must provide evidence that it is IEC 60601-1 compliant.

Be sure to connect only inputs or outputs to the Medical Multiconsole that are appropriate for the intended use of this equipment.

Do not connect equipment with damaged or bridged insulation.

Caresyntax is not liable for any damage or injury resulting from mishandling or improper installation.

The full function of the Medical Multiconsole was tested with the operating system supplied. If another system with its own settings is used, not all functions can be guaranteed.

Service Disconnection

A circuit breaker is installed in the Medical Multiconsole, which can be used to disconnect both poles (L and N). This allows the service technician to work safely on the console.

The circuit breaker only switches off the components behind it. If work has to be carried out on the main power input or the line filter, a shutdown must be clarified with the house electronics.

Sanitation



CAUTION - Risk of Electrical Shock

Unplug and switch off the device before beginning to clean the device. Only reconnect and switch on the device after completing the cleaning process. Failure to comply may result in electrical shock.



NOTICE

No liquids may enter the device. These could destroy the electronics.

Observe these guidelines:

- Clean the device as part of the sanitation procedure following each surgery.
- Ensure that device and its corresponding power cable are handled with dry hands only.
- Except for the LCD screen, never spray or squirt liquids directly onto other device components.
- In the event of liquid spillage during cleaning, unplug the device immediately and contact your nearest service center.
- Do not scratch or rub the LCD screen with a hard object.
- Check the seals for damage or a porous condition before cleaning or disinfection.
- Close all inlets with the caps provided for the entire duration of cleaning.
- Do not clean or disinfect the device if the seal is damaged or porous.
- Take care not to scratch the glass front during cleaning, e.g. by wearing rings or other sharp objects.

Use a cleaning/disinfecting product that is alcohol-, alkali-, water- or chlorine-based. Common examples are:

- Isopropanol 100%
- Ethanol 70%
- 0.5% Chlorhexidine in 70% ethanol/isopropanol
- Ortho-Phthalaldehyde (OPA) 0.55%
- Haemo-sol, 1% in water
- 250 ppm Chlorine solution
- 1.0% Iodine in 70% ethanol
- 1.6% aqueous ammonia
- "Green soap" (USP)
- 0.5% Chlorhexidine in 70% isopropyl alcohol
- Products similar to optical cleaning liquid
- Bacillol AF
- Flux
- Sodium hypochlorite 10%

When selecting an alternative cleaning/disinfecting product, always identify the active ingredients. In case of doubt about a cleaning product, use plain water.

Do not use any of the following products:

- Alcohol in concentrations > 70%
- Strong alkalis lye, strong solvents
- Acetone
- Toluene
- Acids
- Detergents containing fluoride
- Detergents containing ammonia
- Detergents containing abrasives
- Steel wool
- Sponge with abrasives
- Steel blades
- Cloths with steel thread
- Paper-based cloths (e.g. paper towels, facial tissues, toilet paper)

Cleaning

Moisten a soft cloth with a mild soap solution or one of the products mentioned above and wipe the surfaces of the device with it. Soft materials such as cloths, rags or sponges are suitable for cleaning. Scrapers may be used with care. Read and follow all instructions on the cleaning product label.

Disinfection



NOTICE

During disinfection, cover the interface ports using the sealing caps provided.

The disinfectant should be selected on the basis of the VAH (Association for Applied Hygiene) list or in accordance with the applicable national regulations. With regard to the disinfectants in the VAH list, we have no information about properties that could harm the surface of the device. Disinfect the device using a soft cloth moistened with disinfectant. Wipe the surfaces of the device with it.

EMC Notice

General Information

This device is intended for use in professional healthcare facilities only.

When installing the device, use only the supplied external cables and power supplies or a replacement part provided by the approved manufacturer. The use of other parts may result in a reduction in the immunity of the instrument.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should not be used within 30 cm of any part of the Medical Multiconsole, including cables specified by the manufacturer. Failure to do so may result in degraded performance of the result of this device.

The use of accessories, transducers, and cables not specified or supplied by the manufacturer of this instrument, may result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and may result in improper operation.

This equipment is not intended for use in residential areas and may not provide adequate protection for radio reception in such environments.

The EMISSIONS characteristics of this device make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). When used in residential areas (which normally require CISPR 11 Class B is normally required), this equipment may not provide adequate protection for radio frequency communications services. The user may then need to take corrective action, such as relocating or repositioning the of the device.

Electromagnetic Emissions

The Medical Multiconsole is Group 1 medical certification equipment: this means that it does not use internally generated and locally or only locally used radio frequency energy in the frequency range of 9 kHz to 400 GHz in the form of electromagnetic radiation, inductive and/or capacitive coupling, for the treatment of material, for test/analysis purposes or for the transmission of electromagnetic energy.

The Medical Multiconsole complies with applicable medical EMC standards for emitted interference and coupling to surrounding equipment.

Table 8: IEC 60601-1-2

Reference	Requirement	Reference Method	Result
IEC 60601-1-2, Section 7, Table 2	Radiated emissions (housing)	CISPR 11	Passed
IEC 60601-1-2, Section 7, Table 2	Line-borne emissions (AC mains inputs)	CISPR 11	Passed

Turning the Medical Multiconsole off and on may cause brief interference to other equipment.

If the Medical Multiconsole is causing harmful interference to surrounding equipment, or if the equipment is experiencing harmful interference from surrounding equipment, the user should try to correct the interference by one or more of the following measures:

- Reorient the receiving antenna or device, relocate the interfering device.
- Increase the separation between the product and receiver.
- Consult the dealer or an experienced technician for help.
- Connect the interfering equipment into an outlet on a circuit different from that to which the receiver is connected.

Electromagnetic Immunity

The Medical Multiconsole is designed for use in electromagnetic environment as listed below. Before installation, it should be ensured that the device is used in such an environment.

- Floors should be made of wood, concrete or ceramic tiles. If floors are covered with synthetic material, the relative humidity should be at least 30%.
- Mains power conditions should be equivalent to a typical commercial or hospital environment.
- Mains magnetic field frequency should be the level characteristic of a typical site in a normal commercial or clinical environment.
- If the Medical Multiconsole is required for continuous operation during possible power interruptions, we recommend connecting an uninterruptible power supply.

Table 9: Electromagnetic Immunity

IEC 60601-1-2				
Reference	Requirement	Reference Method	Result	Test Level
IEC 60601-1-2, Section 8, Table 4	High-frequency electromagnetic field (housing)	IEC 61000-4-3	Passed	3 V/m 80 MHz to 2,7 GHz 80 % AM at 1 kHz
IEC 60601-1-2, Section 8, Table 4	Mains frequency magnetic field (housing)	IEC 61000-4-8	Passed	30 A/m , 50 Hz
IEC 60601-1-2, Section 8, Table 4	Electrostatic discharge (housing)	IEC 61000-4-2	Passed	± 8 kV Contact ± 2, ± 4, ± 8, ± 15 kV Air
IEC 60601-1-2, Section 8, Table 5	Conducted immunity (AC mains inputs or outputs)	IEC 61000-4-6	Passed	3 V 0,15 MHz to 80 MHz 6 V in ISM and frequency bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz
IEC 60601-1-2, Section 8, Table 5	EFT/burst immunity (AC mains input or output ports)	IEC 61000-4-4	Passed	± 2 kV for power lines 100 kHz repetition frequency
IEC 60601-1-2, Section 8, Table 5	Overvoltages (AC mains inputs or outputs)	IEC 61000-4-5	Passed	± 1 kV line(s) against line(s) ± 2 kV line(s) against ground(s)
IEC 60601-1-2, Section 8, Table 5	Voltage dips and interruptions (AC mains inputs or outputs)	IEC 61000-4-11	Passed	0% UT; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 deg. 0 % UT; 1 period and 70 % UT; 25/30 periods Single phase: at 0 deg. 0 % UT, 250 periods
IEC 60601-1-2, Section 8, Table 8	Electrostatic discharge (SIP/SOP ports)	IEC 61000-4-2	Passed	± 8 kV contact ± 2, ± 4, ± 8, ± 15 kV air
IEC 60601-1-2, Section 8, Table 8	Conducted noise immunity (SIP/SOP ports)	IEC 61000-4-6	Passed	3 V 0.15 MHz to 80 MHz 6 V in ISM and frequency bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz
IEC 60601-1-2, Section 8, Table 8	EFT/burst immunity (SIP/SOP ports)	IEC 61000-4-4	Passed	± 1 kV for SIP/SOP 100 kHz repetition frequency

Table 10: Immunity to devices with RF wireless communication

IEC 60601-1-2					
Frequency [MHz]	Service	Modulation	Level [V/m]	Hold Time [s]	Frequency Level [%]
385	TETRA 400	PM 50% 18 Hz	27	2	1
450	GMRS 460, FRS 460	FM ± 5 kHz 1 kHz	28	2	1
710	LTE-Band 13, 17	PM 50% 217 Hz	9	2	1
745					
780					
810	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTEBand 5	PM 50% 18 Hz	28	2	1
870					
930					
1720	GSM 1800, CDMA 1900, GSM 1900, DECT, LTEBand 1/3/4/25, UMTS	PM 50% 217 Hz	28	2	1
1845					
1970					
2450	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE-Band 7	PM 50% 217 Hz	28	2	1
5240	WLAN 802.11 a/n	PM 50% 217 Hz	9	2	1
5500					
5785					



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