Installation / Operation Manual

CinemaVision CV2020 MRI Audio/Video Patient Comfort System





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Innovative MRI-Compatible Entertainment Systems

Form: RTC-CV2020 Rev 0

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Introduction

1. Introduction

Congratulations on your purchase of the CinemaVision CV2020 Audio/Video MR system for patient comfort. This device represents more than 40 years of development and state-of-the-art engineering. We are confident this product will give you the tools you need for comforting the patient while undergoing MRI scans.

This installation/operation manual outlines how to properly install and operate the system.

Thank you for choosing to purchase this system from Resonance Technology, Inc., the leader in fMRI and MRI patient comfort systems.

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Suggestions on how to improve this system are always welcome.



Sincerely,

<i>Qiarati

Mokhtar Ziarati President and CEO



Resonance Technology Inc.

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2. Safety Information

At Resonance Technology, Inc., patient safety is our top priority. Please review this section completely as its contents are vital to the safety of the installer, the clinician/operator, and the patient.

2.1. Important Warnings for Patient and Operator Safety

WARNING

Prior to every use, inspect all system components that come in contact with the patient. Discontinue product usage immediately if any damage is evident or presents other potential hazards. Use of damaged components may cause injury to the clinician or the patient. Examples of hazardous damage include but is not limited to the following:

- Protective lenses missing from the video goggles
- Cracked housing on video goggles or audio headset
- Microphone boom separated from headset housing (exposing wires)
- Cable padding torn, exposing cable inside
- Any damage potentially exposing wires to the patient

2.2. Precautionary Patient Conditions

Precautionary conditions are to be observed with patients who use the system continuous in excess of 3 hours or more.

Eye Disease / Eye Injury / Glaucoma

If the patient has been diagnosed with or is susceptible to eye disease, eye injuries, or glaucoma, instruct the patient to consult their doctor before using the video goggles. Use of this product by individuals with conditions such as glaucoma is not recommended.

Heart Disease / High Blood Pressure

If the patient has a history of heart disease or high blood pressure, instruct the patient to consult their doctor before using this system. If during viewing any increased anxiety is experienced, stop using this product immediately and instruct the patient to rest. If the symptoms persist after resting, instruct the patient to consult their doctor before continuing using this product.

<u>Seizures</u>

If the patient has a history of temporary spasms, unconsciousness, or epileptic seizures from light stimulation, instruct the patient to consult their doctor before using this system. Use of this product by such individuals may cause spasms, unconsciousness, or seizures. If the patient experiences such symptoms, stop using the product immediately and instruct the patient to consult their doctor.

Sickness / Headache / Nausea

If during use, the patient experiences any of the following symptoms, stop using this product immediately and rest. These symptoms may indicate misuse or overuse of the product or that you should not use the product for health reasons. If the following symptoms persist after rest, consult your doctor.

- Sore eyes, eye fatigue, or double vision
- Headache
- Inability to focus on the screen
- Stiff or sore shoulders or neck

For patient safety, the patient video goggles turn off automatically after six hours of continuous use. Read this user manual for instructions on how to reset the video goggles to continue viewing video images.

Motion Sickness from using the Video Goggles

Some patients may experience motion sickness, headache, or nausea from viewing visual paradigms or video programs, especially those with intense action and movement. If the patient experiences any of these symptoms, stop using the product immediately. To avoid personal injury or injury to others, do not operate a motor vehicle nor do anything that requires concentration until these symptoms disappear.

Loud Sound Volume

Avoid using audio headset with high volume for the patient as hearing expert's advice against continuous loud and extended audio play. If the patient experiences a ringing in their ears, reduce the audio headset volume. The patient is advised to consult their health doctor for further advice.

2.3. Use Restrictions

Shelf-Life and System Maintenance Service Schedule

The CV2020 System comes with a one-year original manufacturer warranty and a shelf life of two years from the date of installation. Optional extended warranty may be purchased for this system. With patient safety in mind, Resonance Technology, Inc. recommends periodic maintenance service for this CV2020 System every six months after the one-year original warranty period.

Restrictions on Using Non-Resonance Technology, Inc. Components with the CV2020 system

The original manufacturer's warranty will be voided if any non-Resonance Technology, Inc. Power Supply is used to provide power the CV2020 Transducer. The original manufacturer's warranty will be voided if other non-Resonance Technology, Inc. approved components are connected to the CV2020 system. In addition, Resonance Technology, Inc. cannot be held responsible or liable for any unauthorized use of this equipment. If you have any questions about how to operate this system, please read this user manual or call Resonance Technology, Inc. customer service at (818) 882-1997 or email support@mrivideo.com.

2.4. MRI Environment Hazards

Installation of materials inside the MRI suite must be done with extreme caution and only by authorized personnel. Care must be taken to keep ferromagnetic materials such as tools, filter plates, screws, etc. at least three meters (approximately 10 feet) away from the energized magnet. Absolutely no work should be done near the filter panel when a scan is in progress.

All cabling inside the MRI environment should either be connected or terminated properly. Failure to do so may result in skin burns related to RF energy. All cables should be run straight and never looped, as this may also cause serious skin burns inside the MRI room.

In addition, no persons with ferromagnetic prosthetic devices such as pacemakers or joint replacements should enter the MRI suite at any time. Extremely high magnetic forces have the potential to dislodge ferrous items at high velocities that can result in serious injury or death.

Only system components explicitly designated for use in the MRI suite should be placed inside the MRI suite. Components not designated for use inside the MRI suite may present a projectile hazard and can become airborne, causing property damage, serious bodily injury, or death. Please refer to the installation block diagram to determine which components belong inside the MRI suite.

Resonance Technology, Inc. will not be held liable for any injuries or property damage which may occur as the result of improper use or installation of this product. By agreeing to this notice, users certify that they are familiar with basic safety procedures in an MRI room environment and that they have read and understand these safety precautions.

For questions regarding installation procedures or this manual, Resonance Technology, Inc. technical support staff may be reached Monday through Friday 8 a.m. to 5 p.m., Pacific Standard Time at (818) 882-1997, or by email at <u>support@mrivideo.com</u>.

2.5. General Warnings for Electronic Products

Electric shock

Failure to observe all operating and maintenance instructions may cause damage to this product and may result in property damage and/or injury or death from electric shock, fire, or other cause.

To avoid the risk of electric shock or fire hazard, a multi-outlet power strip or extension cord should not be connected to the video monitor socket outlet on the CV2020 controller. This socket outlet should only be used to power the CV2020 video monitor provided with the system.

Do not disassemble this product.

Only Resonance Technology, Inc. trained, and authorized personnel should perform all required service for this product. Failure to comply with this warning may result in property damage, injury and/or death from electric shock, fire, or other cause.

Avoid exposing this product to extreme environments.

This product may be damaged by high temperatures, direct sunlight exposure, by dropping this product, or by other mechanical shock. Do not expose this product to rain or excessive moisture. Avoid these conditions as the video goggle lenses may become damaged and may result in eye fatigue to the patient.

Unplug this product when not in use for long periods of time.

Always unplug this product when not in use for extended periods of time or during MRI maintenance. Leave connected if used daily. In addition, to prolong the life of the video goggle, use the Technologist Remote to turn off the power to the video goggle at night or when not in use. Note that if the system is not used for 2 hours, it will hibernate and you may have to press the Tech Remote TALK button to wake up the system.

2.6. Labeling Used to Indicate Device Safety



Type BF Applied Part

Devices that have conductive contact with the patient or have applied parts that are fixed in medium or long term contact with the patient.



MR-Safe Device

Device considered **safe** for use anywhere inside the magnet room.



MR Conditionally-Safe Device

Device considered **safe** in the MR room **under certain conditions**.



MR Unsafe Device

Device considered **unsafe** for use in the MR room. These items should not be taken inside the MR room due to being a projectile hazard in the magnetic field.



Safety Information

2.7. Medical Device Safety Approvals

The CV2020 System has the following safety certifications:

3. Installation Materials

Your CV2020 system comes complete with all the necessary components to complete the system installation at your facility. The following checklist is provided for materials verification purposes:

| Main System Components | | | | | | |
|------------------------|----------|---|--|---------|--------------------------|--|
| Part Number | Quantity | Photo | Description | MR Safe | Installation Location | |
| RTC-750-000-000-000 | 1 | | CV2020 Universal Interface Remote Controller Unit | MR | Control Room | |
| RTC-750-010-XXX-XXX | 1 | | CV2020 Technologist Room Controller | MR | Control Room | |
| RTC-551-070-124-000 | 1 | ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~ | CV2020 Video Goggle | MR | Magnet Room | |
| RTC-650-067-000-XXX | 1 | | Slim Softshell [round] Headset with headband | MR | Magnet Room | |
| RTC-650-051-000-001 | 1 | | CV2020 Transducer | MR | Magnet Room | |
| RTC-750-301-xxx-xxx | 1 | Construction of the second se | CV2020 Transducer Power Supply | | MR Pen Cabinet | |

Installation Materials

| Common Initial Shipment System Components/Accessories | | | | | | |
|---|-----|-------|--|---------|--|--|
| Part Number | Qty | Photo | Description | MR Safe | Installation Location | |
| RTC-CV2020 | 1 | | Installation / Operation Manual (This manual) | MR | Control Room | |
| RTC- | 1 | | Rubber mask (with holes) | MR | Magnet Room | |
| RTC-ALS-HEC | 50 | (0) | Headset Earpiece Covers | MR | Stored/ Control Room | |
| RTC-ALS-TWR | 50 | | Tie Wraps | MR | Control Room | |
| RTC-ALS-TWH | 20 | | Tie Wrap Holders | MR | Control Room | |
| RTC-ALS-HDH | 3 | - | Headset (Visor) Hanging Hooks | MR | Magnet Room | |
| RTC-101- | 2 | | MR Laser Link Cable | MR | Installed From control room to magnet room | |
| RTC-101-239-001-001 | 1 | Q | 5-pin Round Female to 5-pin Round Female Cable (12M/39ft) | MR | Installed in MRI Suite Pen panel cabinets to Transducer Location | |
| RTC-101-306-003-000 | 2 | Q | Hospital Grade AC Power Cord | MR | MRI Suite / Control Room | |

4 Room Layout Overview for Installation

4. Room Layout Overview for Installation

WARNING: Absolutely no ferromagnetic tools should be brought inside the MRI Suite!

While no tools, other than tie wraps, are required to install the system in the MRI suite, absolutely all ferromagnetic tools remain outside of, and away from the door leading to, the MRI suite.

Below is a typical MRI setup. Your individual installation may vary somewhat, but it will generally be spaced into three areas: Control Room, Computer/Equipment Room and MRI Suite or Magnet Room.



The Control room setup consists of placement and connection of the CV2020 Controller and CV2020 Controller Touchscreen Interface.

The Magnet room setup includes a single Laser Link cable bundle that will be connected from the CV2020 Controller unit through the filter panel wave-guide to the CV2020 Transducer in the Magnet Room. With the exception of the audio headset and visor goggles, all the Magnet Room components of the CV2020 must be installed to the side of the magnet shroud also the transducer power cable should never in parallel with magnetic coil. Additionally, these components should be placed in an area with no heavy foot traffic to keep them from being damaged.

4 Room Layout Overview for Installation



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5. Installation Procedure

The installation procedure consists of three major phases:

- Installing the MR Laser Link Cable and Transducer Power Supply Cable
- Magnet Room Component Interconnection
- Control Room Component Interconnection

Before you begin the installation, determine the location where the transducer will be installed. It should be a secure area next to the magnet and away from heavy foot traffic. Please refer to the photo below for typical placement:



5.1. Installing the Transducer Power Supply

WARNING: Please use <u>extreme caution</u> when installing the White Linear Transducer Power Supply (WLPS) into the MRI suite. It is imperative you must properly follow these instructions when installing the Linear Power Supply in the MRI Suite. To stay furthest possible position from the MRI bore, must walk along the wall of the MRI suite as illustrated below.



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5.2. Installing the MR Laser Link Cable and Transducer Power Supply Cables

The preferred method of routing the fiber optic cable is to run the cable from the control room through the overhead ceiling drop tiles and down into the computer room in front of the filter panel through the Fiber Optics Waveguide. Excess fiber cable can be stored above ceiling tiles. It can then be run alongside the other MRI cables going to the magnet. The cable should end where you intend to locate the transducer.

Note: Care must be taken to ensure the cable is not bent in radius of less than 15cm (90 degrees or right angle) or damage to the optical fibers will occur.



The routing of the transducer power cables will vary somewhat depending on the facility layout and the magnet type. For most facilities and magnets, the typical procedure would be as follows:

- **5.2.1.** Route the transducer power cable that will be used in the magnet room, following a similar path to the fiber optic cable. **Avoid running the power cable close and/or in parallel with the high-energy RF cables for the magnet**, as the RF energy may interfere with reliable operation of the system.
- **5.2.2.** In the MRI suite select the cabinet closest to a Power Wall Outlet, also near the Transducer location. Route the remaining transducer power cable from the power supply location to the Transducer can be along the floor or thru the ceiling tiles. When using tools in the MRI, be sure to verify they are non-ferrous (Non-Magnetic).

Installation Procedure

5.3. Magnet Room Component Interconnection

5.3.1. Unravel all the fiber optic cables from the plastic coil. Be sure to line up the cable color to the connection color. Put the unused fibers back into the plastic coil. Remove the plastic dust caps from the five selected fiber optic connectors. Keep the dust caps for future use whenever cables might be removed for service.



Fiber Optic Cable Bundle



On Transducer, Red and Green fiber are required for Audio/Video to patient.



On Transducer, all four connections; Grey, Blue, Red and Green fiber are required for stereoscopic 3D on the Video to patient.

5.3.2. Connect the Fiber Optic cable, Power Supply cable and Visor to the Transducer.



5.4. Controller Connection

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The photo below shows an overview of the CV2020 A/V Console rear panel.



- **5.4.1.** Remove the dust caps on all the fiber optic connection on the controller. Matching the fiber optic connector colors with the colored markers on the controller, align the fiber connection connector with the notch fiber connection on the controller's back panel. Insert the fiber optic cable connector until fully seated (should click into place). Perform the same procedure on the remaining fiber optic cables.
- **5.4.2.** Connect the Tablet Remote Interface to Serial (USB) Cable to the REMOTE CONTROLLER connection.
- 5.4.3. Connect the Tablet Remote Interface HDMI Cable to the HDMI IN 1 connection.
- 5.4.4. Connect an external HDMI Audio/Video Source to HDMI OUT 1. i.e., External Monitor.
- **5.4.5.** Connect the Control Room Speakers Mini stereo cable to the "SYS AUDIO OUT" Connection.
- **5.4.6.** <u>Make sure the Controller power switch is in the off position</u>. Connect the Hospital Grade Power Cord to the Controller and an available active AC power outlet.
- **5.4.7.** Once connections have been made bundle all loose cables together neatly.

Note: All connections have to be made for the CV 2020 System to work. At minimum, Power connection to wall, Fiber optic connection for communication and a single Video/Audio source.

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Installation Procedure



- **5.5.1.** Remote Interface the SERIAL PORT (USB) Cable connects to the Controller back panel "REMOTE CONTROLLER" connection.
- **5.5.2.** Remote Interface HDMI OUT cable connects to the Controller back panel "HDMI IN 1" connection.
- **5.5.3.** Remote Power supply connects to the wall power outlet.

5.6. Control Room Speaker Connection

5.6.1. The control room speakers are connected to the Controller back panel. The Speakers required their own power supply and is supplies via USB 5v Wall plug.



Mini Stereo connection to Controller Rear Panel "SYS AUDIO OUT"



5.7. Stereoscopic 3D Connections:

In order for the CV2020 System to display Stereoscopic 3D on the Visor goggles, a graphics card needs to be used from the source computer with 2 HDMI outputs and G-Sync (Genlock). RTC Recommends using the NVidia Quadro K-Series graphics card. Once the source computer has the Graphic car installed the HDMI outputs are connected to the Front of the CV2020 Controller and the HDMI output on the back side of the Controller two monitors can be plugged in to set up the computer setting.



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CV2020 Controller Front Panel

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6. Operation

Below is a description of the CV2020 control room components. The Controller converts the selected audio and video source signals into optical signals that the MR Laser Link cables route to the Transducer unit inside the magnet room. The Transducer unit receives the fiber signals and displays them on the video visor and audio headset.

6.1. Tech Remote Tablet Interface

Tablet Remote Controls. The innovative Tech Remote Control has been upgraded to be a tablet-based interface in order to connect the CV2020 to the digital age. The Tech Remote has volume adjustable knobs along with the push to talk communication button. Additionally, if customer has USB flash drive/memory stick connection to view digital movies of the memory flash drive/memory stick. The RTC app interface can only recognize MP4 movies.



- Wheel #1 Controls the patient headset audio level.
 - Twist black ring clockwise to increase the headset volume. Twist black ring counterclockwise to decrease the headset volume. Press the center button to mute headset.
- Wheel #2 Controls the Patient Microphone audio level.

Twist black ring clockwise to increase the patient microphone volume.

Twist black ring counterclockwise to decrease the patient microphone volume. Press the center button to activate microphone and communicate with the patient.

Wheel #3 - Controls the system audio level.

Twist black ring clockwise to increases the control room volume. Twist black ring counterclockwise to decreases the control room volume. Press the center button to mute Control Room volume

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Screen - Controls the system settings. The RTC app automatically launches once the Tablet is powered on. The Tech Tablet App system control functions are as follows:



6.1.1. Selecting the **"CONGIF" button** gives you access to the Configuration/Menu portion of the app. When selected, the menu pops on the left side of the screen with six (6) options.

6.1.2. Control button: By selecting Control button the "show clock" and "reset link" button pop up. The Show clock button when pressed had a timer pop up at the bottom of the navigator app screen. The "reset link" button is currently disabled/inactive.

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6.1.3. Debug button: these buttons are for possible troubleshooting of the system, but must be completed under the RTC technical support team instructions if required. If not do not select any of the buttons in "Debug" section under Config menu.

| Configuratio | eview Del | bug | |
|--------------|---------------------|---------------------|--|
| Control | Reboot T | Reboot C | |
| Debug 🕥 | Reboot T Bootloader | Reboot C Bootloader | |
| | Transfer UC | Text Protocol | |
| Settings | Transfer FPGA | | |
| Misc | | | |
| Headset | | | |
| Firmware | | | |
| | | | |
| | | | |
| | A | | |
| Config | ((<u>)</u>)) | | |

6.1.4. Settings button: the "Use Analog Microphone" button selection is for the activation/enabling of the external analog microphone connected to the controller rear panel. When the button is highlighted bluish means the feature is active. HDMI Output 1 and HDMI Output 2 is for selecting the HDMI inputs from the Controller connections labeled accordingly. "Brightness" button selection is to select which volume control knob LED lights brightness intensity is desired.

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6.1.5. Misc button: can be selected to exit out of the "RTC Navigator app". Be aware that the CV2020 System will not function without the use of this interface program.

6.1.6. Headset button: can be selected to custom the image brightness on the CV2020 Visor and set a idle timeout time which can be set to turn off the power off the visor when not in use to avoid damaging the visor OLEDs or imprint image onto the displays by showing the same screen for a long period of time.

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6.1.7. Firmware button: when the system is fully installed/connected; this tab is a reference to the system versions. This information is helpful when troubleshooting the system with RTC technical support team.

6.2. Playing Movie on the Navigator App

6.2.1. Select movie media source by selecting the "Source" button on the right bottom of the navigator app screen. Once you press the "Source" a pop up menu will be displayed on the right side of the tablet display. Once you select the desired movie it should automatically show up on the "Preview" side of the tablet display.

-Note- Internal Tablet memory or External USB Memory drive needs movies to be in MP4 for format in order for the Navigator App to recognize the movie. Also, files cannot be in subfolders on the memory.

Once the Movie is selected, it will begin to play on the Left window "Preview" side of the screen. Press the **"Send to Patient" button** gives you the ability to send the Video in the Preview screen to the Patient visor and can also be seen on the right side of the tablet display under "Patient".

6.3. Movie Playback

6.3.1. The Navigator App has controls on video playback on the video window itself. By pressing on the viewing window, the playback options pops up.

6.4. System Volume Adjustment

6.4.1. Volume Adjustments and Muting are displayed on the Tablet pop up screen in the lower middle part of the screen. This shows when the volume adjustment knobs are adjusted or when the mute/push to talk button is pressed. When the center button is pressed the icon turns red.

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6.5. Synchronization Bell

6.5.1. SYNC Icon (Bell) when pressed can tell the user if the system is fully Synchronized or if there is a bad/missing connection. Pressing on the "Bell" will pop up a diagnostic menu that showed the System connections and if they are work (green) or failed (red).

Interface Communications = This shows if the USB serial port connection has been made between the Interface and Controller.

Controller Communications = Controller is powered on and connected to the Tablet Interface. Controller HDMI Link = Controller and Tablet Interface HDMI Connection is present

Transducer Communications = Transducer is powered on and connected properly with fiber optic cable

6.6. Audio Source for Headset

6.6.1. On the bottom right corner of the Navigator App there is a Headset looking Icon to select the Audio Source for the Control Room speakers and Headset Audio.

In the Control Room/Headset pop up menu, the Audio source can be selected:

Selection **A** is CHANNEL 1 utilizing the Audio Input Controller Connection on the rear panel. Selection **B** is CHANNEL 2 utilizing the Audio Input Controller Connection on the Front Panel. Selection **C** is Audio produced by the currently playing video on the Tablet Interface "Patient" Side.

NOTE: External Audio/Video Sources: When utilizing the HDMI inputs on the Controller for example using an External DVD Player, the **Analog Microphone** needs to be activated to enable the 2-way communication.

6.7. Enabling Stereoscopic 3D On Tablet Interface

6.7.1. After the connections from the computer are made (reference Page 15) to the CV2020 Controller and the computer settings are set to "mosaic" mode. The CV2020 setting need to be set to receive the video (stereo) signal to the visor by selecting the "Source" button → then select "HDMI" → then select "Front Stereo" to have the stereoscopic image on the visor video.

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6.8. Computer Settings Set up for Stereoscopic 3D

Computer Set-up steps:

1. System requirement: Gen-Lock Graphic card has to be installed in order to use the stereo mode feature. RTC Recommends using the NVidia Quadro K-Series graphics card.

2. Connect two external monitors, preferably same model and size, in order to set up Mosaic screen.

3. Right click on Desktop and select NVIDIA Control Panel.

4. On the right and under workstation select Set Up Mosaic. And select Create New Configuration.

5. A new window will pop open, make sure that the Number of displays is set to 2 and the Topology is set to 1×2 . Then click Next.

| anta Otaniaria | Transformed and | | | _ |
|--|---|------|------|---|
| saic Displays | Topology: 1 × 2 | | | |
| elect topology 2, Select displays 3, Arrange display | vs 4. Adjust overlap and bezel correction | | | |
| | / | | | |
| Number of displays: | Configuration Name | | | |
| 2 ~ | Mosaic setup | | | |
| Topology (rows x columns): | | | | |
| 1 × 2 ~ | | | | |
| Orientation of displays: | | | | |
| Landscape ~ | | | | |
| Maximum CBI Tenelegu | | | | |
| maximum GPU ropology | | | | |
| Minimum GPU Topology | | | | |
| I am using recommended connections for the | selected topology | | | |
| and using recommended connections for the s | selected topology. | | | |
| Enable Mosaic | | | | |
| | | | | |
| elected topology: | | | | |
| elected topology: | | _ | - | |
| elected topology: | | | | |
| elected topology: | | | | |
| elected topology: | | | | |
| leeted topology: | | | | |
| lected topology: | | | | |
| topology: | | | | |
| lected topology: | | | | |
| lected topology: | | | | |
| leeted topology: | | | | |
| lected topology: | | | | |
| | | Back | Next | |

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Operation

- 6. You see numbers 1 and 2 assigned to each of the screens to identify each one.
- 7. In the new window, set Refresh Rate to 60Hz. and Resolution per Display to 1920×1080. click Next.

8. In the left white box write 1, and on the right white box write 2. Then hit Apply.

9. Click Yes on the pop-up to keep changes, and the hit Finish.

10. Now, you find that the two displays are one full extended screen. And now you can do the set-up steps for the CV2020.

11. To disable the Mosaic configuration at any time, simply hit on Disable on the Mosaic Set-up window, the configuration will disable. Note that if you want to re-activate the Mosaic, you have to run the set-up from the beginning, steps 3-10.

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6.9. Patient Setup

6.9.1. Overview

Make sure all cables have been connected securely to the Transducer in the Magnet Room and that the system components do not impede any walkways. Before placing the Video Goggles and Headphones on the patient, make sure that the microphone audio levels on the Control Room Tech Remote Tablet Interface have been set to a comfortable level. Ideally would be to put the user in scanning position and then placing the Video Goggles / Headphones over the patient's ears and eyes and adjust the headband and visor bands if necessary. Your patient is now ready for your scan procedure.

Note: Resonance Technology, Inc. recommends a visual inspection of the visor/headset signal jackets or portions that touch the patient for any breakage or uncleanliness. Any signs damage contact RTC in order to arrange servicing of the item.

6.9.2. Audio Setup

Make sure the system level output on the Tech Remote Control is set to approximately mid-level. The patient headset output level can also be adjusted from the Tech Touchscreen Remote Control. For safety, always notify the patient when making volume level adjustments to the patient audio headset.

6.9.2.1. (Optional) Headset Audio Adjustment knob

The Slim Softshell "Y" adapter has been integrated with a feature "Volume Adjustment".

6.9.3. Video Setup

Select the desired audio / video source from the CV2020 Universal Interface Remote Controller Unit for both the patient and operator using the integrated program.

Caution: Any changes to the RTC default settings can result in loss of video and/or audio. Please Call Technical Support if you experience any problems with your CV2020 System.

6.9.4. How to focus image on the visor

During patient set up, the user or technologist can focus the image for on the video goggle. Using the knobs near the front of the visor turn the knob left or right to focus the image for the patient. Turn clockwise to increase focus and counterclockwise to decrease focus.

6.9.5. How to fit the Video Goggles into the 64 or 32-channel head coil

6.9.5.1. Install the visor into the head coil through the eye window before placing the head coil on the patient. Then slide the Video Goggles under the Head coil center nose bridge section.

6.9.5.2. Fit the patient's head all the way into the coil and slide the Video Goggles down to fit the patient's eyes. Place the patient's head all the way into the head coil.

6.10. Cleaning

For cleaning and disinfecting purposes, Resonance Technology, Inc. recommends using alcohol-free, nonflammable, and non-corrosive cleaning wipes or mild detergent on the video goggles, mask, and audio headset components (ear cushions/cable jacket). Do not use any harsh chemicals on the Visor protective lenses; if any smudges on the lenses use a microfiber or optic cleaning wipes to clean them. Be sure the cleaned items are completely dry before re-use. Daily cleaning of these items is recommended. Visual Inspections are recommended on the heavily used items: Headset and Visor to be sure they are safe to use. Normal wear and Tear visual inspection:

Some Examples of possible external damage to immediate removal from patient use:

| Headset Servicing Required | Visor Servicing Required | | |
|--|--------------------------|---|--------------------------------------|
| Headset housing, jacket or microphone Boom is broken/torn. | | Visor hou: Jamaged exposed v Jacket is t | sing is or has wires. torn. |

Troubleshoot

7. Troubleshooting

System when synchronized the Remote Tablet Interface has all green under the "Bell" notification and the Large Round LEDs are rotating. And when the System is synchronized the Transducer has all six (6) indicator LED lights are Green and the Logo is Rotating at the base of the LOGO acrylic.

Audio LED bar graphs

If the problem arises inside the Magnet Room area:

NOTE: Turn off the Transducer Power Supply to prevent damage to the system components, when plugging in or unplugging the power supply cable, headset, and/or video goggles.

After closing the Transducer and turning on the Transducer power supply:

Check if power is being supplied to the Transducer by checking for lights on the Transducer housing. Logo should rotate clockwise and all six LEDs should be blue.

| Problem | Diagnosis | Solution |
|---|--|---|
| Tablet touchscreen is non- responsive. | The app freezes when the system sync is not stable. | Power Reset the Controller, Tablet and Transudcer. Power on the Controller first, then the tablet and then the Transdcuer power supply in that order. |
| Video on the visor is blurry. | The image on the visor needs to be adjusted. | The visor housing has independent eye focus knobs on the outer part of the visor housing. One on each side. see image below. |
| No Video on external HDMI 2 Monitor | Splitter might not be working properly. | Be sure that the HDMI Splitter has power, and the connections are firmly in place. |
| Images from the External (HDMI 2) connection are displayed on the Visor too small. | The resolution on the external video source needs to be adjusted. | If utilizing a Computer CPU HDMI output, be sure that the resolution of the source [computer settings] are at the appropreate level [for example, 1080p] in order to clearly see the image on the visor. If image is blurry adjust the focus on the ends of the Visor housing. |
| External Video cannot be seen on the Tablet App drop down menu. | The video on the USB Flash/Memory Stick is not the correct format. | The Tablet interface can only currently recognize MP4 formated videos. |

Technical Problems:

- If the system hangs up or doesn't respond to Remote Control or Controller commands, power down the complete system, leave off for approximately 10 seconds, then power up again.
- If the system still does not respond, check synchronization by selecting the "Bell" icon on the RTC App home page to see if there is any issue with system connections.
- If the system still does not respond, please contact Resonance Technology, Inc. for assistance.

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8. Specifications

Measurements of System Components:

| Remote Interface | Controller | Transducer | Transducer Power Supply | |
|--------------------------------|----------------------|---|--------------------------------|--|
| W COOL | | W C C C C C C C C C C C C C C C C C C C | H COM | |
| Dimensions: Inches (MM) | | | | |
| Length (L) = $11''$ (279.4mm) | Length (L) = $18''$ | Length (L) = 8" (203.2mm) | Length (L) = 13.25" (336.55mm) | |
| Width (W) = $11.5''$ | (457.2mm) | Width (W) = 12.5" (317.5mm) | Width (W) = $6''$ (152.4mm) | |
| (292.1mm) | Width (W) = $8''$ | Height (H) = 10.25" (260.35mm) | Height (H) = $7''$ (177.8mm) | |
| Height (H) = $7.5''$ | (203.2mm) | | | |
| (190.50mm) | Height (H) = $3.5''$ | | | |
| | (88.9mm) | | | |
| Weight: Pound lbs. [kilograms] | | | | |
| 7 lbs. [3.17kg] | 9 lbs. [4.08kg] | 12 lbs. [5.44kg] | 25 lbs. [11.34kg] | |

CV2020 Controller Input/Output Power Ratings:

- *AC Inlet:* Voltage Input: 100-240 VAC @ 50-60 Hz Maximum Current: 2A Fuses Power Rating: 250 V @2A
- AC Outlet (Only the Video Monitor provided with this system should be connected to the AC outlet): Voltage Output: 100-240 VAC @ 50-60 Hz Maximum Current: 1A

CV2020 Transducer Power Supply Power Ratings:

• *AC Inlet:* Voltage Input: 100-240 VAC @ 50-60 Hz Maximum Current: 2A Fuses Power Rating: 250 V @2A

CV2020 System Shipping/Storage Environment Conditions:

- **Operating Temperature Range:** 10°C - 40°C
- *Relative Humidity* 30-75 %
- *ATM Pressure Exposure* 700 – 1060 hPa

Below is the Medical Device Safety Test Certificate for the CV2020 System:

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9. Support Information

If you have any questions regarding the CV2020 system use or installation, please don't hesitate to call Resonance Technology, Inc. Customer Service Department. Service and technical support staff may be reached Monday through Friday 8 A.M. to 5 P.M., Pacific Standard Time (USA) at +1 (818) 882-1997, or e-mail to <u>support@mrivideo.com</u>.

Resonance Technology, Inc. Product Recycling Program:

Resonance Technology Inc. actively supports the protection of the environment by efficiently recycling all our electronic products. Our everyday pollution prevention activities reduce the need for electronic waste to go into landfills. At Resonance Technology Inc. we are committed to our customers, our communities and to everyone's environment. In light of the above, Resonance Technology, Inc. recommends that all our customers return their undesired, obsolete, or unused Resonance Technology, Inc. equipment to the following address for recycling:

Resonance Technology, Inc. Attn: Product Recycling Program 18121 Parthenia Street Northridge, CA. 91325

Notes

Resonance Technology, Inc.

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