Installation Instructions

Orion Reclining Chair

Micromedical by Interacoustics



(=) Interacoustics

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Appendix: Return Report



1 Introduction

1.1 About this manual

This instruction details the installation procedure for the Orion Chair used with the VisualEyes™ 515 and VisualEyes™ 525 software version 3.0 and later. Orion Reclining Chair will hereafter be referred to as the 'Orion Chair'.

This product is manufactured by:

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1.2 Environmental conditions

The chair is recommended for indoor use only.

Relative humidity: 30 to 80% (non-condensing)
 Temperature storage: 32° to 125° F (0° to 52° C)
 Operating temperature: 60° to 90° F (16° to 32° C)

• Power supply: 110VAC, 220VAC step down to 110VAC through isolation

transformer

Note: Please refer to the Instructions for Use for VisualEyes[™] 515 and VisualEyes[™] 525 software version 3.1 and later for EMC related information.

1.3 Markings

The following markings can be found on the instrument, accessories, or packaging:

Symbol	Explanation
☀	An applied part that includes a patient connection that is intended to deliver electrical energy or an electrophysiological signal to or from the patient shall be a Type BF part. An EOG amplifier is considered a Type BF part.
†	An applied part that includes a patient connection which can be disconnected from the patient immediately is a Type B part. The Aqua Stim™ caloric irrigator is a Type B part.
(3)	Follow instructions for use
X	WEEE (EU-directive). This symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection for facilities for recovery and recycling.
CE 0123	The CE-mark indicates that the manufacturer meets the requirements of Annex II of the Medical Device Directive 93/42/EEC for the quality system.



Symbol	Explanation
MD	Medical Device
	Manufacturer
\sim	Year of Manufacture
(2)	Do not re-use. Parts like foam cushions and irrigator tips are for single use only.
REF	Reference number used to denote the model of the equipment.
(A)	Do not push symbol used with components that could easily tip over, such as the Digital Light Bar
©	Chinese RoHS compliance standard where the product contains less than the maximum concentration value of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, and polybrominated diphenyl ethers.
*	Keep dry
*	Transport and storage temperature range
<u></u>	Transport and storage humidity limitations

1.4 Disposal of the product

Interacoustics is committed to ensuring that our products are safely disposed of when they are no longer usable. The cooperation of the user is important to ensure this. Interacoustics therefore expects that local sorting and waste regulations for disposal of electric and electronic equipment are followed, and that the device is not discarded together with unsorted waste.

In case the distributor of the product offers a take-back scheme, this should be used to ensure correct disposal of the product.





1.5 Included partsThe following objects provided by the supplier are required to assemble the Orion Chair.

The following objects provided by the supplier are required to assemble the Orion Chair.		
	Orion Reclining Chair 8530926	
-	Installation Instructions 8530912	
	Isolation Transformer 8515235	
	Power Cord for isolation transformer	
	Power Cord for Orion Reclining Chair 3m 8514823	
	USB A-B 3m 8502734	
	Emergency stop box 8528958	
	2-wheel steel hand truck 8530593	

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*COCCOCOCOCOCOCOCOCOCOCOCOCOCOCOCOCOCOC	4x Ø0.375x2.500" hex Screws 8520309
	4x Ø0.375x1.750" Threaded metal anchors 8520310
B BRAUN B BRAUN Alcohol Pads B, Braun Beyropyl Alcohol 70% 1 NEF 910012 Topfer zur Nauf- ins Anwendung. B BRAUN B B	Alcohol Pads 20 pcs 8530569
il-o	Screwdriver - Hex Key Spinner 2.5x75mm 8530595
S6256 SS 6256	5/8" Rotary Hammer drill bit (SDS-Plus shank) 8503521
60	3/8" 0.438" ID 1.000" OD Flat Washer 8502205
	3/8" 0.406" ID 2.000" OD Flat Washer 8502210
	Cable protector 8502981



1.6 Additional required tools

Please note that the following tools are required to assemble the Orion Chair.

	Battery powered drill with Torx 15,20,25,30 bit
	Hammer Drill SDS-Plus
	Standard and Phillips screwdrivers
	16 oz hammer
	Pencil
	Hobby knife
25 25	Tape measure
	Adjustable wrench or socket wrench with ½" /1.27 cm socket
	Vacuum cleaner
(S) (M)	Level
	Paper towels and water for concrete dust clean-up



Ear plugs
Safety glasses
Disposable dust mask
Work gloves



1.7 Define the room layout for chair installation Ensure that you have a very clear floor plan to install the chair and other accessories. The sample room layout with minimum dimensions is provided below see Figure 1.

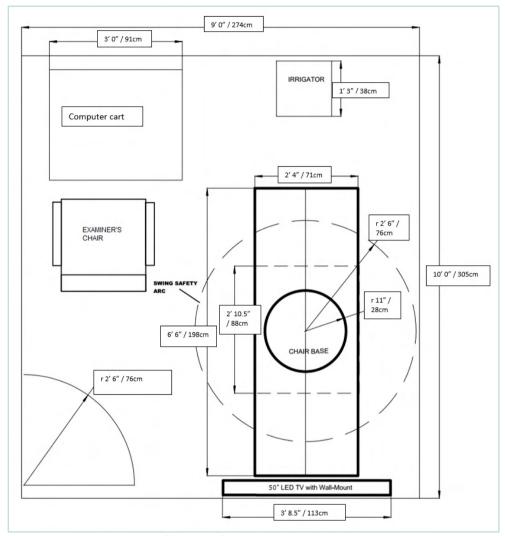


Figure 1: Room layout example



2 Unpacking and inspection

2.1 Inspection of shipment

Check for damage

Ensure that you have received all the components on the shipping checklist during unpackaging. All the components should be checked visually for scratches and missing parts before use. All the contents of the shipment must be checked for their mechanical and electrical functioning. If the equipment is found faulty, please contact your local distributor immediately. Keep the shipping materials for the carrier's inspection and insurance claim.

Keep carton for future shipment

The product comes with shipping cartons, which are specifically designed for the components. It is recommended to keep the cartons for future shipments in case of any need for return or service.

Reporting and returning procedure

Any missing part or malfunction or any damaged components (due to shipment) should be reported immediately to the supplier/local distributor along with the invoice, serial number, and a detailed report of the issue. For any on-site service-related information, please contact your local distributor. If the system / components are to be returned for service, please fill all the details related to product issues in the 'Return Report', which is attached to this manual. It is very important that you describe all the known facts about the issue in the return report, as this will help the engineer to understand and solve the problem to your satisfaction. Your local distributor holds the responsibility for coordinating any service/return procedure and related formalities.

Disposition of packaging materials

If wished to dispose the crates and pallets and materials used for shipment, those shall be recycled according to the local requirements and possibilities.

2.2 Unpacking chair from the crate

Use a battery powered drill with Trox and Phillips bits to remove screws.

Start by removing the top plate of the crate, then the sides marked 1,2,3, and lastly remove the side marked 4, see Figure 2.

Note that a ramp is attached inside chair crate on side with marking 4.



Figure 2: Chair in wooden case with markings





Figure 3: Images from packaging disassemble procedure

The installer can now proceed to unwrap the chair by carefully cutting tape and removing the plastic sheeting, see Figure 3 and Figure 4.





Figure 4: Orion Chair without plastic foil

The isolation transformer, head support and accessories for the Orion Chair are placed in the boxes located on the chair seat, see Figure 4.



2.3 Moving the chair to test room

It is recommended that two persons are present when moving the Orion Chair.

The Orion chair is strapped to a 2-wheel steel hand truck inside the crate. A wooden ramp which is part of the equipment on the pallet, is fastened with screws to the chair pallet, so the installer can roll the Orion chair down from the pallet.

Remove the wooden brace over the footrest of the chair.

Attach the ramp to the front of the pallet using the two screws which fixed the ramp to side four, see Figure 5.



Figure 5: Pallet with fixed ramp

Remove the fixture securing the chair base to the palette.

Use the hand truck to tilt back the Orion Chair and roll it down on the ramp off the palette into the test room where it is to be used. It is recommended that a second person supports and helps to tilt the Orion Chair by the footrest during this step, see Figure 6.





Figure 6: Rolling the chair down from the pallet

With the chair standing in the clinic/room, the installer can now proceed to the setup guide in Section 3.



3 Setup

This section describes the configuration of computer- and chair setup. It is important to follow the steps of this section precisely to succeed with the overall installation of the chair.

3.1 Computer Setup

It is expected that a computer running VisualEyes software is installed in the clinic prior to installation of the Orion Chair. The computer must be configured to meet the requirements of the *Pc setup section* in *VisualEyes Instructions For Use*.

It is recommended that the computer used with the Orion Chair is connected to a powered USB Hub. The hub will be the terminal for USB data connections amplifying signals to ensure the desired data quality. All goggles with USB communication delivered by Interacoustics come with an apt USB Hub, which can be used for Orion chair communication.

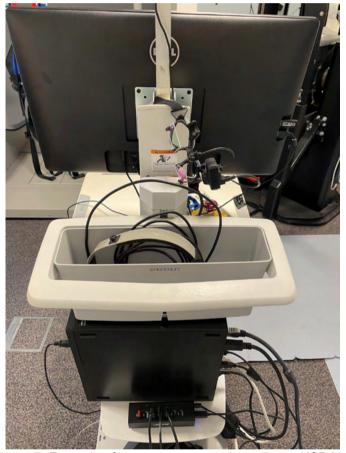


Figure 7: Example of computer setup using a 7-port USB Hub

3.2 Chair Setup

This section is separated in two parts.

Part one (3.2.1) must be completed, after which the installer should jump to Section 4 of this instruction. After completing the installation of the chair, the installer can follow the steps of part two 3.2.2 to finalize the setup of the Orion Chair.

3.2.1 Chair Setup: Part 1 (connections)

The following information guides the installer in connecting the Orion chair to power and data. This is important to activate the locking mechanism of the chair which is used during anchoring of the chair to the floor. The following parts must be at hand for the process:



- o Orion Reclining Chair
- Isolation Transformer
- Power Cord for isolation transformer
- o Power Cord for Orion Reclining chair 3m
- o USB A-B 3m
- o Emergency stop box
- VNG goggle

3.2.1.1 Isolation Transformer

The installer must check the setting of the Isolation Transformer before it is plugged in the wall outlet. The Transformer is set by factory, however; it is expected that the installer makes sure that the input voltage for the Transformer is matching the mains power of the wall outlet (115V or 230V).

If not, use a flathead screwdriver to unlock the protective case. Using the same screwdriver, pry and slide out the fuse sections. Rotate the module 180 degrees so that the right voltage setting is at the top. Slide the module into place while pressing firmly with your finger. Secure the connector, see Figure 8.



Figure 8: Changing input voltage setting of the Isolation Transformer



3.2.1.2 Emergency stop box

The Emergency stop box is a safety button, which the operator can press to stop the Orion Chair if something unexpected happens. When the button is pressed, it will stay down wherefrom it must be turned clockwise to unlock and turn the system back on, see Figure 9.

Operation instructions of the Emergency stop box is provided below:

- Press the red button to shut off the Orion Chair
- Rotate the red button to activate the Orion Chair
- When rotated, the red button will spring up and emit a red light, meaning that the Orion Chair is powered



Figure 9: Emergency stop box: left (closed/switched off), middle (rotating the button clockwise), left (open/turned on)



3.2.1.3 Connect chair to power and computer

Step 1:

Flip the chair base power switch to off, see Figure 10

Step 2:

Connect the Emergency Stop box to the base of the chair and place it on the desk or equipment cart for easy operator access, see Figure 10

Step 3:

Connect the USB A-B cable from the base of the chair to the computer USB HUB, see Figure 10

Step 4:

Connect the Orion Chair power cord from the chair base to the isolation transformer, see Figure 10

Step 5:

Connect the isolation transformer to wall power mains. The transformer output voltage is preset from the factory, see Figure 10

Step 6:

Flip the chair base power switch to on, see Figure 10

Step 7:

Check that the power switch on the isolation transformer is set to on

Step 8:

When the system is powered on and the Emergency Stop Box is lit up, connect the goggle USB cables to the side of the Orion Chair Figure 10, and click them into the cable support clip next to the USB ports

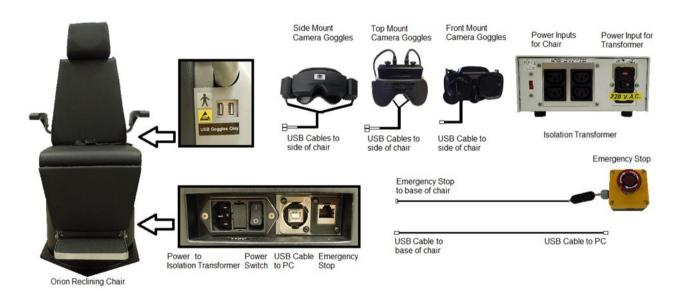


Figure 10: Orion Reclining Chair connection diagram

The Orion Chair is now connected, and the installer can start installing drivers. Instruction hereof can be found in the following sections.



3.2.1.4 Install Orion Chair drivers

Step 1:

Follow the guide from Figure 11 Error! Reference source not found. to install the InstaCal software.

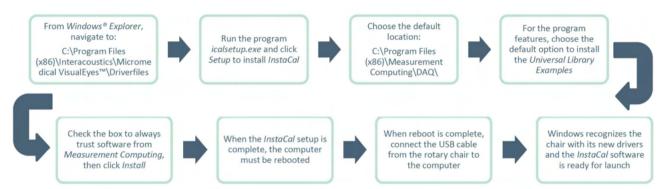


Figure 11: InstaCal installation process

Step 2:

Launch the InstaCal software, select the Orion Chair named USB-231 and click *ok* to register the device in the program



Figure 12: InstaCal Board Detection

Step 3:

In InstaCal, click the fourth icon illustrating a gear in the top horizontal bar.



Figure 13: InstaCal Settings symbol

Step 4:

In the combo box choose Single Ended (8 ch) for the number of channels field and click OK, finish off by exiting InstaCal.



Figure 14: InstaCal Board Configuration





With the drives set up, the installer can proceed to the registration of the Orion Chair in the VisualEyes software.

3.2.1.5 Orion Chair registration in VisualEyes

There are two possible registration scenarios for the Orion Chair.

Scenario one (New complete VNG setup)

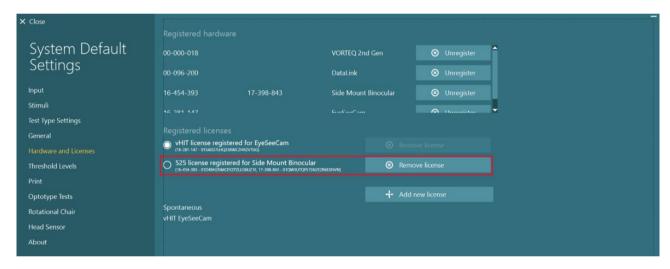
Installing a system ordered with new computer, VNG system, and accessories including Orion Chair. This scenario will have licenses for both VNG system and Orion Chair installed from the factory, thus; the installer can open the VisualEyes software entering testing directly. In this case the installer can now jump to locking of the chair, see section 4.

Scenario two (Installing Orion Chair to existing VisualEyes system)

When new hardware is connected to an existing VisualEyes[™] system it needs to be registered in the software to be recognized correctly.

Step 1:

If a VisualEyes system is running with goggles and no Orion Chair, the installer must remove the goggles currently used. This is done via *System Configuration – Hardware and Licenses* clicking *Remove license* then click *Unregister* in the row mentioning the goggles, see figure 12 below.



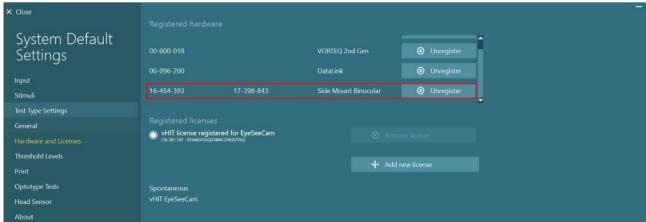
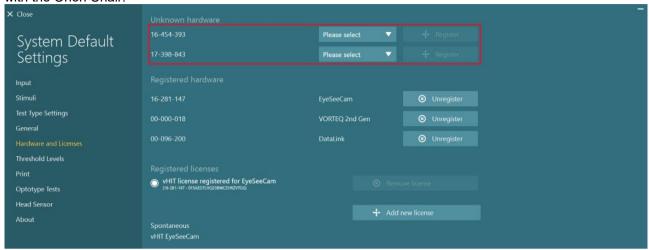


Figure 15: Removing existing goggle licenses



Step 2:

Plug the goggles in the side of the Orion Chair back rest and plug the Orion Chair USB cable into the Computer USB. New rows will appear under Unknown hardware. Click the drop-down list and select the type of goggles used, see Figure 16. The Orion Chair will be implemented through the goggle licenses delivered with the Orion Chair.



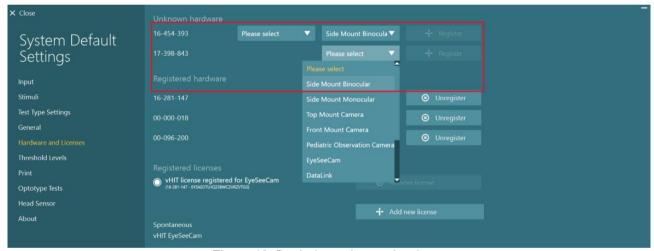
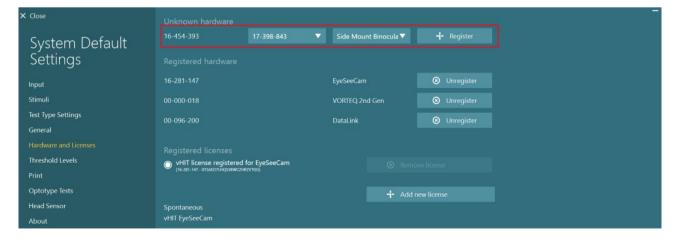


Figure 16: Declaring unknown hardware

Step 3:

When the unknown hardware has been defined as goggles, click *Register*, whereafter a new row containing goggles should appear under *Registered hardware*.





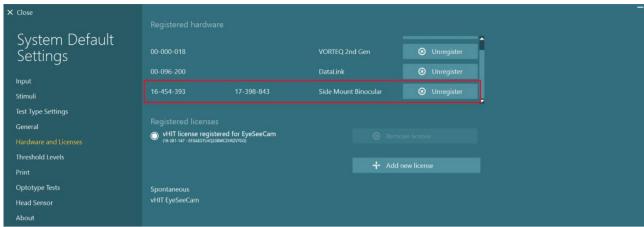
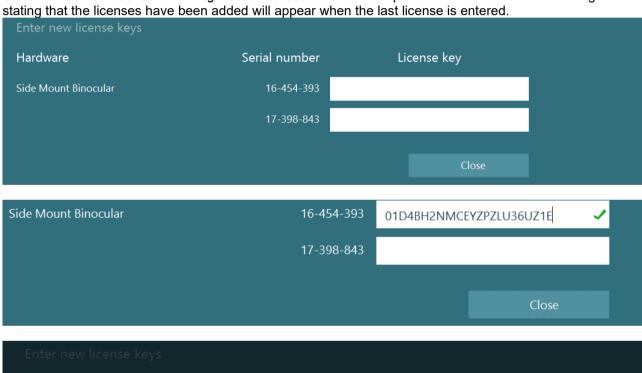


Figure 17: Registering goggles

Step 4:

Click the Add new license under registered licenses and enter the provided license codes. A message



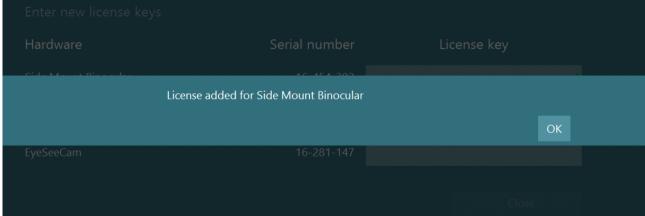


Figure 18: Entering license keys





The licenses for the goggles with appertaining Orion Chair are now added successfully. The *Hardware and Licenses* screen should show a row under *Registered licenses* containing a VNG system such as 525 as seen in Figure 19. The tests battery of a license containing an Orion Chair should include Rotational Chair tests such as Step Velocity, SHA, and VOR Suppression.

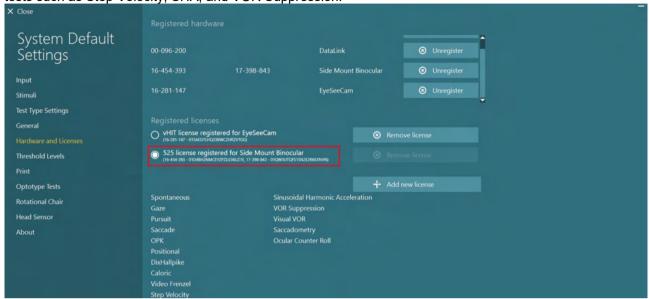


Figure 19: 525 system added successfully

3.2.1.6 Locking the Chair

This is the last step of part one. The chair must be locked before anchoring it to the floor to ensure alignment between patient and screen. Locking is accomplished by opening an ocular motor test or clicking the lock chair symbol in the VisualEyes software. Use the disengage switch on top of the backrest to lock the Orion Chair in a specific position, see Figure 20.



Figure 20: Chair lock switch

This was the last step of part one in the setup sequence. Jump to section 4 if the chair is yet not anchored to the floor.

When the chair is anchored to the floor, proceed with the steps provided in section 3.2.2.

3.2.2 Chair Setup: Part 2 (calibration and validation)

The following information guides the installer in the calibration and validation of the Orion Chair. It is important that the chair is anchored to the floor before continuing with the calibration and validation.

The Rotation of the Orion Chair is controlled via the computer. Corrections for chair drift or tach velocity, can be done by chair calibration.





To retrieve the settings for the Orion Chair, follow the path in Figure 21 from the VisualEyes home screen:



Figure 21: Path to Orion Reclining settings

Figure 22 below illustrates the Orion Chairs setting page, wherefrom modifications to chair performance can be adjusted.

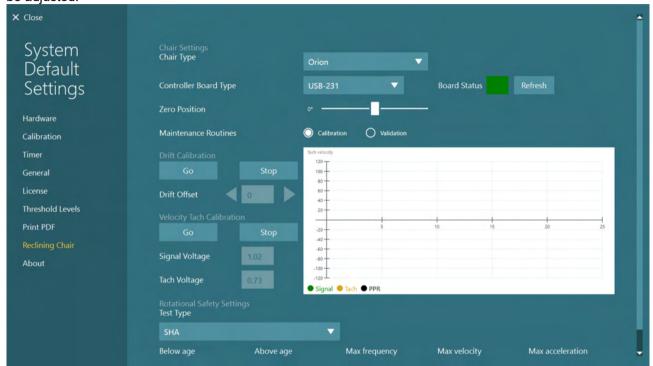


Figure 22: Orion Reclining settings page

3.2.2.1 Drift calibration

It is recommended to place a reference object close to the Orion Chair footrest (~1mm = 0,04inch) during drift calibration, to tell if the Orion Chair is moving towards or away from the reference. The drift calibration procedure is described in Figure 23.



Figure 23: Orion Reclining drift calibration process



3.2.2.2 Velocity tach calibration

Once the chair's drift has been corrected, click *Go* for the *Velocity tach calibration*. The software will then spin the chair to optimize the signal voltage and tach voltage values to synchronize the traces. After two spins past the chair's zero position (seen by the deflections in the PPR trace), the software will stop the chair and update the signal and tach voltage values. Click *Stop* to clear the traces from the graph or stop the test early.

It is important the there are no PPR pulses under the acceleration of the Orion Chair (linear increase of Tach). If a PPR pulse is seen under the acceleration period, the calibration must be repeated.

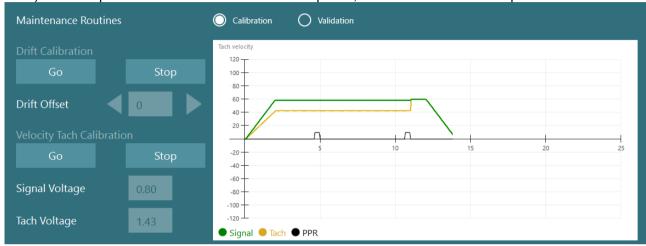


Figure 24: Example of Orion Reclining calibration

3.2.2.3 Sine wave validation

Once both calibration tests have been performed, select *Validation* for the maintenance routines to perform the *Sine wave validation* test. Click *Go* to run a sinusoidal test for one cycle at 60 degrees per second at 0.04 Hz. These settings can be adjusted if necessary.

The chair will rotate using the calibrated settings and should have the signal and tach traces appear superimposed. If the traces are not adequately aligned, perform the calibration tests again.

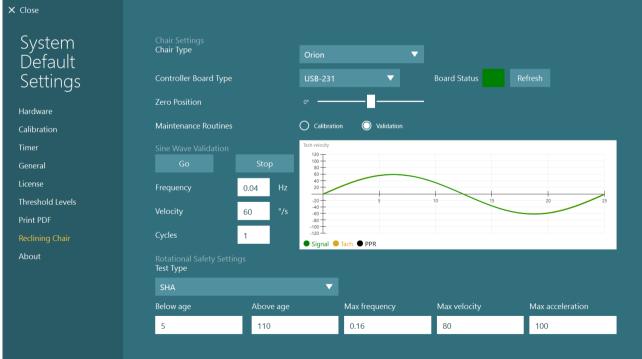


Figure 25: Example of Orion Reclining validation



The Orion Chair is now ready to be used in clinical testing. The goggles should be connected through the USB ports on the side of the Orion Chair backrest when having the patient placed in it, see Figure 10.





4 Chair installation

This section guides the installer in the mechanical installation of the Orion Chair. It is important to follow the guidelines of this section to get a functional setup that fits the specific clinic.

4.1 Prepare for chair installation

Ensure that you have all the tools and mounting hardware listed in sections 1.5 and 1.6. Pay attention to warnings related to the tools used and meet the safety measures provided by tool manufactures, such as ear protection and so forth.



Ensure to comply with client relevant electrostatic discharge regulations before handling electrical parts during chair installation.

4.2 Determine chair position

Ensure that the following points are considered before positioning the Orion Chair in the room.



It is very important that the chair is anchored in the correct position. Hence, do not proceed with drilling the anchor holes before you confirm that the lock is fully engaged from the software and chair is centered to television. The software will lock the chair during ocular motor testing, meaning that if the chair is not positioned correctly where the lock is engaged with the chair facing the TV, the patient will end up being off-center to the TV during testing.

- The Orion Chair should have a clear circumference to complete the rotation in sitting position with a radius of at least 30"/0.76 m and 39"/1.00 m for the reclining position, see Figure 1.
 Note: Distance from the chair to the TV should be measured from the center of the chair base to the
 - **Note:** Distance from the chair to the TV should be measured from the center of the chair base to the front panel of the TV (not the wall).
- It is recommended to align the mechanical zero position of the chair to the center of the television. If the alignment of mechanical zero results in bad placement of the cables, it is allowed to rotate the base, so the wire panel is in the direction of the computer/cart used. However, it is still important to achieve mechanical locking and setting a new zero.

Note: Center of the cable access panel is called Mechanical zero position, see Figure 26.

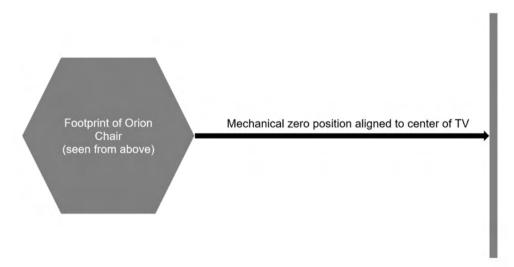


Figure 26: Illustration of mechanical zero facing television



Follow the steps mentioned below the achieve correct alignment:

- Establish all connections between chair, PC, goggles, and safety transformer so the system is fully functioning. Turn on the PC and enter the license codes as from section 3.2.1.
- Place the chair in a position where the service door and connection panel are facing the center of the
 TV
- Press the 'Home Chair" button in the software and check that the chair stops and locks with the center of the chair seat aligned to the center of the TV.
- Open the service chair panel to verify that the lock is fully engaged with the sprocket. If not fully engaged, move the chair seat a few degrees by hand until the lock engages fully.
- Adjust the chair base till the center of the chair seat and the TV center are aligned, see Figure 27. If required, it is possible to create a different home position than the mechanical zero position. This is done in the System Default Settings under the Rotary Chair tab.
- Once you have determined the final position of the chair base, you can proceed with the drilling process.



Figure 27: Orion Chair center illustration

4.3 Drilling anchor holes

After careful assessment of the chair position, mark the area where the three holes are to be drilled.

You can either move the chair to the side after marking the positions for drilling or continue with drilling by keeping the chair in place. Mark drill bit with electrical tape for hole depth of 1.75 to 2 inches (4.5 to 5 cm), see Figure 28.



Figure 28: Drill bit with tape marking





Secure the drill bit in the chuck of the hammer drill. Place the drill in the middle of the target hole. Keep the drill bit vertical. Be careful not to drill at an angle, because this may cause difficulty in keeping the anchor screw head flush on the washer.



Wear appropriate PPE (face mask, safety glasses, ear plug, etc.) when you drill in concrete as it produces dust and noise. PPE prevents breathing the dust and protects against any adverse effect from noise.

It is very important to clean all dust and debris from the hole to prevent the anchor from slipping. Use the hand vacuum with hose attachment to clean out the drilled hole. Repeat the steps for all three holes.

4.4 Variations in flooring

Carpet

If the floor is carpeted, it is recommended to cut a small circle before drilling anchor holes, to avoid pulling threads that visually damage the carpet.

Ceramic tile

If the floor is ceramic tile, then obtain a different drill bit appropriate for drilling through ceramic tile.

Vinyl flooring

If the floor is vinyl tile over concrete, the anchor holes can be drilled with the supplied bit.

Wood floor

If the floor is hard wood, then consult with the building owner about how they want to mount the chair. Consider lag screws, toggle bolts or molly anchors.

Crooked floor

It is important that the Orion Chair is in level after installation. Thus, the installer must make sure to install the Orion Chair at a plan surface and must measure that it is in level after anchoring. If the floor is uneven, the installer must use appropriate shims to level out the Orion Chair.





4.5 Placing anchors

Place the anchor into the drilled hole with the expanded end first.



Figure 29: Anchor with expanded end pointing to hole

Insert the split anchor end into the drilled hole. Make sure the anchor is below the concrete surface. Complete this process for all three anchors. Move the chair back over the anchors. Stack the lag screw with the washers, first the small steel washer then the large washer, see Figure 30.

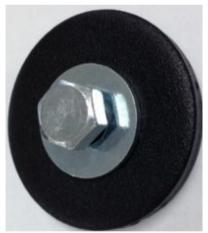


Figure 30: Lag screw with washers

Place the screw with washers into the anchor and tighten firmly with a wrench. The lag screw will expand the anchor in the concrete hole.

If the anchor spins in the hole, remove the anchor, clean out the concrete dust and try again.



4.6 Cable protector

The cable protector (8502981) from the accessories must be installed to avoid potential trip incidents and to protect the Orion Chair wires.

The installer can cut the length of the protector, so it fits the specific installation. Also, the back side of the protector can be cut open to slide the cable into the protector cavity see Figure 31.



Figure 31: Cable protector: left (cut protector length), middle (cut to slice open protector cavity), right (slide cable into protector cavity)

The cable protector can be placed between desk and Orion Chair when the cables are fitted inside it, see Figure 32.



Figure 32: Cable protector final installation



4.7 Head support

Install the head support by following the steps below.

- Take out the head support provided from the box.
- Insert the head support to chair and secure with the screw provided on the backside of the chair.
- The height of head support can also be adjusted with the same screw.



Figure 33: Installing the head support

4.8 Connecting cables

Step 1:

Flip the chair base power switch to off, see Figure 10

Step 2

Connect the Emergency Stop box to the base of the chair and place it on the desk or equipment cart for easy operator access, see Figure 10

Step 3

Connect the USB A-B cable from the base of the chair to the computer USB 3.2 HUB, see Figure 10

Step 4:

Connect the Orion Chair power cord from the chair base to the isolation transformer, see Figure 10

Step 5:

Connect the isolation transformer to wall power mains. The transformer output voltage is preset from the factory, see Figure 10

Step 6:

Flip the chair base power switch to on, see Figure 10

Step 7:

Check that the power switch on the isolation transformer is set to on

Step 8:

Connect the goggle USB cables to the side of the Orion Chair Figure 10, when the system is powered on and the Emergency Stop Box is lit up

Step 9:

Insert the goggle USB cables into the clips located on the back rest of the chair, see Figure 34



MMMM



Figure 34: Cord Clip

For instructions in calibration and validation of the Orion Chair, see section 3.2.2.