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Instructions for Use – US

TRV chair

Interacoustics

8524287 - D-0127726-B – 2021/09

Contents

1 Introduction

1.1 About this manual

This manual is valid for the TRV chair. The equipment is manufactured by:

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1.2 Intended use

The TRV chair is intended to assist in the diagnosis and treatment of balance disorders and vertigo, including benign paroxysmal positional vertigo (BPPV).

Intended user

The TRV chair is intended to be used by an audiologist, ENT, physiotherapist and/or hearing healthcare professional or technician. Every user must be certified as a trained user.

1.3 Contraindications

The TRV chair must not be used if the patient presents with unusual headache symptoms, uncontrolled high blood pressure, some associated neurological symptoms or any other atypical findings. It must not be used if the patient has undergone neurosurgery or cardiac surgery within the past month.

For US only: Federal law restricts the sale, distribution, or use of this device to, by, or on the order of a licensed medical practitioner.

1.4 Product description

The Vertigo Treatment and Rehabilitation (TRV) chair is designed for diagnostic and therapeutic maneuvers in positional vertigo. The chair is manually handled by a health professional specialized in balance/vertigo troubles.

The chair allows for 360° rotation around the vertical and horizontal axes with lockable pre-set positions, in order to place the patient's head in certain angles for specific maneuvers.

1.5 Notes on safety

Throughout this manual, the following meanings of warnings, cautions and notices apply:

WARNING

The WARNING label identifies conditions or practices that may present danger to the patient and/or user.

CAUTION

The CAUTION label identifies conditions or practices that could result in damage to the equipment.

NOTICE

NOTICE is used to address practices not related to personal injury.

1.6 Safety precautions

Follow Instructions for Use - To ensure correct use of the medical device, it is essential to read this documentation and all the instructions and labels carefully and thoroughly.

WARNING

This device must not be used with patients smaller than 140 cm nor taller than 195 cm, or with patients that weigh more than 150 kg.

WARNING

The system should not be used in areas of high humidity.
The system should not be exposed to explosive or flammable gases.

WARNING

The system should only be used by persons who have been trained in its use and who are medically qualified in the field of vestibulometry.

WARNING

In the event of damage to the system or any of its components, it must be repaired before further use.

WARNING

The device must be cleaned after each utilization.

After/before every manipulation, the user must clean every part in contact with the patient (shoulders, shims, seat, headrest, head strap) with the specified cleaning agent.
Always switch the system off before cleaning.

WARNING

The device must be powered off after each utilization.
After every manipulation, the user must switch off the device to avoid any unintended activation of the frame, which could hurt the user and the patient.

WARNING

Always use the handles to manipulate the device.
Failure to use the handles during maneuvers may incur pinch / trapping danger and potential damages.

WARNING

The device may only be used for patients between 140 and 195 cm.
The device is designed to manipulate patients within a certain range of size (140 cm < S < 195 cm), in order to ensure safe use.

WARNING

The device must NOT be used for patients that weigh more than 150 kg.
The device is designed to manipulate patients within a certain range of weight (W < 150 kg), in order to ensure safe use.

WARNING

In case of a serious incident, the manufacturer should be notified as well as the competent authority in the patient's home country.

WARNING

No modification of this equipment is allowed without authorization from Interacoustics.

WARNING

No parts of the equipment can be serviced or maintained while in use with the patient.

CAUTION

Risk of dizziness.
As the chair allows for 360° rotation.

CAUTION

The use, sale and distribution of the system may be regulated, so it is essential to ensure that the device is compliant with any local regulations before being put to use.

Within the European Union, it is illegal to dispose of electrical and electronic waste as unsorted municipal waste. Electrical and electronic waste may contain hazardous substances and must therefore be disposed of separately. Such products will be marked with the crossed-out wheelie-bin image shown to the left. User cooperation is important in order to ensure a high level of reuse and recycling of electrical and electronic waste. Failure to recycle such waste products in an appropriate way may endanger the environment and consequently the health of human beings.

Outside the European Union, local regulations should be followed when disposing of the product.

1.7 Malfunction

In the event of a product malfunction, it is important to protect patients, users, and other persons against harm. Therefore, if the product has caused, or potentially could cause such harm, it must be quarantined immediately.

Both harmful and harmless malfunctions, related to the product itself or to its use, must immediately be reported to the distributor where the product was acquired. Please remember to include as many details as possible e.g. the type of harm, serial number of the product, software version, connected accessories and any other relevant information.

In case of death or serious incident in relation to the use of the device, the incident must immediately be reported to Interacoustics and the local national competent authority.

1.8 Meaning of symbols used

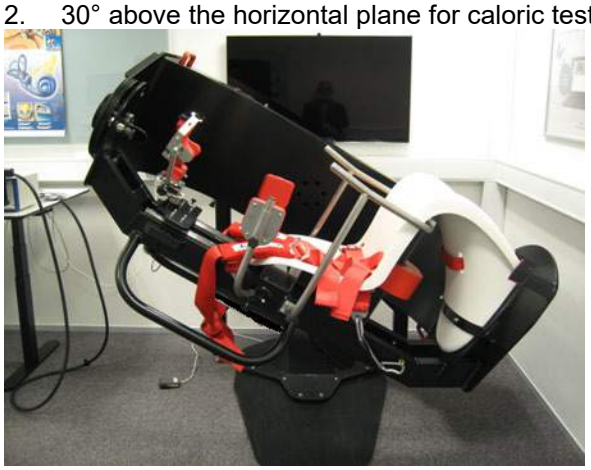
SYMBOL	DESCRIPTION
	Follow Instructions for Use
	General warning sign
	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC
	Medical device
	Manufacturer
	Date of manufacture
	Serial number
	Fragile, handle with care
	Transport and storage temperature range
	Transport and storage humidity limitations
	Keep dry
	WEEE (EU-directive) This symbol indicates that when the end-user wishes to dispose of this product, it must be sent to separate collection facilities for recovery and recycling.
	Direct Current
GREEN indicator	Primary frame is unlocked

2 System description and performance

The TRV chair has a seat equipped with supports (four-point harness, headrest with headband and leg strap) and has two axes of rotation, which are lockable in pre-set positions.

The horizontal axis is locked by the means of an electromagnetic lock (footswitch operated), with the patient in one of the following positions:

1. Standard (vertical, head at top).
2. 30° above the horizontal plane for caloric tests.



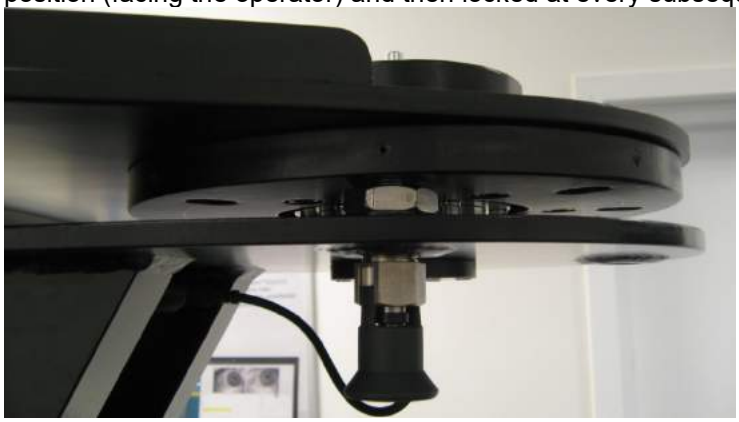
3. 0° or 180° (supine decubitus, left or right decubitus or ventral decubitus).




)

4. Immobilization -45° or +225° (45° below the horizontal plane, head to left or right) for ‘potentiated’ Epley maneuver:

The vertical axis can be locked by the means of a manually operated lock, with the patient in the standard position (facing the operator) and then locked at every subsequent 45°:



A movable counterweight under the patient's seat can be moved to align the patient's center of gravity with the vertical axis of rotation:

Counterweight with manual lock to lock the counterweight in the optimal position for each patient.

The counterweight must be in the central position for patients of average weight (60-90 kg).

On very light patients: Slide the counterweight towards the patient's knees.

On very heavy patients: Slide the counterweight away from the patient's knees.

This will ensure a well-balanced rotation during diagnostic procedures and during the barbecue maneuvers.
The height position of the headrest and the headband can be adjusted to the patient's height by means of a pneumatic lift. The operator pushes a release button and raises or lowers the headrest so that it is in line with the patient's head position:

Release button:
Press and hold to adjust the position of the headrest.

The chair enables the operator to rotate the patient in planes that are very close to the planes of each of the semicircular canals:

Rotations 45° from the sagittal plane will stimulate the anterior or posterior canals, and barbecue rotations along the vertical plane will stimulate the horizontal canals.

These maneuvers are possible in more than full-circle rotations (+360°).

CAUTION

Rotation must only be performed on one axis at a time.

Maneuvers on the horizontal axis can be arrested in two positions by means of a retractable stop:

- In the horizontal plane (for Dynamic Particle Repositioning Maneuvers (DPRM), also known as the TRV maneuver).

Stop position for horizontal canal DPRM.

Stop will engage with upper hydraulic shock absorber during horizontal canal DPRM.

- At 45º below the horizontal plane (for Sémont and Epley maneuvers) to increase therapeutic efficacy:

Stop position for Sémont and Epley maneuvers.

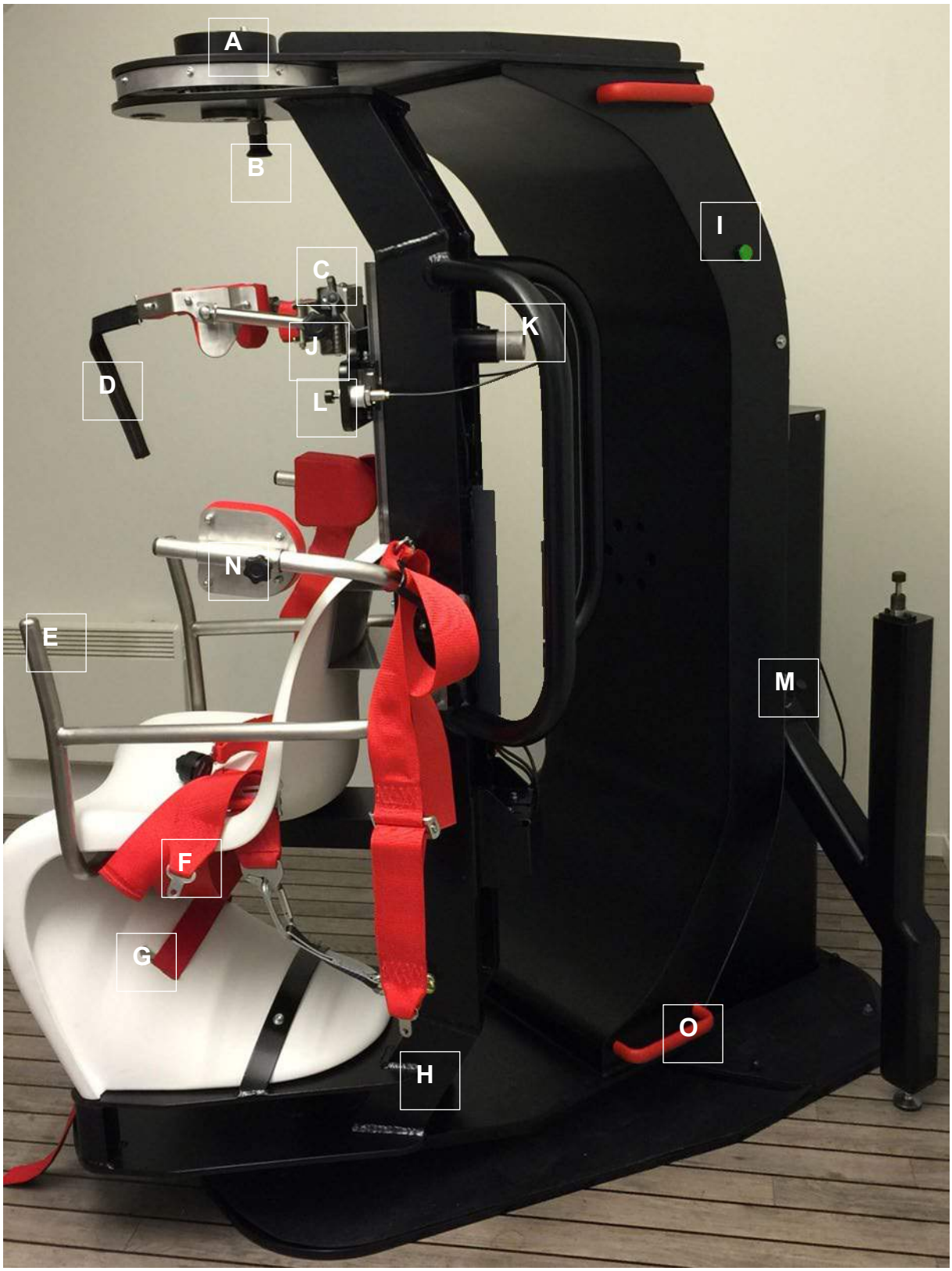
Stop will engage with lower hydraulic shock absorber during vertical canal DPRM.

WARNING

When the electromagnetic lock is locked, the green indicator light is off. To be able to change the position of the primary frame, the operator must press the foot switch, after which the green light switches on and it is then possible to move the chair on its axis.

WARNING

Always keep a hand on the handles to secure the device and always use the handles for the maneuvers.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Key to picture on page 10:

A Secondary frame rotation axis

B Secondary frame lock - lockable every 45°

C Headrest forward travel locking screw

D Headrest locking system

E Handle for patient

F Manually sliding counterweight

G Leg strap

H Secondary frame

I Green light on when electromagnetic locking system of the primary frame is unlocked

J Headrest left temporal support locking screw

K Secondary frame and carrying handle

L Headrest upward and downward travel locking button

M Primary frame shock absorber for Sémont maneuvers

N Shoulder support

O Primary frame and carrying handle

Safety Release Mechanism

In case the battery should run out of power, the battery-powered lock for the main arm can be manually released by pulling the handle knob away from the main arm, and it can be locked in the released position.

3 Using the chair

3.1 Precautions for use – basic safety rules

WARNING

Before seating a patient, make sure that both axle locks are in their locked positions.

WARNING

Always gently seat the patient in the chair. Do not let the patient fall into the chair. It can result in damaging or unbalancing the medical device and can result in the patient falling on the ground. Never release the primary frame lock when there is no patient in the chair.

WARNING

Be aware that the worst mechanical position is secondary frame horizontal with the patient facing the primary frame. In this position, be careful that the patient doesn't move excessively and do not apply strong shocks on the medical device.

WARNING

Whenever a position is selected following rotation of the secondary frame, it is important to check that the mechanical locking system is correctly engaged. Before the primary frame is released, the patient should be informed what type of movement to expect as well as of the probability of vertigo during the maneuver. Throughout the various maneuvers, it is recommended that the operator keeps talking with the patient to provide reassurance.

WARNING

Never release both axles of rotation at the same time.

WARNING

The operator must never be alone in the room with the patient when using the chair. In case of inability on behalf of the operator during a session, a secondary operator will have some instructions fixed to the wall to explain how to free the patient.

WARNING

Always use the handles to manipulate the device. Failure to use the handles during maneuvers may incur pinch / trapping danger and potential damages.

WARNING

During maneuvers, mind not to pull out the wire of the foot switch.

WARNING

No one except the operator and the patient may stand closer than 2 meters from the chair.

WARNING

Even though all the materials are skin-friendly, it is recommended to use normal clothing covering arms, legs and feet during the examination. There might be a minimal risk of skin reactions with bare skin in contact with the safety harness, pads or straps.

Potential side effects:

- Patients presenting with moderate headache may experience a worsened condition after the treatment.
- Patients presenting with nausea may be at risk of vomiting during the diagnostic and therapeutic maneuvers. They must be requested to alert the operator as early as possible if they are about to vomit so the operator can terminate the procedure, put the patient in the upright position, remove the goggles and open the harness and leg strap. A container must be kept available to collect any vomit.

Connection to other medical devices:

- The TRV chair is constructed for use with the IEE1394a FireWire™ Video Frenzel or VNG systems from Interacoustics A/S. Eye images are recorded by means of infra-red video cameras mounted on the goggles. A cable connection with two sets of slip-rings conducts the video signal from the cameras, through the two axles, to a computer. The eye images are analyzed and displayed on an external screen for optimal observation of nystagmus during the diagnostic and therapeutic procedures.

Precautions to be taken in the event of changes in the performance of the device:

- The manufacturer should be advised of any change in the performance of the device. The device should be taken out of use and not returned to use until the necessary corrective actions, as specified by the manufacturer, have been carried out.

3.2 Seating the patient

Once the patient is seated, if the chair is only to be used for a conventional consultation in which only the vertical axis is released, for example in order to examine one ear and then the other without the operator needing to move, no supporting device is necessary.

If the patient is due to be diagnosed and treated for positional vertigo, supporting devices are essential and should be placed as follows:

Adjust the headrest according to the height of the upper body by means of the release button.

Leave enough space above the eyebrows to allow the head strap to be tightened without interfering with the VNG goggles.

WARNING

Always unleash the headrest before the googles.

3.2.1 Fitting the harness:

To fit the harness, start with the abdominal strap; this should be placed as low as possible, below the abdomen, at the root of the thighs, to immobilize the pelvis. Pull the strap as tight as possible.

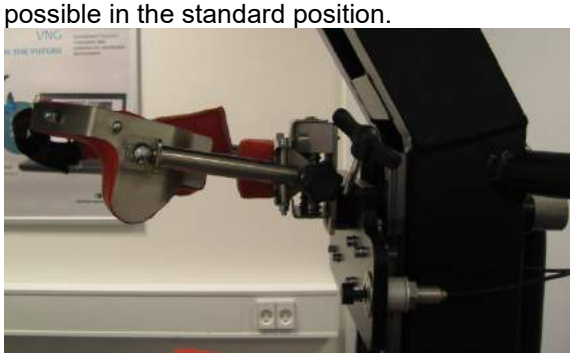
The central buckle should remain in the middle and the strap adjusted alternately to the left and right to keep it in that position. Maximum tightness can be obtained by pressing the strap with the flat of the hand against the side of the pelvis, using the other hand to pull on the free end of the strap; do this on each side in turn.

Next, the two shoulder straps are fitted and tightened by pulling the free end of the strap downwards to ensure full patient support.

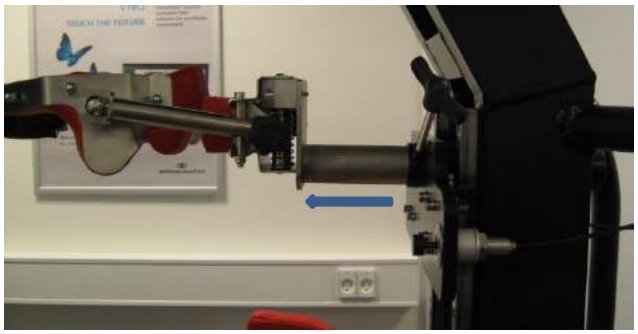
When each strap is fitted into the central buckle, there should be a clearly audible click. Pull on each strap to make sure it is locked in position. Then adjust the shoulder supports.

3.2.2 Placing the headrest:

Adjust the headrest so that the head strap leaves a space of approximately 2 cm above the eyebrows for the VNG goggles. The VNG goggles should be fitted before adjusting the head strap. The purpose of this strap is to hold the head steady to prevent any anteroposterior movements.
With kyphotic or scoliotic patients, the headrest should be moved forwards to the nape if support is not possible in the standard position.



Head support in standard position.



Head support in extended position.

The lower legs are supported by a strap, which holds the ankles tightly against the chair:

WARNING

Never release the horizontal axis unless the patient is held by all four supporting devices, which must be correctly adjusted.

1. Four-point harness.
2. Shoulder supports.
3. Head support with properly tightened head strap.
4. Leg strap.

To release the axle, press the foot switch. When the green lights on both sides of the primary frame are on, the magnetic locking system will be released by a slight pull or push of the primary frame.
The vertical axle is released by pulling the lock button downwards. It is automatically brought back to the locked position by a return spring.

To keep the vertical axle permanently unlocked for barbecue maneuvers etc., pull the button to its fully down position and give it a quarter-turn left or right to prevent it from returning to the locked position. On older versions of the TRV, use the lock at the front for the diagnostic and therapeutic maneuvers and the lock on the left side for the standard position and while the patient is being secured in the chair.

The TRV only has one lock, which covers all positions.

WARNING

Remember that it is strictly forbidden to release both axles of rotation at the same time.

3.3 Emergency exit

In case of unexpected loss of electrical integrity/failure of electrical equipment (like the foot switch), the electromagnetic lock will stay locked.

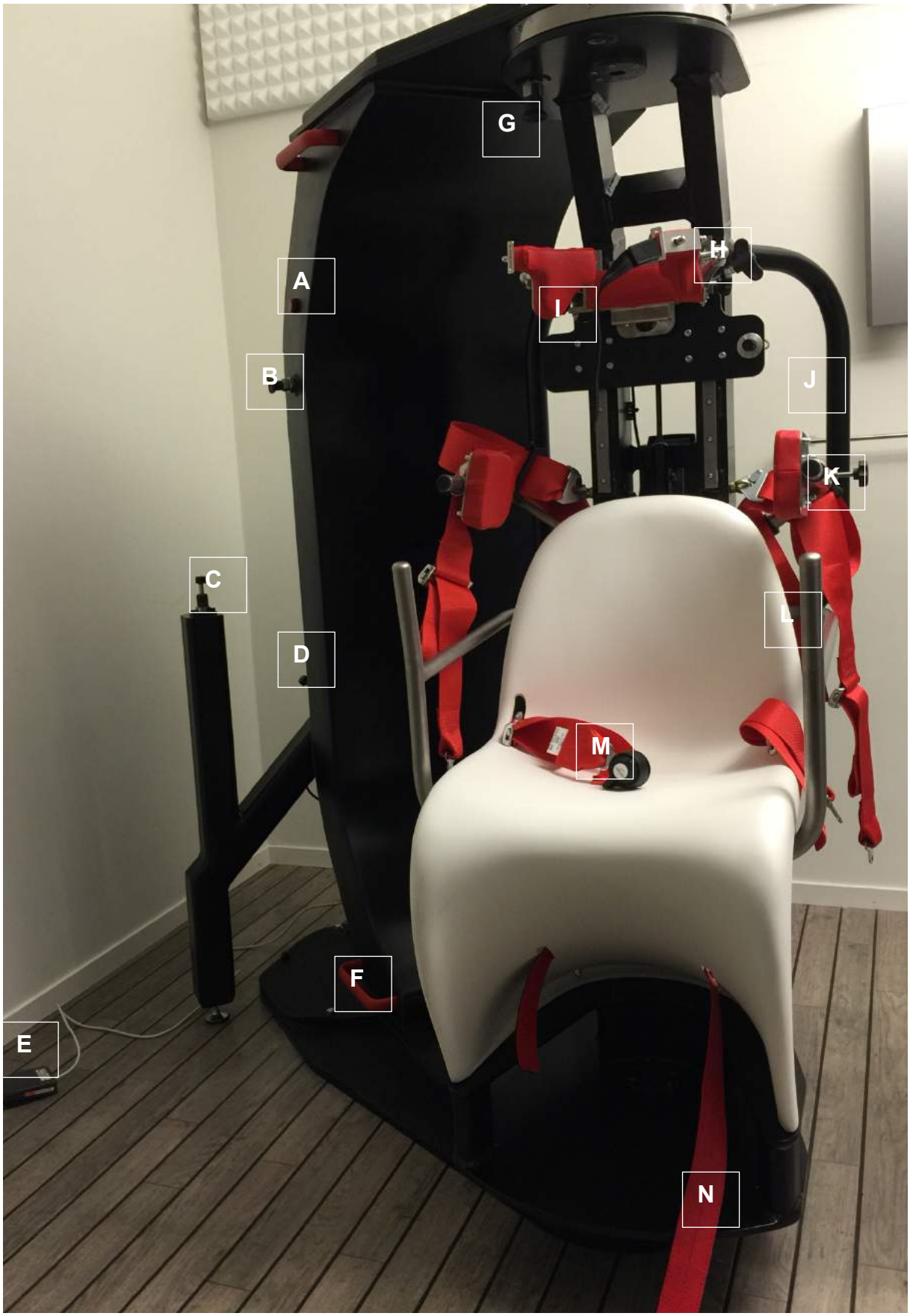
If the primary frame is blocked in a different position than vertical with head upright and if the patient cannot be release safely, the operator can pull on a manual release system (back of the column) to free the shaft and put the patient upright.

3.4 Charging the battery

The TRV chair is equipped with a single 24V battery that powers the magnetic lock for the primary frame. To charge the battery, first release it from the chair by pulling the lever on the backside of the battery's top. Next, place the battery in the wall-mounted battery charger and charge it until the yellow light in the charger station extinguishes.

WARNING

In order to avoid any degradation of the battery, remove it if the equipment is not likely to be used for some time.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Key to picture on page 20:

A Green light on when primary frame is unlocked

B Locking button for retractable limit stop

C Primary frame shock absorber for DPRM

D Primary frame shock absorber for Sémont and accentuated Epley maneuver

E Foot switch for the electromagnetic locking system (primary frame)

F Carrying handle on the primary frame

G Manual mechanical locking system to lock the secondary frame

H Headrest forward travel locking screw

I Control panel to adjust the counterweight system for the barbecue maneuvers

J Carrying handle on the secondary frame

K Lateral shim and adjusting screw

L Handle for patient

M Four-point harness

N Leg strap

4 Diagnostic maneuvers protocol proposal

IMPORTANT: Always check the supports before setting the chair in motion (see green arrows below).

4.1 General

The primary frame must not be released until the patient is in the correct position for the first diagnostic maneuver:

Test of Posterior and Anterior Semicircular Canals (SCCs).

Performing a Left Dix-Hallpike to test the Left Posterior and Right Anterior SCCs:

- Pull the knob on the manual lock to unlock the secondary frame

- Rotate the patient 45° over the right ear (while pulling the lock-knob) until the left handle on the secondary frame is pointing in the direction of the intended movement

- Lock the vertical arm by releasing the lock-knob. Check that the lock engages fully and in the correct notch for the Dix-Hallpike Left procedure
- Press the foot switch to unlock the primary frame. Gently push/pull the frame arm until the lock releases, and rotate the frame downwards to the position for the Left Dix-Hallpike test

- The Dix-Hallpike Left is a test of the Left Posterior SCC and of the co-planar Right Anterior SCC

Or

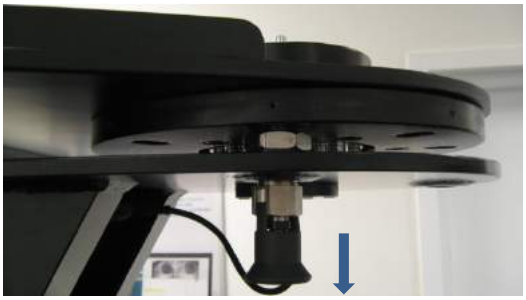
Performing a Right Dix-Hallpike to test the Right Posterior and Left Anterior SCCs:

- Pull the knob on the manual lock to unlock the secondary frame
- Rotate the patient 45° over the left ear (while pulling the lock-knob) until the left handle on the secondary frame is pointing in the direction of the intended movement

- Lock the secondary frame by releasing the lock-knob. Verify that the lock engages fully and in the correct notch for the Dix-Hallpike Right procedure
- Press the foot switch to unlock the primary frame. Gently push/pull the frame until the lock releases and rotate the frame downwards to the position for the Right Dix-Hallpike test of Right Posterior SCC and Left Anterior SCC

Procedure for Examining the Lateral SCCs:

- Pull the knob on the manual lock to unlock the secondary frame



- Rotate the secondary frame until the patient's left ear is in the same plane as the intended movement of rotation

- Release the knob to lock the secondary frame
- Press the foot switch to release the primary frame magnetic lock. The green indicator for unlocked condition turns on.
- Rotate the primary frame into a horizontal position with the patient's left ear pointing to the floor
- Lock the primary frame in the horizontal position by means of the foot switch. Observe that the magnetic lock engages correctly and that the green indicator turns off
- The lateral SCCs are now in their vertical position, and a possible left lateral canal BPPV (canal lithiasis) will be indicated by nystagmus in the geotropic form (beating towards the floor)
- To examine the right lateral canal, release the manual lock for the secondary frame and rotate the patient 180° until the right ear is pointing directly to the floor. Observe for positional nystagmus. If present, observe the nystagmus direction – geotropic or apo geotropic?

Alternative procedure to examine the lateral SCCs:

- Press the foot switch to release the magnetic lock holding the primary frame
- The patient is brought into the supine position, nose towards the ceiling

- Press the foot switch to lock the primary frame. Check that the lock engages correctly and that the green indicator light switches off
- Turn the patient 90° towards one side and 180° to the other side - then again 180° back towards the initial side, until the nature and characteristics of the horizontal positional nystagmus are sufficiently documented to determine which side needs treatment.
- The examiner may refer to Ewald's 2nd law (Paganni & Mc Clure maneuver) or to the table below to reach the correct diagnosis: If the horizontal nystagmus is beating towards the undermost ear (geotropic form), the side that needs to be treated is the side that elicits the strongest positional nystagmus when pointed towards the floor.
- If the horizontal nystagmus is beating towards the ceiling (apo geotropic form), the examiner must determine on which side the apo geotropic nystagmus is strongest – if for example this is when the left ear is down, the BPPV is in the right horizontal canal

4.2 Characteristics of positional nystagmus

The following table may be helpful when diagnosing BPPV from eye movements during positional tests:

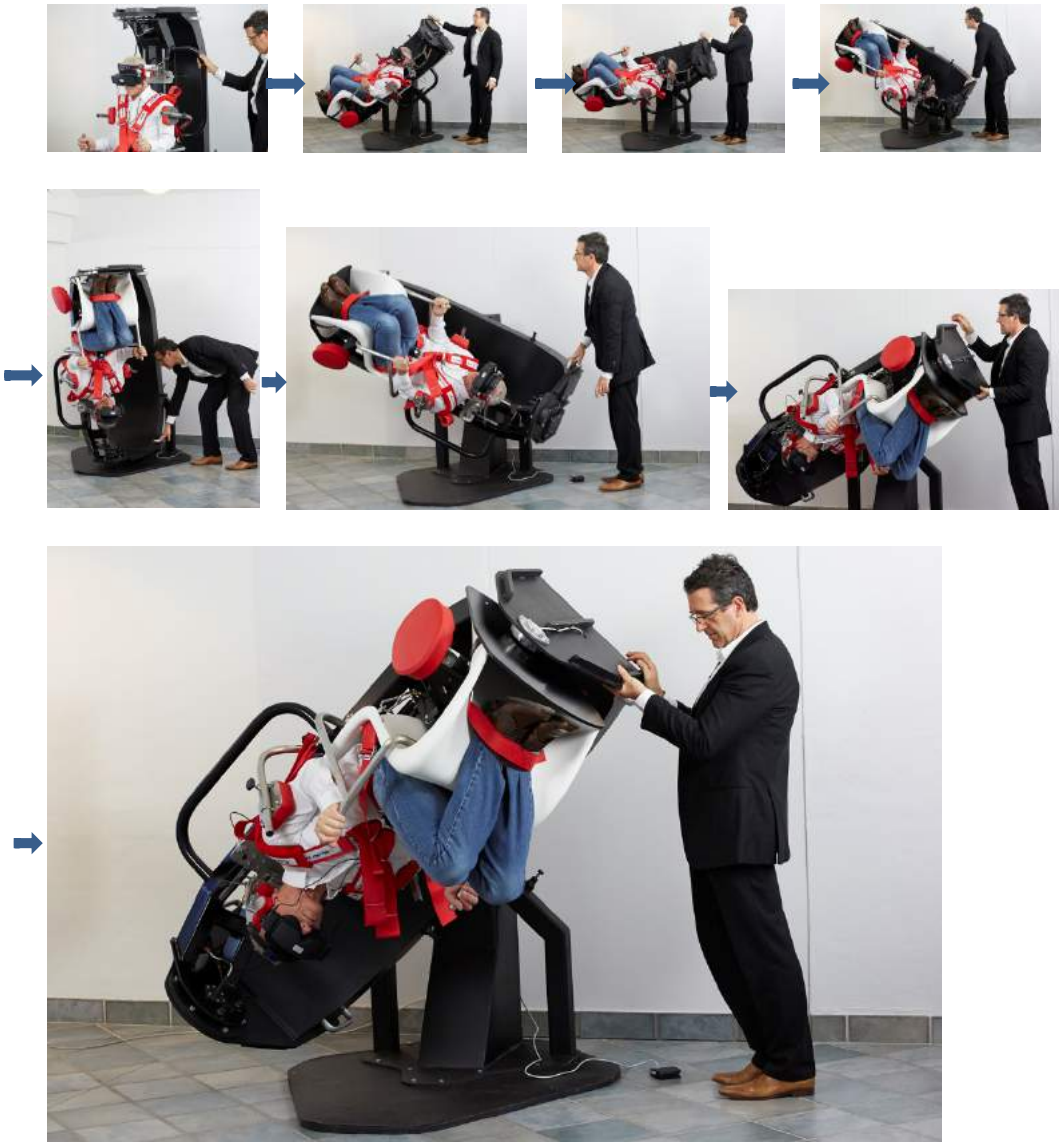
Head Position	Duration	Rotation / Horizontal component observed	Vertical Component	Semicircular Canal Involved and BPPV Variant
Dix-Hallpike/Sidelying Right Ear Down	<30seconds	Right Torsional	Upbeating	Right Posterior Canalithiasis
Dix-Hallpike/Sidelying Right Ear Down	>60 seconds	Right Torsional	Upbeating	Right Posterior Cupololithiasis
Dix-Hallpike/Sidelying Right Ear Down	<30 seconds	Right Torsional	Downbeating	Left Anterior Canalithiasis
Dix-Hallpike/Sidelying Right Ear Down	>60 seconds	Right Torsional	Downbeating	Left Anterior Cupololithiasis
Dix-Hallpike/Sidelying Left Ear Down	<30 seconds	Left Torsional	Upbeating	Left Posterior Canalithiasis
Dix-Hallpike/Sidelying Left Ear Down	>60 seconds	Left Torsional	Upbeating	Left Posterior Cupololithiasis
Dix-Hallpike/Sidelying Left Ear Down	<30 seconds	Left Torsional	Downbeating	Right Anterior Canalithiasis
Dix-Hallpike/Sidelying Left Ear Down	>60 seconds	Left Torsional	Downbeating	Right Anterior Cupololithiasis
Horizontal Head Roll Right/Left	<30 seconds	Geoptropic (horizontal)	n/a	Greater response when affected ear is closest to the ground → indicates HC canalithiasis
Horizontal Head Roll Right/Left	>60 seconds	Ageotropic (horizontal)	n/a	Greater response when affected ear is furthest from the ground →indicates HC cupololithiasis

WARNING

Whenever a position is selected following rotation of the secondary frame, it is important to check that the mechanical locking system is correctly engaged.

Before the primary frame is released, the patient should be informed what type of movement to expect as well as of the probability of vertigo during the maneuver. Throughout the various maneuvers, it is recommended that the operator keeps talking with the patient to provide reassurance.

4.3 Therapeutic maneuvers: protocol proposal for the left posterior canal



In this proposal, gravity is complemented with rapid deceleration, using a limit stop against a hydraulic shock absorber (‘potentiated’ Sémont maneuver). It is essential to lock the system in the working position for the undermost shock absorber system.

Pull the lock button and move the retractable stop into the position where it will hit against the lower shock absorber. Release the locking button.

The limit stop is now in the working position and the Sémont maneuver can commence.

The secondary frame is rotated to an angle of 45º away from the affected side and locked in this position.

The primary frame can then be released for smooth rotation.

Hold the primary frame by the carrying handle, standing on the side towards which the chair is to be tilted (affected side). Once the primary frame has been released, the patient will be rotated over the affected side into 45º below the horizontal plane, patient's face towards the ceiling. This often triggers vertigo, accompanied by a nystagmus typical of an affection of the posterior canal (up beating w. torsional component towards affected ear).

After a pause of about one minute, the potentiated Sémont maneuver can be performed at 270° with brisk deceleration against the purpose-designed limit stop.

With deceleration maneuvers, the rotational speed on the horizontal axis should be around 10 to 15 rpm, which is approximately two to three seconds from start to finish at the limit stop. Excessive rotational speed is to be avoided: it does not increase therapeutic efficacy, and it only causes premature wear on the equipment as well as reduced tolerance in the patient. A liberatory nystagmus may be observed and the patient is left for about one minute in this position, then elevated to the upright position.

At this point, the nystagmus may re-occur, accompanying the transition of otoconia through the crus communis, often with a predominant inferior vertical component.

The posterior canal may also be liberated by pure gravity (Epley's repositioning maneuver) from the -45º position immobilized by the electromagnetic lock on the primary frame. The secondary frame is then rotated 180º towards the healthy side and the otoconia liberated simply by gravity and a liberatory nystagmus may occur, the patient is left for about one minute in this position, then sat up, and it is at this point again that a nystagmus may occur. 360º maneuvers are another way to free the posterior canal. The maneuver is done without the limit stop (locked in the retracted position). The Dix-Hallpike maneuver is then prolonged to make a complete revolution.

4.3.1 Therapeutic maneuvers: protocol proposal for lateral canal cupulolithiasis

The maneuver (DPRM or the so-called TRV maneuver) using hyper gravity is a six-step maneuver with a series of eight to twelve smooth shocks. The retractable abutment is locked in the 'up' position.

The chair is tilted backwards to put the patient in the side-lying position with the involved ear towards the floor.

The first series of eight to twelve shocks is performed with the abutment moving against the upper hydraulic shock absorber, allowing the particles to migrate from the cupula to the first part of the lateral canal.
After the first series of shocks, the manual lock on the secondary frame can be released and the secondary frame turned 45° over the non-involved ear and locked again by means of the manual locking system.

Then a new series of eight to twelve shocks is performed. The patient is again turned 45° over the non-involved ear (now the nose is pointing towards the ceiling) and the same series is carried out. The fourth, fifth and sixth steps are repetitions of the previous step. The sixth step finishes with the patient in the side-lying position, nose 45° downwards and the non-involved ear also downwards.

This position enables the stoma of the canal to be in its vertical orientation, allowing the particles to move into the utricle cavity. The position is maintained for one minute. The chair is then brought into the upright position, where the patient's support devices can then be removed.

4.3.2 Therapeutic maneuvers: protocol proposal for the anterior canal

The maneuver selected is Lorin's method. Here, the limit stop is kept in the fully retracted position.

The patient is maneuvered in the same way as in the Dix-Hallpike maneuver, except that it is extended until the patient's head is fully downwards.

This position is held for 30 seconds, after which the patient is raised 45º in the opposite direction every 30 seconds until verticalized again. In this way, a left anterior canal lithiasis will be treated, commencing with a maneuver identical to the Dix-Hallpike maneuver for a right posterior canal and, conversely, for the right anterior canal.

5 Maintenance and care

The performance and reliability of the Vertigo Treatment and Rehabilitation (TRV) chair will be prolonged if the following recommendations for care and maintenance are adhered to:

Regular:

- Inspect the condition of the leg strap and the headrest and change the Velcro closures at the first signs of wear
- Inspect the condition of the foam on the seating parts and their covering; replace when the foam has ceased to provide any protection
- Inspect the magnetic lock and cylinder
- Inspect all the chair nuts for tightness
- Inspect and test the four shock absorbers
- Inspect and test the electromagnetic lock
- Inspect and test the two manual locks
- Inspect and test the harness and the harness buckle
- Inspect and test the leg strap
- Inspect and test the cylinder and their fastenings
- Inspect and test the two axles of rotation and their bearings

WARNING

If inspection of any of the above components indicates wear and tear, we recommend contacting your local distributor for a service visit to secure optimal safety and performance
For optimal preventive maintenance, a yearly inspection and service conducted by an authorized service technician is prescribed

Every three years:

- Replace the harness by releasing the four snap hooks one by one. When installing the new harness, make sure that the snap hooks are fully closed and locked:

Cleaning:

- Use a soft cloth with a non-aggressive common cleaning agent
- Do not use any solvents or aggressive cleaning liquids
- Do not use disinfectant sprays

5.1 Liability

The manufacturer shall be deemed liable for anything affecting the safety, reliability or performance of the equipment, provided it has been used in accordance with the instructions contained in this manual.

5.2 Guarantee

This equipment carries a one-year parts and labor guarantee, provided it has been used in accordance with this manual.

The guarantee excludes damage resulting from the following:

- Disassembly or modification of the equipment without the consent of the manufacturer
- The introduction of a fluid or conductive particle into the electrical components
- The use of sharp objects on the soft parts of the chair
- Loading and unloading without proper equipment

In case of a warranty issue, please contact your local service center with:

- A picture of the entire chair
- A description of the defective component: how it is no longer functioning, and what the circumstances were when it ceased to function
- A picture of the defective component
- Contact details for Interacoustics A/S to reach the person or department submitting the warranty claim

Based on the information received, Interacoustics A/S will

- Troubleshoot together with the person submitting the claim
- Suggest an action plan for the repair
- Arrange that the required spare parts are ordered and dispatched

This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of Interacoustics. Interacoustics does not give or grant, directly or indirectly, the authority to any representative or other person to assume on behalf of Interacoustics any other liability in connection with the sale of Interacoustics products.

INTERACOUSTICS DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FOR FUNCTION OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.

6 Technical specifications

Medical CE-mark	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. Approval of the quality system is made by TÜV – identification no 0123	
Standards	**Safety:**	IEC 60601-1:2005, A1:2012 Type B applied parts
	EMC:	IEC 60601-1-2:2014

Dimensions:
Length: 160 cm
Width: 120 cm
Height: 190 cm
Weight: 640 kg

Operation conditions
The chair should be used in an area suitable for medical examinations.
Temperature: 5°C to 40°C
Humidity: 30% to 90%

Transport and storage conditions
Temperature: -15°C to 40°C
Humidity: 10% to 95%

The magnetic lock is powered by a rechargeable battery pack (Linak BAJ1 (24 V DC, 2,9 Ah)). A suitable charging station is supplied with the system.

6.1 Electromagnetic Compatibility (EMC)

This instrument is suitable in hospital environments except for near-active HF surgical equipment and RF-shielded rooms of systems for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high.

Use of this instrument adjacent to other equipment should be avoided because it could result in improper operation. If such use is necessary, this instrument and the other equipment should be observed to verify that they are operating normally.

Use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. The list of accessories and cables can be found in this appendix.

NOTICE ESSENTIAL PERFORMANCE for this instrument is defined by the manufacturer as:

This instrument does not have an ESSENTIAL PERFORMANCE Absence or loss of ESSENTIAL PERFORMANCE cannot lead to any unacceptable immediate risk.

Final diagnosis shall always be based on clinical knowledge.

This instrument complies with IEC60601-1-2:2014, emission class B group 1.

NOTICE: There are no deviations from the collateral standard and allowances uses.

NOTICE: All necessary instructions for maintenance comply with EMC and can be found in the general maintenance section in this instruction. No further steps required.

WARNING: The TRV chair have not been tested for known sources of electromagnetic interference such as Magnetic Resonance Imaging (MRI), Computerized Tomography (CT), diathermy, radio frequency identification (RFID) systems, and electromagnetic security systems such as metal detectors, and should not be used in conjunction with or in proximity to such technology.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the TRV, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The ***TRV*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***TRV*** should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The ***TRV*** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The ***TRV*** is suitable for use in all commercial, industrial, business and residential environments.
Harmonic emissions IEC 61000-3-2	Complies Class A Category	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the *TRV*.			
The ***TRV*** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ***TRV*** can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ***TRV*** as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter [W]	**Separation distance according to frequency of transmitter [m]**		
	150 kHz to 80 MHz $d = 1.17P$	**80 MHz to 800 MHz** $d = 1.17P$	**800 MHz to 2.7 GHz** $d = 2.23P$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **Note 1** At 80 MHz and 800 MHZ, the higher frequency range applies. **Note 2** These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The ***TRV*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***TRV*** should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test level**	**Compliance**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%.
Electrical fast transient/burst IEC61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV Line-to-line 100 kHz repetition frequency	± 2 kV ± 1 kV	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	± 1 kV Line-to-line ± 2 kV Line-to-ground	± 1 kV ± 2 kV	Mains power quality should be that of a typical commercial or residential environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	0% *U*T for 0.5 cycle 0 % UT for 1 cycle and 70% *U*T for 25/30 cycles Single phase: at 0°	0% *U*T for 0.5 cycle 0 % UT for 1 cycle and 70% *U*T for 25/30 cycles Single phase: at 0°	Mains power quality should be that of a typical commercial or residential environment. If the user of the ***TRV*** requires continued operation during power mains interruptions, it is recommended that the ***TRV*** be powered from an uninterruptable power supply or its battery.
Power frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.
Note: *U*T is the A.C. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration — Electromagnetic Immunity			
The ***TRV*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***TRV*** should assure that it is used in such an environment,			
Immunity test	**IEC / EN 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any parts of the ***TRV,*** including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC / EN 61000-4-6	3 Vrms 150kHz to 80 MHz 6 Vrms in ISM bands 150kHz to 80 MHz 80 % AM at 1 kHz	3 Vrms 6 Vrms	$d = 1{,}2\sqrt{P}$
Radiated RF IEC / EN 61000-4-3	3 V/m 80 MHz to 2,7 GHz 80 % AM at 1 kHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,7 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ***TRV*** is used exceeds the applicable RF compliance level above, the ***TRV*** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ***TRV.*** [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

To ensure compliance with the EMC requirements as specified in IEC 60601-1-2, it is essential to use only the following accessories:

- Foot switch
- Charging battery

Conformance to the EMC requirements as specified in IEC 60601-1-2 is ensured if the cable types and cable lengths are as specified below:

- No specific cables used