Operation Manual

Rotary Chair Nydiag 200

80705402 ver. 05/2009

Contents Rotary Chair Nydiag 200 Operation Manual

Interacoustics A/S
10/2008 - 80705401
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1 Introduction

1.1 Precautions

Following the ANSI recommendations (American National Standards Institute) for safety notes, specific passages of this instruction manual are clearly marked as safety notes.

	**WARNING** indicates a hazardous situation which, if not avoided, could result in death or serious injury.
	**CAUTION**, used with the safety alert symbol, indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.
	**NOTICE** is used to address practices not related to personal injury

2 Warranty

INTERACOUSTICS warrants that:

- The Nydiag Rotary Chair is free from defects in material and workmanship under normal use and service for a period of 24 months from the date of delivery by Interacoustics to the first purchaser.
- Accessories are free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by Interacoustics to the first purchaser.

If any product requires service during the applicable warranty period, the purchaser should communicate directly with the local Interacoustics service centre to determine the appropriate repair facility. Repair or replacement will be carried out at Interacoustics' expense, subject to the terms of this warranty. The product requiring service should be returned promptly, properly packed, and postage prepaid. Loss or damage in return shipment to Interacoustics shall be at purchaser's risk.

In no event shall Interacoustics be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any Interacoustics product.

This shall apply solely to the original purchaser. This warranty shall not apply to any subsequent owner or holder of the product. Furthermore, this warranty shall not apply to, and Interacoustics shall not be responsible for, any loss arising in connection with the purchase or use of any Interacoustics product that has been:

- repaired by anyone other than an authorized Interacoustics service representative;
- altered in any way so as, in Interacoustics judgement, to affect its stability or reliability;
- subject to misuse or negligence or accident, or which has had the serial or lot number altered, effaced or removed; or
- improperly maintained or used in any manner other than in accordance with the instructions furnished by Interacoustics.

This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of Interacoustics, and 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.

3 Safety Information

3.1 General information

The Rotary Chair is constructed to a maximum patient weight of 135 kilos

This instruction manual is a part of the instrument and should always be kept at hand.

It documents the state of development of the unit, valid at the time of printing, and contains all the information required by the IEC 60601-1.

Exact adherence to the instruction manual is a prerequisite for the perfect and intended functioning of the Interacoustics instrument.

Always be sure to disconnect the power supply before cleaning or disinfecting mains operated instruments.

Interacoustics A/S only guarantees for the safety, reliability and function of the instrument, if: installation, extensions, modifications and repair are exclusively carried out by personnel authorized by Interacoustics A/S;

the room in which the equipment is installed complies with the country-specific regulation;

the installation site complies with the ambient conditions of the instrument;

the unit is used in accordance with the instruction manual after initiation in the operation;

The device is not conceived for operation in potentially explosive rooms or flammable atmospheres.

If fluid gets into the instrument, the instrument will have to be switched off at once. The fluid must immediately be removed by Interacoustics service technicians and the instrument tested for technical safety. Defective connectors and leads must immediately be replaced or repaired by a specialist or by personnel authorized by Interacoustics A/S.

3.2 Electrical safety

Protection Categories:

For the protection of patients and the operating staff, special, country-specific regulations for medically used rooms and electro-medical equipment have been issued.

According to these regulations, mains operated equipment must have reliably isolated live parts as well as an additional protection to prevent mains voltage from being passed onto unprotected parts.

The IEC 60601-1 has classified various protection categories.

Protection Category I, a protective measure with ground conductor, is primarily applied to electro-medical equipment.

Protection Category I includes equipment whose metal case may be live in the case of an error and which is connected to the ground conductor of the mains network via the ground contact. A circuit breaker will be trigged if the insulation fails.

Interacoustics equipment is in compliance with Protection Category I

Connection of equipment of type BF inside or outside medically utilized locations

Due to the increased safety requirements, medically applied instruments must not be connected via an extension flex or a multiple socket outlet.

The instrument must exclusively be connected via a wall socket with a ground contact!

Never connect the instrument to a power outlet before all panels and fittings have been securely mounted

Coupling of equipment to other systems

External equipment intended for connection to signal input, signal output or other connector, shall comply with relevant IEC standard (e.g. IEC 60950 for IT equipment and the IEC 60601 series for medical electrical equipment). In addition, all such combinations - systems - shall comply with the standard 60601-1-1, Safety requirements for medical electrical systems. Equipment not complying with IEC 60601 shall be kept outside patient environment, as defined in standard (at least 1.5 m from the patient).

Any person who connects external equipment to signal input, signal output or other connectors has formed a system and is therefore responsible for the system to comply with the requirements of IEC 60601-1-1. If in doubt, contact your service technician or local representative for help

Should any further information be required, please do not hesitate to contact your Interacoustics representative.

3.3 Ambient conditions

Interacoustics equipment has not been conceived for operation in medically utilized rooms with **potential explosion hazards**.

The equipment should not be installed in the vicinity of e.g. X-ray equipment, motors or transformers with high installed power rating, since electric or magnetic interferences may falsify the results of a measurement or even make measurements impossible.

Therefore, the instrument should not be installed in the vicinity of power lines.

If not otherwise stated in the shipping documents, Interacoustics equipment in the normal encased version has been conceived for operation under normal climatic ambient conditions.

Temperature:	+ 15°C/+59°F	…	+ 35° C/+95°F
Relative humidity:	30	…	90 %
Barometric pressure:	500	…	1060HPA

Thus, the units should be effectively protected against moisture. Ventilations lots should be kept unobstructed for maintaining circulation of air.

The instruments should generally be stored at temperatures between 0° to +50°C/+32° to 122°F.

3.4 Hygiene

Always be sure to pull the plug before cleaning or disinfecting mains operated instruments.

The instrument must be cleaned with a non-fuzzy, slightly moistened piece of cloth (please do not soak it!) Only use a mild alcoholic fluid as a disinfectant.

When cleaning the instrument, any moisture, like e.g. condensation water, must necessarily be prevented from getting inside!

Chemicals required for operation or care of the unit must always be stored, prepared and made available in specially labelled containers to prevent any mistakes.

3.5 Maintenance

Before switching on the instrument make sure that the mains cable, mains plug, socket and input at the instrument are in a perfect state. If the drive of the rotary chair becomes noisy the driving belts should be renewed. We recommend renewing the driving belts after five years.

The operator is responsible for the perfect state of the instrument. It is recommended by Interacoustics to have safety checks carried out at one-year intervals.

Immediate maintenance is required if:

the instrument was subjected to extreme mechanical stress (impact, defective cable due to inadmissible traction);
fluid gets into the instrument;
cables and/or connectors are defective;
rubber-joints have developed cracks.

For further details please contact your Interacoustics representative.

SYMBOLS ON INTERACOUSTICS COMPONENTS

Ground conductor connection

Unit of type B

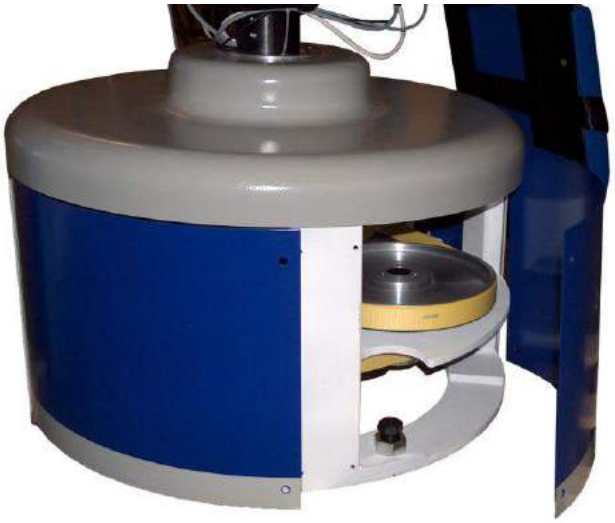
4 Installation

NOTICE

Never pull the backrest or the armrests to move the chair.
Before attempting to move the chair, the four side panels must be unscrewed to provide access to the frame. With the panels removed, the chair can be lifted and moved by the frame.

1. To get access to the frame, first loosen the resin cover. This is done by unscrewing the 4 hexagon screws holding the upper steel ring (use a 3.0 mm hexagon key):

2. Unscrew the curved side panels. Each panel is fixed with 4 screws. Use a 3.0 mm hexagon key to loosen the screws:



After removing all four curved panels, the bared frame can easily be gripped to lift and move the chair.

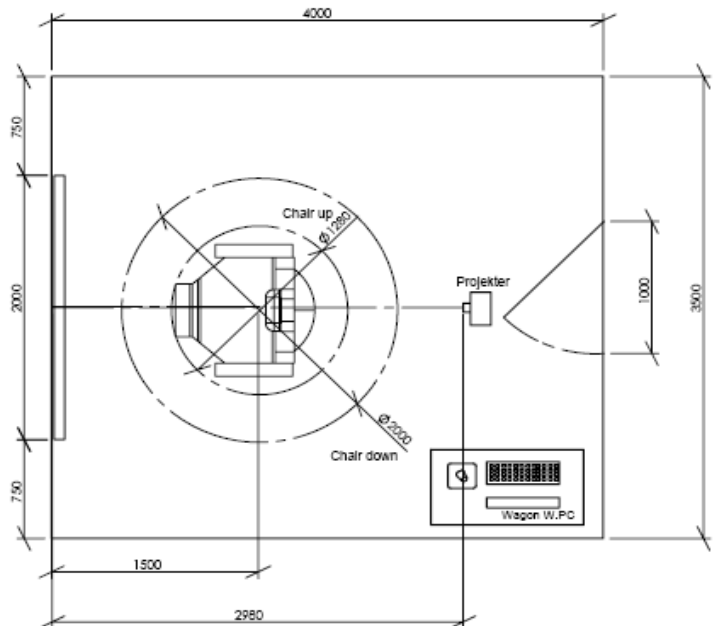
Once the instrument has been positioned in its final location, re-mount the side panels and the top cover, and secure with correct type of hexagon screws.

5 Putting the Unit into Operation

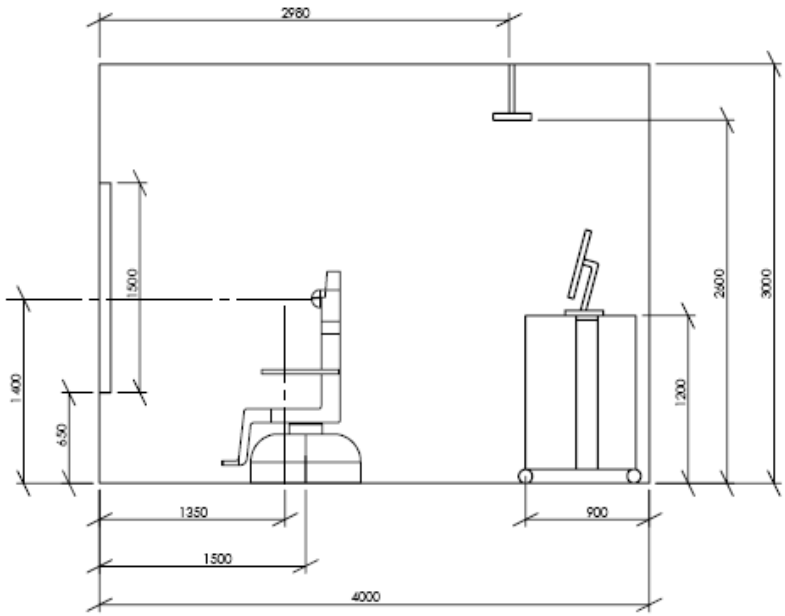
5.1 Examination Room Layout

The Rotary Chair may be installed using the following guidelines for room size and hardware installation:

Top view



Side view



5.2 Hardware installation

WARNING The rotary chair must be secured to the floor with 4 screws through the bottom rim of the base. Please use 14 mm dowels and 10 mm screws.

When orienting the chair in the examination room please observe that the default zero position of the chair is indicated by the exit point of the cables from the chair.

WARNING Never connect the instrument to the power outlet before the side panels and the top cover have been correctly refitted and secured.

Consult with the product specification plate on the unit for compliance between the unit's own data and those of the local power supply system (mains voltage and mains frequency) before connecting the unit.

NOTICE Connect only if all data agrees!

Inspect the mains connection cables for visible damage prior to establishing the connection. Damaged cables or plugs must immediately be replaced by Interacoustics service technicians, an authorized person or specialist.

Connection Panel

The backrest features a connection panel with purpose specific connections:

2 x 6-pM FireWire ports
1 x USB 2.0 port
1 x DC out (not active)

One or both of the 6-pM FireWire ports are used to connect the FireWire VNG cameras, depending on goggle configuration (one or two cameras). Illustration below shows a configuration with two cameras:

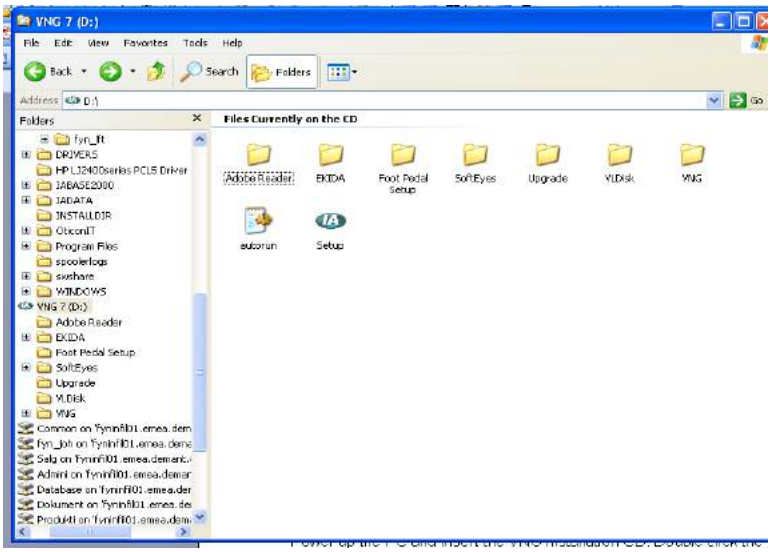
5.3 Software Installation

The VNG installation CD received with the VNG system holds the relevant software for the CanBus-to-USB adapter and the Rotary Chair Control software.

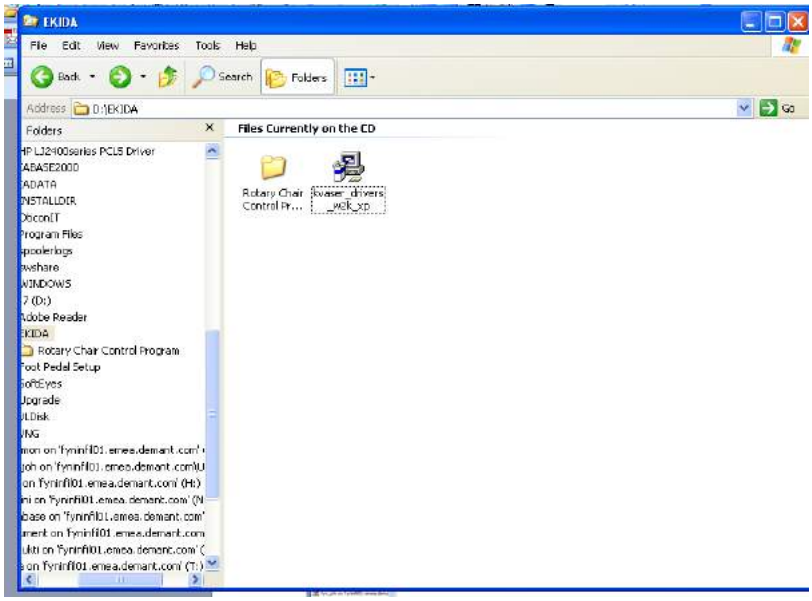
The Rotary Chair can be connected to any laptop or desktop PC with the following specifications:

- Intel Core 2 Duo processor 1.8 GHz or better
- Minimum 1 GB of RAM
- Laptop PC: One 34 mm PCExpressCard slot available
- Desktop PC: Texas Instruments chipset PCI FireWire® board with dual 6-pM ports
- Three USB ports available
- One VGA port available
- Monitor resolution 1024 x 768 or better
- WindowsXP™ Operating system

Power up the PC and insert the VNG 7.x installation CD. Double click the EKIDA folder to access the rotary chair installation programs.

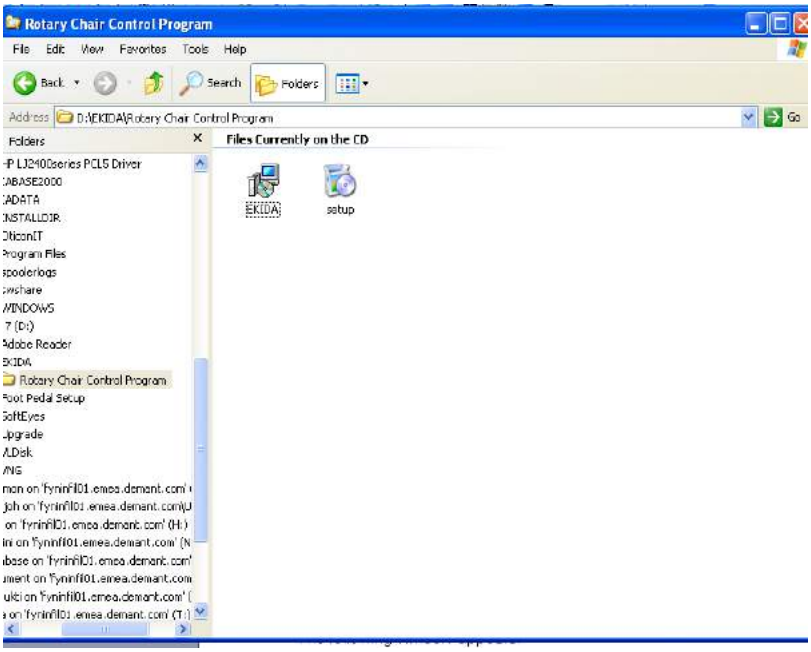


The following window appears:

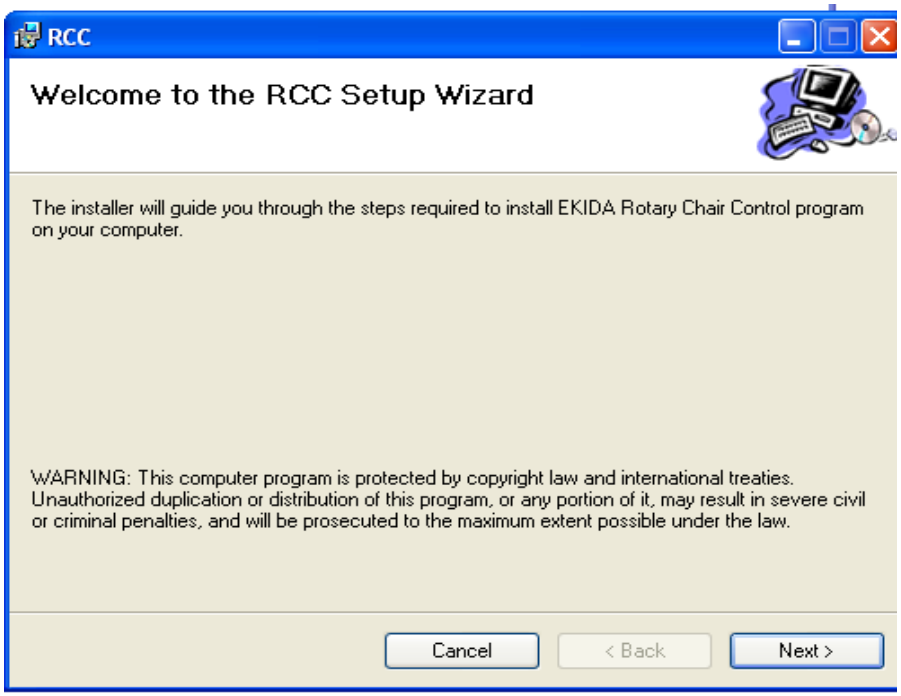


Double-click the Kvaser driver icon to install the can bus-to-USB driver.

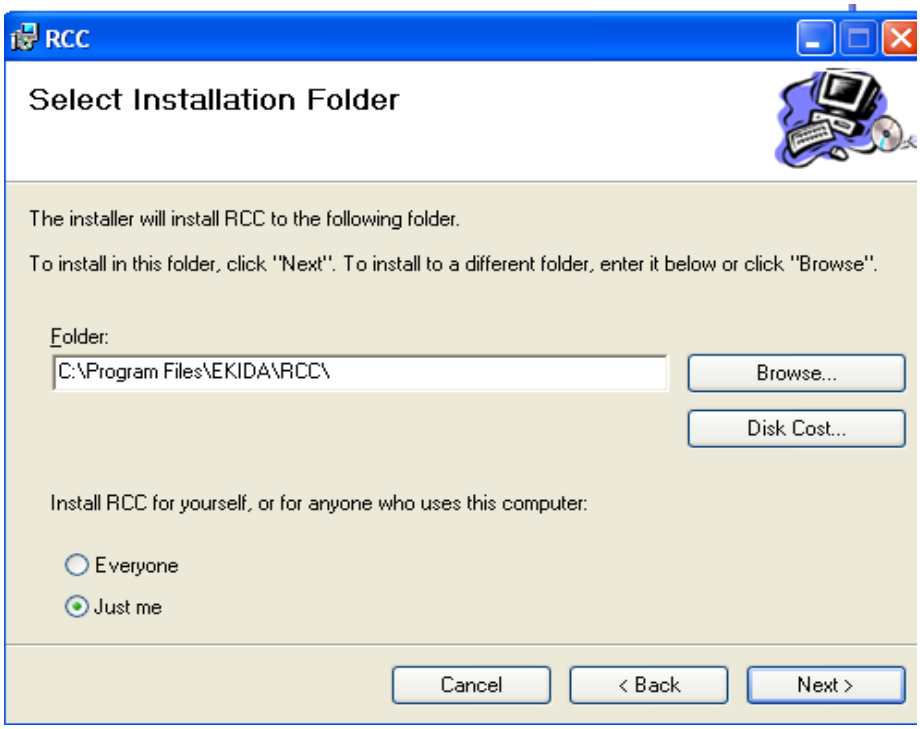
Next, double-click the Rotary Chair Control folder to access the EKIDA setup installer package:



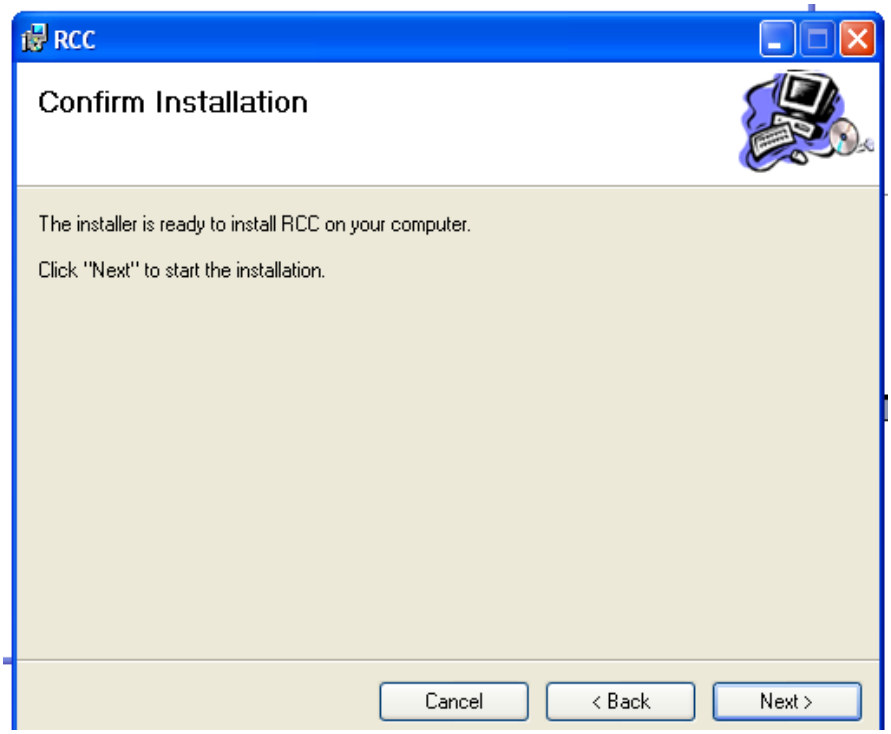
Double-click the EKIDA setup installer package icon - this will lead you to the RCC Setup Wizard:



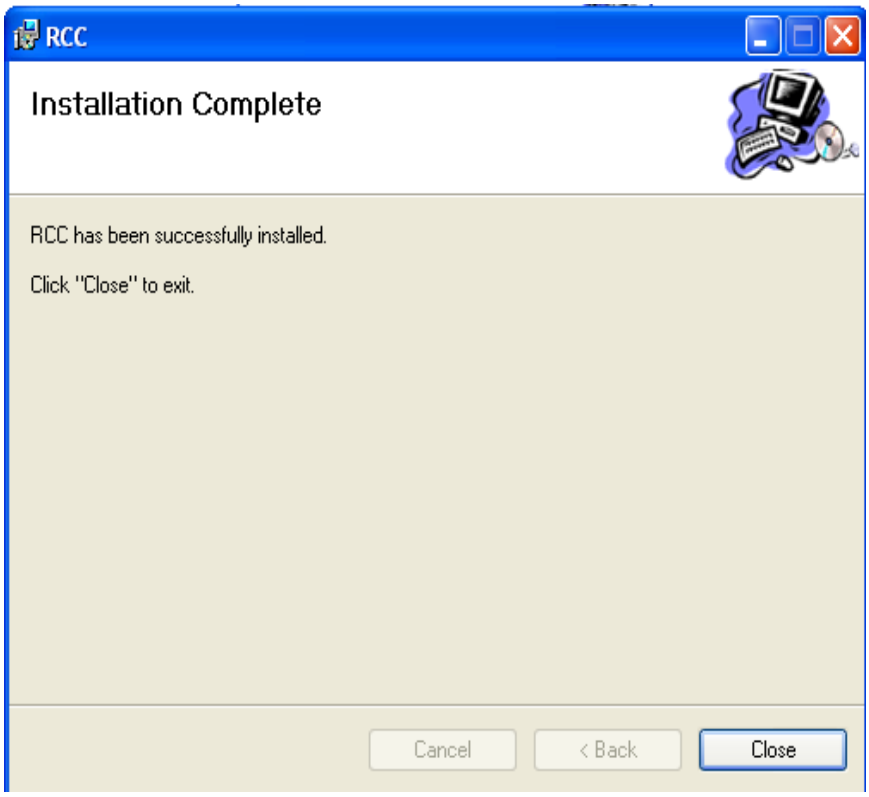
Click ‘Next’ to select installation folder:



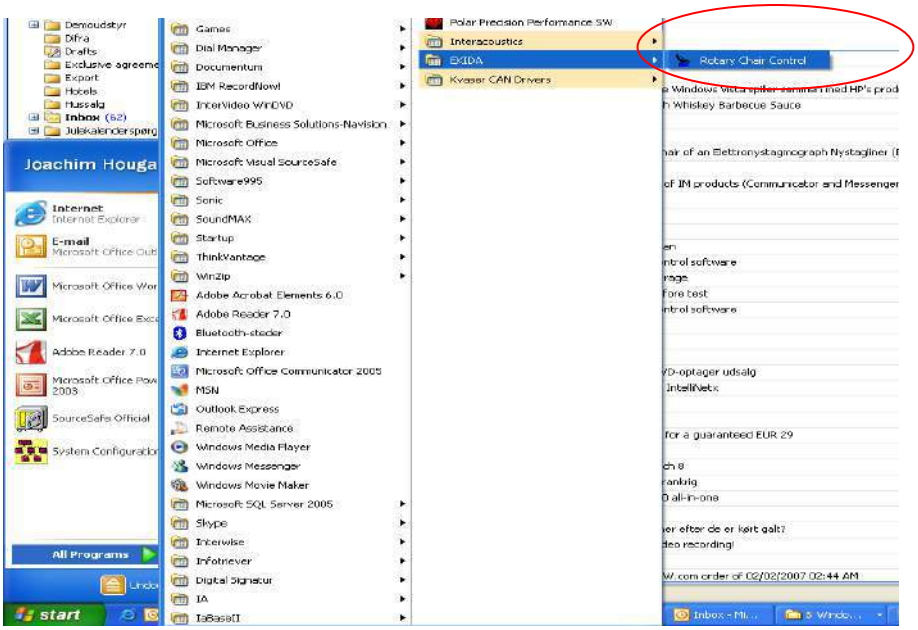
Again, click ‘Next’ - this time to confirm installation:



The software will be installed, and after a few seconds a message appears that the installation has been completed:



Click ‘Close’ to exit the installation program.



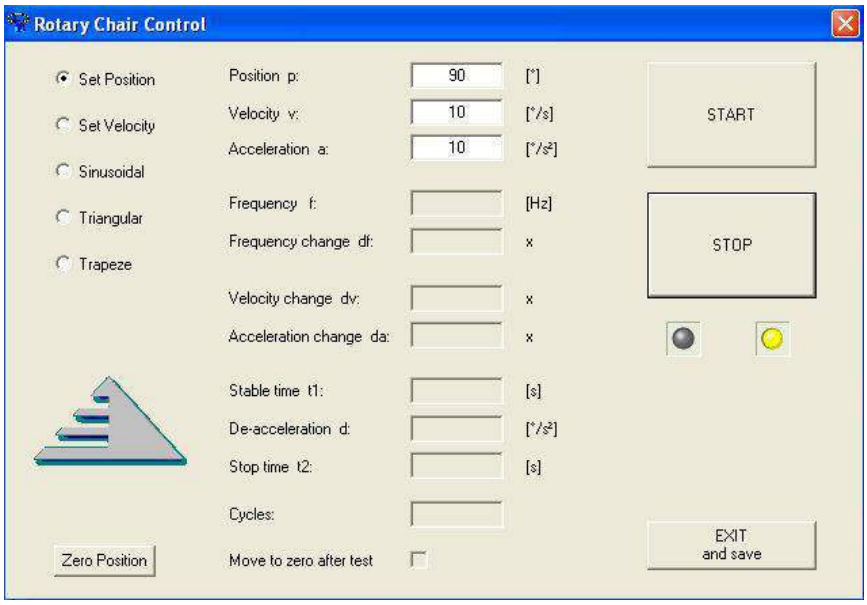
Right-click the Rotary Chair Control-bar and create a shortcut from your Desktop.

6 Operating Instruction

6.1 Starting the program

After switching on the power of the rotary chair, double-click the icon

on your Desktop. The following window appears.



Functions:

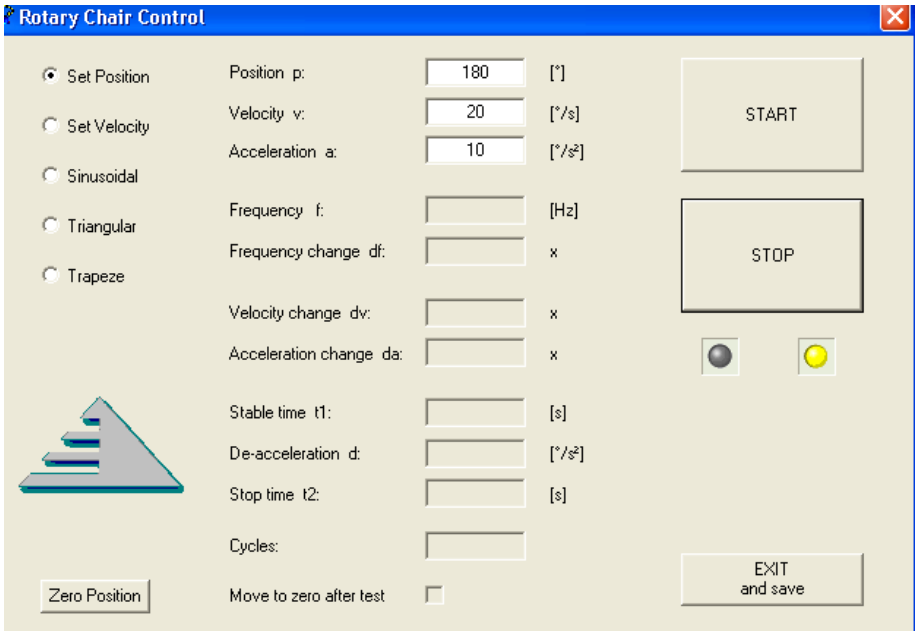
On the left hand side of the setup window you will find the five different modes of chair movements:

- Set position: Sets the chair to the angle defined in the setup
- Set velocity: Starts to move the chair to a certain velocity after pressing the start-button
- Sinusoidal: Sinusoidal smooth pursuit movement
- Triangular: Triangular smooth pursuit movement
- Trapeze: The chair velocity follows a trapeze pattern. This is used for velocity-step test and similar rotary tests.

1. Set Position Tab
2. Set Velocity Tab
3. Sinusoidal Tab
4. Triangular Tab
5. Trapeze Tab

6.2 Set position function

- In the **Set Position** mode the chair is moved to a pre-defined position; a default “Zero Position”. After a test the chair will move to this position.
- If the examiner wants to define a second “Zero Position” where the chair faces a screen or similar, this position is defined in relation to the default Zero Position.



- Overview:

The **Position p** can be set between -180° ... 180°. **Velocity v** sets the velocity of the movement. **Acceleration a** sets the acceleration until **Velocity v** is reached and the deceleration from **Velocity v** until the chair stops.

- Comments:
  a. After a test the chair returns to the default zero position which we define as zero degrees. As an example we now want the patient to face an object which is 180° to the right (a half cycle) of the zero position. The value ‘180’ is entered in the window, and the ‘Start’ button is activated. The chair must perform a rightward half cycle rotation.
  b. For leftward movements towards the second zero position simply add a ‘minus’ sign before the value, like in “-180°”
  c. Velocity: low values such as 20°/s produce slow movements, whereas high values such as 100 °/s produce fast movements.

- **Testing the Set Position Function:**
  - **Position – target of chair movement**
  - **Velocity – speed of rotation to the intended position**
  - **Acceleration – time to reach velocity**

First, press “Zero Position” button in the lower left corner of the Rotary Chair Control window.

1. **Position:** Enter a value such as 45, 90, 135 or similar in the ***Position p:*** box and press “Start”.
   Measure the number of degrees of movement – must equal the value entered in ***‘Position p:’*** box.

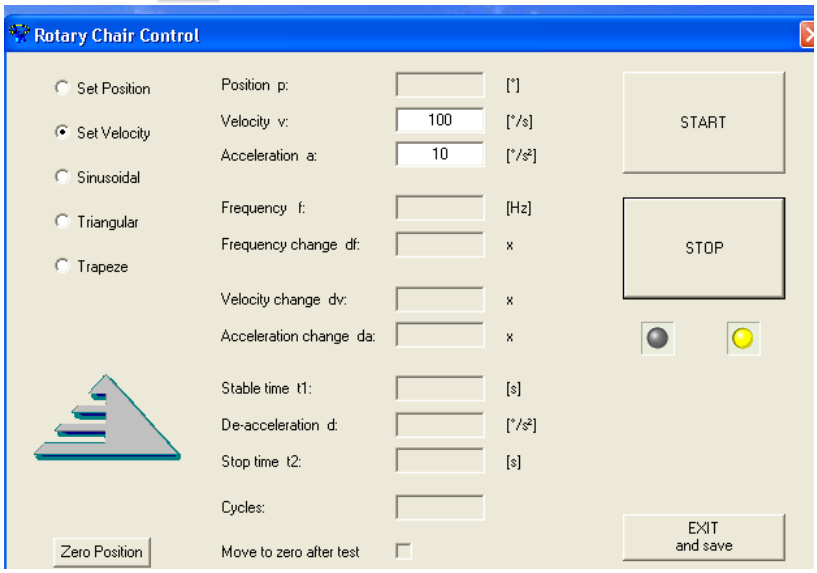
2. **Velocity:** Check that velocity changes with different values entered in the ***Velocity v:*** box – low values produce slow movements and high values produce fast movements.
   Enter the value ‘20’ in the ***‘Velocity v:’*** box and press “Start” button.
   Allow the chair to accelerate up to set velocity (approx. 2 seconds with acceleration set at 10°/s²) and measure the time consumed for a full circle. Should be 18 seconds at velocity of 20 °/s
   In order to obtain sufficiently long cycles it may be necessary to enter high values such as 720 in ***Position p:*** box – this will give at least 2 full circle rotations for measurement.

3. **Acceleration**: check that low values (such as 10°/s²) produce soft acceleration, whereas high values (such as 50°/s²) produce abrupt acceleration.
   Enter the following values:
   i. *Position* = *720*
   ii. Velocity = 100
   iii. Acceleration = 20
   Expected acceleration time is 5 seconds – check using a stop watch

Maximum acceleration is 100°/S² and must never exceed this value.

6.3 Set velocity function

- In the **Set Velocity** mode the chair is rotated at a constant, pre-defined velocity until it is stopped via the “Stop” button.
- Once the acceleration phase is completed the chair will have reached its target velocity which it will keep until the “Stop” button is activated.
- Relevant VO25 test protocol: Data from **Set Velocity** can be recorded and analyzed in the StepRotation test
- VNG toolbar icon: 



- Overview:

The **Velocity v** can be set between -200°/s ... 200°/s. If the velocity is negative, the chair moves anti-clockwise, while at positive velocity-values it moves clockwise. **Acceleration a** sets the acceleration until this velocity is reached and the deceleration from the **Velocity v** until the chair stops.

- Comments:
  1. A velocity of 90°/s means that the chair will do 1/4 or 0,25 full rotations per second – or take 4 seconds to do a full 360° cycle.
  2. An acceleration value of 10°/s² indicates an acceleration time of 9 seconds before the set velocity of 90°/s is reached

- **Testing the Set Velocity Function:**
  - **Velocity °/s – constant velocity**
  - **Acceleration °/s² – linear increase in velocity up to constant velocity**

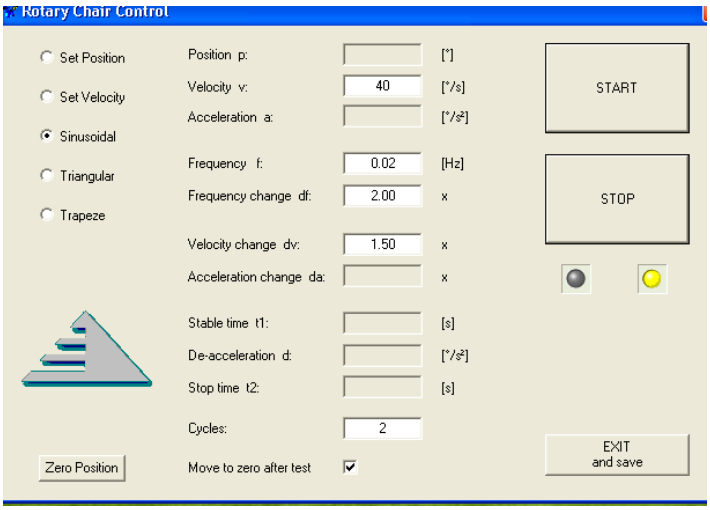
  1. A stopwatch is used to measure the velocity. Enter the value '90' in the ***Velocity v:*** box and press "Start". Allow the chair to accelerate to the set velocity and with the stopwatch, measure how long it takes for the chair to make a 360° cycle. At a constant speed of 90°/s it will take 4 seconds to do a full 360° cycle.
  2. Check that acceleration is fast with high values and moderate with low values

NOTICE

Maximum acceleration is 100°/S² and must never exceed this value.

6.4 Sinusoidal test function (smooth pursuit, SHAT)

- In the **Sinusoidal** mode the system performs the movement which is used in the Smooth Pursuit test and in the SHAT test. The Smooth Pursuit test requires sinusoidal or triangular movements at a pre-defined frequency and amplitude.
- Purpose of **Sinusoidal**: The chair will rotate in pendular movements to the left and to the right or vice versa. Either with constant amplitude or with diminishing amplitude.
- Stimulus: Acceleration up to peak velocity, followed by deceleration of similar proportions.
- Relevant VNG test protocol: Data from **Sinusoidal** can be recorded and analyzed in the SinusPendular test
- VNG Toolbar icon: 
-



Conversion of Frequency to Acceleration

In order to avoid exceeding the maximum acceleration performance during higher frequencies of Slow Harmonics Acceleration Testing, please refer to the following conversion table for observation of upper limits:

Frequency	Acceleration @ Peak Velocity 60º/s	Acceleration @ Peak Velocity 50º/s	Acceleration @ Peak Velocity 40º/s
Hz	º/s²	º/s²	º/s²
0.01	3.8	3.1	2.5
0.02	7.5	6.3	5.0
0.04	15.1	12.6	10.1
0.08	30.2	25.1	20.1
0.16	60.3	50.3	40.2
0.32	Not possible	100.5	80.4

SHAT test

For the SHAT test the frequency increases after each period. A commonly used procedure employs oscillation frequencies of 0.01, 0.02, 0.04, 0.08, 0.16 and 0.32 with peak angular velocities of 50º/sec at each frequency. The patient undergoes multiple cycles of oscillation at each frequency.

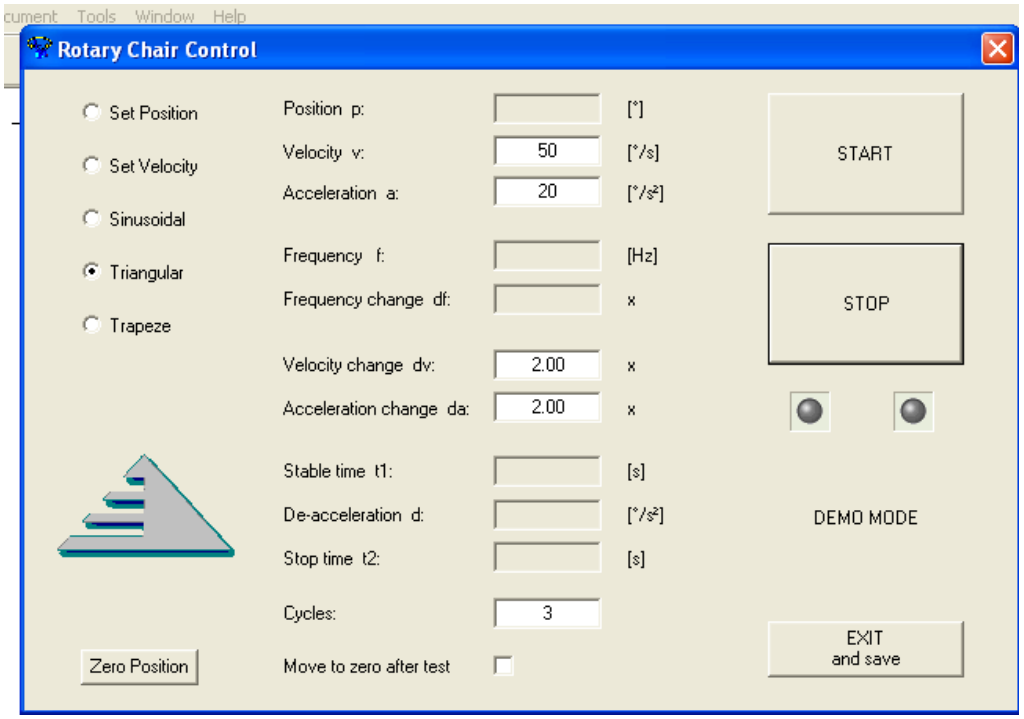
- **Testing the Sinusoidal Function:**
  - **Velocity °/s – peak angular velocity between turning points**
  - **Frequency Hz – duration of cycles between turning points/cycles**
  - **Frequency change – steady or changing period length for each cycle**
  - **Velocity change – steady or changing velocity for each cycle**
  - **Number of cycles**

The various parameters of the sinusoidal test are difficult to test objectively. Apart from the number of cycles that can be counted, only subjective assessment is possible:

1. Velocity: does the chair move faster with increasing values for velocity? Compare values 20°/s with 50°/s – with Frequency Hz, Frequency change df and Velocity Change dv = 1
2. Frequency: With velocity fixed at a given value, does the period length increase with decreasing values for Frequency Hz? Compare with values ‘0,10’ and ‘0,02’ in the ***Frequency Hz*** box and press “Start” – at ‘0.10’ the period should be shorter than at ‘0.02’
3. Frequency Change: values > 1 produce smaller cycles in terms of degrees rotated, whereas values < 1 produce longer cycles in terms of degrees rotated
4. Velocity Change dv: values >1 produce faster movements whereas values >1 produce slower movements
5. Cycles: check that the chair rotates the number of cycles ordered. One cycle is half the pendular movement; i.e. from zero, acceleration phase and then de-acceleration into zero again.

6.5 Triangular test

- The Smooth Pursuit and the SHAT test can also be performed with a triangular movement. During each slope of the movement the acceleration is maintained at a constant level until the maximum velocity is reached.
- Purpose of Triangular: Rotation from right to left and back, or vice versa.
- Stimulus: Acceleration up to peak velocity, then stop.
- Relevant VNG test protocol: Data from “Triangular” can be recorded and analyzed in the SinusPendular test 



The picture shows a SHAT-test with three **Cycles**. In the cycle the chair accelerates at 20°/s² until the final velocity of 50°/s is reached. Then it decelerates to zero at -20°/s². For the second period the parameters are multiplied by two according to **Velocity change dv** and **Accelaration change da**, i.e. maximum velocity is 100°/s and the acceleration is 40°/s².

- **Testing the Triangular Function:**
  - **Velocity °/s – peak velocity just before end of cycle**
  - **Acceleration °/s² – time to reach velocity**
  - **Acceleration change – steady or increasing/decreasing acceleration from cycle to cycle**
  - **Velocity change – steady or changing velocity from cycle to cycle**
  - **Number of cycles**

NOTICE

Maximum acceleration is 100°/S² and must never exceed this value.

Like in the sinusoidal test, the various parameters of the triangular test are difficult to test objectively. Apart from the number of cycles that can be counted, only subjective assessment is possible:

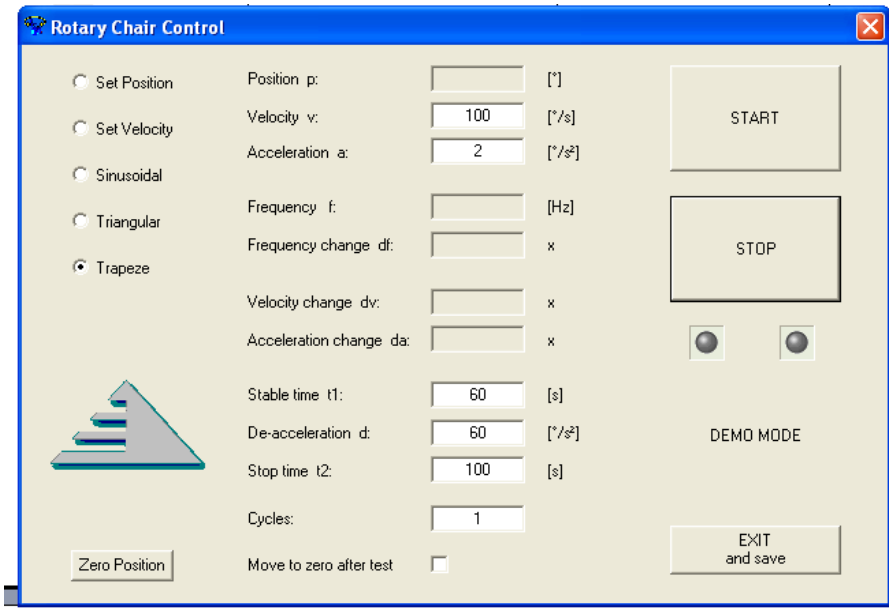
1. Velocity: does the chair move faster with increasing values for velocity? Compare values 20°/s with 60°/s – with Acceleration change and Velocity Change dv = 1
2. Acceleration: Check that low values (such as 10°/s²) produce soft acceleration and that high values (such as 50°/s²) produce abrupt acceleration.
3. Acceleration change: Does the chair accelerate faster from one cycle to another with values >1 entered in the acceleration change box?
4. Velocity Change dv: values >1 produce faster movements whereas values >1 produce slower movements
5. Cycles: check that the chair rotates the number of cycles ordered. One cycle is half the pendular movement; i.e. from zero, acceleration phase and then deceleration into zero again.

6.6 Trapeze test

(Also referred to as Step-Rotation test or Velocity-Step Test)

- Purpose of Trapeze Test: Measurement of perrotatory and postrotatory nystagmus response in terms of
  - Response ***Gain***, which is the ratio of peak eye velocity to head velocity
  - Response ***Time Constant***, which is the time, in seconds, for the response to decline to 37% of its peak value
- Stimulus: Acceleration up to peak velocity (typically 100 °/s) which is then kept for a certain period (typically 60 seconds) followed by de-acceleration - this is the Perrotatory Period.
  The postrotatory period which is a pause before next cycle is initiated.

Relevant VNG test protocol: Data from “Set Velocity” can be recorded and analyzed in the StepRotation test 



The figure above shows a typical velocity-step test setup. The chair accelerates slowly at 2°/s² until the final **Velocity v** of 100°/s is reached. This velocity is kept for 60 seconds with **Stable time t1** set at 60 – then the chair decelerates with 60°/s². The deceleration is the stimulus for the patient.

The eye movements are measured as soon as the stimulation has been terminated. During the measurement the chair should not be moving at all (= **Stop time t2**). After that, the chair can be moved manually by clicking the **Zero position** button, or automatically if the **Move to zero after test** box has been ticked.

- **Testing the Trapeze Function:**
  - **Velocity °/s – constant velocity during "stable time"**
  - **Acceleration °/s² – linear increase in velocity up to peak velocity**
  - **Stable time – period of constant velocity**
  - **De-acceleration – linear decrease in velocity before complete stop.**
  - **Stop time – pause before next cycle is initiated**

Maximum acceleration is 100°/S² and must never exceed this value.

1. Velocity: does the chair move faster with increasing values for velocity? Compare values 20°/s with 100°/s
2. Acceleration: Check that low values (such as 10°/s²) produce soft acceleration and that high values (such as 50°/s²) produce abrupt acceleration.
3. Stable time: Enter the value '50' in the ***Stable Time t1*** box and measure the duration of the Stable time period
4. De-acceleration: Does the chair de-accelerate faster from one cycle to another with values >1 entered in the acceleration change box?
5. Cycles: check that the chair performs the number of cycles ordered. One cycle is the combined duration of acceleration, stable time and de-acceleration.

After clicking the ok-button the program must be left pressing the **EXIT and save** button. The program now saves the parameters which have been used last.

7 Technical Specifications

Maximum speed	200 deg/s
Maximum acceleration	100 deg/s²
Maximum patient weight	135 kilos
Reclining backrest	manually operated from 0 deg (horizontal) to 90 deg (upright)
Emergency stop	emergency stop button disconnects the motor power
Patient alarm button	sends an alarm signal to the computer and turns off power to the motor
Weight	175 kg
Shipping weight	210 kg
Dimensions	90 cm x 70 cm x 160 cm
Shipping dimensions	100 cm x 120 cm x 190 cm
Power supply	110-230 V~ (50/60 Hz)/ 4A max

1.1.1 **Return Report** – Form 001

Opr. dato:	*af:*	*Rev. dato:*	*af:*	*Rev. nr.:*	
2003-02-24	EC	2003-02-24	EC	1	

Address
Drejervaenget 8
5610 Assens
Denmark

Phone
(+45) 63713555

Fax
(+45) 63713522

Company: _____

Address: _____

_____

Phone: _____

Fax: _____

Contact person: _____ Date : _____

Following item is reported to be:

☐ returned to INTERACOUSTICS for: ☐ repair, ☐ exchange, ☐ other: _____

☐ defective as described below with request of assistance

☐ repaired locally as described below

☐ showing general problems as described below

Item: Type: _____ Quantity: _____

Serial No.: _____ Supplied by: _____

Included parts: _____

_____

Description of problem or the performed local repair: _____

_____

_____

_____

_____

Returned according to agreement with: ☐ Interacoustics, ☐ Other : _____

Date : _____ Person : _____

☐ **The above mentioned item is reported to be dangerous to patient or user** [1]

In order to ensure instant and effective treatment of returned goods, it is important that this form is filled in and placed together with the item.
Please note that the goods must be carefully packed, preferably in original packing, in order to avoid damage during transport. (Packing material may be ordered from Interacoustics).

[6] EC Medical Device Directive rules require immediate report to be sent, if the device by malfunction deterioration of performance or characteristics and/or by inadequacy in labelling or instructions for use, has caused or could have caused death or serious deterioration of health to patient or user.