

# OCCIFLEX



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PARTNER FOR LIFE



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## INSTRUCTIONS FOR USE

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## 1 FOREWORD

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We greatly appreciate your purchase of the Occiflex, the first computerized treatment table to relieve chronic neck pain and headache. Our patented solution is based on proven physiotherapy principles and is:

- Safe
- Effective
- Non-invasive.

The Occiflex incorporates cutting-edge technologies and has the capability to perform both passive and active-assisted mobilization, supporting a therapist to accurately treat specific pain types.

Extra attention has been paid to reliability, safety, ease of use and durability.

*The Occiflex is not suitable for diagnostic purposes. Supplementary equipment must be used.  
The operation of the Occiflex may only be done by a qualified person (doctor/physiotherapist), capable of doing manual therapy.*

You have chosen wisely with your purchase of the Occiflex. We are sure that you will enjoy working with the device for many years to come. Should you have any further questions after reading this manual, please consult your supplier.

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## 2 GENERAL INSTRUCTIONS

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*It is **MANDATORY** that you read, understand, and observe the following precautionary and operating instructions carefully, before using your Occiflex.*



*Should the use of this device lead to an undesirable event such as death or serious injury to the user, the manufacturer and the competent authority of the Member State **MUST** be informed without delay!*

The following typographic conventions are used in this manual:

- *Italics* are used for text which appears in the display
- **Bold** is used to refer to menu options and the names of buttons

***Ensure that this manual is always available to all the relevant staff.***

When using the Occiflex, pay particular attention to the following:

1. You must acquaint yourself with the safety instructions (section 4) and contra-indications (section 7).
2. The device may not be used in the vicinity (i.e. at a distance of less than 2 metres) of a short-wave device.
3. The patient must always be in full view of the therapist.
4. The device may not be used in so-called “wet rooms” (hydrotherapy rooms).
5. Do not use the Occiflex outside.



Repairs not carried out by service technicians authorised by Enraf-Nonius and/or the use of non-original (spare) parts and/or ancillary materials will cause the guarantee to lapse and may even be hazardous.

The manufacturer will not be held responsible for

- the results of maintenance or repairs by unauthorized persons.
- the consequences of the use of the device other than as described in this manual.

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### 3 SAFETY INSTRUCTIONS AND PRECAUTIONS

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The safe implementation of the procedures described requires sufficient knowledge of the human locomotor system and physiology, alongside technical experience, and knowledge of the safety precautions.

The terms **WARNING**, **CAUTION** and **PLEASE NOTE** are used in this manual to bring important issues to the attention of the reader.



**WARNING!** means danger to the user or the technician.



**CAUTION!** Means an action which may damage the device.

**PLEASE NOTE** indicates a statement which deserves more attention than the general text, but which does not signify the danger implicit in **WARNING** or **CAUTION**.

The order in which the steps of a procedure are carried out is important for the safe operation of the device and for preventing injury or harm. It is therefore important not to change the specified order in which the steps of a procedure are carried out.

#### LEGAL ASPECTS

This manual and the information contained therein are the property of Enraf-Nonius B.V. (Rotterdam, the Netherlands).



Enraf-Nonius cannot be held liable for personal injury or damage to equipment caused by ignoring or failing to comply with actions such as those marked **WARNING** or **CAUTION**, for example.

- Any deviation from the procedures described.
- The performance of actions which are not described in this manual.
- Ignorance of general safety precautions which apply when working with equipment and electricity.
- The use of the equipment other than as described in this manual.



## **WARNING!**

### **General**


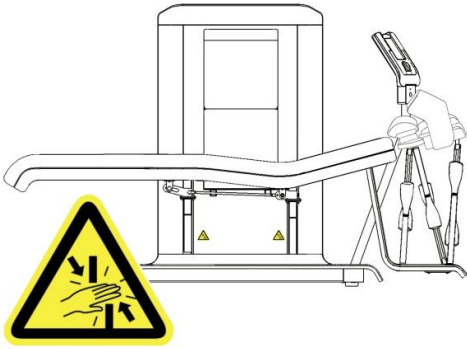

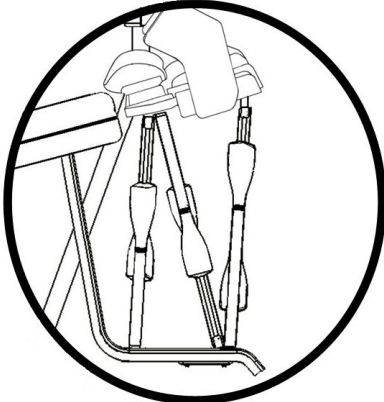

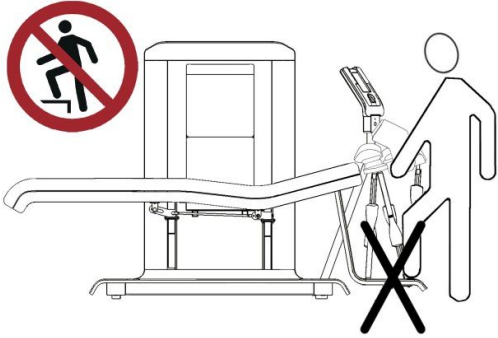
- The operator must be medically trained in manual therapy. Enraf-Nonius cannot be held responsible for the erroneous execution of manual therapy which may lead to injuries to the patient
- The operator must be familiar with the equipment and this user manual
- Misapplication of the operating instructions may lead to injuries to the patient
- Do not treat patients with absolute contra - indications
- Do not remove any housing parts. Service must be performed by the manufacturer or an authorized service technician.
- If the patient has long hair, the practitioner must provide a hairnet to the patient in order to prevent the hair from getting trapped between the moving parts of the hexapod.
- The maximum permitted patient weight on the couch is 200 kg.
- Maintain your Occiflex in accordance with the stated guidelines (see section 11).
- Always remain at a sufficient distance from a device.
- The Occiflex is subject to special EMC regulations and must be installed and maintained in accordance with the EMC information as specified elsewhere in this user manual (see section 13, technical specifications).
- Portable and mobile radio-frequency devices may affect your Occiflex.
- Your Occiflex may not be used in the immediate vicinity of other equipment. Should this nonetheless prove necessary, the proper functioning of the device must be demonstrable and evident.
- The device must not be installed near a source of heat such as a radiator. Exposure to direct sunlight, excessive dust, moisture, vibrations, and impacts must be avoided.
- The Occiflex computer with Occilink software is a dedicated system. No other software should be installed on this PC. This PC should also not be connected to the internet (see section 5)

### **WARNINGS with regards to the CROM tests, recording and therapy.**

Before performing a CROM test, recording or therapy under paramedical training supervision, a number of important conditions must be met. These Conditions are:

- The participant must receive clear information about the test, recording or therapy. The caregiver states the purpose, how long it is going to take, what is going to happen and what is expected of the person concerned.
- There must be sufficient attention to the standardisation of the environmental conditions; temperature (5 - 30 °C), humidity (10 - 90%) and atmospheric pressure: 500 - 1060 hPa.
- The device may not be used in surroundings where physical agents like draft and sound (especially high frequency sounds [i.e. construction sounds like hammering and drilling, ultrasound sources from burglary prevention systems, etc) are manifest. These agents might interfere with the Occiflex measurement sensors and will cause the recording to be inaccurate!
- The caregiver must be adequately trained in field of manual therapy.

- The equipment used must be well maintained and calibrated to obtain reliable measurements.
- The patient must at all times be able to interrupt the test, recoding or therapy.
- The patient is instructed to remove jewelleries(like earrings and necklaces) as it can become hazardous during the movement recording or playback.

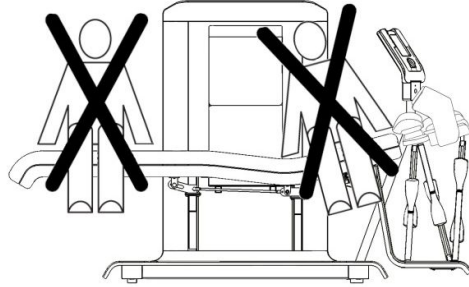
<ul style="list-style-type: none"> <li>• Height adjustment and inclination of the bed.</li> </ul>  <p>Ensure that neither the patient nor the operator can get any part of the body or clothes near or in between the moving parts of the mechanism when the couch is being raised, lowered, or inclined.</p> <p>Be particularly careful for the hands to get trapped in the openings indicated below the couch.</p>	
<ul style="list-style-type: none"> <li>• Moving parts of the hexapod.</li> </ul>  <p>Ensure that neither the patient nor the operator can get any part of the body or clothes trapped into the moving motors and spindles of the motors of the hexapod during therapy.</p>	
<ul style="list-style-type: none"> <li>• <b>CAUTION</b> for damaging the hexapod</li> </ul>  <p>Do not step on the hexapod support.</p>	



- Danger of tilting



We advise against sitting on the back and leg section of the couch.



### CAUTION

The device is mains-powered. Only use parts supplied or recommended by Enraf-Nonius. An incorrect supply voltage may damage the device or lead to increased emissions from or reduced immunity for the Occiflex. Damage may result if this instruction is not followed.

### PLEASE NOTE

- During therapy, the patient is able to stop the therapy with the patient stop.
- In case a technical error occurs please contact your supplier or Enraf-Nonius B.V. (Rotterdam, the Netherlands). Repairs and installations may only be carried out by a service technician who has been authorised by Enraf-Nonius.
- Repairs not carried out by service technicians authorised by Enraf-Nonius and/or the use of non-original (spare) parts and/or ancillary materials will cause the guarantee to lapse.

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## 4 PACKAGE CONTENTS

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1660.901	Occiflex
1660.757	CD-ROM with Instructions for Use.
1660.759	Information booklet
1660.801	Foot switch
1660.802	PC with Occilink (including widescreen monitor, keyboard, mouse and cables)
1471.800	Patient Stop Switch
3444.290	Power cord
2570.249	CAT6 FTP cable
0660101	Calibration Plate Assembly Headstrap



### **CAUTION**

Use of accessories, transducers 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

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## 5 INSTALLATION

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### GENERAL

- Installation can only be done under supervision of Enraf-Nonius authorised personnel. For installation details refer to the information Sheet Unpacking and Installation Occiflex (0167345), which is on the outside of the packaging.
- Install the device with at least 2 persons.
- Check the entire unit for possible damage caused during transit.
- Place the Occiflex on a level, hard surface. If a soft surface cannot be avoided, measures must be taken to prevent the device from wobbling during use.
- The device must be set up in a place where no liquids can enter. Should any liquids nonetheless penetrate into the housing, unplug the device from the electrical socket (where applicable). Have the device checked by an authorised expert.
- Do not set up the device near a source of heat such as a radiator.
- The use of the device must not be obstructed by other objects. Keep a distance of at least 1 m free around the appliance.
- Avoid exposure to direct sunlight, excessive dust, moisture, vibrations, and impacts.
- The device may not be used in so-called “wet rooms” (hydrotherapy rooms).
- The device may not be used in surroundings where physical agents like draft and sound (especially high frequency sounds [i.e. construction sounds like hammering and drilling, ultrasound sources from burglary prevention systems, etc) are manifest. These agents might interfere with the Occiflex measurement sensors and will cause the recording to be inaccurate!
- Always use original accessories and parts stipulated by the manufacturer for this device.

### OCCIFLEX

The installation requirements for the Occiflex are as follows:

Accessibility of the space:

- Doors at least 90 cm wide
- Preferably no stairs
- An earthed plug sockets. This product **must** be earthed. If the Occiflex is not working properly or breaks down, the earth forms the path of least resistance for the current and reduces the risk of electric shock. This product has an earthed electrical cable and an earthed plug. The plug must be inserted into the correct type of socket which is properly earthed, installed in accordance with local rules and regulations.

### THE OCCILINK COMPUTER

In order to use the Occiflex treatment table, a computer is delivered on which the Occilink software programme is pre-installed. A smart-card reader is required in order to read and write to the smart cards. You will need a printer in order to print out documents (reports).



#### **WARNING!**

Occilink IS NOT ALLOWED to be connected to the internet. Auto updates of Windows, software background tasking or malware could impose a serious safety issue and is therefore forbidden

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## Installing the computer system

The Occiflex is delivered with a dedicated computer system.

The computer is connected with the Occiflex by means of an RJ45 network cable.



You are NOT allowed to

- Connect the computer to the internet.
- Install any other software on the dedicated Occiflex computer. By installing software on the Occiflex computer you jeopardise the safety of you patients!

## CONNECTING THE DEVICE

- The incoming electrical supply must meet the local requirements for rooms used for medical purposes.
- First check that the mains voltage and frequency, as stated on the data plate, correspond to those of the mains supply.
- We advise 1 separate mains group per device.

Connecting the mains cable:

- First check that the mains voltage and frequency, as stated on the data plate, correspond to those of the mains supply of the computer and screen.
- Connect the computer to the Occiflex with the RJ45 cable.

## POWER UP AND SELF-TEST

- Switch on the device using the on/Off switch (figure 2, P12).
- When it is switched on, the device will perform a self-test.

Check that the **LCD screen illuminates** and that a bleep is audible at the end of the test.

Contact your supplier if this is not the case.

## SYSTEM SETTINGS

The factory setting for the instructions displayed in the information screen is English.

All the display values are set to SI units (metric) in the factory. The units and/or language can be modified by changing the default settings in the system menu (see section 9).

## ELECTROMAGNETIC INTERFERENCE



Electromagnetic interference could degrade the accuracy of the device described in the technical specifications.

- If the Occiflex is used in the immediate vicinity (i.e. at a distance of 2 metres or less) of short-wave equipment which is in operation, instability of the information in the operating console of the Occiflex may occur.
- In order to avoid electromagnetic influence, we would advise connecting the Occiflex and the short-wave equipment to different mains supply groups.
- Ensure that the mains cable of the short-wave equipment does not pass near the Occiflex or the patient.

In the case of persistent disturbance caused by electromagnetic interference, contact your supplier.

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## AFTER INSTALLATION



Once the Occiflex is installed and operational the system **may NOT be changed** by anyone without written authorization of Enraf-Nonius. This implies:

- No hardware modifications are allowed
- No software updates are allowed
- No additional software is allowed on the Occilink PC
- No operating system updates are allowed on the Occilink PC

## RELOCATION

When relocating, the device must be disconnected from mains.

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## 6 INTENDED USE AND INTENDED USER

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The Occiflex is a medical device intended to support the patients head while the device is copying the 3D movements with the head that have been taught by the supervising medical professional (user). With the Occiflex, the therapist is also able to monitor the neck and head pain experienced by the patient and the progression of the Range of Motion of the neck of the patient.

The Occiflex can be used for pain management (neck pain and headache), muscle relaxation, and range of motion and flexibility of the neck of the patient.

The device can be combined with other therapeutic modalities such as neck exercises, trigger point injections, biofeedback and psychotherapy to accomplish better pain control for patients suffering from head and neck pain.

The Occiflex is a prescription device and is intended to be used, and shall **ONLY** be used by or under the supervision of professional users in the field of physical medicine and rehabilitation.

**PLEASE NOTE:** The Occiflex is not suitable for diagnostic purposes.

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## 7 INDICATIONS AND CONTRA INDICATIONS

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The section describes the indications and contra-indications for the treatment with the Occiflex.

### INDICATIONS FOR TREATMENT WITH THE OCCIFLEX

There are numerous studies proving or indicating a positive effect of Manual Mobilisation / Therapy as performed by the Occiflex on pain, muscle relaxation, range of motion and flexibility of the neck.

The Occiflex can be used for the support of movements that will help with:

- Neck pain reduction (including post-whiplash, mechanical, idiopathic, cervicogenic)
- Increased range of motion
- Reduced disability, improved posture, and muscle function

### ABSOLUTE CONTRA-INDICATIONS

Absolute contra-indication means that a test, recording or therapy cannot be performed responsibly.

- Bone tumors (e.g. metastatic)
- Infections (e.g. tuberculosis)
- Bone loss (e.g. osteomalacia)
- Congenital abnormalities (e.g. dysplasia)
- Iatrogenic disorders (e.g. prolonged use of corticosteroids)
- Inflammation (e.g. severe rheumatoid arthritis)
- Trauma (e.g., fractures)
- Neurological: compression of the spinal cord or the cauda equina
- Nerve root compression with increasing neurological deficit
- Vascular: aortic aneurysm; intra-articular hemorrhage
- The patient does not consent to the treatment
- The patient, the starting position can which is required for the treatment is not taken in by the pain or resistance.

### RELATIVE CONTRA INDICATIONS

A relative contra-indication means that possible complications may occur. The advantages must outweigh the risks.

- Negative reaction to previous manual therapy;
- Herniated nucleus pulposus (HNP) (with radicular syndrome)
- Atherogenic inflammation;
- Spondylolysis;
- Spondylolisthesis;
- Spondylodese
- Pregnancy;
- Osteoporosis;
- Use of anticoagulants or prolonged use of corticosteroids;
- Substantial degeneration of the joint or spondylosis;
- Psychological dependence on manual therapy;
- Ligamentous laxity

## 8 OPERATION (GENERAL)

This section summarises the various components and controls. It explains the functional buttons and different information screens.

### CONTROLS / COMPONENTS

#### Most important features

- [1] Occilink application PC
- [2] Height adjustable couch
- [3] D-sense panel
- [4] Touch screen control panel
- [5] Head Strap with sensor
- [6] Cradle (head and neck support)
- [7] Hexapod (3D movement)
- [8] Foot pedal switch
- [9] Patient Stop

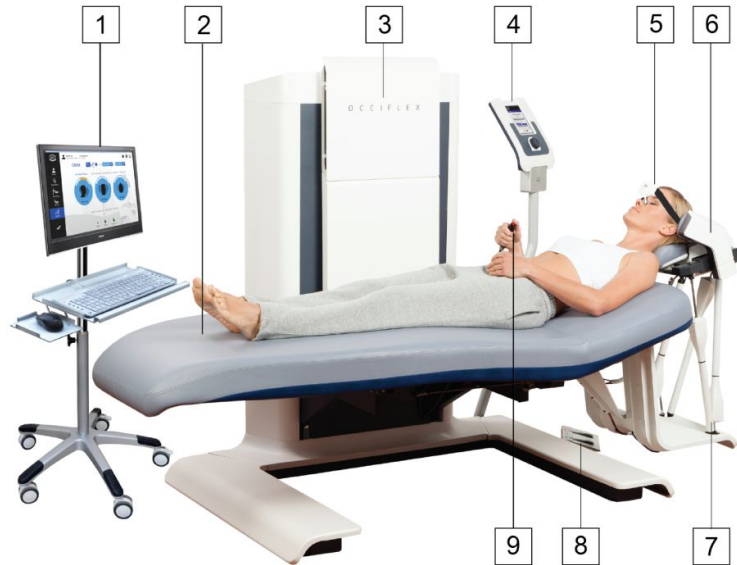


fig. 1

#### Backside

- [1] Connection for 230V mains cable and fuse holder
- [2] On/off switch
- [3] Footswitch connector
- [4] Reference label
- [5] RJ45 Connector to connect Occilink.



fig. 2

#### Control panel

- [1] LCD-information, touchscreen
- [2] Central controller (rotary knob)
- [3] Slot for USB Stick
- [4] Rotary support



fig. 3



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## APPLICATION AND TOUCH SCREEN CONTROL PANEL

The Occiflex has two different operating interfaces,

1. a computer with a screen, keyboard, and mouse (see fig. 1 item [1]), with the Occilink application.
2. a touch screen control panel on the treatment table itself for the operation of the bed and the hexapod (see fig. 1 item [4] and fig 3.).

The Occilink application enables you to store and recall data and displays recordings and measurements.

The therapy data can be sent from the Occilink application to the Occiflex.



Be sure that the touch screen control panel is in the “Home screen” when the data is sent to the Occiflex.

The occiflex can also be operated from the touch screen control panel itself (without input from the Occilink application).

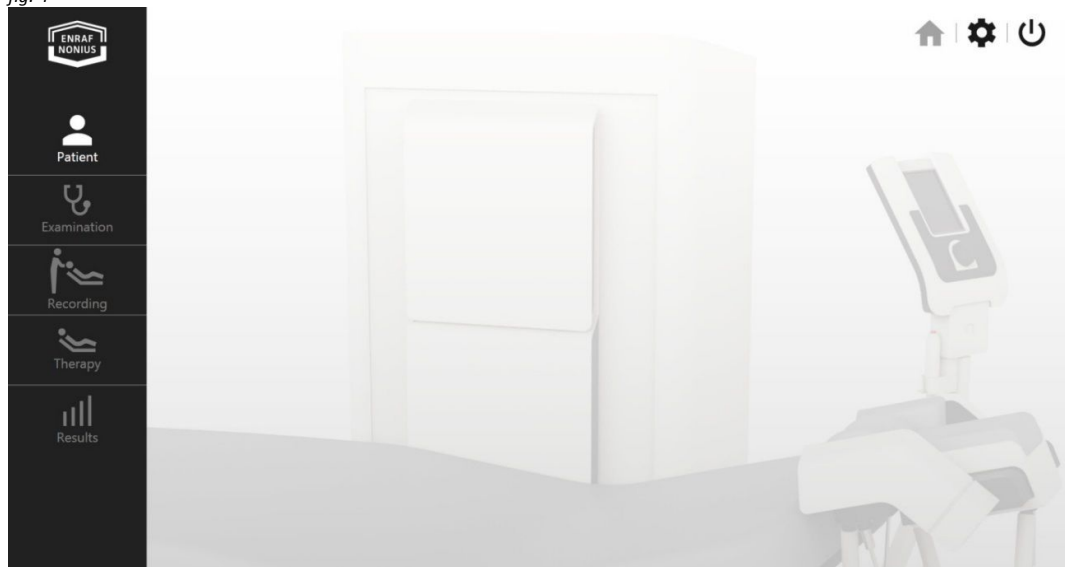
Much attention has been paid to a user-friendly operation of the Occiflex. Clear screens, understandable symbols, and supportive use of color contributes to the intuitive use of the device. When a mouse pointer moves over the buttons, they light up and give access to the underlying screens providing fast and convenient navigation.

### Occilink application

With the Occilink application on the computer, patient data can be created and managed, and progress of treatment is captured. Reports can be generated in pdf -format.

The application consists of a navigation bar, an editable field and three buttons "Home, Settings and Quit" (fig. 4).

fig. 4



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When the mouse pointer moves over the navigation bar, the main control functions are highlighted and provide access to the underlying screens. This way of navigating is fast and convenient.

See Section 10 for a detailed explanation of the Occilink application.

### The Occiflex touch screen control panel

The Occiflex touch screen control panel is a color touch screen display that is rotatable mounted on an arm on the frame of the treatment bed and can therefore be read out from a variety of user positions. The panel is used to edit the bed- and hexapos settings and to provide visual feedback during various stages of use.






The control panel can be used for the “Quick Start”, see chapter 9 for more information.

## FLOWCHART BASIC OPERATION

### Operation via the Occilink application

See section 10 Operation with the "Occilink application"





<b>Intake</b>	<b>Patient data</b>  Patient	Enter patient related data <ul style="list-style-type: none"> <li>• Enter name, id</li> <li>• Enter indication</li> </ul>
	<b>Examination</b>  Examination	CROM measurement <ul style="list-style-type: none"> <li>• Define movement(s)</li> <li>• Send to Occiflex</li> <li>• Perform test on Occiflex</li> <li>• Send results back to occiflex</li> </ul> NDI questionnaire HIT6 questionnaire NRS
<b>Recording</b>	 Recording	Record a movement <ul style="list-style-type: none"> <li>• Define therapy movement(s)</li> <li>• Send to Occiflex</li> <li>• Record the movement(s) on Occiflex</li> <li>• Send results back to occiflex</li> <li>• Now proceed to the "Record" step in the touch screen panel</li> </ul>
<b>Therapy</b>	 Therapy	Create a therapy <ul style="list-style-type: none"> <li>• Select a recorded movement</li> <li>• Enter variables (velocity, cycles, time etc.)</li> <li>• Send to Occiflex</li> <li>• Execute therapy (proceed to the "Record" step in the touch screen panel)</li> </ul>
<b>Results</b>	 Results	View results and report <ul style="list-style-type: none"> <li>• Select one of the Examinations (CROM, NDI, HIT6, NRS)</li> <li>• View examination results</li> <li>• Export examination results</li> </ul>

### Operation via the touch screen control panel

See section 9 Operation "Quick Start"



<b>Record</b>	<ul style="list-style-type: none"> <li>• Position the patient on the Occiflex</li> <li>• Place the Head Strap</li> <li>• NOTE: the head strap should be in line with the Occiflex couch (see fig 8A)</li> <li>• Open the D-sence</li> <li>• Close the cradle for a 0-measurement</li> <li>• Once done, open the cradle again</li> <li>• Continue by "Start recording" - the hexapod moves sideways</li> <li>• Do the movement.</li> <li>• NOTE - start- and end-position should match</li> <li>• End recording - the hexapod moves into parking position again</li> </ul> <p>In case the recording was part of a treatment with the Occilink application (either "Record a movement"  or "Create a therapy" , see left column on this page) you can send the data back to Occilink in order to proceed.</p>
<b>Play back</b>	<ul style="list-style-type: none"> <li>• On the touch screen control panel continue from the recording to therapy</li> <li>• Once started you can change the duration and/or the velocity</li> </ul>

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## RECORDING AND PLAY BACK

The „recording“ on the Occiflex is the proceeding where the movement, performed by the therapist, is measured by the system. The recording uses the movement sensor on the headstrap. This sensor communicates with the D-sense plate in order to measure the movement trajectory in all directions and around all axes.



*Head strap sensor and D-sense plate communicating during a recording*

The recording can be used for

1. Measurement of the Range Of Motion
2. Movement recording for therapeutical play-back

### **Ad 1 Measurement of the Range Of Motion (ROM)**

For evaluation purposes it is possible to measure the Range Of Motion (ROM) with the Occiflex. This measurement can be done via the Occilink application and can be compared with previous measurements and/or with a normative database. A ROM measurement allows for free movement in space with no boundaries or limitations. The data gathered during a ROM measurement are not used for play-back. Further details about ROM measurement are described in 10.3 Examination

### **Ad 2 Movement recording for therapeutical play-back**

A movement recording for therapeutical play-back is a recording that will be used for therapeutical playback by the hexapod. This recording can be stored in the Occilink application (for re-use later) or it can be done on the Occiflex unit itself – allowing you to immediatly replay the movement, but restricting it only to one session.

A movement recording for therapeutical play-back therefor has to limit it's range to the maximum trajectory that can be executed by the hexapod in the therapy (or play-back) phase. In case you exceed this permissable range during your recording a "Range Check Error !" message is displayed. Please repeat the movement recording in that case and limit the range.



*Example for the difference between a ROM measurement (1) and a therapy recording (2)*

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## 9 OPERATION "QUICK START"

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In this chapter, we take you step by step through the operation of the Occiflex system by means of the touch screen control panel. The user actions of the "Quick Start" will be explained in this chapter. In chapter 10 the operation by means of the Occilink application (via the computer) will be explained.

The "Quick Start" allows you to quickly create a therapy without the need of preparation on the Occilink computer. Simply record and play. The function is in particular suitable to try out a movement and to get familiar with the system.

Note: **NO** recording will be saved.

***We recommend to begin using the Occiflex with the "Quick Start" so that you will learn the system quickly and easily.***

### QUICK START RECORDING

Invite your patient to take place in the middle of the couch (fig. 5, 7).

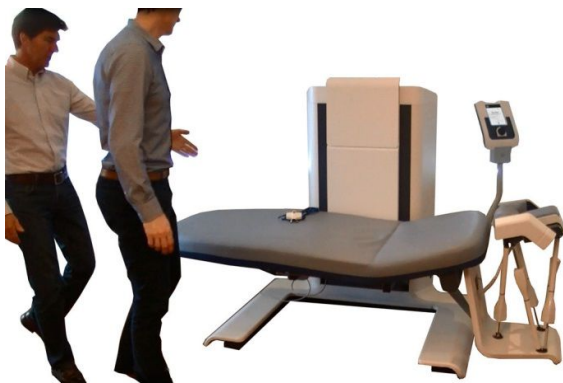


Fig. 5



Fig. 6 The Head Strap that records the positions and the angles of the head movements

- Place the Head Strap on the forehead of your patient and is cantered in the middle of the head (fig. 7).
- Accompany your patient to the supine position. Make sure that the Head Strap aligns with the Occiflex bed (fig. 8A) and that the shoulders are equalled to the top section of the bed (fig. 8B).



Fig. 7

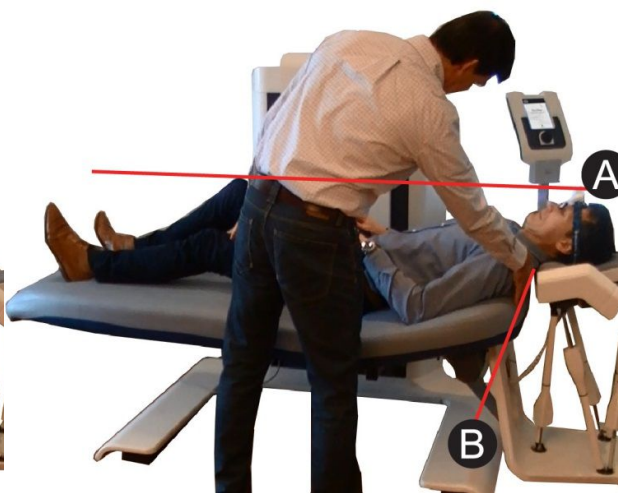


Fig. 8

- Open the “D-sense” panel completely (fig. 9, 10) in order to do a recording. If the panel is closed, an error message will appear.  
When the panel is opened completely and the Head Strap is positioned correct, the recording of 3D movements can start.
- Stand behind the rotatable touch screen control panel and set the desired parameters. At the same time, you can check the neck and the head position of your patient (fig. 10).



Fig. 9



Fig. 10



On the control panel, the “**Quick Start**” screen is visible (fig. 11).

- Press “*Quick Start*” (fig. 12).



Fig. 11

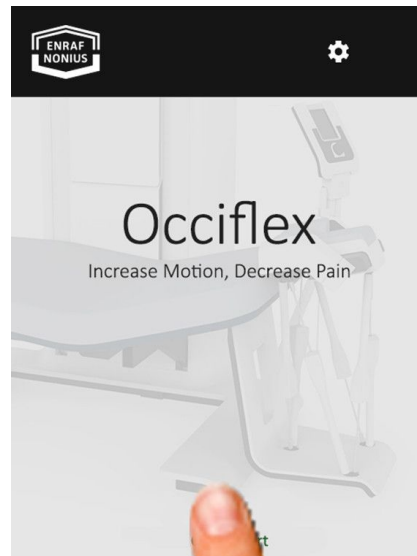


Fig. 12

The setting menu of the bed and the head support (cradle) appears in the screen “**Record**” (fig. 13).

The default (or zero-position) of the Occiflex is defined as the lowest position of the bed. In the 0-position the cradle is positioned to the back support, at the same angle and at the same height.

For most patients, the default of the bed and the cradle provides sufficient support.

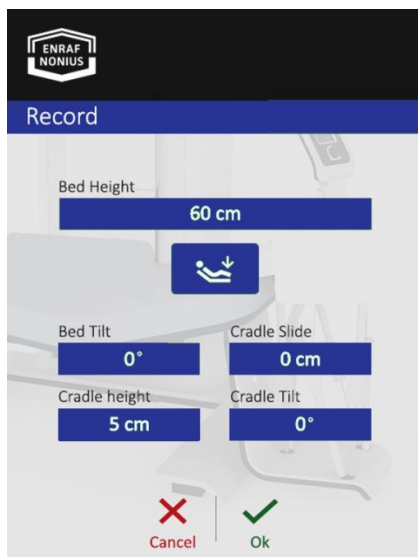


Fig. 13



Fig. 14

Adjust the height of the bed to support the head of the patient comfortably while recording.

- Select “*bed height*” and set the desired value (fig. 15 and 16).



Notice that as soon as you touch a button it becomes active, changes color and enables you to set another value with the rotary knob (fig. 16). Once you stop turning, the value remains visible, freezes and changes to a darker color.

We recommend a bed height at which you are comfortable support the head of your patient with both hands, standing in an upright position with slightly spreading your legs and bending your knees and arms.

If you are comfortable with the default bed and cradle setting and have set the bed height, press “OK” at the bottom of the screen and proceed to page 21.

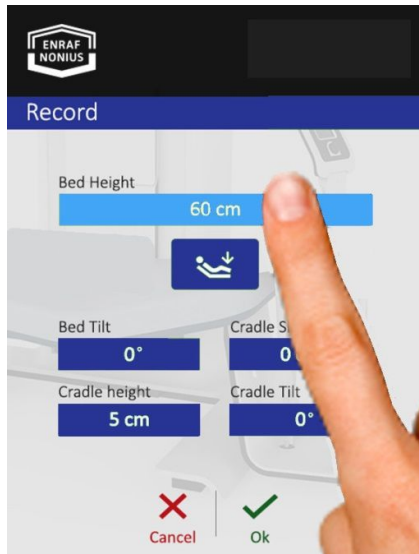


Fig. 15

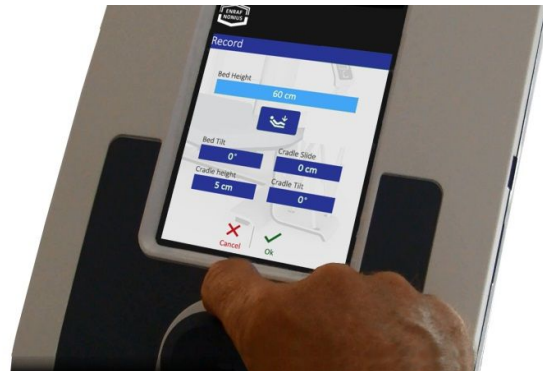


Fig. 16

In case the neck or head of the patient is **not** supported sufficiently or the bed must have a specific angle, you are able to manually set the bed and cradle. The following instruction will guide you through the process.

- Select “Cradle Slide” to put the cradle forward or backward (fig. 17 and 18).

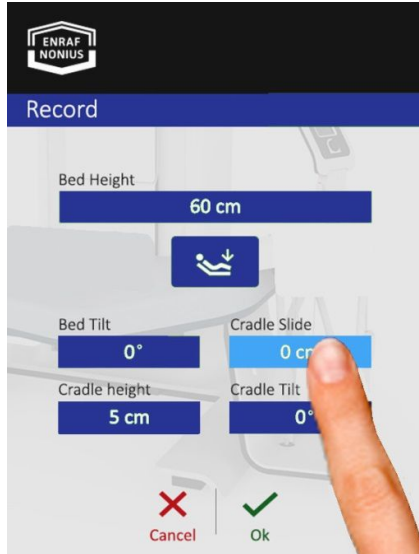


Fig. 17



Fig. 18

- Select “Cradle Height” to set a new height of the cradle (fig. 19 and 20).

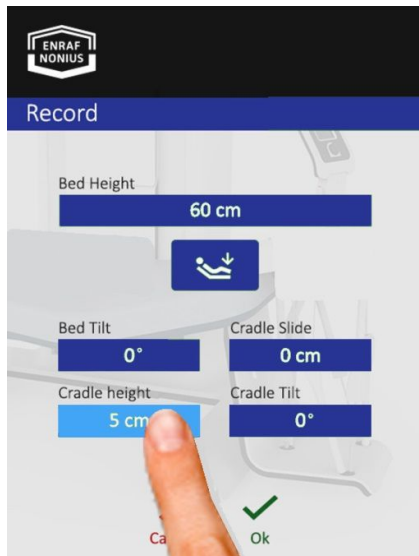


Fig. 19



Fig. 20

- Select "*Cradle Tilt*" to set a new angle of the cradle (fig. 21 and 22).

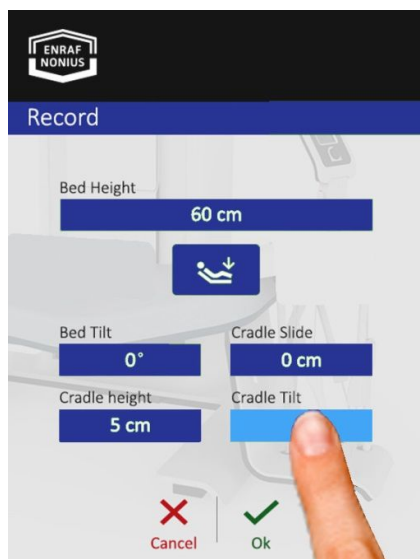


Fig. 21



Fig. 22

- Select "*Bed Tilt*" to set a new angle of the bed (fig. 23 and 24.).

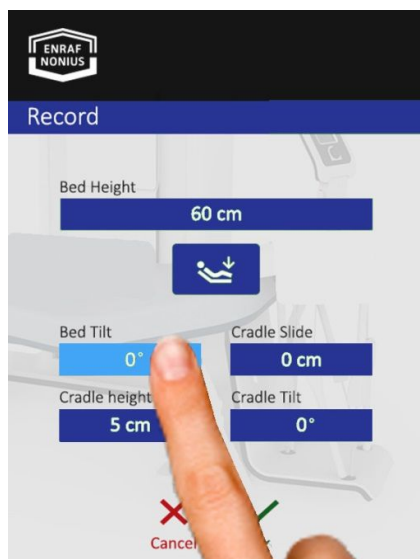


Fig. 23



Fig. 24

After the required bed and Cradle settings are entered and confirmed with "OK", a screen appears (fig. 25) to inform you that the Head Strap should be placed correctly and the Cradle is closed.

**PLEASE NOTE:**



Follow the procedure described below correctly in order not to affect the measurement system negatively.

Fig. 26a, b, c show how the Cradle must be closed.

- Make sure that the head of your patient is centered in the cradle.
- Position yourself behind the Cradle and take the side supports with both hands. Pull the release on the right-side support (fig. 26.a).
- Turn the side supports and fix them just above or on the ears of the patient (26.b).
- Slide the supports to the inside, in such a way that the head is sufficiently fixated (26.c).
- Confirm by pressing the "OK" button.

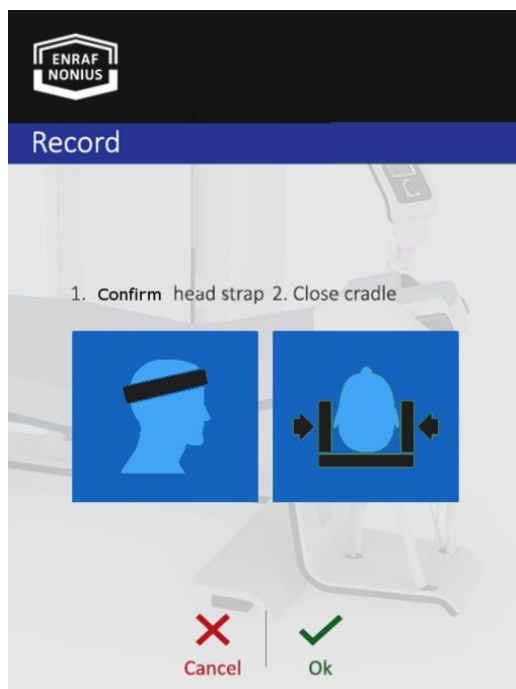


Fig. 25



26.a



26.b



26.c

Fig. 26 a.b.c.

- Follow the instructions on the next screen. *"1. Open the Cradle, 2. Hold patient's head"* (fig. 27, 28).

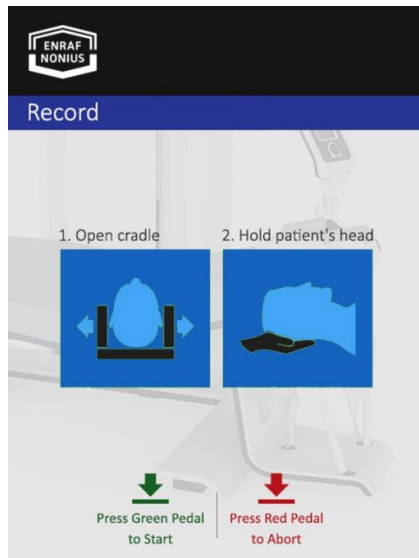


Fig. 27



Fig. 28

- Press the "OK" with the green pedal (fig. 29).

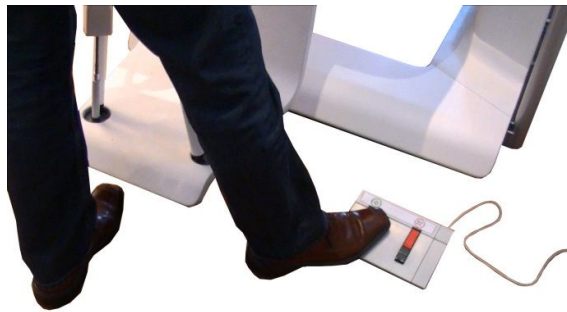


Fig. 29



Fig. 30

This action can only be realised by means of the foot pedal. The touch screen button is disabled for this action as both hands are needed to support the patients head.

Note that the Cradle descends and moves to the left in the lowered position so space is created to record the movements (Fig. 30).



**PLEASE NOTE:**



The head should be as close as possible to the patient 0-position when the recording starts.

The Head Strap should be aligned with the Occiflex bed when you start recording. Not aligning properly (for instance starting in a later flexion position) will result in invalid.

- Start recording by pressing the “OK” with the foot pedal (fig. 32).

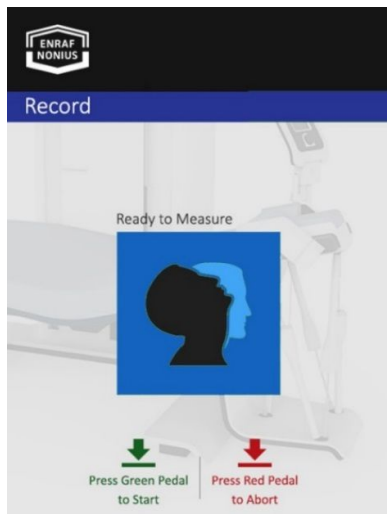


Fig. 31

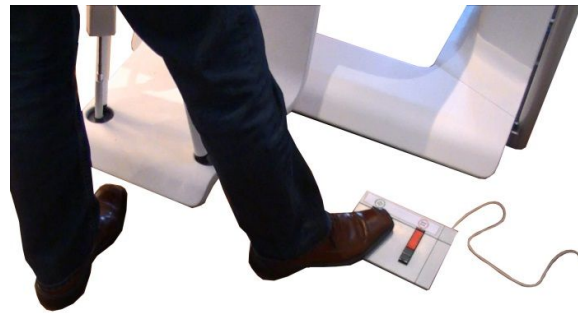


Fig. 32

Now you are able to perform the recording. (fig. 33).

- Press the green pedal and start recording.
- When the recording is finished, press the green pedal to stop the recording (fig. 34).

**PLEASE NOTE:**



The begin and end position of the head should be approximately the same. When the begin and end position are deviating an error message will be displayed ("Begin End Check Error!", see section 12)

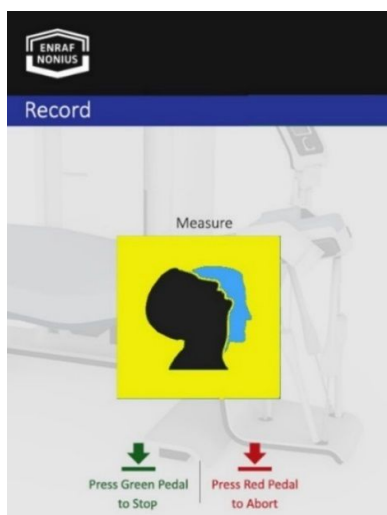


Fig. 33

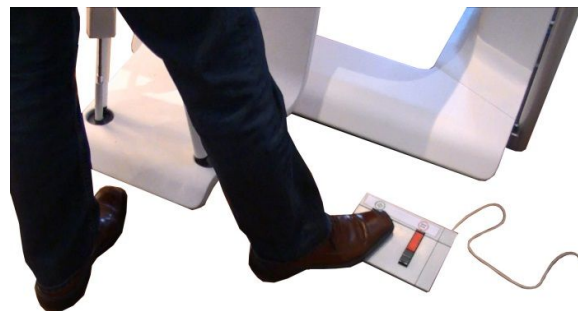


Fig. 34

---

After the recording has ended, the cradle returns to the original position (fig. 35, 36).



Fig. 35



Fig. 36

Gently support the patients head into the cradle.

## QUICK START THERAPY

After the recording has been performed the Therapy (or 'playback ') can start. The recorded movements will be exactly reproduced by the hexapod robot.

The control panel displays the screen "**Therapy Protocol Overview**" on which the movement and the time is visible (fig. 37).

- Close the cradle.
- Ensure that the patient holds the Stop button and is informed about its use.
- Inform the patient that the motion begins.
- Press "Ok", to start the movement.

During playback, the progression is displayed (fig. 38). The bar represents the total treatment time and fills until the entire movement is reproduced. During playback, the angular velocity can be adjusted by pressing "*angular velocity*" in combination with the rotary knob. It ranges from 0.5 ° / sec. to 2.5 ° / sec. Also, the total playback time can be adjusted by pressing "*Total time*" in combination with the rotary knob.

When the "Stop" button on the control panel or the "Stop" button on the foot pedal is pressed, the movement stops.

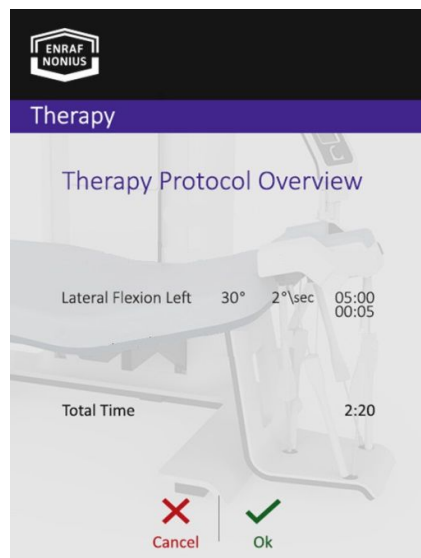


Fig. 37

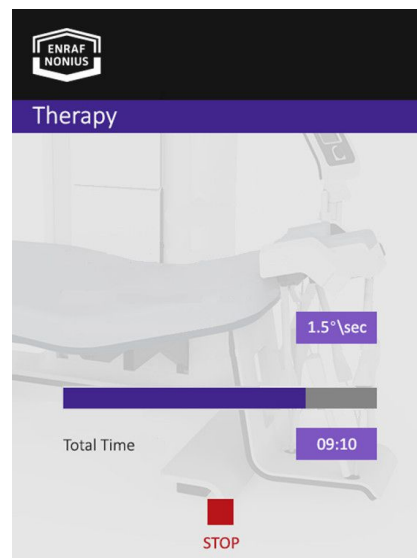


Fig. 38



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## 10 OPERATION WITH THE "OCCILINK APPLICATION"

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In addition to the "Quick Start", the Occiflex has several measuring tools, a unique patient tailored therapy module and a powerful presentation tool to provide direct insight into the progress of your patient. These functions are embedded in the "Occilink application" on the dedicated Occiflex PC and are explained in this chapter.

To provide safe and adequate therapy, the contact - and indication details of your patient must first be entered into the database. This information will be linked to the patients tailored examination, recording, therapy and results.

### LOGIN

- Start the Occilink application.

The "**Login**" appears (fig. 39).



Fig. 39

The program is protected by a username and a password. To log in the first time, you must fill in the fields "User" and "Password" with "0000".

User : 0000  
Password : 0000

After entering the code, the "**Opening**" screen appears (fig. 40).

The password can be changed in the "**Settings**" menu.

## OPENING SCREEN

The black navigation bar on the left side gives access to the main functions. The fields become coloured when the mouse pointer runs across the active (white coloured) functions. The inactive functions are greyed out and not accessible (fig. 40).



fig. 40

## New Patient

When the mouse pointer moves across the active function "**Patient**" (fig. 41), the field turns orange and the underlying functionality "**Add Patient, select patient and search patient**" becomes accessible (1, 2).

- Choose "**Add patient**" (3). Notice that the field turns light orange.
- Click "**Add patient**".

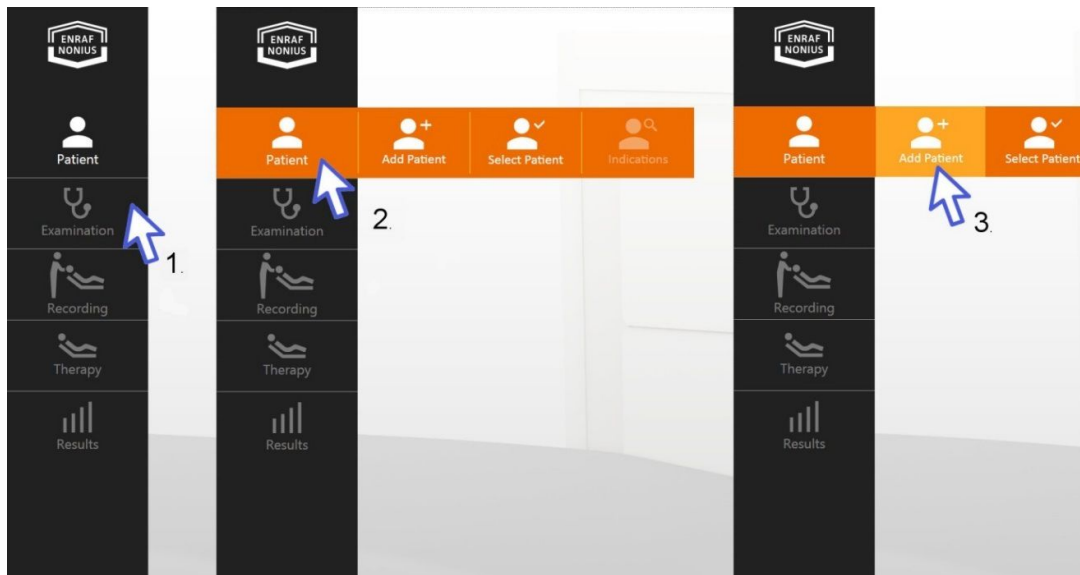


fig. 41

The “**Add Patient**” screen appears (fig. 42) to enter and manage the relevant contact data of your patients. Following fields are mandatory, “**Last Name, First Name, Date of Birth, Gender and Patient ID**” (Identification Number, for example the patient’s insurance number).

The non-mandatory fields are: “**Body Length, Body weight, Middle Name, Home Phone, Mobile Telephone, Work Phone, Email, Insurance company, Address, City, State, Country**”.

**Add Patient**

Last Name	Middle Name	First Name
Date Of Birth	Home Phone	Insurance Co
Gender	Mobile Phone	Address
Patient ID	Work Phone	City
Body Length (inch)	Email	State
Body Weight (pounds)		Country

**Save** **Cancel**

fig. 42

After (at least) the mandatory fields have been completed:

- Click “**Save**” (fig. 43).

**Edit Patient Details**

Last Name	Middle Name	First Name
Marc	de	Vries
Date Of Birth	Home Phone	Insurance Co
10-4-1975	123-4567890	CZ
Gender	Mobile Phone	Address
Male	06-12345678	Vareseweg 127
Patient ID	Work Phone	City
12345	123-456788	Rotterdam
Body Length (inch)	Email	State
77.08	marc@enraf.com	Zuid - Holland
Body Weight (pounds)		Country
187		Nederland

**Save** **Cancel**

fig. 43

## Patient Indication

The field “Add New Indication” appears.

- Select and click “Add New Indication” (fig. 44.1, 2).

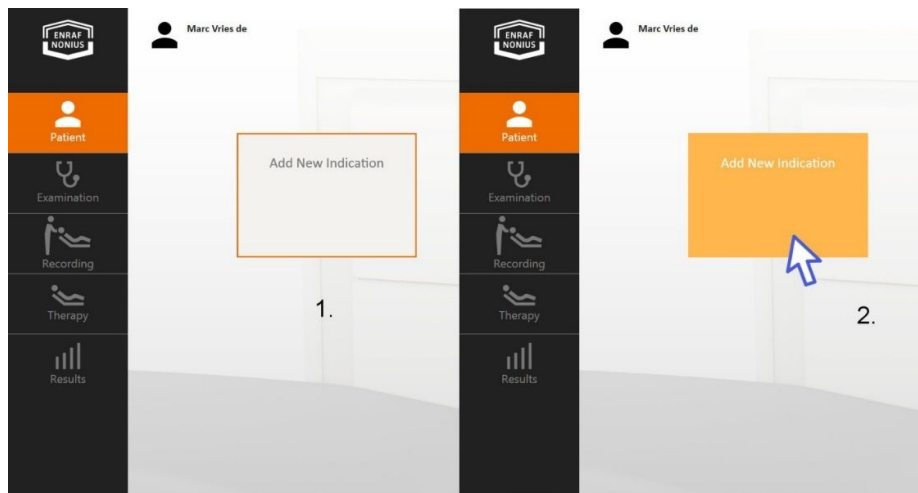


fig. 44

“**New Indication**” is the screen where the patient’s status is entered into the system as the starting point for tailored treatment. “**Patient name**” and “**Indication date**” are filled in automatically.

The fields “**Impairment**” and “**NRS**” are mandatory. “**Impairment**”, has a drop-down list of indications to be selected. The “**NRS**” (Numeric Rating Scale) indicates the intensity of the pain, as experienced by the patient. The value 0 means no pain and 10 means the worst possible pain.

Non-mandatory fields are: “**Referring Clinic, referring Physician, and Therapist**”. In the field “**Clinical findings**” additional information on the patient’s condition can be entered.

“**New Indication**” filled in (fig. 46).

- Confirm by clicking “**save**”. The “**Examination**” menu becomes active and available.

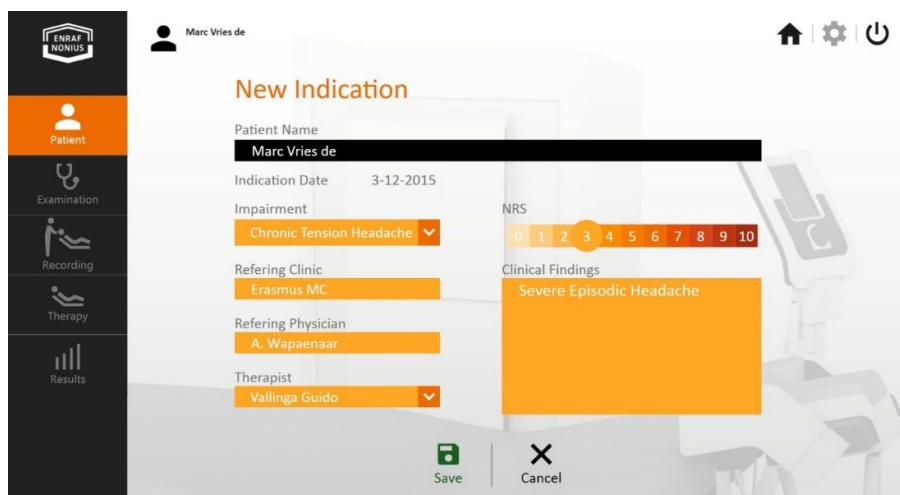


Fig. 46

## EXAMINATION

With “**Examination**” the actual condition of your patient can be measured. You have access to a CROM test and to scales that quantify the pain intensity. The Cervical Range of Motion (CROM) test enables the measurement of the maximal motion of your patient’s head and neck.

- Select “**Examination**” then “**CROM**” (fig. 47.1, 2 and 3).



fig. 47

The field “**CROM Movements**” screen opens (fig. 48).

- Select “**All Movements**” (1) (to be recorded in the orthogonal planes).
- Select “**Send to Occiflex**” (2).
- Accompany your patient to treatment table.

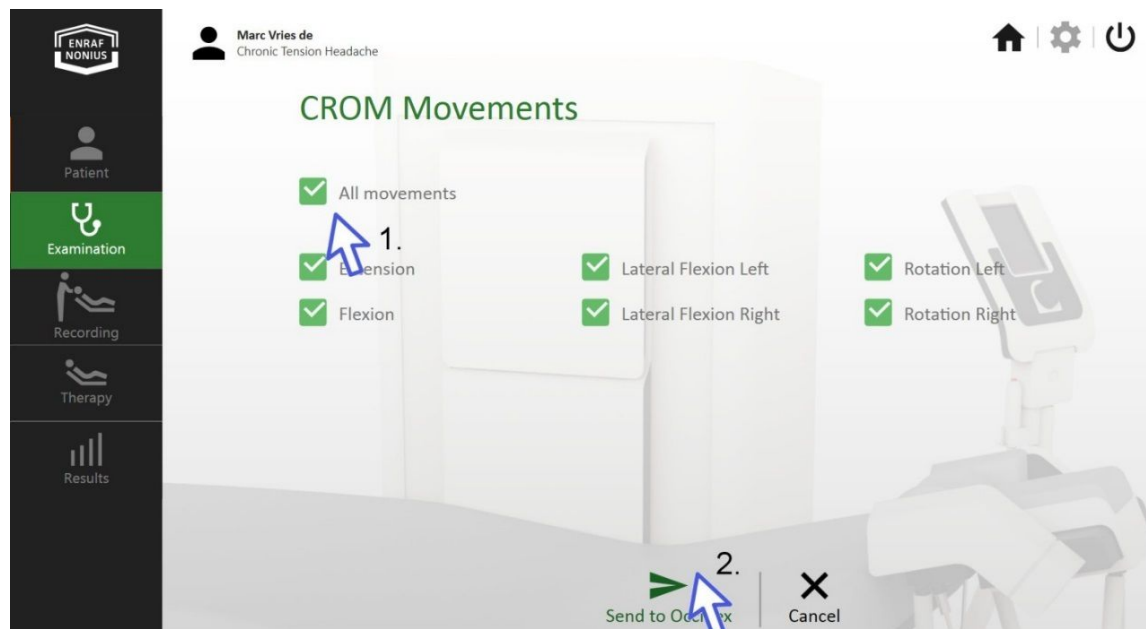
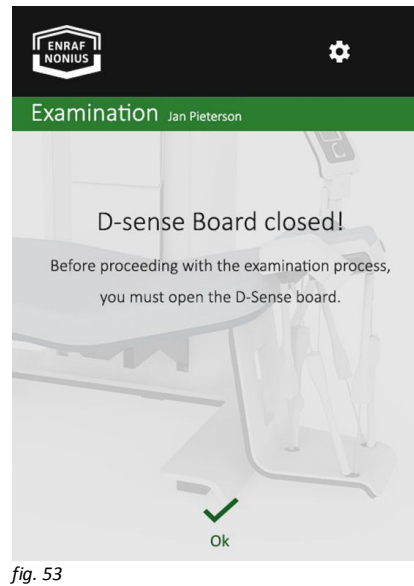
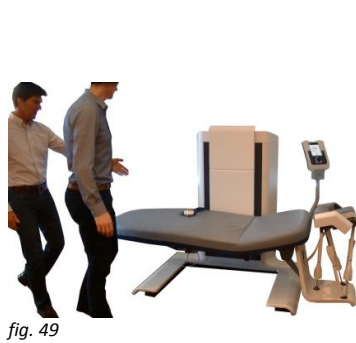


fig. 48

## Perform the examination on the treatment table

The explanations of the CROM examination overlaps with some of the operator actions that are explained in the "**Quick Start**" (see "**Quick Start**" for details).

- Invite your patient to sit on the treatment couch (fig. 49).
- Place Head - Strap centered on the forehead (fig. 50).
- Accompany your patient to supine position (fig. 51).
- Open the D-sense panel (fig. 52).
- Make sure the D-sense panel is opened correctly. If the board is not correctly opened the message "**D-sense panel closed!**" is presented (fig. 53).
- Position yourself behind the control panel (fig. 54).





On the User Interface panel, the name and ID of your patient is visible and must be confirmed. In the example: "Jan Pieterse, ID 12345678".

- Confirm name and identification code by pressing "OK" (fig. 55).

The "CROM test Overview" screen (Fig. 56) presents the selected movements to perform.

- Confirm that the correct movements are presented by pressing "OK".

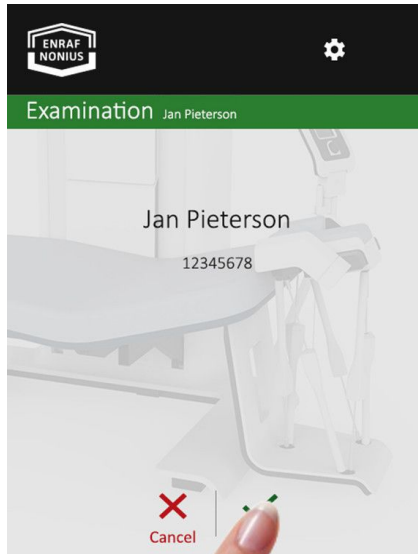


fig. 55

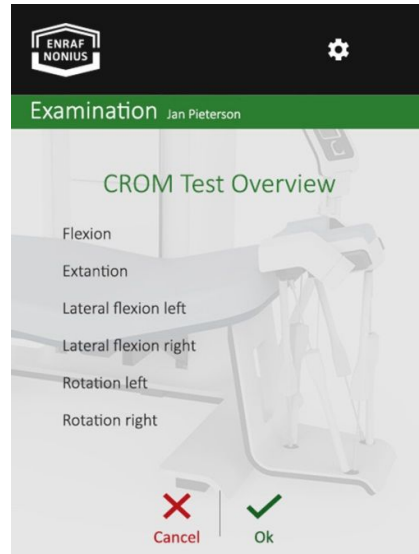


fig. 56

The setting screen of the bed and hexapod appears (fig. 57). The green colours of the layout represent the "Examination" mode. Set the bed and cradle to your patient's comfort (fig. 58) (see also 9.1.1 Quick Start).

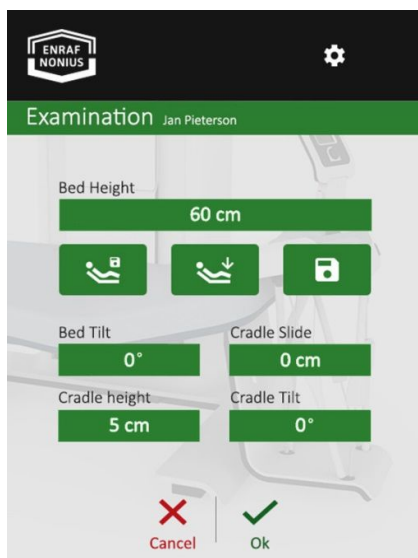


fig. 57

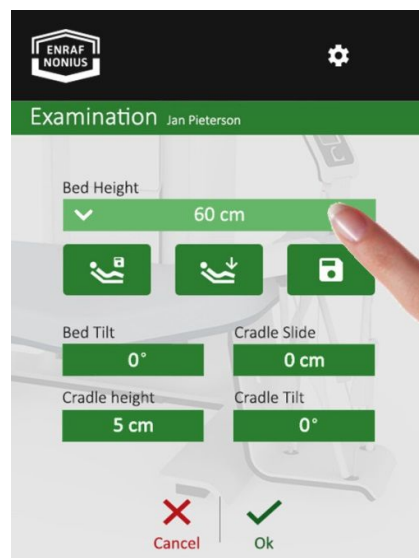


fig. 58



In the setting menu of Examination, the following 2 buttons are added.



fig. 59

The “**save**” button, saves the bed and hexapod settings of your patient and of your preferred recording height. If the button is pressed, the settings are saved (fig. 59).



fig. 60

When the “**saved bed and hexapod**” button is pressed, bed and hexapod return to the saved position (fig. 60).

- Place Head - Strap, close the Cradle (fig. 61) and confirm with "ok".
- Open the Cradle, take the head of your patient in both hands (fig. 62) and confirm by pressing the green pedal.

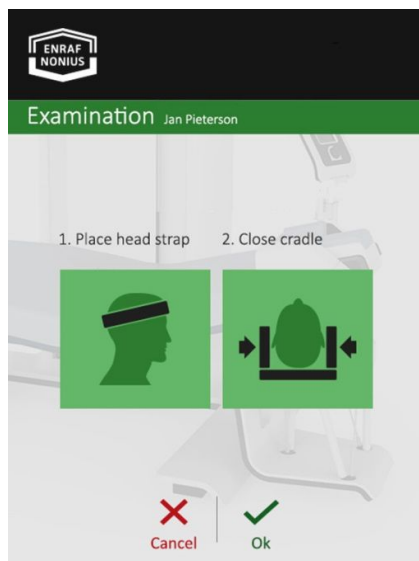


Fig. 61

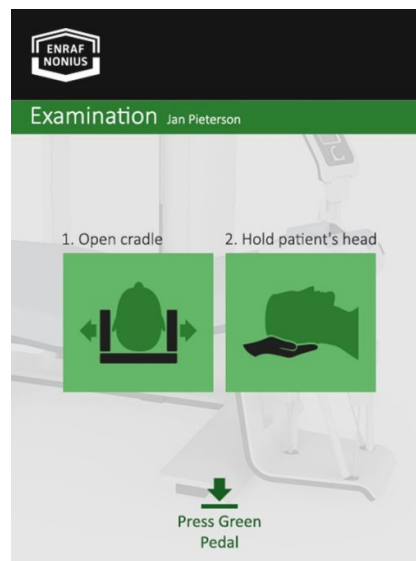


Fig. 62

When the cradle is lowered and completely slide to the side (fig. 63),



Fig. 63

the screen of the first measurement is displayed. In the example, “**Extension**” (fig. 64).



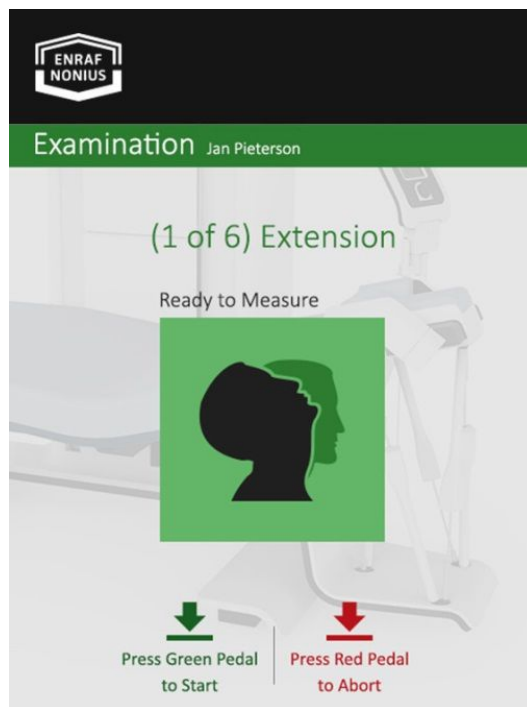


Fig. 64

Press the green pedal to start recording (fig. 65).



Fig. 64

In the screen, the words "**Ready to Measure**" change in "**Measuring**", to indicate that the measurement has been started (fig. 66). The measurements are numbered. The last measurement (no.6 in our example), is a "**Rotation Right**" (fig. 67).

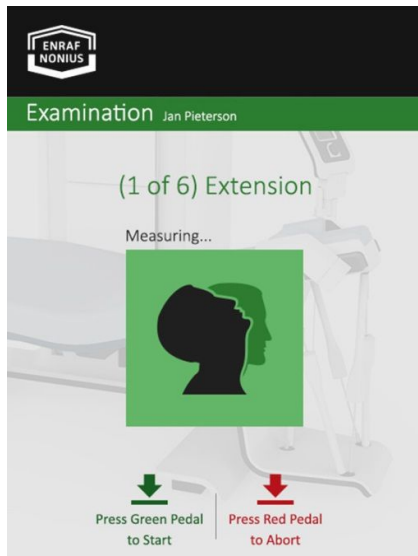


Fig. 66

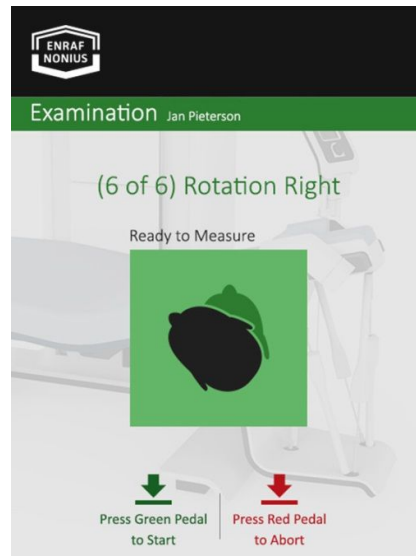


Fig. 67

After all measurements have been completed, the message "**Measurement Completed**" appears (fig. 68).

- Press the green, pedal, and wait until the hexapod and cradle are fully returned.
- Then gently lower the head of your patient back into the cradle.

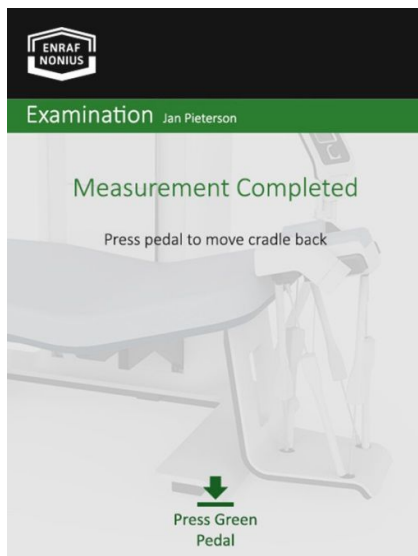


Fig. 68

After confirmation, the measurement data are sent back to the Occilink computer.

## CROM RESULTS

Return to the Occilink computer once the measurement data has been sent back to the Occilink computer. Notice that the **"Results"** icon has become accessible.

### CROM

- Select **"Results"** and click **"CROM"** in the main menu (fig. 69).

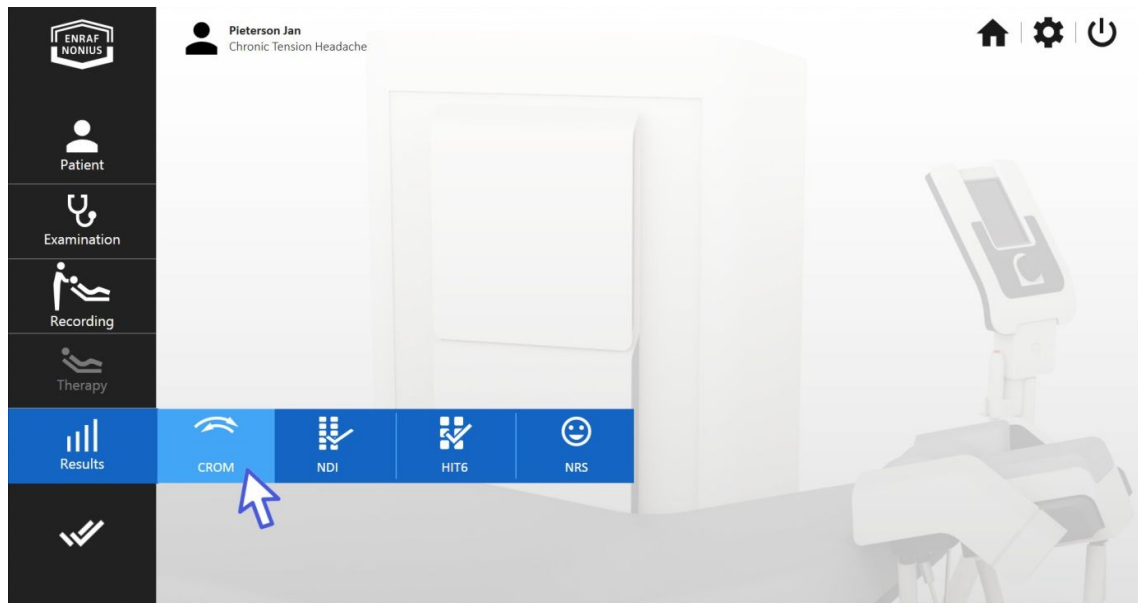


fig. 69

The **"CROM"** screen now provides an overview of measured movements of which a selection can be made (fig. 70).

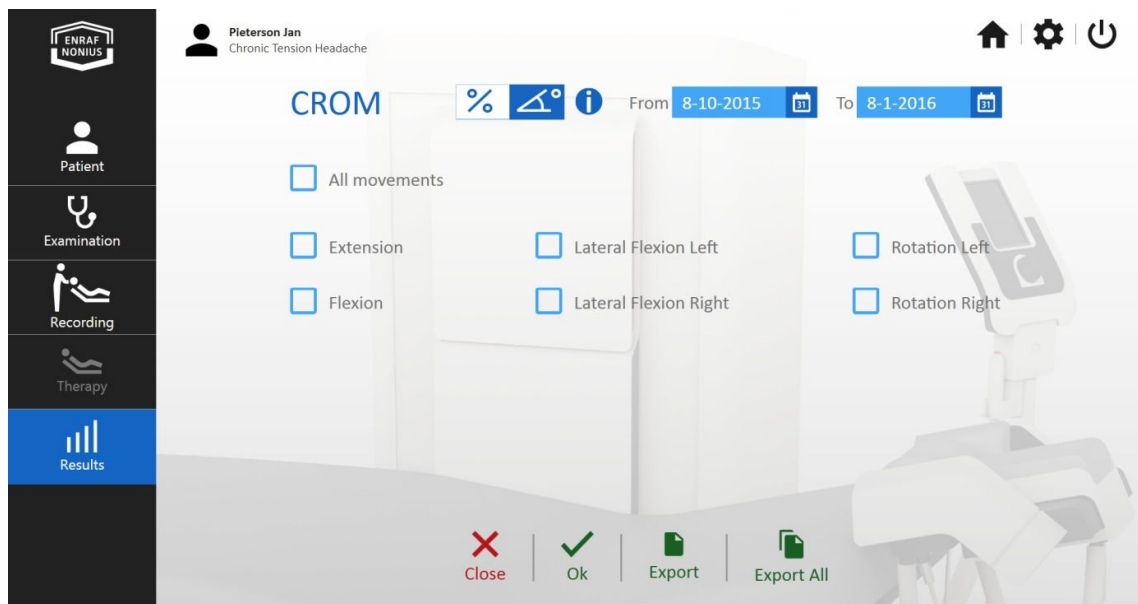


Fig. 70

- Select “All Movements” (1.) and confirm with “OK” (2.) (fig. 71).

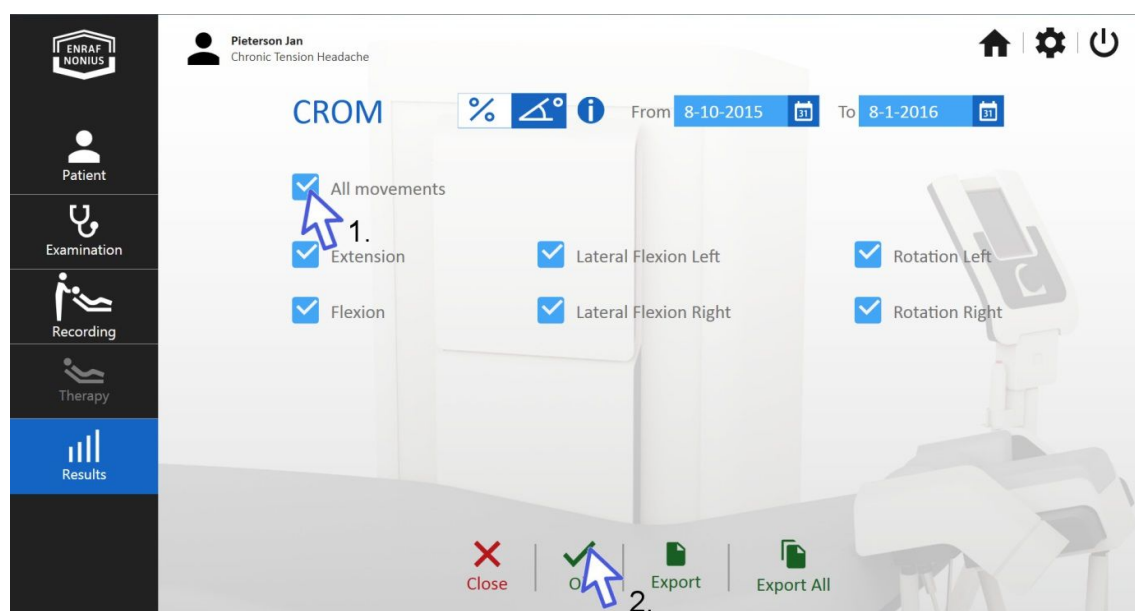


fig. 71

The results of the CROM measurements are displayed. Make sure that the calendar is set correctly, only the measurements between the set calendar dates are displayed.

Changing the date:

- Click the end date (fig. 72).

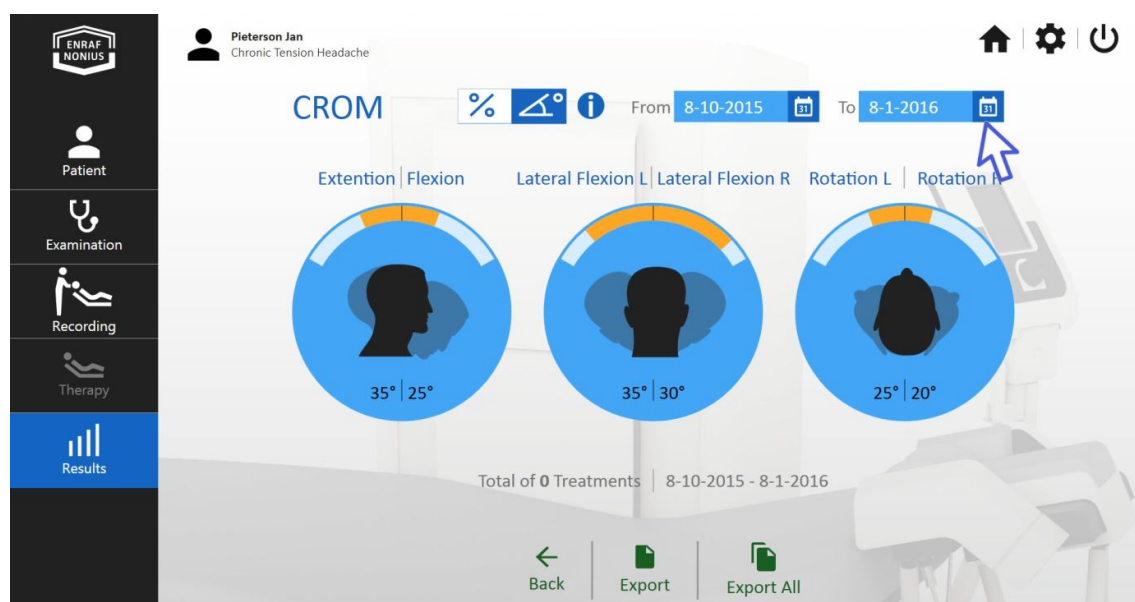


fig. 72

When the calendar is opened you are able to set a new date (fig. 73).

- Choose a new date.

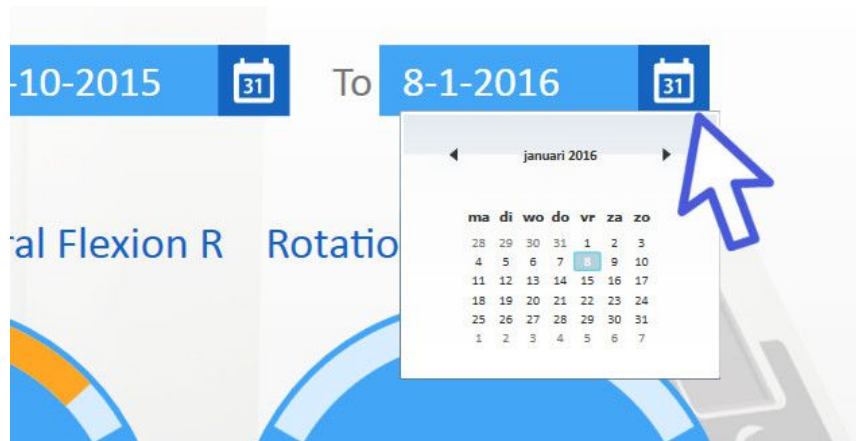


fig. 73

- Select "Extension, Flexion" (fig. 74).



fig. 74

All the results of the previously performed Extension and Flexion measurements are now accessible and displayed graphically and numerically. In our example only one measurement is made. Date of the measurement, maximum angle in degrees and percentage of the maximum on the basis of scientific ergonomic data are presented (fig. 75).



fig. 75

When the CROM percentage is selected (fig. 76), the maximal measured ROM of the patient is presented as a percentage of the maximal ROM of accurate ergonomic patient data. This data can be viewed by selecting the “i” icon, next to the percentage and angle icon.



Fig. 76

The Occilink program has a powerful "**Export**" tool that enables you to track the progression of your patient.

- Select "**Export**" (fig. 77).

A pdf is created presenting a numerical and graphical overview of the results (fig. 78).

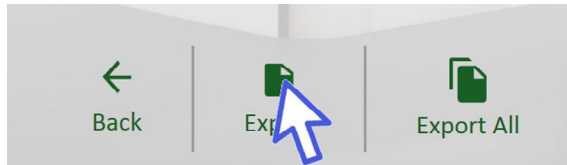


fig. 77

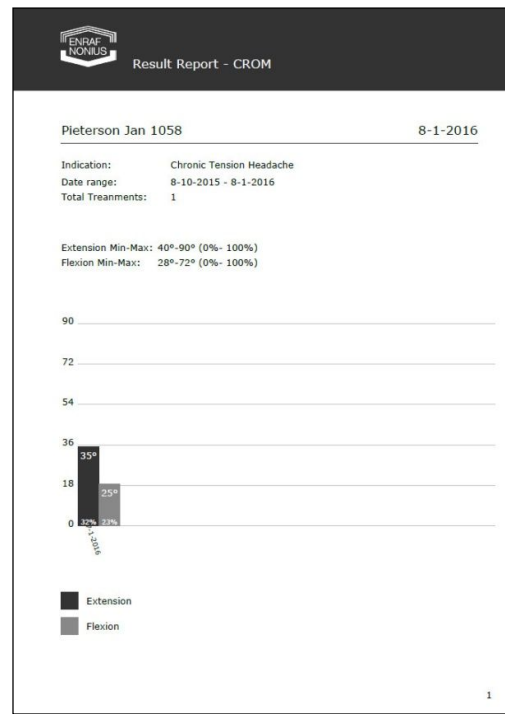


fig. 78

## NDI, HIT6, NRS

After the examination has been carried out, the NDI, HIT6 and NRS are accessible.

The "**NDI**" (Neck Disability Index) is a questionnaire that gives an insight into the daily limitations of patients with neck pain. It measures self-reported pain, headache intensity and limitations in performing daily work activities, work, lifting and concentration and of non-work-related activities such as personal care, reading, driving, sleeping and leisure. The NDI can indicate to what extent neck problems affect daily activities.

The "**HIT6**" (Headache Impact Test) is a questionnaire for the measurement of the influence of headache. Six questions focus on daily activities such as work, education, home environment and leisure. HIT-6 gives a general overview of the impact of headache, including pain intensity, disability, and other items. A higher score reflects many complaints.

The "**NRS**" (Numerical scale for pain) runs from 0 to 10. 0 is no pain and 10 is the worst pain.

The questionnaires can be found in the "**Examination**" menu (fig. 79).

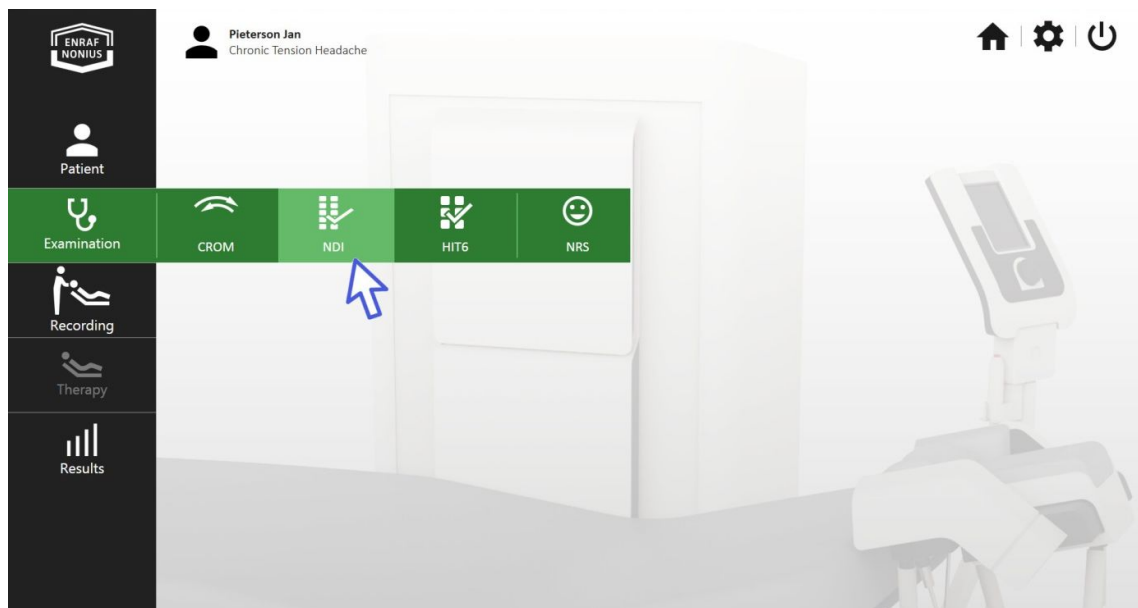


fig. 79

## RECORDING

### Preparation at the Occilink computer

Recording is the basis for therapy. Any previously recorded 3D movement can be 'played back' by the Occiflex in a precise and uniform manner, during a certain time and at an angular velocity of choice.

- Move the mouse pointer across "**Recording**" in the main menu.

The field "**Add New Recording**" appears.

- Click "**Add New Recording**" (fig. 80).

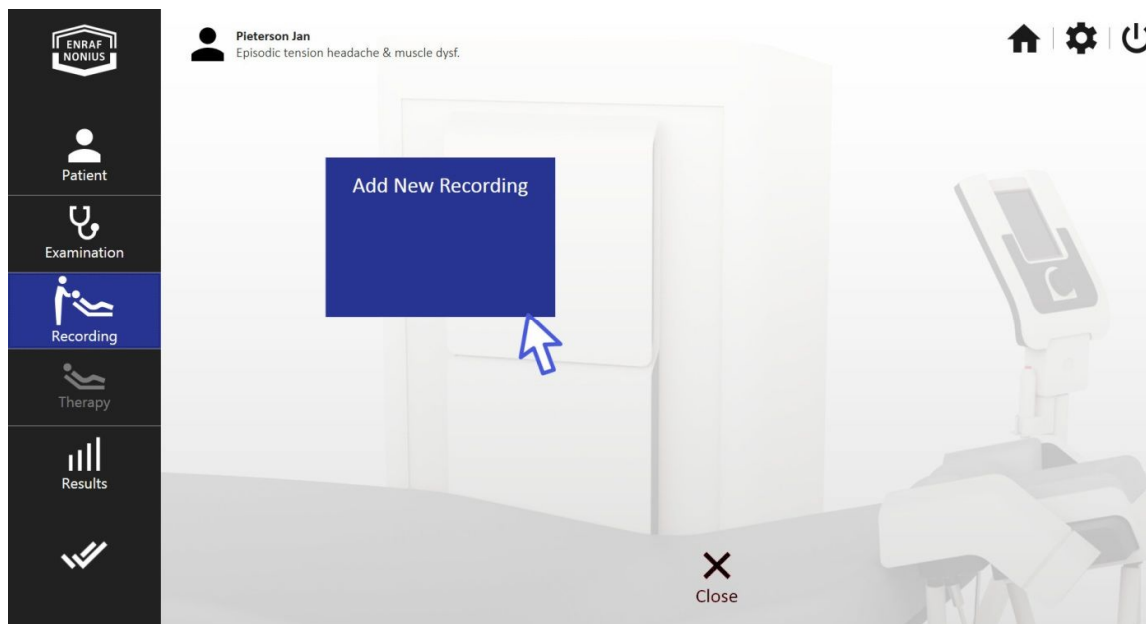


fig. 80



The screen “**New Recording**” opens (fig. 81).

It enables you to create a list of motions to record in any particular order, as many as needed. The dropdown list provides a list of movements to select from.

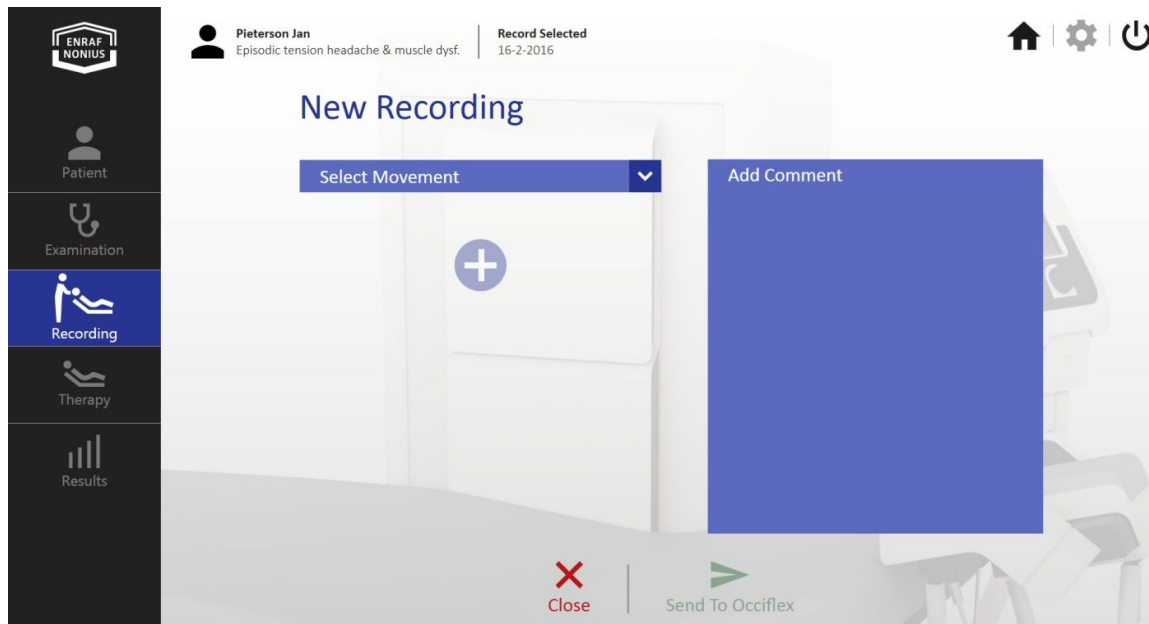


fig. 81

A single recording can be prepared and performed but also a sequential of up to 10 different recordings.

- Select “**Flexion**” (fig. 82).

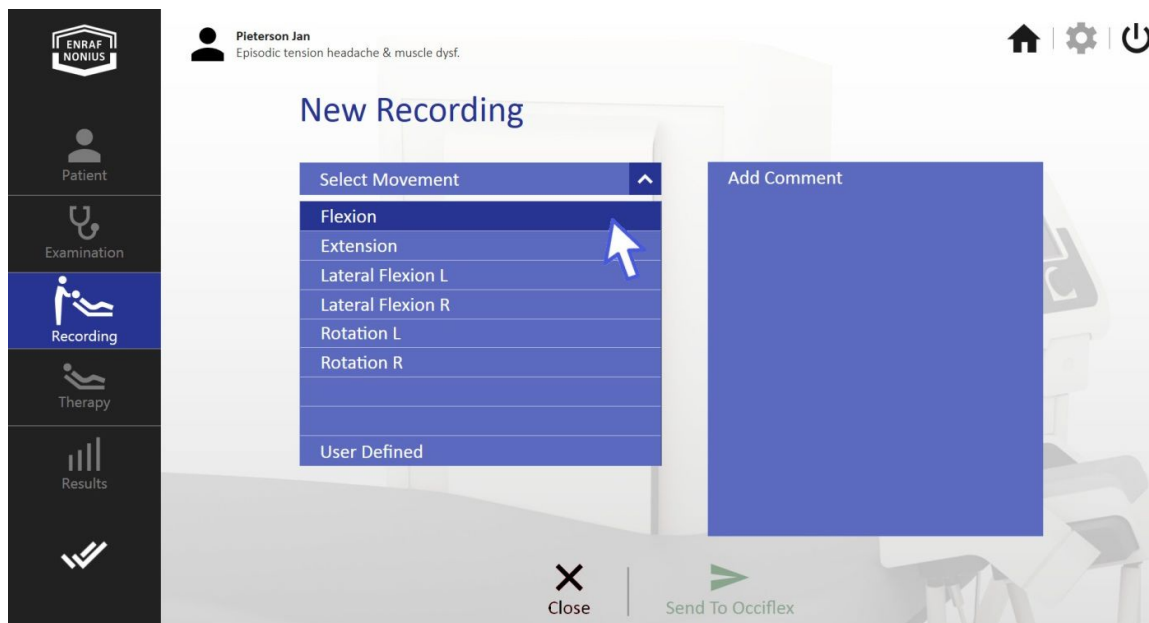


fig. 82

After Flexion has been selected, the bar “**Flexion**” is created (fig. 83).



fig. 83

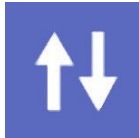


fig. 84



fig. 85



fig. 86

= Move icon to change order (fig. 84).

= Edit icon, enables editing of the movement (fig. 85).

= Discard icon, makes it possible to discard a movement (fig. 86).

- Select “**User Defined**” (fig. 87).
- You can rename the User defined movement. In the example, we name it: “*3D cervical procedure*”

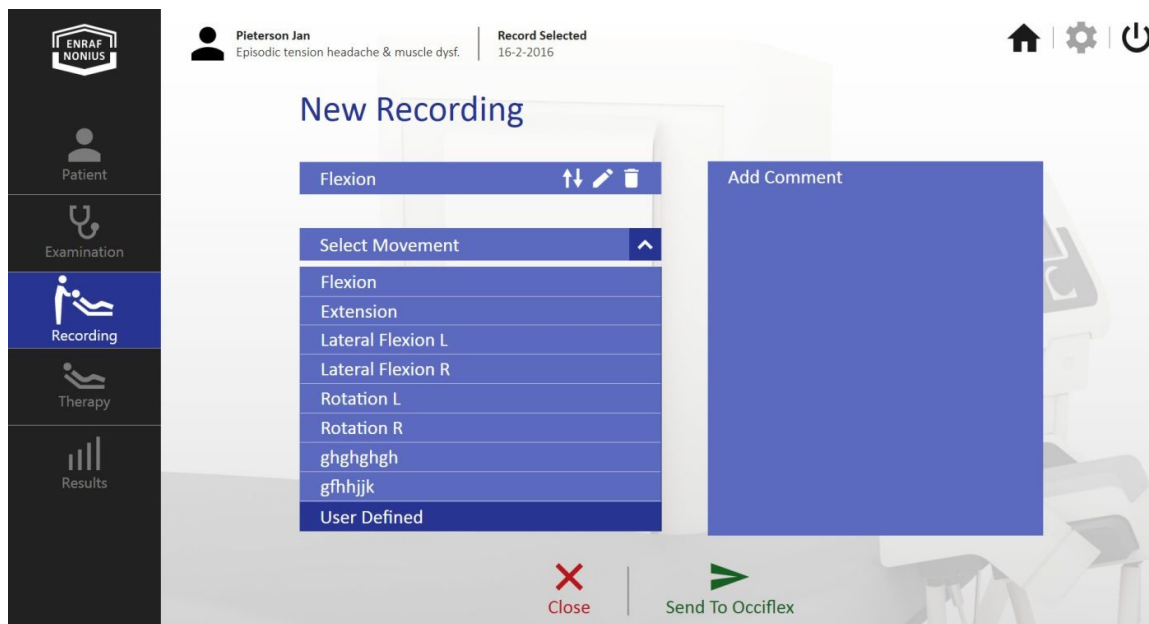


fig. 87

- Select “**Send to Occiflex**” (fig. 88).
- Accompany your patient to the treatment table.

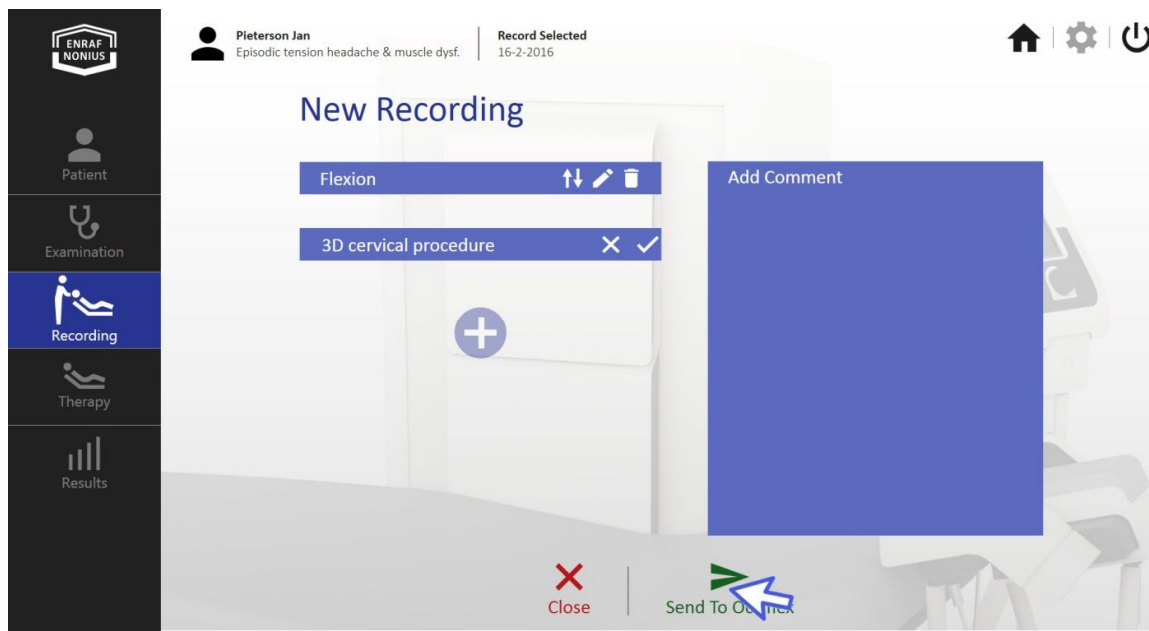


fig. 88

### Recording at the treatment couch

For the recording on the treatment couch, follow the same procedure as explained under "Recording". Notice that the colours and the annotation "**Recording**" on the user interface of the treatment couch remind you that you are in the "**Recording**" function.

## THERAPY

### Preparing the therapy at the Occilink computer

The recorded motions can be reproduced or 'played back' with the treatment couch. At great accuracy, the 3D movements can be repeated at low speed with the Hexapod robot. The preparation of the therapy goes as follows:

- Select "**Therapy**" in the main menu, then "**Add New Therapy**" (fig. 89, 1 and 2).

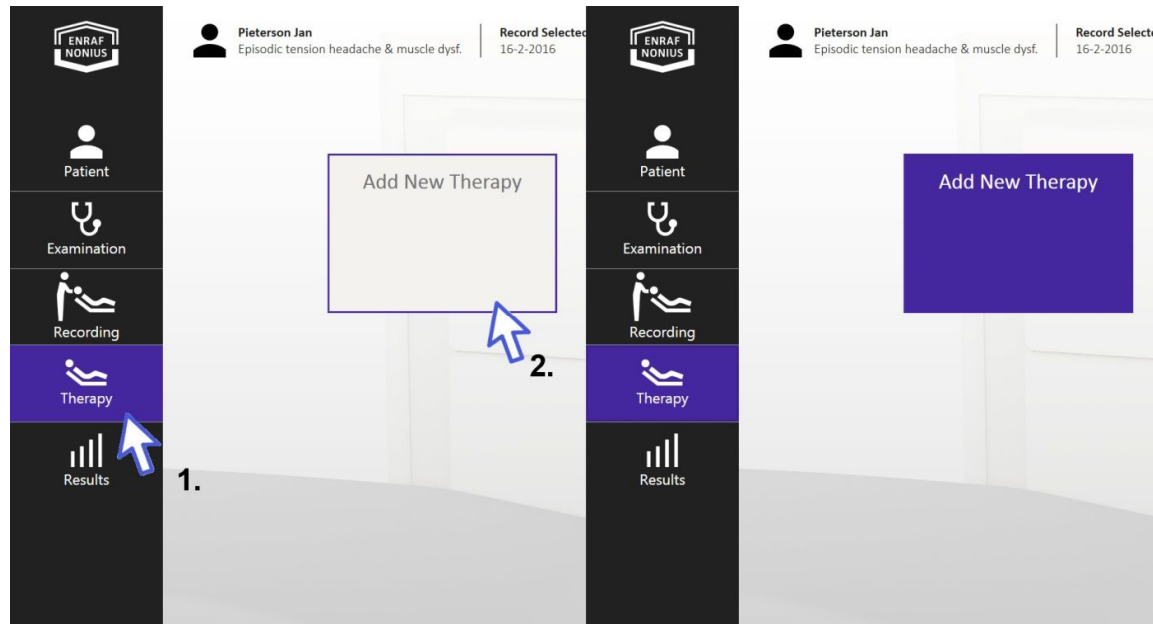


fig. 89

In the screen "**Add Therapy**" (fig. 90), a therapy can be made on the basis of a selected recording(s). The last recording is automatically loaded as the basis for therapy. If you want to select an earlier recording, select, and activate it via the main menu.

The underlying recording comprises of one or more movements that can be played with an angular velocity of choice during a number of cycles. The accumulated time of the therapy is presented in "**Treatment time**".

In between the movements, a pause can be set with "**Step Interval Time**". If you want to play the movements without pause, select "**Step Interval Time**" = 0 seconds (fig. 90).

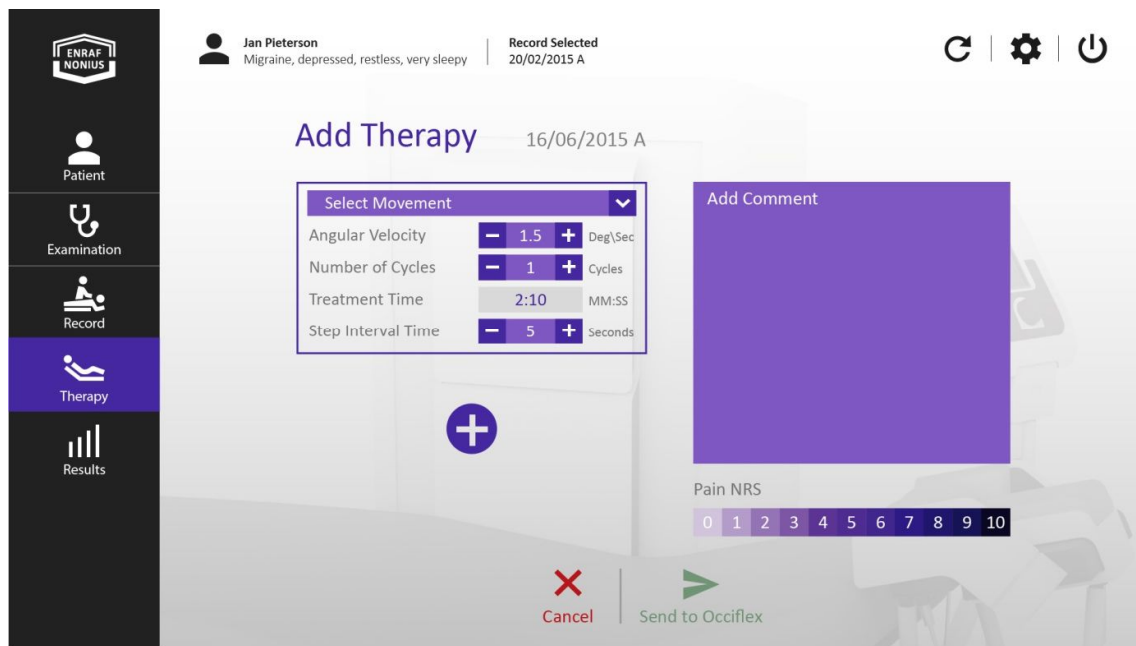


fig. 90

When you have created a therapy movement it is presented in a purple field. In the example, it is a Flexion with a maximal angle of 25°, an angular velocity of 1.5°/sec. and is composed of 5 cycles with a step interval time of 1 seconds that adds up to a total treatment time of 10:40 min. (fig. 91).

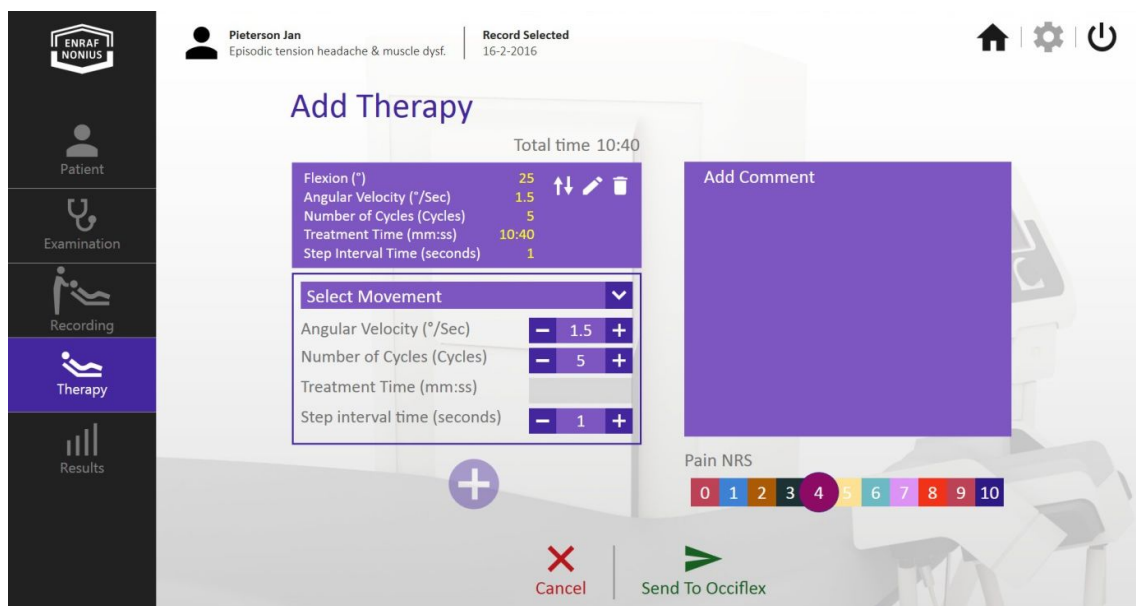


fig. 91

- Click “**Send to Occiflex**” after the therapy is composed and the NRS is selected (fig. 92).
- Accompany your patient to the treatment couch.

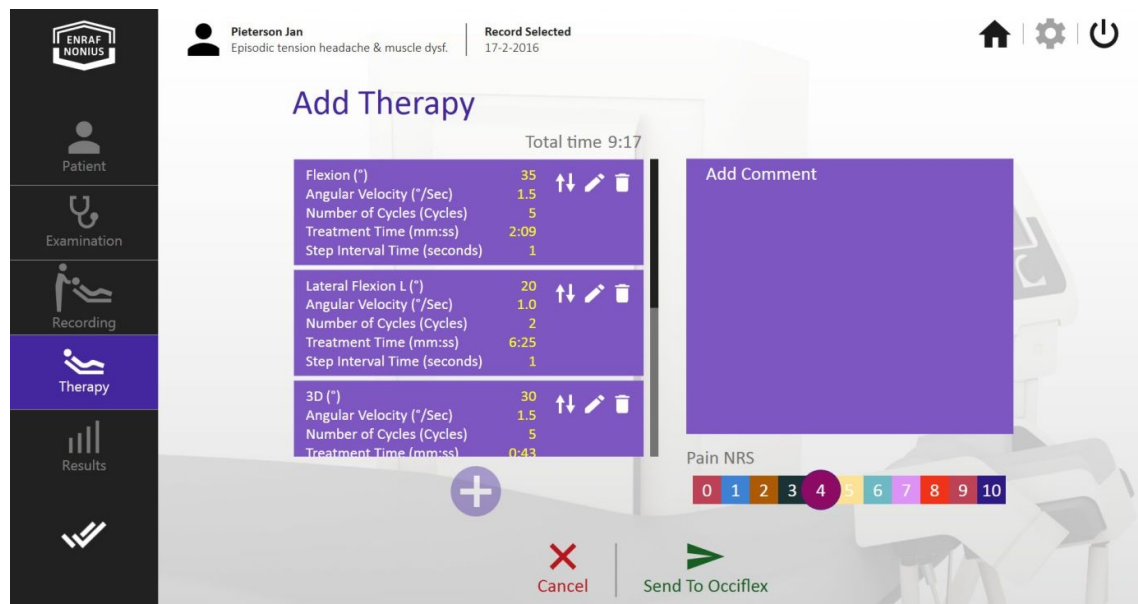


fig. 92

### Therapy on the treatment couch

- Invite your patient to sit on the treatment couch.
- Hand the patient stops to your patient and instruct your patient that when the stop is pressed all the movements of the device will immediately freeze.
- Accompany your patient to supine position with the head and neck in the Cradle.
- Close the Cradle.
- Stand behind the control panel and check the Therapy Protocol Overview screen.

The “*Therapy protocol*” screen (fig. 93) gives an overview of the selected therapy movements and duration.

Select “OK” to start the first movement.

The Occiflex plays the defined therapy. On the User Interface, the first movement is visible. In the example, the movement “Extension “is played. Duration and angular speed can be edited during playback (fig. 94).

When the “**Pause**” button is pressed the movement pauses and will continue by pressing the “**Resume**” button. When “**Cancel**” is pressed the Therapy session is aborted.



fig. 93

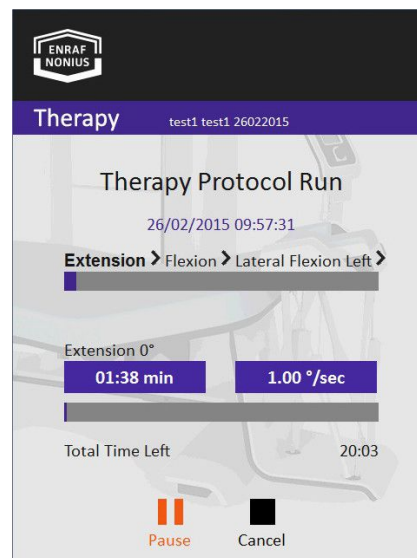


fig. 94

After the Therapy is completed, open the cradle, and help your patient to get of the Occiflex bed.

## SETTINGS

The **System settings** menu, allows you to edit default values as set by the manufacturer.

- Select the setting icon in the main menu (fig. 95).

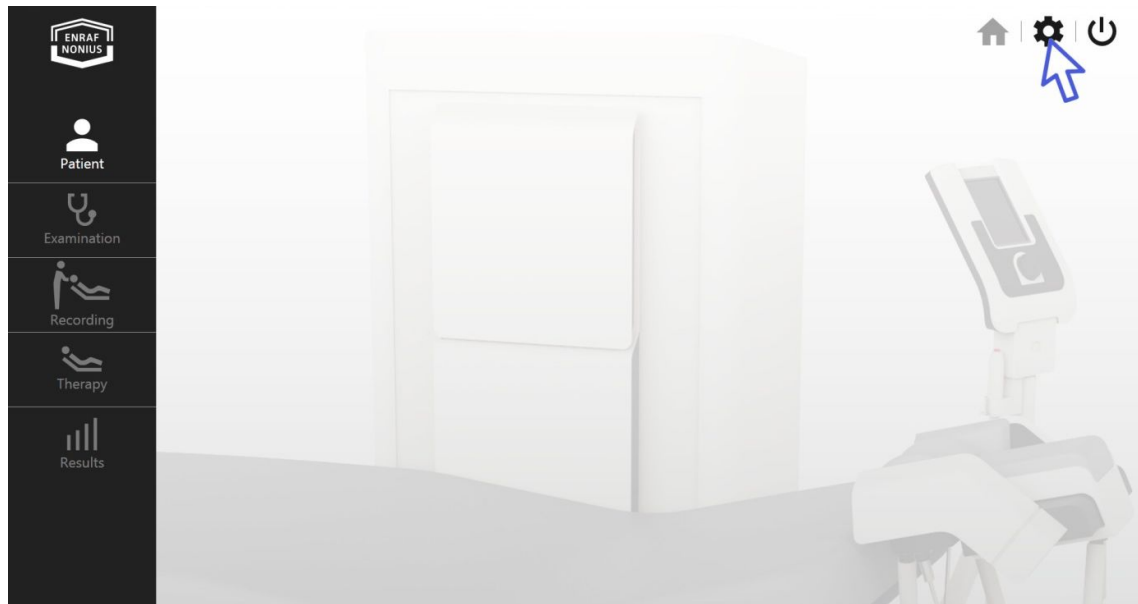


fig. 95

The settings become visible and can be divided into database management tools, network information and connection check, change of password, choice of language, sound set, software version, NRS on / off switch, inch or metric selection, factory reset, default settings of therapy interval time, number of cycles, angular velocity, result display and the setting of the saved bed height (fig. 96).

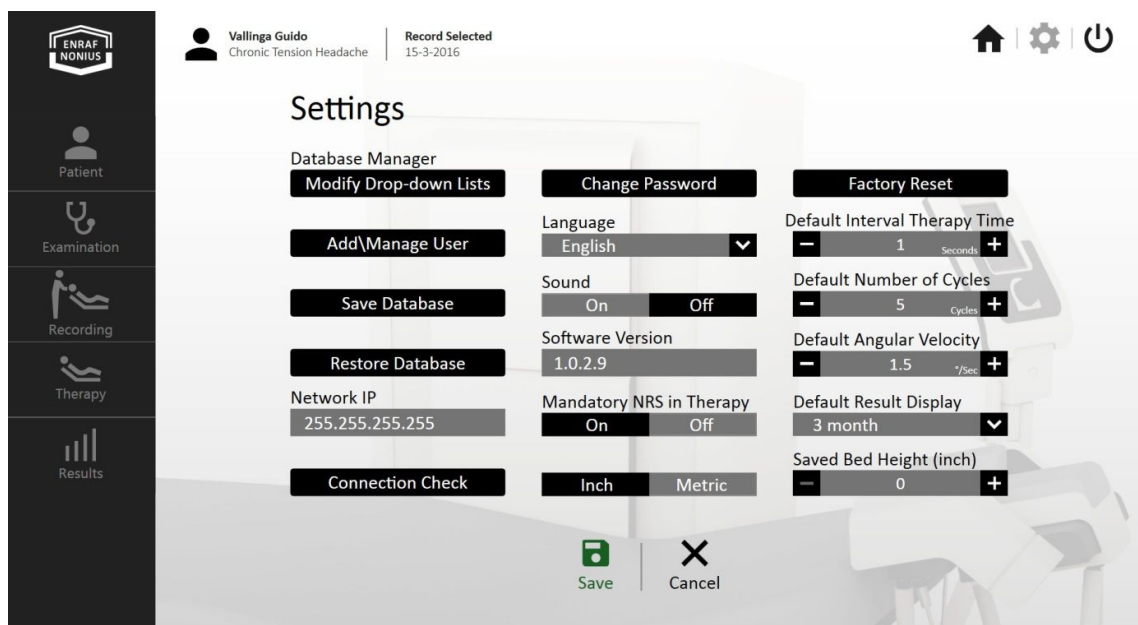


fig. 96



## Database Manager

With the database manager, you are able to modify the following database features.

### Modify Drop – down lists

Select **“Modify Drop – down Lists”**.

The opened screen provides access to supplement or delete information in the lists of Insurance companies (Patient Data), Impairment (Indication) or Movement names (Recording). In fig. 97 the function **“Insurance Companies”** is active and can be edited (as an example). Use the same procedure for modifying **“Impairment”** and **“Movement Names”**.

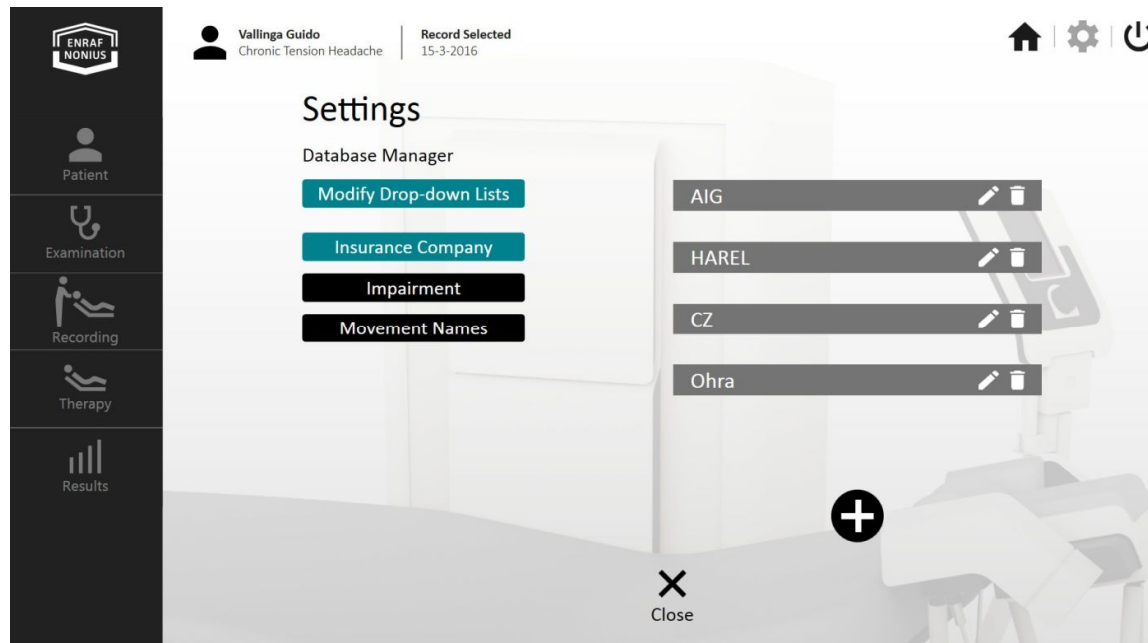


fig. 97

### Add \ Manage User

The Add \ Manage User functionality allows you to define new operators (users) and add them to the list. Deleting or modifying of a name is also possible.

- Select **“Add \ Manage User”** of the Database Manager (fig. 98) and add, delete, or edit a user.

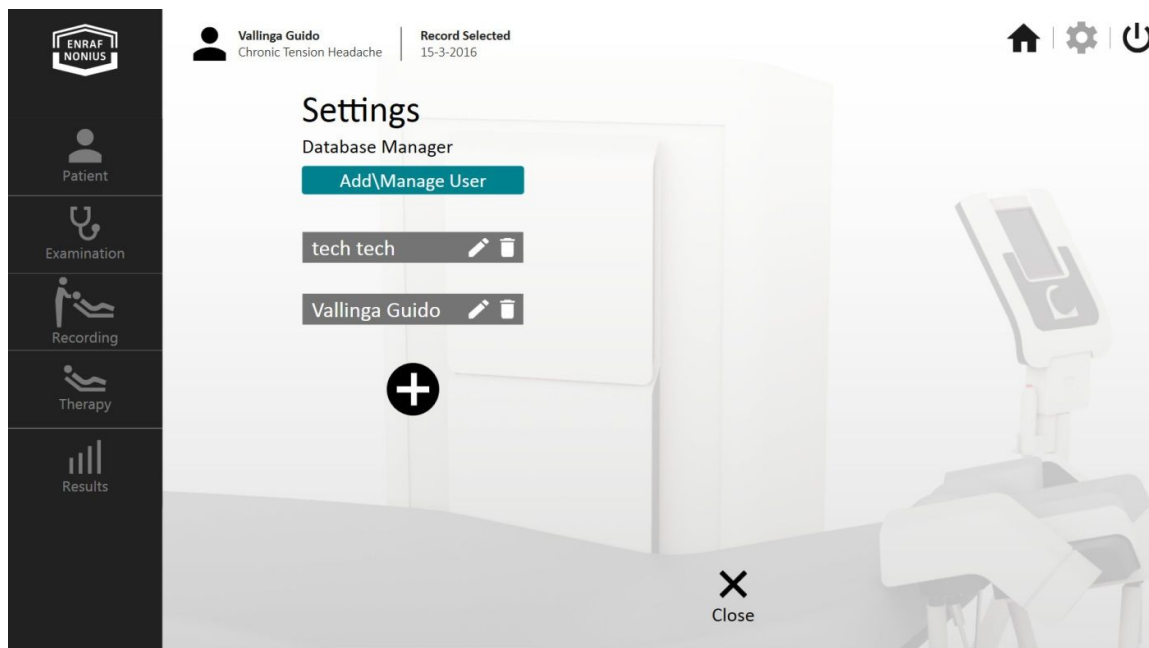


fig. 98

#### Save Database, Backup the current Database

- Select “Save Database” in the Database Manager and click “Save Database or Backup the Current Database” to save or backup.(fig 99)

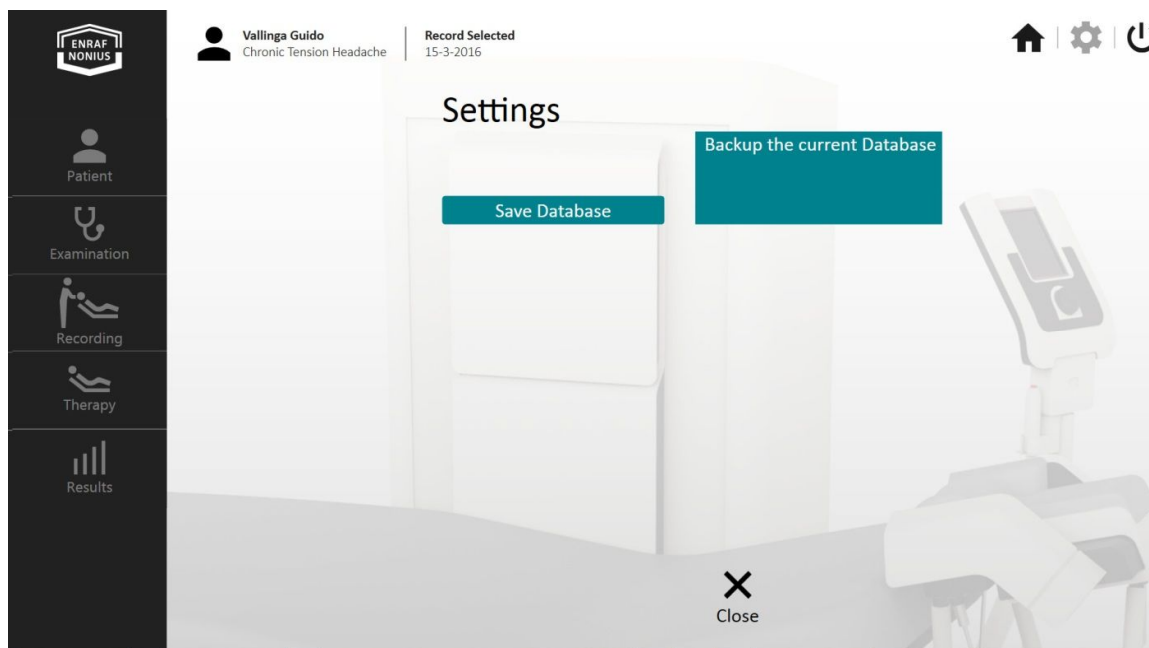


fig. 99

#### Restore Database, Restore the last saved Database

- Select “Restore Database” in the Database Manager and click “Restore Database or Restore the last saved Database” to restore. (fig 100)

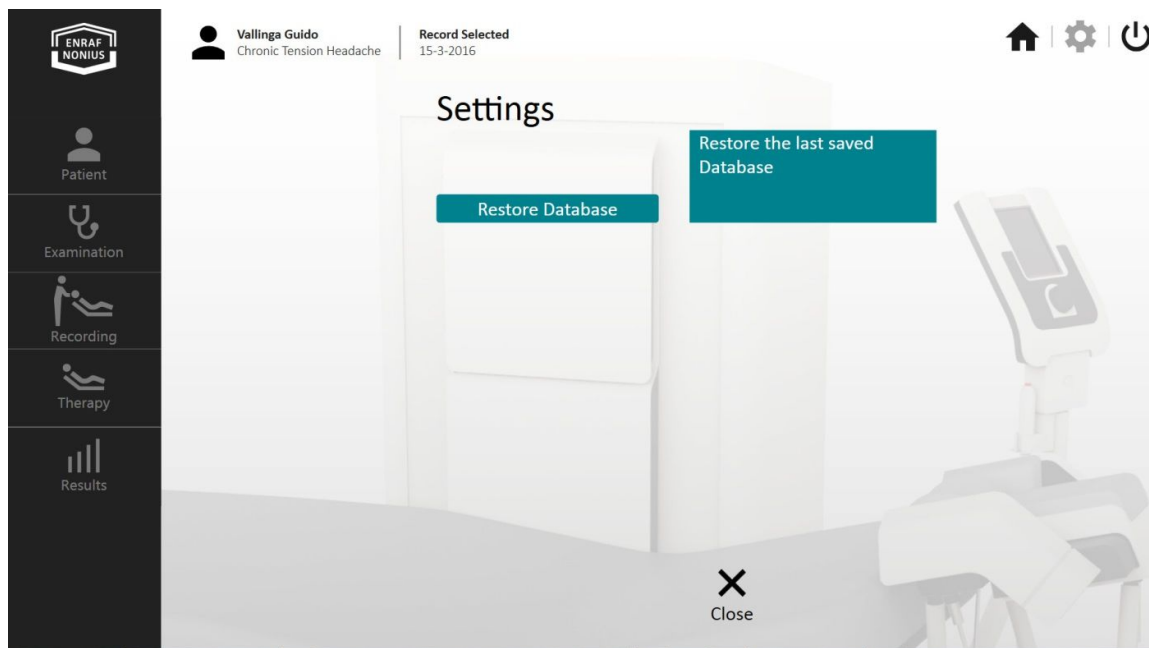


fig. 100

## Network IP

Network IP gives access to the “**Connection Check**” and the “**Change Password**” functionality. Also, the IP address of the Occiflex can be viewed.

### Connection Check

- Select “**Connection Check**” under Network IP to check the connection.

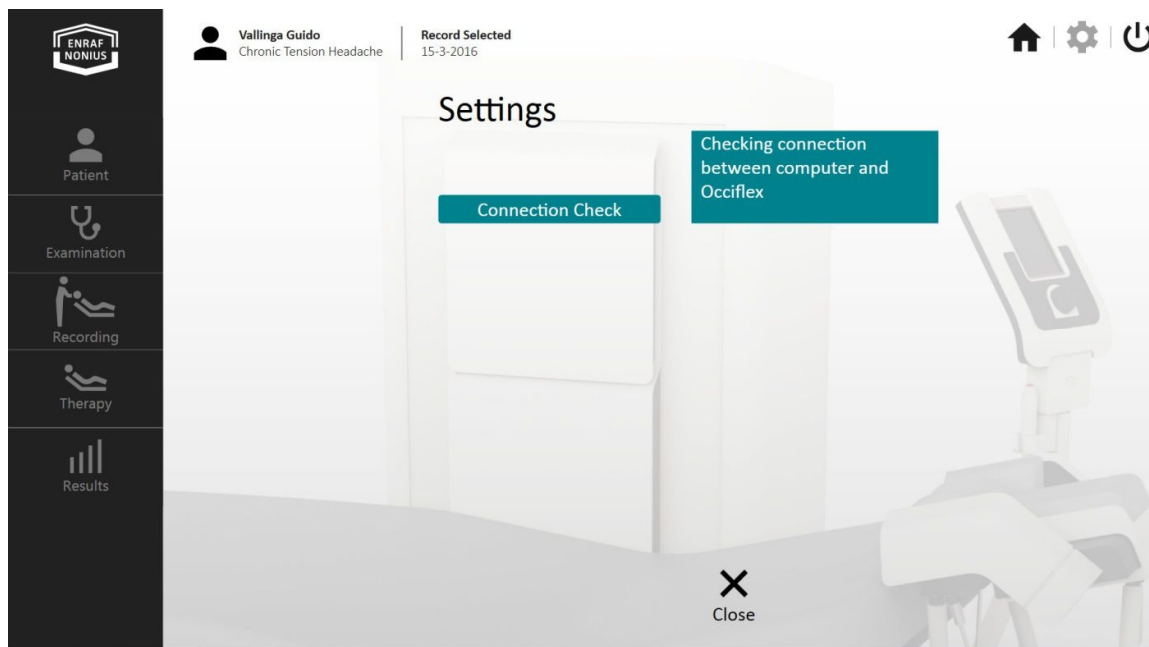


fig. 101

### Change Password

- Select “**Change Password**” under Network IP to change the Password.

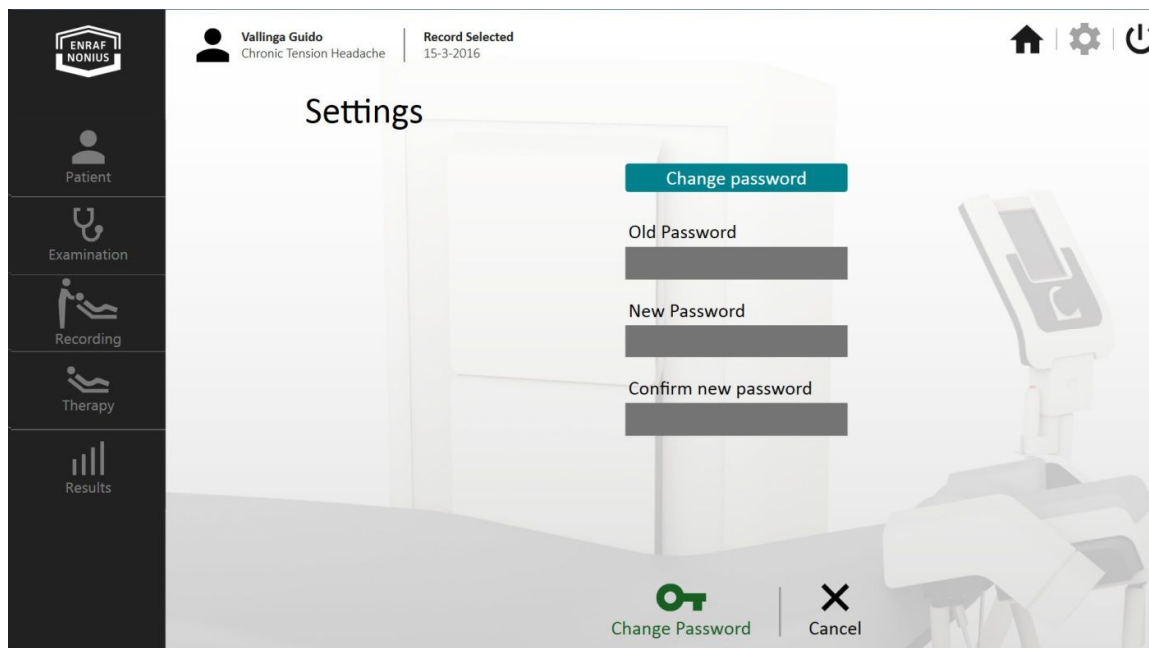


fig. 102

## Language, sound set, etc setting

These items can be selected and easily modified in the settings menu.

### Language

The language can be changed to Dutch, English, German, Italian, French, and Spanish (if implemented).

### Sound

The sound (acoustical signal) used in the software can be enabled or disabled.

### Software version

Displays the installed software version.

### Mandatory NRS in Therapy

Allows you to enable or disable the NRS questionnaire during therapy.

### Default Therapy interval time

Enables default setting of the interval time.

### Default number of cycles

Enables default setting of the number of the cycles.

### Default Angular Velocity

Enables default setting of the Angular Velocity.

### Default Result Display

Enables results to be displayed at a chosen time interval.

### Saved Bed Height

Saves the preferred bed height for the therapist when recording.

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## 11 CLEANING AND MAINTENANCE

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### CLEANING THE DEVICE

First switch off the device and unplug it from the wall socket.

#### Cleaning

- The Occiflex must be cleaned before it is first used and before it is disinfected.
- Clean the couch with a damp cloth.
- Do not use agents that contain alcohol or other aggressive cleaners.
- Remove soap residue with a damp cloth and clean water.

#### Disinfecting

- Clean the couch as described above before proceeding to disinfect the couch.
- Follow the disinfectant's instructions for use.
- Never use a mixture of disinfectants or a disinfectant and soap mixture.
- Preferably use a cloth to apply the agent to the imitation leather.
- Avoid water accumulation in the hinge points of the metal frame. (In the worst case, exposing the hinges to water in the long-term can result in rust formation)
- The disinfectants listed on the information sheet, are tested and safe for use on the imitation leather of the Occiflex.
- For the most current version of the list see [www.enraf-nonius.com](http://www.enraf-nonius.com).

#### Remarks:

*Since we have no control over the production and raw materials used for the disinfectants, we are unable to give a general guarantee that these agents will not damage the upholstery.*

### MAINTENANCE

Taking good care of your Occiflex and its surroundings minimises maintenance problems and servicing requirements.

We recommend the following preventive maintenance schedules:

#### Daily checks

- Switch off the Occiflex using the on/Off switch.
- Wipe down the frame, the bed and head-support, the console, the stop button, and the head - strap with a damp cloth. Never use solvents as these can damage the device.

#### Weekly checks

Clean the device by following these steps:

- Clean the control panel and the exterior of the Occiflex.
- Remove dust from underneath the device.
- Make sure the patient emergency stops functions.
- Make sure the Head- strap functions.

---

## Regular, monthly checks

The regular maintenance depends on the intensity of use. Given an average use of 8 hours a day, 5 days a week, we would advise you to check the various visible parts, such as the frame, the bed, cradle, and hexapod for wear on a regular basis (monthly).

### PLEASE NOTE:



In the event of possible damage or defects noted by you during one of the checks above, you must stop using the Occiflex and contact your supplier.

## TECHNICAL MAINTENANCE

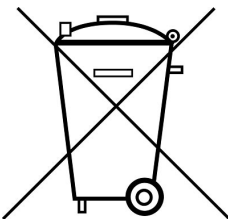
We recommend to have the unit checked annually. This may be done by your supplier, or by another agency, authorised by Enraf-Nonius. It is also recommended that a record of the service history is kept for all activities relating to service and maintenance. In some countries, this is even obligatory.

Maintenance and all repairs should only be carried out by an authorised agency. Enraf-Nonius will not be held responsible for the results of maintenance or repairs by unauthorised persons. Opening of the equipment by unauthorised agencies is not allowed and will terminate any claim to warranty.

## EXPECTED SERVICE LIFE

Expected service life of this device is 8000 hours of use or 10 years after purchase, whichever comes first.

## END OF LIFE



Your Occiflex and accessories contains materials which can be recycled and/or are noxious for the environment.



**Please ensure that you are well informed of the local rules and regulations regarding to the removal of apparatus and accessories.**

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## 12 TROUBLESHOOTING

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Should your Occiflex develop a fault, please contact the supplier of the device or Enraf-Nonius B.V.(the Netherlands). Repairs and installations should only be carried out by a service technician who has been authorised by Enraf-Nonius.



The device should not be used when **any sort of damage is noticed**.

### LEDs and/or displays fail to illuminate

- Ensure that the plug is properly inserted into the wall socket.
- Check that the wall socket is working.
- Check/replace the safety fuses in the power input.

### ERROR CODES ON THE TOUCH SCREEN CONTROL PANEL

The Occiflex has an internal check which means that it is self-monitoring. Error codes are indicated either in the touch screen control panel by means of a textual message or by means of a small triangular WARNING symbol (see fig. 103). You can click the error code symbol in order to see the error message (see fig. 104).



fig. 103

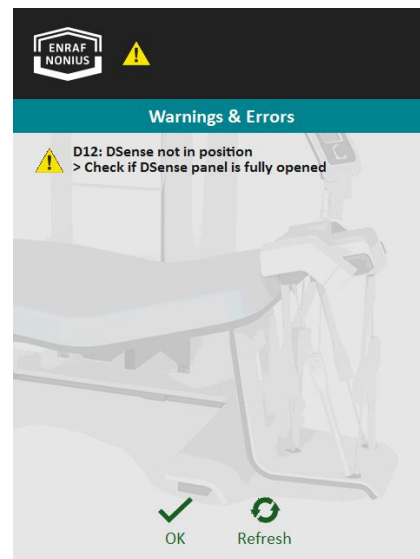


fig. 104

The WARNING symbol can be yellow or red.



Should an error code appear as a red WARNING symbol then you will need to contact the supplier of the device.

In case of a yellow WARNING symbol then click on the symbol to read what action should be carried out in order to proceed.



fig. 105



fig. 106

## Boot errors (B errors)

Booth errors are indicated as a red WARNING symbol when starting the system. In case this WARNING symbol appears then please contact your Enraf-Nonius authorised service organisation.

The booth errors are:

### **B01 "Failed to read Settings"**

*Indicated action: "Contact Service..."*

### **B02 "Failed to write Settings"**

*Indicated action: "Contact Service..."*

### **B03 "Ramdisk failure"**

*Indicated action: "Contact Service..."*

### **B04 "Flash disk failure"**

*Indicated action: "Contact Service..."*

### **B05 "Power down Failure"**

*Indicated action: "Fix Errors and Power cycle!"*

### **B13 "Hexapod not Calibrated"**

*Indicated action: "Calibrate Hexapod and Power cycle"*

### **B14 "Bed not Calibrated"**

*Indicated action: "Calibrate Bed and Power cycle"*

### **B15 "Power down Failure"**

*Indicated action: "Fix Errors and Power cycle!"*

### **B16 "FATAL BOOT Error(s)"**

*Indicated action: "Power cycle, Contact Service..."*



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## Device failure errors (F errors)

Device failure errors are also indicated as a red WARNING symbol. In case this WARNING symbol appears then please contact your Enraf-Nonius authorised service organisation.

The device failure errors are:

### **F01 "Hexapod Base Master Failure"**

*Indicated action:* "Contact Service..."

### **F02 "Hexapod Base MCtrl Failure"**

*Indicated action:* "Check Calibration, Contact Service..."

### **F03 "Hexapod Platform Failure"**

*Indicated action:* "Contact Service..."

### **F04 "DSense Failure"**

*Indicated action:* "Contact Service..."

### **F05 "Headstrap Failure";**

*Indicated action:* "Check connection, Contact Service..."

### **F14 "Bed Control Failure"**

*Indicated action:* "Check Calibration, Contact Service..."

### **F15 "Park Control Failure"**

*Indicated action:* "Try Park/Unpark, Contact Service..."

### **F16 "No Communication..."**

*Indicated action:* "Powercycle if problem persists..."

### **Error 137: Motor failure**

*Indicated action:* check the cables

### **Error 139: File error**

*Indicated action:* resend the data from the Occiflex to the Occilink PC

### **Error 140: I2C error**

*Indicated action:* check the cables

---

## Device WARNINGS (D errors)

Device WARNINGS are indicated as a yellow WARNING symbol. In case this WARNING symbol appears then click on it and take the appropriate action as presented in the screen.

The device WARNINGS are:

### **D12 "D-sense not in position"**

*Cause of WARNING:* you are trying to make a recording while the D-sense board is closed.

*Indicated action:* "Check if DSense panel is fully opened"

### **D13 "Hexapod needs calibration"**

*Indicated action:* "Re-Calibrate Hexapod"

### **D15 "Hexapod Park State !!"**

*Cause of WARNING:* For the demanded proceedings, the hexapod is in the wrong position (either in parked or in unparked position).

*Indicated action:* "Park/Unpark Hexapod"

### **D16 "Cradle flaps not in correct position"**

*Cause of WARNING:* To perform an 0-position measurement the head needs to be fixed in the cradle. Therefore the cradle flaps must be in position.

*Indicated action:* "Check Cradle flaps..."

### **D17 "Patient switch not connected?"**

*Cause of WARNING:* the patient switch is not connected. This can be caused by a cable disconnection, a broken wire, or a broken connection.

*Indicated action:* "Check Patient switch..."

## Textual message errors

Textual message errors are displayed in the touch screen display during operation. Please act according to the message displayed.

### **Error message: "Patient Stop"**

*Cause of message:* someone clicked on the emergency / patient stop button

*Indicated action:* restart the therapy.

In "Quick start" a new movement measurement (teach) has to be performed.

When working with the "Occilink application" then please return to the home screen in the touch screen display panel and resend the therapy from the "Occilink application".

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**Error message: "Therapist Stop"**

*Cause of message:* someone clicked on the stop button of the foot switch.

*Indicated action:* restart the therapy.

In "Quick start" a new movement measurement (teach) has to be performed.

When working with the "Occilink application" then please return to the home screen in the touch screen display panel and resend the therapy from the "Occilink application".

**Error message: "Processing Error!"**

*Cause of message:* the filtering of the raw data could not be completed. Overflow of data.

*Indicated action:* restart the measurement. Please use a shorter measurement cycle/movement.

**Error message: "Hexapod Collision!"**

*Cause of message:* During a movement measurement (without the hexapod) the Occiflex calculates the trajectory that the hexapod will perform afterwards during the movement playback (the therapy). If the measurement movement is too close to the bed, causing the hexapod to collide with the bed during the playback, this message is indicated

*Indicated action:* Redo the measurement whereby the trajectory is not in close vicinity of the bed.

Note: this error is particularly relevant for later flexion movements. To prevent is you can also use a more proximal starting point by moving the hexapod away from the bed before starting the measurement.

**Error message: "Range Check Error!"**

*Cause of message:* During a movement measurement (without the hexapod) the Occiflex calculates the trajectory that the hexapod will perform afterwards during the movement playback (the therapy). If the measurement movement is too large, meaning the hexapod movement cannot reproduce this movement because of its mechanical limitations, this error will be displayed.

*Indicated action:* Redo the measurement whereby the movement trajectory is smaller.

**Error message: "Begin End Check Error!"**

*Cause of message:* During a movement measurement (without the hexapod) the trajectory is calculated based on the starting position and end position. The starting and end position should be (approximately) identical. So, during a movement measurement you need to end your movement in the position where you started it (that is, the position when you hit the footswitch in order to start recording. In case the starting and end position are too far from each other the "Begin End Check Error!" will be displayed.

*Indicated action:* Redo the measurement whereby the movement trajectory starts and ends in the same position of the head.


Note: there is a tolerance between the starting and end position of +/- 10 degrees and/or +/- 10 centimetre, providing you with ample space to perform a correct measurement within the boundaries of the system.

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## 13 SPECIFICATIONS

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### TECHNICAL DATA

Main dimensions	220 x 110 x 145 cm (L x B x H)
Dimensions of the bed	185 x 79 cm
Minimum workspace (l x w)	270 x 150 cm
Height adjustment	65 - 88 cm
Angle adjustment	10° from 70 cm. to 83 cm -5° from 75 cm. to 85 cm 0° at max.bed height (88cm) and min. bed height (65 cm)
Accuracy	Cradle translation: <=30mm. Cradle rotation <= 7°
Weight Occiflex	220 kg
Max. allowable patient weight on the bed	200 kg
Upholstery	Type AKV Peri, phthalates free
Fire safety	DIN EN 1021 part 1/2
Biological	DIN EN ISO 10993-5 DIN EN ISO 10993-10
Display	LCD / TFT colordisplay (with backlight)
Computer	The Occiflex system includes a “dedicated” computer with pre- installed software (‘Occilink ‘).
Technical specifications	
Mains voltage	100 - 240 V ± 10%, max.320VA
Frequency	50 / 60 Hz
Marking	

### ENVIRONMENT CONDITIONS

#### Environmental conditions for transport and storage

Environment temperature :	-10° till +70° C
Relative humidity :	10 till 90 %
Atmospheric pressure :	500 till 1060 hPa

#### Environmental conditions for normal use

Environment temperature:	5° till +30° C
Relative humidity:	10 till 90 %
Atmospheric pressure:	500 till 1060 hPa

*The technical specifications are subject to changes.*

## SAFETY AND PERFORMANCE STANDARDS

Medical device classification	Ila
The Occiflex complies with all the requirements of the Medical Devices Directive (MDD 93/42/EEC)	
Safety Class according to IEC 60601-1	Class 1 Type B
The unit is equipped with a safety earth and must be connected to a main plug with earthed contact.	

## EMC DETAILS

### Guideline and manufacturer's declaration – electromagnetic emission and immunity



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



Use of accessories, transducers 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.



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 Occiflex, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.



This device is a Group1, Class B device.

Group 1: Those ME equipment in which, radio-frequency energy is generated and/or used for their internal functioning (or) ME equipment intended to deliver energy to the PATIENT, but in a form, that is other than RF electromagnetic.

Class B: Those ME equipment that is predominantly intended for use in domestic establishments and connected to the PUBLIC MAINS NETWORK (e.g. Home care ME EQUIPMENT for doctor's offices in residential areas).



The Occiflex is intended for use in the electromagnetic environment specified in below tables. The customer or the user of the Occiflex should assure that it is used in such an environment.

<b>Electromagnetic interference</b>		
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment</b>
RF emissions CISPR 11	Group 1	The RF that the Occiflex emits are side effects of the electrical components used. RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

<b>Electromagnetic immunity of the enclosure port of the Occiflex</b>			
<b>Phenomenon</b>	<b>Basic EMC standard or test method</b>	<b>IMMUNITY TEST LEVELS</b>	<b>Compliance level</b>
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8 kV contact  ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Complies <sup>a)</sup>
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	Complies
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Test levels according to: table 9 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment of 60601-1-2 IEC:2014	Complies
RATED power frequency magnetic fields d) e)	IEC 61000-4-8	30 A/m 50 Hz	N/A
<sup>a)</sup> The head strap is considered an ESD sensitive part. In order to prevent damage, never touch the transmitter on the head strap.			

<b>Electromagnetic immunity of the input a.c. power port of the Occiflex</b>			
<b>Phenomenon</b>	<b>Basic EMC standard or test method</b>	<b>IMMUNITY TEST LEVELS</b>	<b>Compliance level</b>
Electrical fast transients / bursts	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	Complies
Surges a) b) j) o) Line-to-line	IEC 61000-4-5	± 0,5 kV, ± 1 kV	Complies
Surges a) b) j) k) o) Line-to-ground	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV	Complies

<b>Electromagnetic immunity of the input a.c. power port of the Occiflex</b>			
<b>Phenomenon</b>	<b>Basic EMC standard or test method</b>	<b>IMMUNITY TEST LEVELS</b>	<b>Compliance level</b>
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V  0,15 MHz – 80 MHz  6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz  80 % AM at 1 kHz	Complies
Voltage dips	IEC 61000-4-11	0 % UT; 0,5 cycle  At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°  0 % UT; 1 cycle  And  70 % UT; 25/30 cycles Single phase: at 0°	Complies
Voltage interruptions f)	IEC 61000-4-11	0 % UT; 250/300 cycle	

<b>Electromagnetic immunity of the signal input/output parts of the Occiflex</b>			
<b>Phenomenon</b>	<b>Basic EMC standard or test method</b>	<b>IMMUNITY TEST LEVELS</b>	<b>Compliance level</b>
ELECTROSTATIC DISCHARGE e)	IEC 61000-4-2	± 8 kV contact  ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Complies <sup>a)</sup>
Electrical fast transients / bursts b)	IEC 61000-4-4	± 1 kV 100 kHz repetition frequency	Complies
Surges Line-to-ground a)	IEC 61000-4-5	± 2 kV	Complies
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V  0,15 MHz – 80 MHz  6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz  80 % AM at 1 kHz	Complies
<sup>a)</sup> The head strap is considered an ESD sensitive part. In order to prevent damage, never touch the transmitter on the head strap			

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## 14 TECHNICAL ASSISTANCE AND ORDERING INFORMATION

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For technical assistance, please visit our website

<http://www.enraf-nonius.com/>

The latest version of this Instructions for Use (in electronic or printed format) can be obtained free of charge

- ❖ from our website <http://www.enraf-nonius.com/> or,
- ❖ by contacting distributor or,
- ❖ by calling the telephone number: **+31-(0)10-2030600**

The Instructions for use will be sent **(free of charge)** to you within **7 (seven) calendar days**.

For the ordering data of the Occiflex standard accessories and additional accessories we refer to <http://www.enraf-nonius.com/>

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## 15 PRODUCT LIABILITY

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A law on Product Liability has become effective in many countries. This Product Liability law implies, amongst other things, that once a period of 10 years has elapsed after a product has been brought into circulation, the manufacturer can no longer be held responsible for possible shortcomings of the product.

To the maximum extent permitted by applicable law, in no event will Enraf-Nonius or its suppliers or resellers be liable for any indirect, special, incidental or consequential damages arising from the use of or inability to use the product, including, without limitation, damages for loss of goodwill, work and productivity, computer failure or malfunction, or any and all other commercial damages or losses, even if advised of the possibility thereof, and regardless of the legal or equitable theory (contract, tort or otherwise) upon which the claim is based. In any case, Enraf-Nonius's entire liability under any provision of this agreement shall not exceed in the aggregate the sum of the fees paid for this product and fees for support of the product received by Enraf-Nonius under a separate support agreement (if any), with the exception of death or personal injury caused by the negligence of Enraf-Nonius to the extent applicable law prohibits the limitation of damages in such cases.

The opposing party (product's user or its representative) shall disclaim Enraf-Nonius from all claims arising from third parties, whatever nature, or whatever relationship to the opposing party.



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## 16 SYMBOLS USED IN THE INSTRUCTIONS FOR USE AND ON DEVICE

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Follow the instructions in the user manual

It is important that you read, understand and observe the precautionary and operating instructions.



Indicates a hazardous situation which, if not avoided, could result in

- Death or serious injury to the patient or operator (or)
- Minor to moderate injury to the patient or operator (or)
- Damage to the equipment



General prohibition sign

Prohibition is used to mean, "You must not..."



General mandatory action sign

Mandatory action is used to mean, "You must..."



Waste electrical items – that can be recycled

Indicates the electrical and electronic components of the device can be recycled and has to be disposed separately.



CE Mark along with number indicates conformity with European Council of directive concerning Medical Devices and this device is under the direct supervision of the Notified Body.

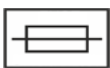


Serial Number

Indicates the manufacturer's serial number so that a specific medical device can be identified.



Reference Number or Part Number



Fuse

Ratings are described in chapter "Specifications"



Safety Class I device.

To avoid the risk of electric shock, this equipment must only be connected to supply mains with protective earth.



Indicates Type B applied parts.



Manufacturer name, address and date of manufacture.



Temperature Limits

Indicates acceptable temperature range



Humidity Limits

Indicates acceptable relative humidity



Atmospheric Pressure Limits

Indicates the range of atmospheric pressure to which the medical device can be safely exposed.



Keep the device dry

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