

Nr. 4.1. Spalvotas monitoriaus ekranas:



## Instructions for Use

**C2 Xplore (REF: 508288)**

Head Box (REF: 540430)

Body Box (REF: 540431)

SEP Box (REF: 540432)

plOM Box (REF: 540433)

Software Version 4.3

Rx Only



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## Abbreviations

Abbreviation	Meaning
pIOM	Pelvic intraoperative neuromonitoring
EMG	Electromyography
SEP	Somatosensory evoked potentials
CoMEP	Corticobulbar motor evoked potentials
EP recording	Evoked potential recording
HF	High frequency
OP	Operation / surgical procedure
ID	Identification number
STIM	Stimulator
cIONM	Continuous intraoperative neuromonitoring

Table 1: Abbreviations

## 1 GENERAL INFORMATION

### 1.1 GENERAL INFORMATION ABOUT THE INSTRUCTIONS FOR USE

These Instructions for Use is a translation of the original German document D010135-DE Rev.1.3 – 2022/12.

These Instructions for Use and all applicable documents must be stored in a location that is accessible for subsequent use.

The Instructions for Use and the safety and warning instructions must be read and understood.

Failure to read and understand or comply with these Instructions for Use can have the following consequences:

- Death or serious injury to the patient
- Serious injury to the user
- Serious injury to third parties
- Damage to the products

The information included in these Instructions for Use represents the technical specifications that are approved at the time of printing. Changes will be incorporated in a new version of the Instructions for Use.

The document number, version number and the date of creation of these Instructions for Use is shown in the footer.

### 1.2 MANUFACTURER

The C2 Xplore device has been manufactured by inomed Medizintechnik GmbH. inomed Medizintechnik GmbH is therefore referred to as the manufacturer in these Instructions for Use.

Contact details of the manufacturer:

inomed Medizintechnik GmbH  
Im Hausgrün 29  
79312 Emmendingen  
Germany  
E-mail: [info@inomed.com](mailto:info@inomed.com)  
Tel: +49 7641 94 14-0

### 1.3 MARKINGS AND SYMBOLS USED IN THESE INSTRUCTIONS FOR USE

#### Instructions for Use

Different graphical symbols and structures are used in these Instructions for Use. These are used as follows:

Structure / symbol	Meaning
1.	Instruction with a defined sequence
➤	Result of an action step
•	Listing without a defined sequence
<i>“italics”</i>	Reference to a section
DISPLAY	Elements on the touchscreen (e.g. buttons, pop-up screens, display)
	Danger!
	Warning!
	Caution!
<b>i</b>	<i>Note</i>

Table 2: Symbols used in the IFU

#### Labels and symbols on the device

The following symbols are used on the device, the type plate or on labels:

Symbol	Description	Standard
	Manufacturer: The manufacturer of the medical device.	EU Directives 90/385/EEC, 93/42/EEC, 98/79/EC, ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
	Date of Manufacture: The date on which a product was manufactured.	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
	Separate collection of electrical devices	Directive 2012/19/EU – on waste electrical and electronic equipment (WEEE)

Symbol	Description	Standard
	General warning symbol: For highlighting a general warning.	DIN EN 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
	Caution: For labelling on the device to warn that care must be taken near the symbol if the device is in use.	ISO 7010-W001
	Consult Instructions for Use: The user must consult the Instructions for Use.	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
	Type BF Applied Part: A type BF (body floating) applied part is connected to the body of the patient in order to transmit electrical energy or an electro-physiological signal to or from the body.	DIN EN 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
	Catalogue Number: Catalogue number of the manufacturer for identification of the medical device.	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
	Serial Number: A clear, unambiguous sequence of digits or letters in a series for identification of an individual unit of a medical device.	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
	Batch Code: The batch code of the manufacturer ensures that the batch or lot can be clearly identified with no doubt.	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
Rx Only	Prescription-only: Under US Federal Law, the sale of this device is restricted, and it can only be sold to or on the order of a physician.	FDA Rule 81 FR 38911
	MR unsafe: Object that represents a known threat or is a danger in all MR environments.	ASTM F2503-13, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

Symbol	Description	Standard
	<p>Atmospheric Pressure Limitation:</p> <p>Indicates the range of atmospheric pressure to which the medical device can be safely exposed for transport, storage and use.</p>	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
	<p>Humidity Limitation:</p> <p>Indicates the range of humidity to which the medical device can be safely exposed for transport, storage and use.</p>	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
	<p>Temperature Limit:</p> <p>Upper and lower temperature limits for transport, storage and use.</p>	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
	<p>CSA:</p> <p>certified product, certification requirements met for electrical, plumbing and/or mechanical products.</p>	CAN/CSA – C22.2 no. 60601-1:14 and ANSI/AAMI ES60601-1:2005/(R)2012 (IEC 60601-1:2005 + A1:2012)
	<p>Non-sterile:</p> <p>Indicates a medical device that has not been subjected to a sterilization process.</p>	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
	<p>Keep Dry</p> <p>Indicates a medical device that needs to be protected from moisture.</p>	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
	<p>Equipotentiality:</p> <p>To identify the terminals that, when connected, bring the various parts of an equipment or of a system to the same potential, not necessarily being the ground potential, e.g. for local connection.</p>	IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance features
	<p>Fuse:</p> <p>To identify fuse boxes or their location.</p>	Graphical symbols for use on equipment - Part 1: Overview and application

	Foot switch: To identify a foot switch or the connection for a foot switch.	IEC 60417 Graphical symbols for use on equipment
	Characteristics of the European Union: main identifier for the conformity of a product with the applicable legal provisions of the EU.	COUNCIL DIRECTIVE 93/42/EEC concerning medical devices

Table 3: Symbols used in the IFU and labels

## 1.4 LAYOUT OF SAFETY INSTRUCTIONS AND WARNINGS

### Safety instructions

Safety instructions refer to the entire Instructions for Use and must always be followed before, during and after use of the device.

### Warnings

Warnings apply to entire chapters or sections, subsections or individual paragraphs within these Instructions for Use.

Safety instructions and warnings use the following layout:



#### **SIGNAL WORD!**

- Type and source of danger!  
Explanation of the type and source of danger.  
Precautions taken to avoid the danger.

### Classification of safety instructions and warnings

- **DANGER!**  
Describes an immediate danger. If not avoided, the situation will result in death or serious injury.
- **WARNING!**  
Describes a potentially dangerous situation. If not avoided, the situation can result in death or serious injury.
- **CAUTION!**  
Describes a potentially dangerous situation. If not avoided, the situation can result in slight or minor injuries. This can also be used for warnings about material damage.
- **Note:**  
A note provides important information about correct operation of the device or will help make your work easier.

## 1.5 DEFINITION OF THE PATIENT ENVIRONMENT

According to DIN EN 60601-1, the patient environment is defined as follows:

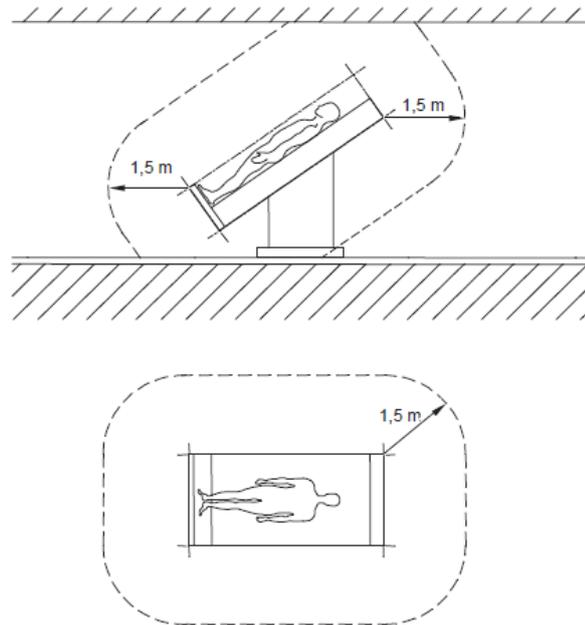


Figure 1: Patient environment

Use the C2 Xplore always outside the patient environment.

## 1.6 GENERAL DESCRIPTION OF THE DEVICE

C2 Xplore is a further development of the previous intraoperative neurophysiological monitoring systems from inomed Medizintechnik GmbH and has been developed for routine intraoperative applications.

The modular layout of the C2 Xplore can be used to implement various system configurations in the specialist areas of neurosurgery, ENT surgery, orthopaedics, trauma surgery, vascular surgery, general surgery and abdominal surgery with the matching accessories in each field.

Depending on the configuration, the system is equipped with up to 8 differential amplifier channels and two independent stimulators.

All components can be operated via the integrated software of the device.

In the following the C2 Xplore is referred to as the "device".

## 1.7 ACCESSORIES

Depending on the equipment and application, special accessories are available for stimulation and recording. In accordance with IEC60601-1 cl.7.9.2.14 you will find an overview of approved accessories in *section "10 C2 Xplore – Accessories"* in these Instructions for Use.

The device must only be used with accessories from inomed Medizintechnik GmbH, which have been expressly tested and approved by inomed Medizintechnik GmbH.

## 1.8 SOFTWARE

These Instructions for Use are valid for software version 4.3 of the C2 Xplore software.

## 2 INDICATION FOR USE

### 2.1 INTENDED USE OF C2 XPLORE

C2 Xplore paskirtis

- Nr. 1. The C2 Xplore is intended for intraoperative neuromonitoring; for recording of electrophysiological signals and stimulating of nerve and muscle tissues. C2 Xplore skirtas intraoperaciniam neuromonitoringui; įrašymui elektrofiziologinių signalų ir nervų bei raumenų audinių stimuliavimui. The C2 Xplore is designed for use in the operating room to measure and display the physiological signals generated by muscles, peripheral nerves and the central nervous system. The system supports the clinical application of Electromyography (EMG), Somatosensory Evoked Potentials (SEP), cortical Motor Evoked Potentials (CoMEP), and pelvic neuromonitoring (pIONM). C2 Xplore skirtas naudoti operacinėje, kad būtų galima matuoti ir rodyti raumenų, periferinių nervų ir centrinės nervų sistemos generuojamus fiziologinius signalus.

The system is not intended for monitoring life-sustaining functions.

Sistema palaiko klinikinį elektromiografijos (EMG), somatosensorinių iššauktų potencialų (SEP), smegenų žievės motorinių iššauktų potencialų (CoMEP) taikymą.

### 2.2 CONTRAINDICATIONS

The application of the C2 Xplore is contraindicated for the use of muscle relaxants during CoMEP and EMG measurement, as these cause significant reductions in the muscle potentials.

Relative contraindications of cortical electrical motor evoked potentials (CoMEP), somatosensory evoked potential (SEP) and electromyographical recording (EMG) include epilepsy, cortical lesions, convexity skull defects, raised intracranial pressure, cardiac disease, proconvulsant medications, intracranial electrodes, vascular clips or shunts, and cardiac pacemakers or other implanted biomedical devices. Otherwise intraoperative seizures and possibly arrhythmias are indications to abort stimulation.

Every contraindication must be weighed against the risk and benefits associated with use of the product.

### 2.3 ESSENTIAL PERFORMANCE

- Nr. 9.2.1. C2 Xplore applies electric stimulation pulses within application-specific programs. This leads to visual and acoustic feedback via EMG and EP recording. C2 Xplore taiko elektros stimuliacijos impulsus konkrečioms programoms. Tai veda prie vizualinio ir akustinio grįžtamojo ryšio naudojant EMG ir EP įrašymą.

The pulse amplitude, the pulse width and the stimulation frequency of the C2 Xplore stimulation signal correspond to the set value with a tolerance of 30% (IEC 60601-2-40:2016, section 201.12.1).

C2 Xplore delivers the biosignal feedback within a defined latency of  $\leq 3$  s.

## 2.4 INTENDED USE OF THE ADAPTER BOXES

### **Adapter box: Head Box (REF: 540430)**

This accessory product is intended for transmission of energy between the C2 Xplore and patient-side electrodes or stimulation accessories for application in electromyography (EMG).

### **Adapter box: Body Box (REF: 540431)**

This accessory product is intended for transmission of energy between the C2 Xplore and patient-side electrodes or stimulation accessories for application in corticobulbar motor evoked potentials (CoMEP).

### **Adapter box: SEP Box (REF: 540432)**

This accessory product is intended for transmission of energy between the C2 Xplore and patient-side electrodes or stimulation accessories for application in somatosensory evoked potentials (SEP).

### **Adapter box: pIOM Box (REF: 540433)**

This accessory product is intended for transmission of energy between the C2 Xplore and patient-side electrodes or stimulation accessories for application in pelvic interoperative neuromonitoring (pIOM).

## 2.5 TARGET GROUP

**WARNING!**

- Risk of injury if personnel are not sufficiently well qualified!

The device must only be used by qualified personnel, such as surgeons or clinically experienced and trained personnel under the supervision of a surgeon.

Target group	Training	Knowledge
General surgeons	<ul style="list-style-type: none"> <li>• Training in general surgery AND</li> <li>• State licence to practice medicine, as evidence of completion of training in general surgery</li> </ul>	<ul style="list-style-type: none"> <li>• Familiar with surgical methods for protecting nerves</li> </ul> <p>Optional:</p> <ul style="list-style-type: none"> <li>• Basic knowledge of EMG measurements and methodology</li> <li>• Basic knowledge of cystomanometric measurements and methodology</li> <li>• Current changes to the user interface</li> </ul>
Neurosurgeons	<ul style="list-style-type: none"> <li>• Training in neurosurgery AND</li> <li>• State licence to practice medicine, as evidence of completion of training in neurosurgery AND</li> <li>• Experience in clinical neurophysiology and in intraoperative neurophysiological monitoring</li> </ul>	<ul style="list-style-type: none"> <li>• Command of the foundations of EMG, SEP, and MEP measurements.</li> </ul> <p>Training:</p> <ul style="list-style-type: none"> <li>• Introduction to signal displays as well as optical and acoustic feedback from the system</li> <li>• Current changes to the user interface</li> </ul>
Vascular surgeons	<ul style="list-style-type: none"> <li>• Training in vascular surgery AND</li> <li>• State licence to practice medicine, as evidence of completion of training in vascular surgery</li> </ul>	<ul style="list-style-type: none"> <li>• Command of the foundations of SEP measurements.</li> </ul> <p>Training:</p> <ul style="list-style-type: none"> <li>• Introduction to signal displays and optical and acoustic feedback from the system during the procedure.</li> <li>• Current changes to the user interface</li> </ul>

Target group	Training	Knowledge
ENT surgeons	<ul style="list-style-type: none"> <li>• Training in ENT surgery AND</li> <li>• State licence to practice medicine, as evidence of completion of training in ENT surgery.</li> </ul>	<ul style="list-style-type: none"> <li>• Command of the foundations of EMG measurements.</li> </ul> <p>Training:</p> <ul style="list-style-type: none"> <li>• Introduction to signal displays and optical and acoustic feedback from the system during the procedure</li> <li>• Current changes to the user interface</li> </ul>
Orthopaedists	<ul style="list-style-type: none"> <li>• Training in orthopaedics and trauma surgery AND</li> <li>• State licence to practice medicine, as evidence of completion of training in orthopaedics and trauma surgery</li> </ul>	<ul style="list-style-type: none"> <li>• Command of the foundations of EMG measurements.</li> </ul> <p>Training:</p> <ul style="list-style-type: none"> <li>• Introduction to signal displays and optical and acoustic feedback from the system during the procedure</li> <li>• Current changes to the user interface</li> </ul>
Operating theatre care staff, care staff, assistants for surgical procedures, medical assistants	<ul style="list-style-type: none"> <li>• Intermediate school leaving certificate for operating theatre care staff</li> <li>• Training on the standard workflow for general surgical procedures</li> </ul>	<p>Training:</p> <ul style="list-style-type: none"> <li>• System configuration and setup with an explanation of the individual system components</li> <li>• Instructions for the standard workflow and connection diagrams in operating theatres</li> <li>• Complete process for a sample surgical procedure after initial training This includes electrode placement and cabling and connection to the adapter boxes. Plus, hardware and all software settings as well as first measurements.</li> <li>• Current changes to the user interface</li> </ul>

Table 4: Target group

## 3 SAFETY INFORMATION

### 3.1 GENERAL SAFETY INFORMATION:



#### **WARNING!**

- 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 C2 Xplore, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- If the essential performance is temporarily lost due to excessive electromagnetic disturbances – expected behaviour: The user application will generally signal a warning. It will be possible to proceed with the scenario settings in the user Application C2 Xplore. Requirements and guidelines for acceptable system behaviour during temporarily loss of essential performance are maintained: IEC 60601-1-2 Ed. 4 (2014) + IEC 60601-2-40 (2016).
- **Severing of nerves!**  
The device cannot actively prevent severing of nerves. Always rely on your specialist expertise as a surgeon.
- **Serious injury!**  
Monitoring of nerves with the C2 Xplore is no replacement for the anatomical expertise of the surgeon. Always rely on your specialist expertise as a surgeon.
- **Serious injury!**  
Only use the absence of an EMG response to decide on your next steps during the surgical procedure if you have previously measured an initial nerve response signal.
- **Serious injury!**  
Only use the absence of an EMG response to decide on your next steps during the surgical procedure if you can ensure that no changes have been made to the setup.

**WARNING!**

- **Incorrect measurement!**  
The device and the electrodes are not properly connected. Do not use the device until you have performed a reference measurement.
- **Incorrect measurement!**  
Check the electrode connections as soon as a corresponding signal tone indicates that this is necessary.
- **Localised tissue burns!**  
Only use accessories recommended by the manufacturer inomed Medizintechnik GmbH.
- **Injuries to patients and users!**  
The device and its accessories are classed as MR-unsafe. Do not use the device in an MR environment.
- **Malfunction of implanted medical devices!**  
Only stimulate patients with implanted medical devices after consultation with a specialist, but generally never through the thorax.
- **Electric shock!**  
All maintenance work must only be performed by inomed Medizintechnik GmbH or by an agent authorised by inomed to carry out such work.
- **Electric shock!**  
Never make any modifications or repairs to the device or remove parts of it.
- **Risk of explosion!**  
Do not use the device in an environment with an increased risk of explosion.
- **Injury to the patient!**  
Every time before using the device, make sure that the settings for the emission of stimulation signals match the application-specific stimulation parameters.
- **Incorrect measurements due to personal user settings!**  
The user has set up the application with the energy level too low. Always perform a reference measurement every time before using the device.

**CAUTION!**

- **Slight electric shock!**  
All mains-operated devices must be supplied from a medically approved power supply unit, or the device must be connected using a medical isolator.
- **Slight electric shock!**  
Always use a medical isolator to connect the device to a network.

**CAUTION!**

- Electromagnetic interference!  
Blocked nerve conduction – always install the device in accordance with the EMC information in the Instructions for Use. The system requires special safety precautions in relation to EMC and must be installed and used in accordance with the EMC instructions in *section “8 Technical specifications”*.
- Device failure during a surgical procedure!  
Stop the surgical procedure or rely on alternative methods, surgical skills and anatomical knowledge.
- Device failure due to HF interference during a surgical procedure!  
Do not place the device near an HF transmitter.
- Slight electric shock!  
Place the device outside the operating theatre field and at a safe distance to other systems from which liquids could leak.
- Slight electric shock!  
The device must only be connected to a supply network that is equipped with a protective ground.
- Slight electric shock!  
Do not connect the device to an additional socket strip with multiple sockets or to an extension cable.
- Incorrect measurement due to signal interference!  
Position the cables of the measuring electrodes as far as possible away from other electric devices.
- Incorrect measurement due to signal interference!  
Interference caused by strong electromagnetic fields, e.g. thermal lesion generators or radiofrequency generators, can cause faults. Shield the C2 Xplore against this type of interference.
- Incorrect measurement due to signal interference!  
When positioning the cables of the measuring electrodes, make sure there are no loops in the cables.
- Incorrect measurements due to anaesthetics with muscle relaxants!  
Do not use anaesthetics with muscle relaxants.
- Neurological seizure!  
Observe all rules on the simultaneous application of electrosurgery and neuromonitoring.
- Slight electric shock!  
Never clean or moisten the C2 Xplore and the adapter boxes during a surgical procedure if the patient is still connected.

### 3.2 USE OF HIGH-FREQUENCY SURGICAL DEVICES

The emissions properties of this device make the C2 Xplore suitable for use in industrial areas and hospitals (CISPR 11 Class A).

If the device is used in a residential environment (for which CISPR 11 Class B would normally be required), this device may possibly not offer sufficient protection for high-frequency communication services. The user may need to take measures to mitigate this, e.g. by moving the device to a different location or changing its orientation.

When using the C2 Xplore in combination with monopolar and bipolar high-frequency surgical devices (HF devices), the following precautions must be taken to protect the patient against the risk of burns:



#### **WARNING!**

- Burns to the patient!  
Place the HF electrodes in accordance with the requirements of the manufacturer.  
The neutral electrode with its large surface area is normally placed on the thigh, upper arm or shoulder.
- Burns to the patient!  
Place the electrodes outside the HF coagulation pathway.
- Burns to the patient!  
Only use accessories that are suitable and approved for use in HF surgery applications.
- Burns to the patient!  
Never use a HF device simultaneously with stimulation from the C2 Xplore device. It is not permitted to start or continue stimulation while an HF device is activated. Remove the stimulation probe from the surgery area.
- Interference with the measurement signal!  
Leakage currents are incorrectly conducted away via patient cables or connecting cables. Check whether the neutral electrode of the electrosurgery device is correctly positioned on the patient.
- Interference with the measurement signal!  
Capacitive coupling or induction of high-frequency currents. Position the connecting cable as far as possible from the HF cable of the HF device.
- Interference with the measurement signal!  
Always use the lowest possible HF power for cutting or coagulating.

## 4 DEVICE DESCRIPTION – C2 XPLORE

### 4.1 SCOPE OF DELIVERY

The C2 Xplore basic unit includes:

- C2 Xplore – REF: 508288
- Software, Software-Version 4.3
- C2 Xplore accessories, refer to *section “10 C2 Xplore – Accessories”*
- C2 Xplore Instructions for Use

### 4.2 UNPACKING THE DEVICE

1. Place the carton on a level surface.
  - Make sure that the carton is placed the right way up – refer to the arrows.
2. Open the carton.
3. Take out the inside carton with the cables and the adapter boxes (if applicable).
4. Carefully pull the C2 Xplore out of the carton.
5. Remove the foam padding.
6. Dispose of the packaging materials in accordance with the rules and regulations that apply in your country.

### 4.3 UNPACKING THE ADAPTER BOXES

1. Place the carton on a level surface.
2. Open the carton.
3. Take out the adapter box.
4. Remove the adapter box from the clip-seal bag.
5. Dispose of the packaging materials in accordance with the rules and regulations that apply in your country.

### 4.4 INSTALLING THE DEVICE

After delivery, the device will be installed by a service engineer from inomed Medizintechnik GmbH or by a trained medical devices consultant.

**i** **Note:**

Depending on the particular C2 Xplore configuration purchased, it is possible that not all of the functions described in the Instructions for Use have been activated.

To enable additional software modules, please get in touch with inomed Medizintechnik GmbH and request a corresponding licence file. The file will be copied to a USB stick, which will then be connected to the C2 Xplore by a service engineer.

#### 4.5 INSTALLING THE ADAPTER BOXES

Detailed instructions for connecting the adapter boxes to the device can be found in *section 4.7 Adapter boxes*.

#### 4.6 SETTING UP THE DEVICE

The following section contains a description of the functions of the device and shows its operating controls.

Elements described in this section are only in contact with the user and are not in the patient environment. For a definition of the patient environment, refer to *section “1.1 General information about the Instructions for Use”*.

Elements with potential contact to the patient are accessories and are discussed in a separate part of this manual.

##### Front panel

Priekinis skydelis

The device is operated via a combination of touchscreen and operating controls.

Įrenginys valdomas liečiamo ekrano ir valdymo valdiklių deriniu.



Figure 2: C2 Xplore – front view

Key to Figure 2: C2 Xplore – front view

A, B, C: Operating controls and interfaces on the front panel

D, E, F: Components on the right-hand side

G: Interfaces on the rear panel

The detailed functions of the components A to G are described in the sections below.

**Front panel – A**

Figure 3: Front panel – A

**Key to Figure 3: Front panel – A**

1: Device family

2: Manufacturer of the device

The touchscreen of the C2 Xplore shows the measurement and settings screens and allows many device functions to be controlled. The scaling of the displayed signals can be changed on the touchscreen.

**Touchscreen – B**

Liecīamais ekrāns

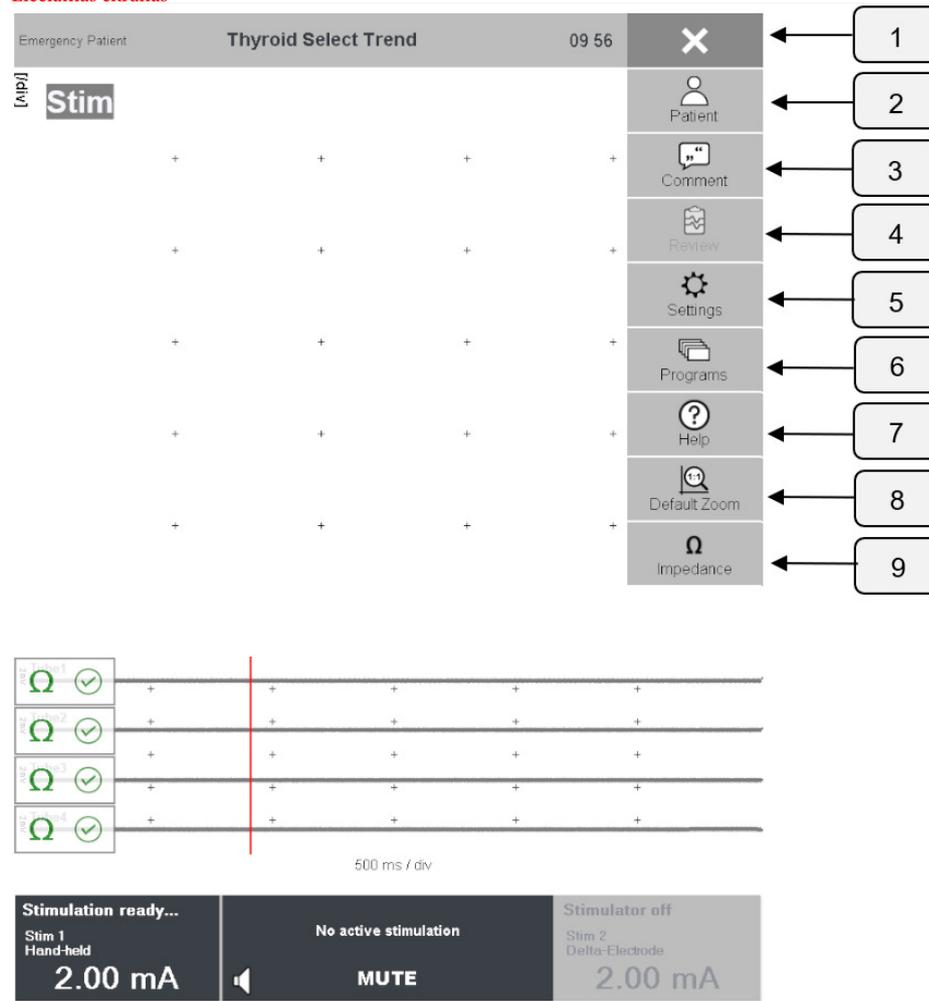


Figure 4: Touchscreen elements – B

Key to Figure 4: Touchscreen elements – B

- 1: Menu bar: Open/hide the menu bar
- 2: Patient: Create patient data
- 3: Comments: Opens the Comments menu
- 4: Analysis and printing: Print report
- 5: Settings: Adjust settings
- 6: Programs: Select programs
- 7: Help: Read help topics
- 8: Standard zoom: Return to standard size
- 9: Impedance: Perform impedance test

The menus are called up by pressing the corresponding button. The number of buttons that are visible depends on the selected program.

**Front panel – C**

Priekinė valdymo panelė

Zoom out: Place two fingers on the touchscreen and move them together.

Zoom in: Place two fingers on the touchscreen and move them apart.

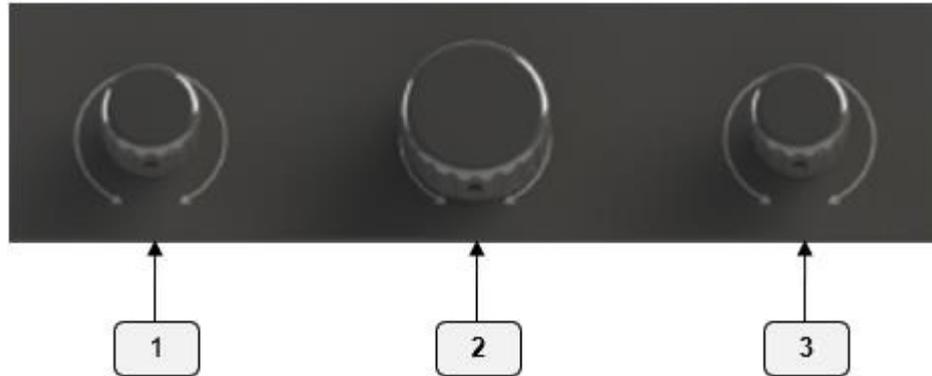


Figure 5: Operating controls at the bottom – C

Key to Figure 5: Operating controls at the bottom – C

1: Current control for the left-hand stimulator for EMG, SEP, Cortical or navigation for Spine, pIOM

**2: Volume control**, navigation in menus

Garso valdymas

3: Current control for the right-hand stimulator for EMG, SEP, Cortical or navigation for Spine, pIOM

Middle rotary knob:

The function of the middle rotary knob is dynamic and changes depending on the selected menu.

- Turn the middle rotary knob (2) to adjust the volume.
- Press the middle rotary knob (2) to switch the loudspeaker on or off.
- Press the middle rotary knob in submenus to select, edit and confirm parameters.

Left / right-hand rotary knob:

- Press the left/right-hand rotary knob (2, 3) in the EMG, SEP, or Cortical programs to activate the stimulators. Once activated, the stimulation is automatically triggered after current confirmation.
- Press the left/right-hand rotary knob (2, 3) in the Spine and pIOM programs to navigate through the different areas of the software.

**Right-hand side – D, E, F**

The right-hand side of the device features a USB port, a loudspeaker opening, and a barcode scanner.

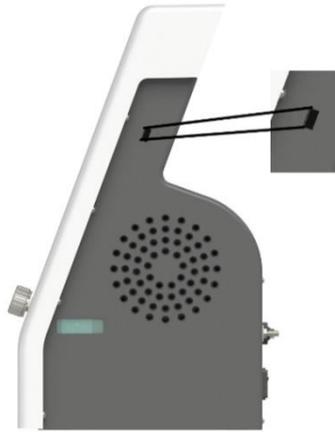
**USB port – D**

Figure 6 View of the right-hand side, USB port – D

Saving patient data:

1. Insert a USB stick into the USB port on the right-hand side.
  - The database or report can be saved to the USB stick – refer to section “5.8 Exporting patient data”.

**Loudspeaker – E**

Garsiakalbis



Figure 7 View of the right-hand side, loudspeaker – E

Acoustic feedback for the measured signal is provided via the loudspeaker.

Registruojamo signalo akustinis grįžtamasis ryšys pateikiamas per garsiakalbį.

Nr. T2.1. **Barcode scanner – F**  
 Brūkšninių kodų skaitytuvas

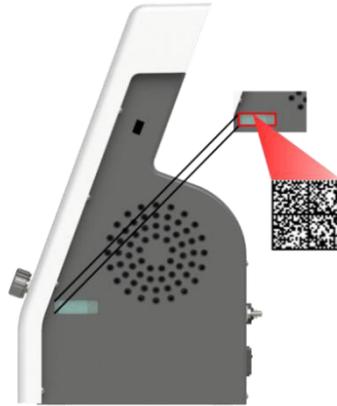


Figure 8 View of the right-hand side, barcode scanner – F



**WARNING!**

- Electric shock!

You must not perform any maintenance on the barcode scanner yourself. If you need maintenance work to be carried out, please call out a service engineer from inomed Medizintechnik GmbH.

The barcode scanner reads patient data or the patient ID using a 1D or 2D barcode, see *Figure 8 View of the right-hand side, barcode scanner – F*.

1. Hold the barcode up against the right-hand side of the C2 Xplore.
  - The barcode scanner automatically reads in the patient data and adds it to the ongoing surgical procedure.
  - An acoustic feedback signal sounds to confirm the action.
  - If a patient is already present, then the scanning process is ignored, and there is no acoustic feedback.

It is also possible to add a barcode with the patient ID after the surgical procedure.

**Specifications of the barcode scanner**

The barcode scanner can read 1D and 2D barcodes that are positioned in a certain area. The following tables show the field of view and the illumination area.

Nom FOV (X x Y)	45.7° x 29.8°
Max FOV (X x Y)	50.1° x 34.4°
Conjugated distance	115 mm

Table 5: Field of view for imaging – Nom FOV (X x Y)

Required illumination area for the maximum field of view at 20° (X x Y)	47.15° x 33.50°
---	-----------------

Table 6 Illumination area

**i Note:**

The following barcodes are supported:

Palaikomi šie brūkšniniai kodai:

- EAN 8
- EAN 13
- UPC – E
- UPC – A
- Code 39
- Interleave 2 of 5
- Code 128
- EAN 128
- MSI/Plessey
- Codabar
- Aztec
- Datamatrix
- Han Xin
- MaxiCode
- MicroPDF417
- PDF417
- QR Code
- Micro QR Code

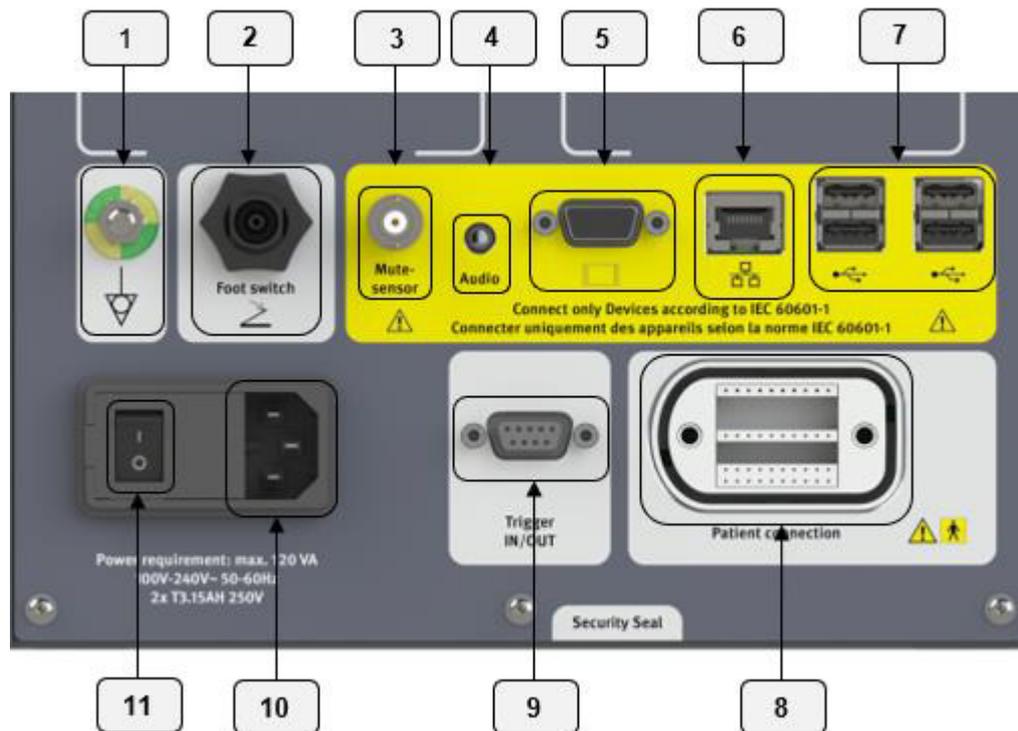
**Rear panel – G**

Figure 9: Connectivity options on the rear panel – G

Key to Figure 9: Connectivity options on the rear panel – G

- 1: Equipotential bonding
- 2: Foot switch: For opening the Comments menu
- 3: Mute sensor: Suppression of HF artefacts
- 4: Audio: For connection of an external loudspeaker; 3.5 mm jack
- 5: VGA: Connection of an external monitor
- 6: Network connection: RJ45 plug
- 7: USB 2.0 port
- 8: Patient connection: Connection of the adapter box
- 9: Trigger IN / OUT: For use by service technicians only
- 10: Mains plug: Connection to the power supply
- 11: Main switch: On/off switch

Explanation for 1: Equipotential bonding: Connect the device to the equipotential bonding bar of the hospital power supply network. As a result, possible voltages between the ground cable and the medical device are avoided. It also improves the suppression of line disturbances on the C2 Xplore.

### Connection of the adapter box

1. Connect the adapter box to the C2 Xplore at the patient connection.
2. Connect single-use and reusable stimulation probes via the stimulation outputs STIM 1 and STIM 2 on the relevant adapter box to each stimulator.

The device has two independent stimulators. Each stimulator is adjusted via the left/right-hand rotary knob, see *Figure 5: Operating controls at the bottom – C*.

For details of the parameter range refer to *section “8 Technical specifications”*.

All connections are protected against accidental touching and rotation.

## 4.7 ADAPTER BOXES

Adapter boxes are required to connect stimulation and recording accessories to the C2 Xplore. Each of the specific programs involves the use of the corresponding adapter box.

Four different adapter boxes are available for the C2 Xplore.

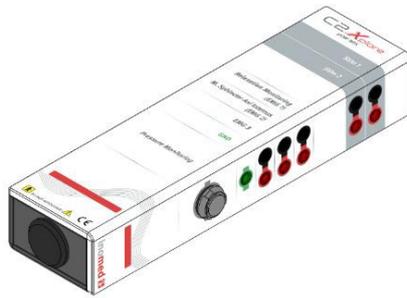


Figure 11: C2 Xplore pIOM Box (Ref 540433)

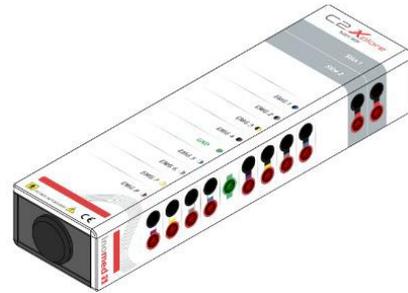


Figure 10: C2 Xplore Body Box (Ref 540431)

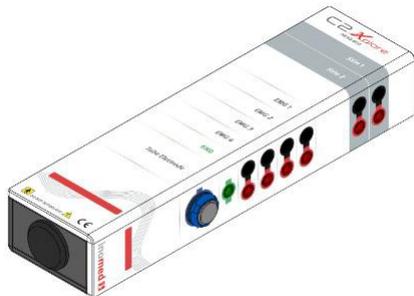


Figure 13: C2 Xplore Head Box (Ref 540430)



Figure 12: C2 Xplore SEP Box (Ref 540432)

The table below lists the recommended adapter boxes for different software modules and applications.

Name	Reference number	Area of application
Head Box	540430	Thyroid surgery, ENT surgery
Body Box	540431	Spinal surgery, neurosurgery
SEP Box	540432	Vascular surgery
pIOM Box	540433	Rectal surgery

Table 7: Adapter boxes for different applications

All the available adapter boxes are connected with a plug to the patient connection on the rear panel of the C2 Xplore.

## 4.8 START OF THE SURGICAL PROCEDURE

### Before taking the device into an operation

1. Visually inspect the components of the device and accessories to make sure that they are in the correct condition.
2. Perform a visual inspection to check the device components or accessories for electrical or mechanical defects.
3. Check that the device is in a stable position.
4. Interference caused by strong electromagnetic fields, e.g. thermal lesion generators or radiofrequency generators, can cause faults. Shield the C2 Xplore against this type of interference.
5. Devices with a power consumption above 100 W can represent sources of interference in the region of the mains frequency (50 - 60 Hz). Reduce artefacts by repositioning the device in the room.

## 4.9 STARTING THE DEVICE

1. Connect the device with the mains cable via a mains socket (100 - 240 V) to the power supply network (50 - 60 Hz).
2. Connect the electrodes and probes to the device.
3. Switch the device on at the back via the main switch.
  - The device is now ready for use.

#### 4.10 SWITCHING THE DEVICE OFF

No particular procedure is required to shut down the software on the device.

1. Switch the device off at the back via the main switch.

- The device is switched off.

Data is saved – there is no risk of it being lost.

## 5 OPERATION

Taikymo sritys:

There are pre-defined programs for different applications for the C2 Xplore:

- Nr. 2. • **Thyroid surgery: Struma Select, Struma Select Trend: These programs are suitable for neuromonitoring during procedures on the thyroid.**  
Skydliaukės chirurgijai
- Nr. 3.1. • **ENT surgery: Facial nerve - 2C, Facial nerve - 4C**  
Otolaringologija
- Nr. T1.3. • **Spinal surgery: Spine program: This program is suitable for monitoring during the use of pedicle screws for intercorporeal fusion of the cervical spine or lumbar spine and lateral access procedures to the lumbar spine.**  
Stuburo chirurgija
- Nr. T1.1. • **Rectal surgery: pIOM program: This program is suitable for the area of rectal surgery.**  
Tiesiosios žarnos chirurgija
- Nr. 3.2. • **Vascular surgery: Carotid artery - 1C, Carotid artery - 2C: This program is suitable for the area of vascular surgery on the carotid artery.**  
Kraujagyslių chirurgijai
- Nr. T1.2. • **Neurosurgery: Cortical stimulator, MEP programs: This program is suitable for cortical stimulation with or without CoMEP recording.**  
Galvos smegenų chirurgija

The following sections describe the operation of the software in measurement mode and the available settings options.

### 5.1 GENERAL PREPARATIONS

The C2 Xplore unit must be positioned in a safe and well-visible location in the operating theatre outside of the patient environment.

The device is switched on at the rear panel for use.

The device starts up with the last used configuration.

#### 5.1.1 PROGRAM SELECTION



Select the required program by tapping the PROGRAMS button on the measurement screen.

The available programs can be saved in the PROGRAMS menu for direct selection. The assignment of the buttons is described in *section "6.1.4 Assignment of the Programs menu"*.

#### 5.1.2 ENTERING PATIENT DATA

Paciento duomenų įvedimas



Nr. 10.1. **In the PATIENT menu, a new patient is created either via the integrated barcode scanner (1D or 2D) or manually.** It is possible to manually add information to the identification number by inputting additional patient or surgical procedure-specific data.



Meniu skiltyje "PATIENT", naujas pacientas sukuriamas naudojant integruotą bar kodų skaitytuvą (1D arba 2D) arba rankiniu būdu. To enter patient information, tap PATIENT or NEW on the measurement screen.

### Manual recording of patient information

1. Select the required editing field.
  - A virtual keyboard is displayed.
2. Enter the name of the patient and other required information. To select a letter, tap the touchscreen or make the selection with the rotary knob.
3. Press the Enter key on the virtual keyboard to confirm when you have finished entering the information for a field.
4. If you need to edit your entry, press the middle rotary knob again.
5. Press the Enter key to confirm the patient data.
  - The measurement screen is displayed.

### Entry via barcode scan

Įvedimas naudojant bar kodo nuskaitymą

1. Use the barcode scanner to scan the barcode.
  - Norėdami nuskaityti bar kodą, naudokite bar kodo skaitytuvą.
  - The scanned patient is automatically added to the current measurement.
    - Nuskaitytas pacientas automatiškai įtraukiamas į srovės matavimus.

### No patient entered

1. Start stimulation and measurement.
  - A new patient is added with the designation “Emergency patient”.
2. If required, patient information can also be added later on in the PATIENT menu.

With the software modules SPINE and PIOM, patient data can already be entered before the start of the surgical procedure.

## 5.2 THYROID SURGERY

Skydliaukės chirurgija

- Nr. 3.1. Intraoperative neuromonitoring via electromyography (EMG) is performed in thyroid surgery in order to monitor the laryngeal nerve and the external branch of the superior laryngeal nerve. Skydliaukės chirurgijos metu atliekama intraoperacinė neuromoniografija elektromiografijos būdu (EMG), siekiant stebėti gerklų nervą ir viršutinio gerklų nervo išorinę šaką.

Neuromonitoring can be performed both intermittently or continuously.

The following section provides a detailed description of the use of the C2 Xplore for EMG monitoring in thyroid surgery.

### 5.2.1 CONNECTION TO THE DEVICE

Before starting the surgical procedure, connect the recording electrodes via the Head Box (REF: 540430) to the patient and the C2 Xplore.

In thyroid surgery, the EMG signals are recorded via the adhesive laryngeal electrode for tube or via the ALM tube on the vocal muscle. For detailed application information, please refer to the Instructions For Use of the adhesive laryngeal electrode for tube or ALM tube.

#### Application

1. Apply the adhesive laryngeal electrode to the intubation tube or use the ALM tube.
2. Connect the adhesive laryngeal electrode or the ALM tube to the connecting cable.
3. Apply the neutral electrode.
4. Connect the neutral electrode to the connecting cable.
5. Connect the connecting cable to the Head Box.
6. Connect the Head Box to the C2 Xplore.
7. Connect the stimulation probe to the STIM 1 output of the Head Box.

For continuous monitoring of the vagus nerve (cIONM) the DELTA electrode (REF: 522623) is also used. The DELTA electrode is connected to STIM 2 on the Head Box.

The connection diagram for thyroid surgery is shown in *Figure 14: Connection diagram for thyroid surgery*.



Figure 14: Connection diagram for thyroid surgery



### Impedance measurement

Varžos matavimas

1. Connect all components to the device as described above under Application.
- Nr. 9.1. 2. **Periodic impedance measurements are carried out automatically by the device.**  
Prietaisas automatiškai atlieka periodinius varžos matavimus.
  - **The green symbol shows that the electrode impedance is within range.**  
Žalias simbolis rodo, kad elektrodo varža yra intervale.
  - The red symbol indicates inadequate impedance or that the electrode is not connected.
3. A manual impedance measurement can also be performed by pressing the IMPEDANCE button.

**If the electrode is successfully connected and tissue contact is made, then a green symbol is displayed.** Jei elektrodas sėkmingai prijungtas ir užmezgamas kontaktas su audiniu, rodomas žalias simbolis.

Symbol	Meaning
	Poor impedance or electrode not connected
	<b>Good impedance of the electrode</b> Gera elektrodo varža

Table 8 Impedance states

## 5.2.2 APPLICATION

### Program selection

Two pre-configured programs are available for thyroid surgery:

- Struma Select: Neuromonitoring for interventions on the thyroid
- Struma Select Trend: Neuromonitoring for interventions on the thyroid with the option of continuous monitoring of the vagus nerve

### Adjustment of the stimulator

1. Adjust the current of the left / right-hand stimulator by twisting the corresponding rotary knob.
  - STIMULATION ON is displayed when there is contact between the tissue of the patient and the stimulation probe.
  - Acoustic feedback sounds.
- Nr. 9.2.2. **As soon as muscle activity is triggered by the stimulation, this is displayed visually on the measurement screen. In addition, there is also an acoustic feedback signal.**  
Kai tik stimuliacija sužadina raumenų aktyvumą, tai vizualiai parodoma matavimo ekrane. Be to, yra ir garsinis grįžtamojo ryšio signalas.  
On the measurement screen, the amplitude and latency of each signal is also displayed next to it.

### Measurement screen

#### Channel Select

The function CHANNEL SELECT is available for the programs "Struma Select" and "Struma Select Trend". Via the ALM tube or the adhesive laryngeal electrode for tube, 4 differential channels are formed from 8 measuring contacts for signal recording. The channel with the highest current amplitude is displayed on the measurement screen. All four signal recordings are displayed in the lower part of the measurement screen.



## Trend function for cIONM



### Caution!

- Incorrect measurement!  
Always initialise a baseline before using the trend function.

The trend function is available in the program “Struma Select Trend” and additionally offers continuous monitoring of the vagus nerve.

1. To activate the trend function, tap the **BASELINE BUTTON**. This button is only displayed during the continuous stimulation of the vagus nerve.
  - The baseline can be updated at any time, e.g. when changing the side of the surgical procedure.
  - Acoustic and visual warnings are output if the continuous signal (amplitude or latency) drops below or exceeds a certain threshold.
  - An acoustic signal sounds if a certain pre-defined threshold value is reached.

You can set up to three threshold values for amplitude and latency.

For information about the trend settings, refer to the *section “5.2.3 Settings”*.



## Comments

You can add comments to the current measurement:

1. Tap the **COMMENTS BUTTON**.
  - The Comments menu is opened.
2. Press the corresponding button to save the current measurement.
  - Acoustic feedback sounds.

Instead of pressing **COMMENTS**, you can also drag & drop the current signal to the corresponding comment. The stimulation and EMG measurement is not interrupted during this time. The time during which the curve was recorded is selected as the time index.

The comments dialog can also be opened by pressing the footswitch.

Comments can also be entered via a connected tablet. See *section “6.6 Tablet connection via WIFI”*.

## Exporting patient data

For information about exporting patient data, refer to *section “5.8 Exporting patient data”*.

### 5.2.3 SETTINGS



The basic settings for stimulation and EMG recording can be adjusted in the SETTINGS menu. Operation is performed via the middle rotary knob or by tapping the parameter.

The following parameters can be adjusted in the SETUP menu:

- Stimulation frequency of stimulator 1: 1 - 7 Hz, intermittent monitoring
- Stimulation frequency of stimulator 2: 1 - 2 Hz, continuous monitoring
- Stimulator initial settings, status: ON / OFF
- Stimulator initial settings, starting current: 0.1 - 5 mA
- Switching artefact suppression ON or OFF for the stimulation artefact: 0.5 - 2 ms



In the program “Struma Select Trend”, you can define up to three event threshold values for amplitude and latency. You can define relative and absolute values. Every event threshold value has its own acoustic feedback.

1. Tap the SETTINGS BUTTON.
2. Tap the TREND SETTINGS BUTTON.
3. Change the amplitude and latency threshold values.

## 5.3 ENT SURGERY

LOR chirurgija

Nr. 1.2. Intraoperative neuromonitoring is performed in ENT surgery, for example, in the areas of parotidectomy, tympanoplasty, mastoidectomy, cochlear implants (CI), and facial surgery. Intraoperacinė neuromonitoringa naudojamas LOR chirurgijoje, pavyzdžiui, parotidektomijos, timpanoplastikos, mastoidektomijos, kochlearinių implantų (CI) ir veido chirurgijos srityse.

Neuromonitoring can be performed in two different ways:

- Free-running recording of the EMG for detection of muscle activity caused by contact between the surgical instruments and the nerve branches or by other forms of mechanical manipulation of the nerves.
- Direct electrical nerve stimulation via hand-held stimulation probes for targeted localisation, progression, and function testing of individual nerve branches.

The following section provides a detailed description of the use of the C2 Xplore for EMG monitoring in ENT surgery.

### 5.3.1 CONNECTION TO THE DEVICE

Prior to monitoring, the needle electrodes must be placed for recording in the muscles to be monitored and connected via the adapter box Head Box (REF: 540430) to the C2 Xplore.

During monitoring of the facial nerve, EMG signals are recorded with needle electrode pairs. A separate needle electrode pair is used for every muscle group that is to be monitored.

This recording requires an additional neutral electrode (GND), which is placed in the neck or shoulder area.

### Application

1. Place the needle electrodes and the neutral electrode (GND) in the corresponding muscles.
2. Connect the needle electrodes to the Head Box, corresponding to the colour code (EMG 1-4).
3. Connect the neutral electrode (GND).
4. Connect the Head Box to the rear panel of the C2 Xplore.
5. Connect the stimulation probe to the STIM 1 output of the Head Box.

The recommended electrode positions for the software modules "Facial – 2Ch" and "Facial – 4Ch" are listed below.

	Facial – 2Ch		Facial – 4Ch	
Channel 1	Orbicularis muscle	oculi	Frontalis muscle	
Channel 2	Orbicularis muscle	oris	Orbicularis muscle	oculi
Channel 3	-		Orbicularis muscle	oris
Channel 4	-		Mentalis muscle	

Table 9: Electrode positions for ENT surgery

As an option, a second stimulation probe can be connected to the output STIM 2 of the Head Box.

The complete setup for ENT surgery is shown in Figure 15.



Figure 15: Connection diagram for ENT surgery



### Impedance measurement

1. Connect all components to the device as described above under "Application."
2. Periodic impedance measurements are carried out automatically by the device.
  - The green symbol shows that the electrode impedance is good.
  - The red symbol indicates poor impedance or that the electrode is not connected.
3. A manual impedance measurement can also be performed by pressing the IMPEDANCE button.

If the electrode is successfully connected and tissue contact is made, then a green symbol is displayed.

Symbol	Meaning
	Poor impedance or electrode not connected
	Good impedance of the electrode

Table 10 Impedance states

## 5.3.2 APPLICATION

### Program selection

The program "Facial – 2Ch" or "Facial - 4Ch" is selected from the Programs menu.

### Adjustment of the stimulator

1. Adjust the current of the left / right-hand stimulator by twisting the corresponding rotary knob.
  - STIMULATION ON is displayed when there is contact between the tissue of the patient and the stimulation probe.
  - Acoustic feedback sounds.

As soon as muscle activity is triggered by the stimulation, this is displayed visually on the measurement screen. In addition, there is also an acoustic feedback signal.

On the measurement screen, the amplitude and latency of each signal is also displayed next to it.

### Measurement screen

Matavimų ekranas

All EMG signals are displayed on the measurement screen.

Visi EMG signalai rodomi matavimo ekrane.

A distinction can be made between two waveforms:

- Spontaneous events:

In the event of contact between surgical instruments and nerve branches or mechanical manipulation of the nerves, or due to signals that are caused by direct nerve stimulation.

Both signal forms take place both acoustically and visually.

Spontaneous activities are displayed in the free-running EMG without active stimulation and are marked with the text SPONTANEOUS ACTIVITY.

The maximum amplitude is displayed underneath each curve.

- Stimulated events:

A manual probe is used to directly stimulate the localisation and progression of individual nerve branches.

The resulting muscle response is also displayed acoustically and visually.

The amplitude and latency of each signal are displayed underneath the corresponding curve.



### Channel Ident

The function CHANNEL IDENT can be used to acoustically identify the stimulated nerve branch. A separate sound is assigned to each channel in the facial program.

Here, the channel that detects the largest muscle response dominates.



### Comments

You can add comments to the current measurement:

1. Tap the COMMENTS BUTTON.
  - The Comments menu is opened.
2. Press the corresponding button to save the current measurement.
  - Acoustic feedback sounds.

Instead of pressing COMMENTS, you can also drag & drop the current signal to the corresponding comment. The stimulation and EMG measurement is not interrupted during this time. The time during which the curve was recorded is selected as the time index.

The comments dialog can also be opened by pressing the footswitch.

Comments can also be entered via a connected tablet. Refer to *section "6.6 Tablet connection via WIFI"* for more information about using a tablet in the operating theatre.

### Exporting patient data

For information about exporting patient data, refer to *section "5.8 Exporting patient data"*.

### 5.3.3 SETTINGS



Set up the basic settings for stimulation and EMG recording in the **SETUP** menu. Operation is performed via the middle rotary knob or by tapping the parameter.

The following parameters can be adjusted in the **SETTINGS** menu:

- Stimulation frequency of the stimulators: 1 - 7 Hz
- Initial settings for the stimulator: Status activated or deactivated and initial current: 0.01 - 3 mA
- Switching artefact suppression ON or OFF for the stimulation artefact: 0.5 - 1.5 ms

## 5.4 VASCULAR SURGERY

Kraujagyslių chirurgija



### WARNING!

- Incorrect measurement!  
The use of inhalational anesthetics will reduce SEP response activity. Before and during the surgical procedure, the surgeon and anesthetist must communicate about the anesthetic used.

SEP monitoring enables the monitoring of neuronal activity in the ascending pathways and of the sensory cortex.

The SEP functions of the C2 Xplore have been developed, especially for early detection of insufficient blood supply to the brain hemisphere in vascular surgery of the carotid artery to avoid the resulting damage.

SEP signals are evoked by electric stimulation of the median nerve and can be continuously measured and monitored. The SEP signals are recorded from the sensory cortex and presented both as an averaging signal and in the form of a trend curve as a function of the initial value.

The following section provides a detailed description of the use of the C2 Xplore for SEP monitoring in carotid artery facial surgery.

### 5.4.1 CONNECTION TO THE DEVICE

Prior to monitoring, the stimulation and recording electrodes must be connected via the adapter box SEP Box (REF: 540432) to the patient and to the C2 Xplore.

A pair of needle electrodes are placed for stimulation of the median nerve. The electrodes for recording the SEPs are applied via the sensory cortex, corresponding to the 10-20 system. Detailed placement is described in the following section.

#### Application:

1. Place the stimulation electrodes on the median nerve.
2. Connect the stimulation electrodes to the output STIM 1.
3. Place the recording needles in accordance to the 10-20 system above the sensory cortex.
4. Connect the electrodes of the recording needle to the SEP Box.
5. Connect the SEP Box to the rear panel of the C2 Xplore.

#### Placement of the stimulation electrodes

Coupled needle electrodes are used for stimulation during SEP monitoring. The median nerve stimulates the long, sensitive pathways. Stimulation takes place contralaterally to the side of the surgical procedure.

The placement of the stimulation electrodes is shown in Figure 16.

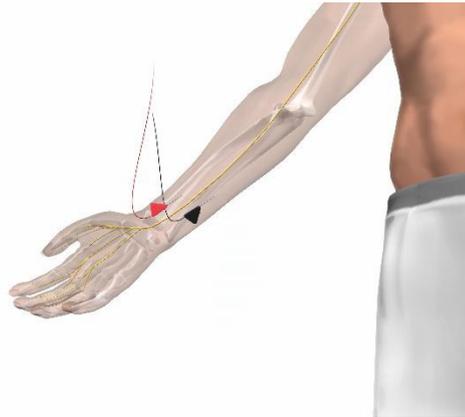


Figure 16: Stimulation of the median nerve for SEP measurement

### Placement of the recording electrodes

The potentials are recorded ipsilaterally to the surgical procedure side above the sensory cortex. In addition, a comparison measurement can be useful in the plane of the cervical vertebra C7.

For the recording of SEPs above the sensory cortex, the electrodes are placed in accordance to the 10-20 system.

1. Place the electrode on C3' for the upper right extremity.
2. Place the electrode on C4' for the upper left extremity.
3. Place a reference electrode. This is necessary because the SEPs are a reference recording.
4. Place an additional neutral electrode in the neck or shoulder area. This is necessary because this is required for the discharge.

The connection of the recording electrodes for single-channel measurement with the program "Carotid artery – 1Ch" is shown in Figure 17.

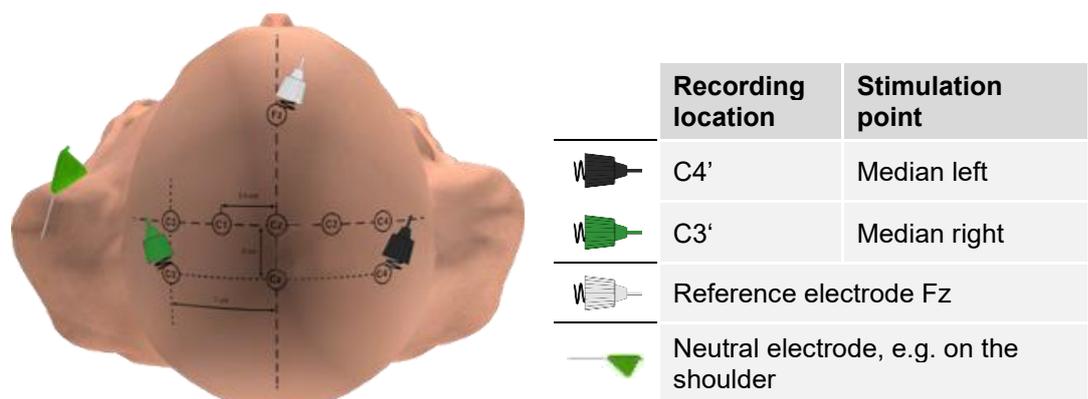


Figure 17: Electrode positions for 1-channel SEP signal (Carotid artery – 1Ch)

For two-channel recording with the program “Carotid artery – 2Ch”, the cervical vertebra C7 is also recorded in addition to the sensory cortex. This additional recording is used to monitor the cervical signal.

If cerebral ischemia occurs, the cervical recording at C7 remains unchanged. In this case, the amplitude decreases for recordings on the sensory cortex - and the latency increases.

The connection of the recording electrodes for two-channel measurement with the program “Carotid artery – 2Ch” is shown in Figure 18.

The colour of the electrodes can be individually defined.

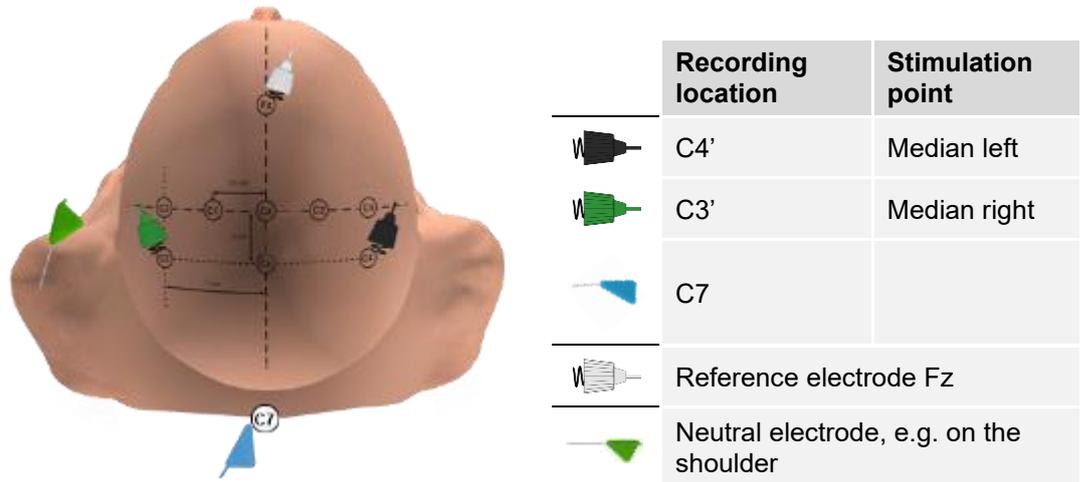


Figure 18: Electrode positions for 2-channel SEP signals (Carotid artery – 2Ch)

**i Note:**

If you use the program “Carotid artery - 1Ch”, the connection labelled “C7” on the SEP Box remains unused.



Figure 19: Connection diagram for vascular surgery



### Impedance measurement

1. Connect all components to the device as described above under “Application”.
2. Periodic impedance measurements are carried out automatically by the device.
  - The green symbol shows that the electrode impedance is good.
  - The red symbol indicates poor impedance or that the electrode is not connected.
3. A manual impedance measurement can also be performed by pressing the IMPEDANCE button.

If the electrode is successfully connected and tissue contact is made, then a green symbol is displayed.

Symbol	Meaning
	Poor impedance or electrode not connected
	Good impedance of the electrode

Table 11 Impedance states

#### 5.4.2 APPLICATION



#### CAUTION!

Incorrect measurements!

Make sure that the artefact threshold value is correctly adjusted.

#### Adjusting the artefact threshold value

Once the electrodes have been correctly connected, the artefact threshold value needs to be determined:

1. Press the middle rotary knob.
  - The artefact threshold value is displayed in blue.
2. Change the artefact threshold value by turning the middle rotary knob.
  - The signal must be underneath the threshold value range.
3. Press the middle rotary knob again to confirm the threshold value.
  - The artefact threshold value is now defined.

### Adjustment of the stimulator

1. Activate the stimulator by pressing the left-hand rotary knob.
2. Adjust the current of the stimulator by turning the left-hand rotary knob.
  - STIMULATION ON is displayed (with a green background) when correct stimulation is present.

Stimulation is only possible when the measurement screen is visible or if a comment is added. If you select a submenu, the stimulation will stop.

### Measurement screen

After the start of the stimulation, 200 measuring signals are initially averaged. This is necessary in order to separate the measuring signals from the noise generated by electric wires and devices in the vicinity. The current averaging status is displayed via a green progress bar above the measurement screen, see *Figure 20: Measurement screen – 1-channel*.

If artefacts occur, e.g. due to the use of electrosurgery devices, these are counted up, and the stimulation is interrupted for the duration of the fault, see *Figure 21: Manual marker positioning (right-hand image)*. Averaging is then continued automatically.

Somatosensory activities in the cortex are displayed on the measurement screen. For the upper extremity, the median nerve has a typical interpretation point after approx. 20 ms, the so-called N20 marker.

For the recording at the 7th cervical vertebra, this interpretation point is at around 13 ms, the so-called N13 marker.

To calculate the amplitude, the maximum and minimum of the response signal are recorded within a marker that lies around the expectancy range of the peaks N13 and N20.

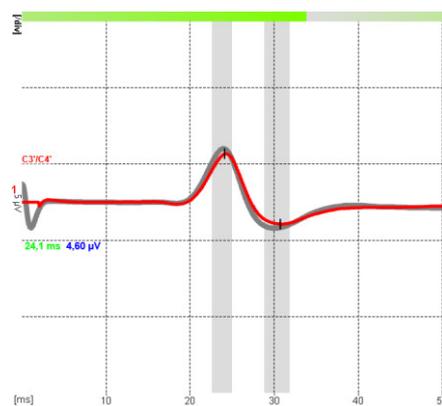


Figure 20: Measurement screen – 1-channel

Depending on the anatomical conditions, previous/current illnesses, or external influences, the minima and maxima can be outside of the expected range.

In this case, you need to manually adjust the expectancy ranges:

1. Press the middle rotary knob.
2. Move the expectancy range to the left or right by turning the middle rotary knob.

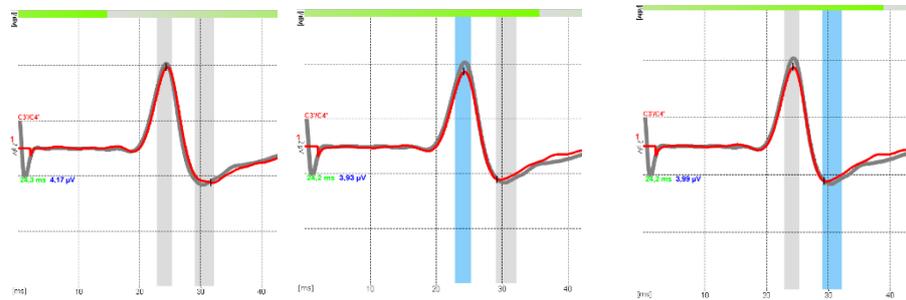


Figure 21: Manual marker positioning

3. Press the middle rotary knob to confirm the new marker position.
  - The system switches to the next marker.
4. Change the artefact threshold value.
5. Press the middle rotary knob again to perform further measurements.

As soon as the first 200 pulses have been averaged, a trend curve will automatically start in the bottom area of the touchscreen.

In the trend settings, set up to 3 event thresholds for amplitude and latency, see *section "5.4.3 Settings"*. If for example, during clamping of the carotid artery, the amplitude decreases by 50% in comparison to the starting amplitude or the latency increases by 10% in comparison to the starting latency, this is an indication that cerebral ischemia is occurring.

In this case, we strongly recommend the use of a shunt.



### Comments

You can add comments to the current measurement:

1. Tap the COMMENTS BUTTON.
  - The Comments menu is opened.
2. Press the corresponding button to save the current measurement.
  - Acoustic feedback sounds.

Instead of pressing COMMENTS, you can also drag & drop the current signal to the corresponding comment. The stimulation and SEP measurement is not interrupted during this time. The time during which the curve was recorded is selected as the time index.

The comments dialog can also be opened by pressing the footswitch.

Comments can also be entered via a connected tablet. Refer to *section "6.6 Tablet – Connection via Wifi"* for more information about using a tablet in the operating theatre.

## Exporting patient data

For information about exporting patient data refer to *section "5.8 Exporting patient data"*.

### 5.4.3 SETTINGS



The basic settings for stimulation and EMG recording can be adjusted in the SETUP menu. Operation is performed via the middle rotary knob or by tapping the parameter.

The following parameters can be adjusted in the SETTINGS menu:

- Stimulation frequency of the stimulator: 2.7, 3.1, 3.7, 4.7 or 5.1 Hz
- Initial settings for the stimulator for its status (activated or deactivated) and its initial current: 0.01 - 25 mA
- Switching artefact suppression ON or OFF for the stimulation artefact: 0 - 2 ms



In the carotid artery programs, you can define up to three event threshold values for amplitude and latency. You can define relative and absolute values. Every event threshold value has its own acoustic feedback.

1. Tap the SETTINGS BUTTON.
2. Tap the TREND SETTINGS BUTTON.

Change the amplitude and latency threshold values in this menu.

### 5.5 SPINAL SURGERY

The Spine software enables spinal neuromonitoring in spinal surgery for posterior cervical intercorporeal fusions and posterior lumbar intercorporeal fusions, as well as in lateral access procedures.

The Spine software of the C2 Xplore is based on a wizard layout, which guides the user step-by-step through the application.

#### The wizard is divided into the following steps:

- Entry of patient data
- Level selection
- Electrode placement
- Relaxation control (TOF test)
- Measurement
- Documentation
- Report

You can navigate through the Spine program using the rotary knobs or by tapping the buttons on the touchscreen.

### 5.5.1 CONNECTION TO THE DEVICE

Before starting monitoring, enter the patient and surgical procedure data via the wizard interface.

Connect the recording and stimulation electrodes via the adapter box Body Box (REF: 540431) to the patient and to the C2 Xplore.

In the case of anterior cervical access procedures, the monitoring of the recurrent laryngeal nerve is performed with the software for thyroid surgery, see *section "5.2 Thyroid surgery"*. Cervical monitoring of the stages C3 to TH1, lumbar from L2 to S2 is supported.

The Body Box is connected to the patient connection on the rear panel of the C2 Xplore.

The following section provides a detailed description of the use of the C2 Xplore for Spine monitoring in spinal surgery.

After every step, press the right-hand rotary knob or touch the touchscreen to continue.

#### Application

1. Enter the patient data and surgery-related data. The patient ID or surname are required information.
2. Level selection: Select the cervical or lumbar level of the surgical procedure.
3. Place the electrodes in accordance with the colour scheme of the wizard interface.
4. Apply the neutral electrode. More information about this can be found below under "Electrode placement."
  - After the successful connection of the electrodes, the muscle groups will change colour from yellow to green.
  - A confirmation tick appears next to each muscle group.
5. Connect the stimulation probe to the STIM 1 output of the Body Box.

#### Electrode placement

Depending on the selection, in the electrode placement area, you will see the necessary setup either for cervical intercorporeal fusions or lumbar intercorporeal fusions. The muscle groups that are monitored at every level are listed below.

Cervical		Lumbar spine	
Spinal nerve	Muscle	Spinal nerve	Muscle
C3, C4	Trapezius muscle	L2, L3, L4	Vastus medialis muscle
C5, C6	Deltoideus muscle	L4, L5, S1	Tibialis anterior muscle
C6, C7	Flexor carpi radialis muscle	L5, S1	Biceps femoris muscle
C8, T1	Thenar muscle, hypothenar muscle	S1, S2	Gastrocnemius muscle

Table 12: Electrode positions for spinal surgery

1. Place the colour-coded, paired needle electrodes on the patient, as shown in the displayed diagram.
2. Connect the needle electrodes to the Body Box.
3. Connect the Body Box to the C2 Xplore.
4. To switch between the front and rear view, turn the middle rotary knob.
  - If there is contact between the measuring electrodes and between the GND electrode and patient tissue, the colour of the corresponding muscle group will change from yellow to green.
  - A confirmation tick is displayed.

**i**

**Note:**

A positive display does not mean that the needle electrode has been inserted in the displayed muscle. It merely recognises the contact to patient tissue.

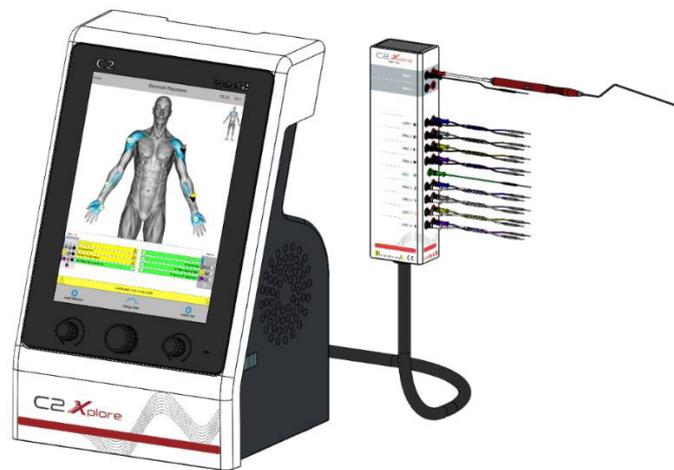


Figure 22: Connection diagram for spinal surgery

## 5.5.2 APPLICATION

### TOF test

To ensure that no muscle relaxants have been administered and that the muscles are responsive to electrical or mechanical stimulation, an automatic relaxation test (so-called TOF test) is performed.

On the cervical spine segment, the stimulation takes place on the median nerve and the thenar muscle, on the lumbar spine segment on the peroneal nerve and the tibialis anterior muscle:

1. Apply coupled needle electrodes to the patient, as stated in the Wizard menu.
2. Connect the needle electrodes to the STIM 2 output of the adapter box.
3. Press the middle rotary knob.
  - The twitch test is started.

The stimulation and recording settings for the TOF test are listed below.

Cervical		Lumbar spine	
Nerve	Median nerve	Nerve	Peroneal nerve
Muscle	Thenar muscle (channel 4)	Muscle	Tibialis anterior muscle (channel 2)
Amplitude	25 mA	Amplitude	25 mA
Frequency	2 Hz	Frequency	2 Hz
Repetition	4 pulses	Repetition	4 pulses

Table 13: TOF test settings

After completion of the test, the TOF number and the TOF ratio are automatically output (TOF = train-of-four).

The TOF number indicates how many muscle responses are detected. If four stimuli produce four muscle responses, the corresponding TOF number = 4.

If the TOF number < 4, then it is assumed that there is a high concentration of muscle relaxants in the body of the patient, and a red “Stop” message is displayed – see *Figure 23: Warning message of the twitch test for TOF number < 4*.

We strongly recommend not starting the measurement until after the successful completion of the TOF test (antagonising of the muscle relaxants). If you go against this recommendation and carry out the measurement without a twitch test, an additional warning message will be displayed – see *Figure 23: Warning message of the twitch test for TOF number < 4*, right-hand side.

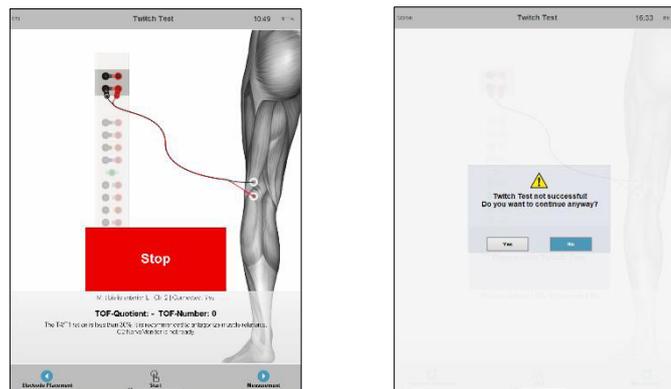
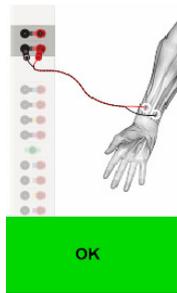


Figure 23: Warning message of the twitch test for TOF number < 4

The TOF ratio determines the degree of relaxation if the TOF number = 4. This is calculated by dividing the amplitude of the fourth response signal by the amplitude of the first response signal. If a patient has not been relaxed, the ratio is 100%; the value drops with increasing degrees of relaxation.

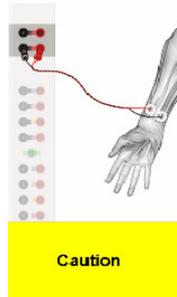
Once the TOF test has been completed, a green OK screen is displayed.

Switch to the measurement screen now by pressing the right-hand rotary knob.



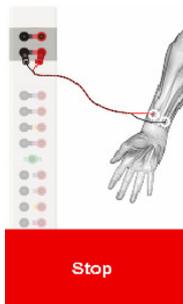
TOF ratio > 70%: Green display: OK

The muscles are not relaxed and the ratio of T4/T1 is over 70%.  
C2 Xplore is ready.



TOF ratio < 70% and > 30%: Yellow display: Caution

The ratio of T4/T1 is below 70%. It is recommended that muscle relaxants are antagonised.  
C2 Xplore is not ready.



TOF ratio < 30% or TOF number < 4: Red display: Stop

The ratio of T4/T1 is below 30%. It is recommended that the muscle relaxants are antagonised.  
C2 Xplore is not ready.

### Measurement screen

In measurement mode, the spinal nerves are monitored both through continuous monitoring of spontaneous EMG activity and through automated nerve stimulation via the manual probe.

During activity, the continuous monitoring of the musculature triggers a visual and acoustic signal – this happens e.g., during direct mechanical manipulation of a motor spinal nerve, see *Figure 24: Display of the measurement screen for spinal surgery*.

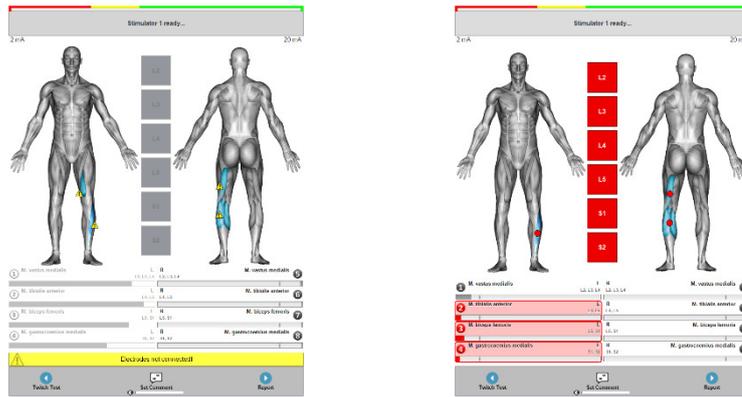


Figure 24: Display of the measurement screen for spinal surgery

The bar charts show the EMG activity of the associated muscles. If there is spontaneous activity, the corresponding channel and the associated spinal nerves are displayed with colours and an acoustic signal sounds.

Use the automatic stimulation function to localise nerve structures in the surgical area, to test the bone wall in the pedicle or charge the pedicle screws with electricity and test them.

The stimulation function enables automatic determination of the minimum current value that is sufficient to invoke a muscle response. For this purpose, the stimulator STIM 1 of the C2 Xplore starts an automatic stimulation ramp with a linear current increase as soon as contact to tissue or indirect contact via a pedicle screw is established.

The stimulation ramp stops when an evoked muscle potential is detected, or the pre-set ramp maximum is reached.

Depending on the calculated current value, a green, yellow or red display is output with an acoustic signal.

By listening to the different pitches of the response signal, you can decide at which current the response was triggered without needing to look up from the surgical area.

The relevant currents and corresponding displays in the Spine software are detailed below.

Cervical		Lumbar	
Stimulation amplitude	Display	Stimulation amplitude	Display
1 – 4 mA	ROT	2 – 7 mA	RED
> 4mA	GELB	7 – 10 mA	YELLOW
-	-	> 10 mA	GREEN

Table 14: Currents

During stimulation mode, all muscle response signals are saved and are available for subsequent analysis. In addition, the relevant stimulation threshold values, the corresponding colour output and the muscle groups in which the relevant response signal was recorded and are saved in the report.



## Comments

You can add comments to the current measurement:

1. Tap the COMMENTS BUTTON.
  - The Comments menu is opened.
2. Press the corresponding button to save the current measurement.
  - Acoustic feedback sounds.

Instead of pressing COMMENTS, you can also drag & drop the current signal to the corresponding comment. The stimulation and EMG measurement is not interrupted during this time. The time during which the curve was recorded is selected as the time index.

The comments dialog can also be opened by pressing the footswitch.

Comments can also be entered via a connected tablet, see *section “6.6 Tablet connection via WIFI”*.

### 5.5.3 EXPORTING PATIENT DATA

#### Printing patient data

Proceed as follows to print out the report after the measurement:

1. Press the right-hand rotary knob or tap the button with the arrow symbol in the bottom right-hand corner.
2. Check all wave shapes and change or add comments.
3. Press the right-hand rotary knob or tap the button in the bottom right-hand corner to call up the print preview screen.
  - A print preview is generated.
4. Confirm the printout.

Nr. 10.2.1. **Via the Print menu, you can print out recorded EMG curves, save them as PDF files**  
 Nr. 10.3.1 **and export them to a USB stick or to a network drive.**

The device offers various options:

- **If a USB stick is connected to the device, then data can be exported directly from the Print menu.** Naudodamiesi meniu „Spausdinti“, galite atsispausdinti įrašytas EMG kreives, išsaugoti jas kaip PDF failus ir eksportuoti į USB atmintinę arba tinklo diską.
  - **If no USB stick is connected, the data can be saved to the internal hard disk of the device.** Jei prie įrenginio prijungta USB atmintinė, duomenis galima eksportuoti tiesiai iš meniu „Spausdinti“. Jei USB atmintinė neprijungta, duomenis galima išsaugoti įrenginio vidiniame standžiajame diske.
- Available report exports are displayed with the Export icon.

Proceed as follows to export data from the memory:

1. Open the Patient menu
2. Insert a USB stick.
3. Confirm the transfer.
  - The data is copied to the USB stick.

For information about exporting data to a network drive, refer to *section “6.1.5 Printer settings”*.

The scaling of the curves displayed in the printout is automatically adapted to the curve with the highest amplitude. If required, the scaling can be adjusted in the analysis view by zooming with two fingers on the touchscreen.

#### 5.5.4 SETTINGS

1. Go back to the SURGICAL PROCEDURE DATA screen.
2. Open the menu bar.
3. Tap SETTINGS.
  - The following settings become visible:
    - Settings
    - Programs
    - Help
4. Edit the comments under SETTINGS / ADVANCED SETTINGS.

#### 5.6 RECTAL SURGERY



##### **WARNING!**

- Incorrect measurement!  
The use of inhalational anesthetics reduces the amplitudes of the response signal during bladder and EMG measurements. Before and during the surgical procedure, the surgeon and anesthetist must communicate about the anesthetic used.
- Incorrect measurement!  
False-positive signals may be displayed if you are using the wrong anaesthetics. Use muscle relaxants in order to be able to monitor the electric activity of the smooth musculature.



##### **CAUTION!**

- Incorrect measurement!  
Do not carry out manipulations on the electrocauterization instrument during initialisation.

Pelvic intraoperative neuromonitoring (pIOM) can protect the functionality of the rectum and anal channel. The urogenital and anorectal functions are monitored through the measurement of the bladder pressure and recording of the internal anal sphincter with the pIOM software.

The pIOM software of the C2 Xplore is based on a wizard layout, which guides the user step-by-step through the application.

The wizard is divided into the following steps:

- Entry of patient data
- Electrode type selection
- Pressure sensor placement
- Electrode placement
- Measurement
- Documentation
- Report

You can navigate through the Spine program using the rotary knobs or by tapping the buttons on the touchscreen.

### 5.6.1 CONNECTION TO THE DEVICE



#### **CAUTION!**

- **Malfunction!**  
Always follow the diagrams on the C2 Xplore when connecting the sensor for the bladder pressure measurement.

Before starting monitoring, enter the patient and surgical procedure data via the wizard interface. The electrode type needs to be selected, and the pressure sensor must be connected. Both elements are connected via the adapter box pIOM Box (REF: 540433) to the C2 Xplore.

The pIOM Box is connected to the patient connection port on the rear panel of the C2 Xplore.

The application description below sets out each step for making the connection to the device.

After every step, press the right-hand rotary knob or tap the button to continue

#### **Application**

1. Enter the patient data and surgery-related data in the start screen of the software. The patient ID or surname is required information.
2. Select the needle electrodes or rectal electrode.
3. Connect the pressure sensor for the bladder pressure measurement as directed in the Wizard menu – for more information, see further below under “Placement of the pressure sensor”.
  - After a successful connection, a green confirmation tick is displayed.

4. Place the electrodes as directed in the Wizard menu – for more information see “Placement of the electrode”.
  - After a successful connection and placement of the electrodes, a green confirmation appears.
5. Connect the stimulation probe to the STIM 1 output of the pIOM Box.

### Placement of the pressure sensors

Correct connection of the catheter connection set for bladder pressure measurement is described in the following:

1. Prior to the surgical procedure, remove all air bubbles from the catheter connection kit by filling all hoses with saline solution.
2. Before connecting the bladder catheter and the urine bag, use syringes to fill the hose system with saline solution until no more bubbles can be seen.
3. Place the 3-way valve in the immediate vicinity of the anesthetist to provide simple intraoperative access.
4. Place the pressure sensor in line with the patient's urinary bladder.
  - Stable sensor positioning is recommended, as the relative positioning of the sensor and the urinary bladder can influence the absolute pressure during the measurement.
5. Adjust the 3-way valve so that liquid can flow between the catheter and the urine bag during the surgical procedure.
  - The inlet of the pressure sensor is closed, as a result of which unhindered urine flow from the catheter to the urine bag is ensured.

### Placement of the electrode



#### **Note:**

Use an endosonographic aid for monitoring during the positioning of the electrode.

Needle electrodes or a non-invasive rectal electrode can be used for monitoring of the anal sphincter in order to display the EMG activity.

Place the selected electrode type in accordance with the instructions on the touchscreen:

#### Needle electrodes

1. Place the needle electrodes in the internal and external anal sphincters.
2. Place the neutral electrode in the fatty tissue of a buttock.

### Rectal electrode

1. Insert the rectal electrode in the anal opening.
2. Place the neutral electrode in the fatty tissue of a buttock.



Figure 25: Connection diagram for rectal surgery

## 5.6.2 APPLICATION

### WARNING!

- Incorrect measurement!  
Always initialise the threshold value for the bladder and EMG measurement prior to the surgical procedure.
- Incorrect measurement!  
Mechanical manipulation of the measurement accessories can lead to incorrect overpressure signals. Take care to use the equipment carefully.

### CAUTION!

- Incorrect measurement!  
Always fill the bladder prior to the measurements. Otherwise, it is not possible to clearly assign the signals.
- Incorrect measurement!  
Check for correct connection: Prior to the surgical procedure, start by pressing on the catheter hose and observe the response signal while doing this.

In order to be able to record clear EMG signals from the autonomously innervated, smooth musculature of the internal anal sphincter, neuromonitoring can only be performed when the patient is completely relaxed.

### Adjustment of the stimulator

Adjust the stimulator current with the "+" and "-" buttons on the touchscreen. If there is no electric contact between the tissue and the stimulation probe, "NO CURRENT CONFIRM" is displayed. The measurement bars have a grey background. If no electrodes are connected and/or the pressure sensor is not connected, a yellow warning is displayed.

### Measurement screen

Use a manual probe for stimulation and localisation of nerve structures in the lesser pelvis.

The colour of the measurement bar changes depending on the evoked muscle response amplitude.



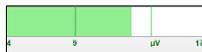
Internal anal sphincter – grey, display: NO CURRENT CONFIRM



No signal – blue



In the proximity of a nerve – yellow



Nerve – green

Figure 26: Measurement screen during stimulation

Depending on the signal, an acoustic signal may also be generated.

Initialisation needs to be carried out for preparation for the pressure measurement:

1. Tap the INITIALISATION button on the touchscreen.
  - Initialisation of the bladder pressure measurement is performed.
2. Return to the measurement screen to finish the preparations. To do this, tap the button at the bottom right-hand edge of the touchscreen or press the right-hand rotary knob.
  - The measurement is ready.



### Comments

You can add comments to the current measurement:

1. Tap the COMMENTS BUTTON.
  - The Comments menu is opened.

2. Press the corresponding button to save the current measurement.
  - Acoustic feedback sounds.

Instead of pressing COMMENTS, you can also drag & drop the current signal to the corresponding comment. The stimulation and SEP measurement is not interrupted during this time. The time during which the curve was recorded is selected as the time index.

The comments dialog can also be opened by pressing the footswitch.

Comments can also be entered via a connected tablet. Refer to *section "6.6 Tablet connection via WIFI"* for more information about using a tablet in the operating theatre.

### 5.6.3 EXPORTING PATIENT DATA

Proceed as follows to print out the report after the measurement:

1. Press the right-hand rotary knob or tap the button with the arrow symbol in the bottom right-hand corner.
2. Check all wave shapes and change or add comments.
3. Press the right-hand rotary knob or tap the button in the bottom right-hand corner to call up the print preview screen.
  - A print preview is generated.
4. Confirm the printout.

Via the Print menu, you can print out recorded EMG curves, save them as PDF files and export them to a USB stick or to a network drive. The device offers various options:

- If a USB stick is connected to the device, then data can be exported directly from the Print menu.
- If no USB stick is connected, the data can be saved to the internal hard disk of the device. Available report exports are displayed with the Export icon.

Proceed as follows to export data from the memory:

1. Open the Patient menu
2. Insert a USB stick.
3. Confirm the transfer.
  - The data is copied to the USB stick.

For information about exporting data to a network drive, refer to *section "6.1.5 Printer settings"*.

The scaling of the curves displayed in the printout is automatically adapted to the curve with the highest amplitude. If required, the scaling can be adjusted in the analysis view by zooming with two fingers on the touchscreen.

## 5.6.4 SETTINGS

1. Tap the button. ENTER PATIENT DATA to access the SETUP menu of the pIOM software.
  - The following settings become visible:
    - Settings
    - Programs
    - Help
2. Alternatively, you can also call up the settings from the measurement screen by tapping the SETTINGS button.
3. Edit the comments under SETTINGS / ADVANCED SETTINGS.

## 5.7 NEUROSURGERY

For cortical stimulation, the C2 Xplore can be used as a pure cortical stimulator with up to 8 channels for MEP recording.

### 5.7.1 CORTICAL STIMULATION



#### **WARNING!**

- **Incorrect measurement!**  
Do not use inhalational or neuromuscular blocking anesthetics, as this would minimise MEP responsiveness.
- **Incorrect measurement!**  
Before and during the surgical procedure, the surgeon and the anaesthetist must communicate with each other. Notify the surgeon about the anesthetic used, as well as any changes to the type or depth of anesthesia.
- **Incorrect measurement!**  
Before and during the surgical procedure, the surgeon and the anaesthetist must communicate with each other. You must notify the surgeon about changes to the vital functions (e.g. blood pressure, temperature).
- **Incorrect measurement!**  
Make sure that the MEP detection threshold value is accurately adjusted.
- **Risk of injury!**  
Inform the anesthetist about the risk of epileptic seizures during the surgical procedure.

The program CORTICAL STIMULATOR is used for direct neurophysiological stimulation of motor and eloquent brain areas in neurosurgery.

The function is restricted to pure stimulation. It is not possible to derive and record muscle activity in this software module.

The stimulation program is particularly well suited to speech mapping but can also be used for motor mapping.

The exposed cortex is directly stimulated via a stimulation probe, as a result of which motor and speech-related areas can be localised. With the aid of continuous monitoring of these regions, damage can be minimised during the surgical removal of tumours.

The following section provides a detailed description of the use of the C2 Xplore for direct cortical stimulation.



Figure 27: Connection diagram for direct cortical stimulation

### Connection to the device

The stimulation probe is connected to the stimulator STIM 1 of the Body Box (REF: 540431). As an option, a second stimulation probe can be connected to the stimulator STIM 2 of the adapter box of the C2 Xplore.

### Application

1. Connect the adapter box to the rear panel of the C2 Xplore.
2. Connect the stimulation probe to the STIM 1 output of the Body Box.

### Program selection

In the CORTICAL STIMULATION program, there are four stimulation configurations available.

1. To select a program, turn the middle rotary knob.

2. Alternatively, you can also tap the corresponding button on the touchscreen. A program is selected by pressing the middle rotary knob or tapping the button.
  - The selected program is highlighted in blue and positioned in the middle of the touchscreen.

The following programs are available:

- Speech Mapping: bi-phasic pulse
- Speech Mapping 4s: bi-phasic pulse, time-limited stimulation for 4 s
- Motor Mapping: cortical
- Motor Mapping: subcortical

The stimulation parameters saved in the selected program can be seen on the measurement screen:

- Current
- Frequency
- Pulse width
- Number of pulses
- Interstimulus interval (ISI), if more than 1 pulse is executed
- Graphical representation of the pulse

### Adjustment of the stimulator

1. To start or stop the stimulation, press the left-hand rotary knob STIM 1 or the right-hand rotary knob STIM 2.
2. Adjust the current by turning the left or right-hand rotary knob.
  - The stimulation is only active if the measurement screen is open or a comment is set.

The stimulation is automatically stopped when the submenu is opened.

The program cannot be changed while a stimulator is active.

If current flows during the stimulation, the display turns green and displays STIMULATION ON.

### Measurement screen

1. Activate the stimulator.
  - The display switches from STIMULATION OFF to STIMULATION READY.
  - The display CURRENT CONFIRM is shown with a green background.
  - An additional acoustic signal sounds during the stimulation.

## Report

A report with all the relevant parameters is generated throughout the entire stimulation. During the surgical procedure, you can find the report at the bottom edge of the measurement screen.

In addition, the start and end of the stimulation are logged.



## Comments

You can add comments to the current measurement:

1. Tap the COMMENTS BUTTON.
  - The Comments menu is opened.
2. Press the corresponding button to save the current measurement.
  - Acoustic feedback sounds.

Instead of pressing COMMENTS, you can also drag & drop the current signal to the corresponding comment. The stimulation is not interrupted during this time.

Alternatively, you can open the Comments function by pressing the foot switch.

Comments can also be entered via a connected tablet. See *section "6.6 Tablet connection via WIFI"*.

## Exporting patient data

For information about exporting patient data, refer to *section "5.6.3 Exporting patient data"*.

## Settings

1. Press the SETTINGS button to access the SETUP menu.
  - If the button is not visible, tap the MENU icon at the top right-hand corner of the touchscreen.
2. Turn the rotary knob in the middle or tap the parameters with your fingertip on the touchscreen to navigate through the options.

The following options are available for selection. Depending on the program and parameter selection, not all the adjustment points will be visible:

Name	Meaning
Program	Selection of the 4 standard programs and the programs you have created yourself.
Mode	Selection of continuous or time-limited stimulation. CONTINUOUS or DURATION buttons.
Duration	For setting the duration of the time-limited stimulation in [s].
Polarity	Selection of the pulse form (positive symmetrical square-wave pulse, negative symmetrical square-wave pulse, bi-phasic symmetrical square-wave pulse positive and negative).
Pulses	Number of pulses emitted within a pulse sequence (1-10).
Pulse width	100 - 2000 $\mu$ s

ISI	The interstimulus interval (ISI) describes the time interval between 2 pulses in a pulse sequence (1 - 10 ms).
Initial current value	0.1 - 25 mA
Volume	0 - 100

Table 15 Selection options

If a particular choice of parameters prevents a pulse from being generated, you will be informed about this in a pop-up window.

### Creating a program

To create a new program, tap the button NEW PROGRAM. The program is automatically saved.

### Deleting a program

To delete a program you have created yourself, tap the button DELETE PROGRAM.

## 5.7.2 MOTOR MAPPING

Mapping using motor evoked potentials (MEP) enables monitoring of neuronal activity of the descending motor pathways during interventions on the peripheral and central nervous system.

The stimulation is performed direct-cortically in motor areas, while the recording is performed on the innervated target muscles.

The following section provides a detailed description of the use of the C2 Xplore for MEP monitoring in motor mapping.

### Connection to the device

1. Place the needle electrode pairs and the neutral electrode in the corresponding muscles.
2. Connect the needle electrode pairs to the Body Box adapter box that corresponds to the color code (REF: 540431) – refer to "Electrode placement" further below.
3. Connect the adapter box to the rear panel of the C2 Xplore.
4. Connect the stimulation probe to the STIM 1 output of the Body Box.

Optionally you can also use a second stimulation probe.

### Electrode placement

Needle electrode pairs are used for recording in MEP monitoring. Here, three pre-installed programs are available to the user:

- MEP – 4Ch
- MEP – 6Ch
- MEP – 8Ch

The following table provides an overview of the muscle groups in which the needle electrode pairs are placed in the relevant program:

	MEP – 4-channel	MEP – 6-channel	MEP – 8-channel
<b>Channel 1</b>	Orbicularis oris muscle	Orbicularis oris muscle	Orbicularis oris muscle
<b>Channel 2</b>	Deltoideus muscle	Masseter muscle	Masseter muscle
<b>Channel 3</b>	Thenar muscle	Deltoideus muscle	Deltoideus muscle
<b>Channel 4</b>	Abductor hallucis muscle	Thenar muscle	Biceps brachialis muscle
<b>Channel 5</b>	-	Tibialis anterior muscle	Extensor digitorum muscle
<b>Channel 6</b>	-	Abductor hallucis muscle	Thenar muscle
<b>Channel 7</b>	-	-	Tibialis anterior muscle
<b>Channel 8</b>	-	-	Abductor hallucis muscle

Table 16 Placement of the needle electrode pairs for MEP – 4Ch, MEP – 6Ch and MEP – 8Ch



Figure 28 Connection layout diagram for cortical and subcortical mapping

## Ω

### Impedance measurement

1. Connect the components to the device as shown in the diagram above.
2. Periodic impedance measurements are carried out automatically by the device.
  - The green symbol shows that the electrode impedance is good.
  - The red symbol indicates poor impedance or that the electrode is not connected.
3. A manual impedance measurement can also be performed by pressing the IMPEDANCE button.

If the electrode is successfully connected and tissue contact is made, then a green symbol is displayed.

Symbol	Meaning
	Poor impedance or electrode not connected
	Good impedance of the electrode

### Application

From the Programs menu select "MEP - 4Ch", "MEP - 6Ch" or "MEP - 8Ch".

### Adjustment of the signal threshold

Once the electrodes and adapter box have been correctly connected to the device, start by adjusting the latency and amplitude threshold values. When doing this, make sure that the background noise of the channel is in the grey area.

Adjust the threshold value as follows:

1. Tap the SIGNALS button.
  - The SIGNAL DETECTION menu is opened.
2. Turn the middle rotary knob to select the amplitude or latency of a channel.
3. Press the middle rotary knob to adjust the threshold value.
4. Press again to confirm.
  - The threshold value is now defined.
5. Return to the measurement screen by tapping the MEASUREMENT button.

### Adjustment of the stimulator

1. Adjust the current for both stimulators by turning the left or right-hand rotary knob.
2. Start/stop the stimulation by pressing the rotary knob.
  - STIMULATION ON is displayed (with a green background) when there is contact between the tissue of the patient and the stimulation probe (CURRENT CONFIRM CC).
  - Acoustic feedback sounds.

### Measurement screen

All MEP signals are displayed on the measurement screen.

If a MEP signal is triggered, then an acoustic signal tone will sound.



## Comments

You can add comments to the current measurement:

1. Tap the COMMENTS BUTTON.
  - The Comments menu is opened.
2. Press the corresponding button to save the current measurement.
  - Acoustic feedback sounds.

Instead of pressing COMMENTS, you can also drag & drop the current signal to the corresponding comment. The stimulation and MEP measurement is not interrupted during this time. The time during which the curve was recorded is selected as the time index.

The comments dialog can also be opened by pressing the footswitch.

Comments can also be entered via a connected tablet. See *section “6.6 Tablet connection via WIFI”*.

## Exporting patient data

For information about exporting patient data, refer to *section “5.8 Exporting patient data”*.

## Settings

1. Press the SETTINGS button to access the SETUP menu.
  - If the button is not visible, tap the MENU icon at the top right-hand corner of the touchscreen.
2. Turn the rotary knob in the middle or tap the parameters with your fingertip on the touchscreen to navigate through the options.

The following selection options are available, but depending on the program and parameter selection, not all the adjustment items will be visible:

Name	Meaning
Program	Selection of the 4 standard programs and optionally of any programs you have created yourself.
Mode	Selection of continuous or time-limited stimulation. CONTINUOUS or DURATION buttons.
Duration	For setting the duration of the time-limited stimulation in [s].
Polarity	Selection of the pulse form (positive symmetrical square-wave pulse, negative symmetrical square-wave pulse, bi-phasic symmetrical square-wave pulse positive and negative).
Pulses	Number of pulses emitted within a pulse sequence (1-10).
Pulse width	100 - 2000 $\mu$ s
ISI	The interstimulus interval (ISI) describes the time interval between 2 pulses in a pulse sequence (1 - 10 ms).
Initial current value	0.1 - 25 mA
Volume	0 - 100

Table 17 Selection options

If a particular choice of parameters prevents a pulse from being generated, you will be informed about this in a pop-up window.

### Creating a program

To create a new program, tap the button NEW PROGRAM. The program is automatically saved.

### Deleting a program

To delete a program you have created yourself, tap the DELETE PROGRAM BUTTON.

## 5.8 EXPORTING PATIENT DATA

This description only applies to the export of patient data for thyroid, ENT, vascular, and neurosurgery.

Data export for spinal and rectal surgery is described in the corresponding sections.

### Printing patient data

Via the Print menu you can print out recorded wave shapes and trend graphics where available. They can also be saved as a PDF file and exported to a USB stick or to a network drive.

The device offers various options:

- If a USB stick is connected to the device, then data can be exported directly from the PRINT menu.
- If no USB stick is connected, the data can be saved to the internal hard disk of the device. Available report exports are displayed with the EXPORT symbol.



Proceed as follows to print out the report after the surgical procedure:

1. Tap the button REVIEW or PRINT. The symbols are displayed based on whether or not any intraoperative comments were entered.
2. Select the curves you wish to print out. Further information can be found below under *Analysis of patient data*.
3. Tap the PRINT button again.
  - The printout is generated to the selected medium.



Proceed as follows to export data from the buffer of the hard disk:

1. Tap the PATIENT button.
2. Insert a USB stick.
3. Confirm the transfer.
  - The data is copied to the USB stick.

The scaling of the curves displayed in the printout is automatically adapted to the curve with the highest amplitude.

If required, the view can be adjusted by zooming in or out with two fingers on the touchscreen.

For information about exporting data to a network drive refer to *section "6.1.5 Printer settings"*.

### Analysis of patient data



At the end of a surgical procedure, the recorded curves can be viewed in the analysis and printed out. All recorded curves are displayed on the right-hand half of the touchscreen. All curves for the report are shown on the left-hand half of the touchscreen.

Proceed as follows to add a curve to the report:

1. Select a curve with the right-hand rotary knob. You can jump 100 steps at a time with the middle rotary knob.
2. Press the rotary knob to confirm the selection.
  - The curve is added to the report.

Proceed as follows to remove a curve from the report:

1. Select a curve with the left-hand rotary knob. You can jump 100 steps at a time with the middle rotary knob.
2. Press the rotary knob to confirm the selection.
  - The curve is removed from the report.
3. Press the COMMENTS button to add a postoperative comment.

All curves that were commented on intraoperatively are automatically selected for the report.

## 6 DEVICE SETTINGS

The menus for the system settings are independent of the application or currently selected software and apply to all settings of the device.

1. Go to **ADVANCED SETTINGS**.
2. Enter the password 123456 via the middle rotary knob.
3. Press the middle rotary knob to confirm.
  - The lower menu levels are now open.

### 6.1 GENERAL SETTINGS



Here you can change the general configuration settings, including the system time and hospital name.



The system time is battery buffered. Since it is possible for batteries to become discharged, this can lead to a loss of the time, date, and BIOS settings. In this case, please contact our customer service department to have the batteries changed (battery type: CR2032, 3 V).



You can also restore the default factory settings of the device here, see *section "6.7 Restoring default factory settings"*.

The language of the device can be changed via the **LANGUAGE** menu.

#### 6.1.1 ACTIVATING SOFTWARE MODULES



The activated software modules are listed in the **LICENCE AND UPGRADES** menu.



To perform a licence upgrade:

1. Contact your responsible dealer or sales employee at inomed Medizintechnik GmbH and request a corresponding release file to enable the software module.
2. Copy the file to a USB stick and connect this to the device.
3. Open **SETTINGS** and go to **SERVICE**.
4. Navigate to the **LICENCE AND UPGRADE MENU**.
5. A dialog window will open.
6. To start the upgrade process, tap the **GREEN TICK** that is displayed.

The device will restart automatically after the upgrade.

### 6.1.2 DEFINITION OF COMMENTS



Up to 20 intraoperative comments can be pre-defined for each software module.



To edit a pre-defined comment:

1. Open **SETTINGS** and navigate to **ADVANCED SETTINGS**.
2. Select **COMMENTS SETTINGS**.
3. To edit a comment, select it with the middle rotary knob or tap the corresponding button on the touchscreen.
4. Enter a comment via the virtual keyboard.
5. Tap the **ENTER** button or the tick icon.

In the wizard-controlled software module "pIOM" you can edit comments directly.

In the wizard-controlled software module "Spine" you first need to press the buttons for the cervical spine or lumbar spine region.

### 6.1.3 DEFINITION OF CHANNEL SETTINGS



You can edit the pre-defined channel settings for the EMG, SEP and MEP programs in the **ADVANCED SETTINGS MENU**. Under **CHANNEL SETTINGS** you can activate up to 8 channels ("ON"); these can be renamed via the middle rotary knob. The color of the channels can be changed.



### 6.1.4 ASSIGNMENT OF THE PROGRAMS MENU



The **PROGRAMS** button can be assigned, modified, and deleted here:



1. Tap the **SETTINGS** button.
2. Tap the **SYSTEM** button.
  - The current assignment of the buttons can be seen under **PROGRAMS**.



3. Select a button by selecting it with the middle rotary knob or by tapping the corresponding button on the touchscreen.
4. Select a program by selecting it with the middle rotary knob or by tapping the corresponding button on the touchscreen.
  - The program is now assigned to a particular button.

Once you have defined buttons yourself, you can delete them again or rename them.

### 6.1.5 PRINTER SETTINGS



#### Setting up a printer



1. Tap the SETTINGS button.
2. Tap the SYSTEM button.
3. Open the printer settings by tapping PRINTER.

Printer modes:

- NONE: No printing functions available.
- NETWORK PRINTER: Printing is possible via a network printer.

If you connect the printer via USB it will be installed automatically.

Suggested printer compatible with the C2 Xplore:

- Brother HL-L2350DW

Nr. 10.3.2.  
Nr. 10.2.2.

#### Options for saving as a PDF file:

Išsaugoti kaip PDF failą parinktys:

- **USB stick: The PDF file is saved to a connected USB stick.**  
USB atmintinė: PDF failas išsaugomas prijungtoje USB atmintinėje.
- Network drive: The PDF file is saved to a set-up network drive.

In addition, it is also possible to save reports to a network drive. For further details and support, please contact your inomed Medizintechnik GmbH dealer or sales employee.

#### Setting up a network drive



In order to export a report to a network drive you will need to access the hospital network settings:

1. Tap the SETTINGS BUTTON.
2. Open the SYSTEM menu.
3. Go to NETWORK / STORAGE LOCATION FOR PRINTOUTS.
4. Enter the details of the network storage location.

### 6.1.6 DATABASE



This menu contains information about the current status of the database and the available memory space. This allows you to estimate the number of patients and the storage capacity. In this menu, you can export the database, delete it, or import one from a USB stick.



### Export function

In this window, you can export the database:

1. Go to **SETTINGS**
2. Navigate to the **SYSTEM** menu.
3. Tap the **STORAGE** button.
4. Connect a USB stick to the device.
5. Tap the **EXPORT** button and confirm this by tapping the tick.
  - The database is exported. This may take a few minutes.

Optionally you can also export a ".csv" file.

### Database repairs

If inconsistencies in the database are discovered during start up of the device, the device will independently attempt to repair it. The database is backed up in the process. Patient data is not at risk.

If the database is successfully repaired, a message is displayed on the touchscreen.

If it is not possible to repair the database, then the system will automatically create a new one. The old database is backed up. If you need to access the old one, please contact the Service Department of inomed Medizintechnik GmbH.

## 6.2 HELP FUNCTION



Tap the **HELP** button to open the help function of the C2 Xplore. This contains information that will help you operate the device.

## 6.3 REMOTE MAINTENANCE



Starting remote maintenance:



1. Connect the C2 Xplore to the Internet with an Ethernet cable or using the WIFI adapter.
2. Go to **SETTINGS**.
3. Navigate to the **SERVICE** menu.
4. Under **TECHNOLOGY** select either **NETOP** or **TEAMVIEWER** for the remote maintenance.
5. Tap the button **START REMOTE ACCESS**.
  - A pop-up window showing **CONNECTED** is displayed as soon as the connection is established.

## 6.4 SYSTEM CONFIGURATION



Exporting a system configuration:



1. Connect a USB stick to the device.
2. Go to **SETTINGS**.
3. Navigate to the **SERVICE** menu.
4. Select **SYSTEM CONFIGURATION – EXPORT**.
  - The system configuration is exported.

Alternatively, you can also import a system configuration via the same menu.

## 6.5 LOG FILES



Exporting log files:



1. Connect a USB stick to the device.
2. Go to **SETTINGS**.
3. Navigate to the **SERVICE** menu.
4. Select **EXPORT LOG FILES**.
  - The log files are exported.

## 6.6 TABLET CONNECTION VIA WIFI

Connect a tablet via **WIFI** to the C2 Xplore. The tablet can then be freely placed in the operating theatre. This option enables you to use the tablet as a second screen.

### Accessories required

The following accessories are required in order to connect a tablet to the C2 Xplore:

- C2 Xplore **WIFI** set (REF: 508566)  
Contains the C2 Xplore **WIFI** stick (REF: 508565) and the **inoView V2** software (REF: 508517)
- **inoView V2** App  
Available in the App Store (iOS) and Google Play Store (Android)

Minimum system requirements for wireless tablets:

- iOS 12.1 or Android 8.0 (or higher)
- Memory space: 100 MB
- RAM: 4 GB
- CPU: 2.0 GHz
- **WIFI**: 2.4 GHz, IEEE 802.11 n



### Settings on the C2 Xplore

Enable the software function for wireless connection:



1. Plug in the WIFI stick on the rear panel of the device.
2. Go to SETTINGS and navigate to the SYSTEM menu.
3. Open the NETWORK menu.
4. Select INOVIEW V2.



### Configuring the WIFI connection



1. Go to SETTINGS and navigate to the SYSTEM menu.
2. Open the NETWORK menu.
3. Open the WIFI menu.
4. Tap ENABLE AP in order to enable the access point.



If you also wish to use the network storage option, then you will need to connect the C2 Xplore in Client Mode or use a second WIFI stick.



### Configuring Client Mode



1. Go to SETTINGS.
2. Navigate to the SYSTEM menu.
3. Open the NETWORK menu.
4. Open the WIFI menu.
5. If the access point is enabled, press DISABLE AP to disable it.
6. Select the hospital network via the NETWORK button.

### Settings on the tablet

1. Connect the tablet via the WIFI settings with the WIFI network of the C2 Xplore. The WIFI name can be found in the NETWORK menu under “computer name”.
2. Open the inoView app.
3. Enter the IP address “192.168.137.1”.
4. Enter the password “remote1991”.
5. Tap CONNECT.

### Certificate settings (iOS only)

During initial installation it may be necessary to install required certificates:

1. Open the inoView app.

2. Tap CONNECT.
  - A pop-up window is displayed.
3. Tap ACCEPT.
  - You will be redirected to an external page.
4. Tap DOWNLOAD CERTIFICATE.
  - A pop-up window is displayed.
5. Tap ALLOW.
6. On the iOS device, go to Settings → General → Profiles
7. Select the profile of the C2 Xplore.
8. Tap INSTALL.
9. On the iOS device, go to Settings → General → About → Certificate Trust Settings.
10. Confirm the C2 Xplore.

## 6.7 RESTORING DEFAULT FACTORY SETTINGS

If you restore the device to its default factory settings, any user-defined programs or program button assignments will be deleted. Patient data will not be affected by this.

To restore the device to its default factory settings:

1. Tap the SETTINGS BUTTON.
2. Tap the SYSTEM menu.
3. Tap the GENERAL button.
4. Tap RESTORE.
5. Confirm the process.
  - The device is restored to its default factory settings.

## 7 TROUBLESHOOTING

Before using the device, check connecting cables, supply cables and plugs for visible damage such as cracks or breakage. Damage is usually caused by improper handling during cleaning and disinfection. Electrical contact faults can be caused by vibrations.

Regular maintenance is recommended.

The most common faults and their causes are listed in the section below.

Problem	Cause	Solution
The device cannot be switched on.	The mains cable is loose or does not work.	Check and replace.
The operating system will not start up correctly.	The system was not shut down properly. Program files have been damaged.	Contact the manufacturer or your dealer.
The EMG signal is too weak or invisible.	Interruption in the connecting cable.	Check the cable, check the impedance.
	Electrode has come loose.	Test electrode for correct placement in the application area, test impedance.
	Incorrect scaling	Correctly scale the biosignal, check correct amplification in the system setup.
EMG signals are too large.	HF source or another source of interference is active.	Switch off devices causing interference or switch off the recording of interruptions (also refer to the instructions for use of the individual function modules), use a mute sensor, rescale the signal.
	Incorrect scaling	Correctly scale the biosignal, check correct amplification in the system setup.
No "Current Confirm."	Cable not connected.	Check the cable connection.
	Stimulator not switched on or probe not correctly connected.	Switch on the stimulator or reconnect the probe.
	Probe or cable defective.	Check the current flow by pressing the probe into a wet pad or a ring bone with an isotonic solution.
No acoustic feedback.	Nr. 5.3. <b>Loudspeaker is switched off.</b> Garsiakalbis išjungtas	<b>Press the middle rotary knob to switch on the loudspeaker.</b>
	Nr. 5.2. <b>Volume too low.</b> Garsas per žemas	<b>Increase the volume by turning the middle rotary knob clockwise.</b>

Paspauskite vidurinį sukamąjį mygtuką norėdami įjungti garsiakalbį.

Table 18: Troubleshooting

Padidinkite garsumą pasukdami vidurinį sukamąjį mygtuką laikrodžio rodyklės kryptimi.

Vidurinis sukamasis mygtukas pavaizduotas 26 psl.

## 8 TECHNICAL SPECIFICATIONS

### 8.1 TECHNICAL DATA

#### C2 Xplore (REF.: 508288)

Description	Values
Class in accordance with 60601-1	I
Classification of the applied part	Type BF
Classification in accordance with 93/42/EEC	IIa
CE number	0297
Dimensions (W / H / D):	27 cm / 44 cm / 27 cm
Nr. 12. <b>Weight</b> Svoris	<b>6.6 kg</b>
Safety	IEC 60601-1, IEC 60601-1-2
Ingress protection	IP20

Table 19: Technical data for the C2 Xplore

#### C2 Xplore adapter boxes: Head Box (REF: 540430), Body Box (REF: 540431), SEP Box (REF 540432), pIOM Box (REF: 540433)

Description	Values
Classification in accordance with Regulation (EU) 2017/745	I
Dimensions without cables (W / H / D):	62 mm / 232 mm / 38.5 mm
Cable length	5 m
Weight with cables	1.38 kg
Safety	IEC 60601-1, IEC 60601-1-2
CE certification	

Table 20: Technical data for the adapter boxes

### 8.2 ENVIRONMENTAL CONDITIONS



#### WARNING!

##### Damage to the device

The device must only be operated, transported and stored within the environment specified in the Instructions for Use.

The environmental conditions apply both to the C2 Xplore and to the adapter boxes.

Description	Values
Storage conditions	Humidity: 30% to 85%
	Temperature: 5°C to 40°C (41°F to 104°F)
	Atmospheric pressure 700 hPa - 1060 hPa

Transport conditions	Humidity: 15% to 95% Temperature: -29°C to 55°C (-20°F to 131°F) Atmospheric pressure 700 hPa - 1060 hPa
Operating conditions	Humidity: 30% to 85% Temperature: 5°C to 40°C (41°F to 104°F) Atmospheric pressure 700 hPa - 1060 hPa

Table 21: Environmental conditions

### 8.3 MAINS POWER SUPPLY

Description	Values
Power draw	100 - 240 V~, 50 - 60 Hz max. 120 VA
Fuses	2 x T3.15 AH 250 V
Patient insulation	Protection for up to 4000 V against mains voltage

Table 22: Mains power supply

### 8.4 DATA COLLECTION MODULE

Duomenų surinkimo modulis

Nr. 8.  
Nr. T3

Description	Values
<b>Measuring channels</b> Matavimų kanalai	<b>8 differential channels</b> 8 diferencialiniai kanalai
Scanning rate [ $\pm 2\%$ ]	20 kHz
Resolution of the measured data	16 bits per channel
Common mode rejection ratio (CMRR)	$\geq 100$ dB (50Hz)
Input noise level	$\leq 1.5 \mu\text{V}_{\text{EFF}}$ (with hardware filter 30 Hz to 2.5 kHz)
Input impedance	$> 100 \text{ M}\Omega$
Adjustable measurement range	1 mVpp - 500 mVpp (programmable)
Input sensitivity	12 $\mu\text{Vpp}$ - 500 mVpp
Impedance measurement	For all electrode inputs
Bandwidth / filter [ $\pm 20\%$ & $\pm 0.3$ Hz]	Max. bandwidth: 0.5 Hz - 5 kHz Hardware high-pass filter – cutoff frequency 0.5Hz 3Hz 30Hz 120Hz Hardware low-pass filter – separating frequency 1.25 kHz 2.5 kHz 5 kHz

Table 23: Data collection modules

8.5 **STIMULATOR**

Stimuliatorius

	Description	Values
Nr. 6.	<b>Channels</b> Kanalai	<b>2</b> Stimuliavimo kanalai
	Connections	2, DNS connector and 1.5 mm safety connection
	<b>Frequency</b>	<b>Individually selectable for up to 60 Hz for individual pulses or up to 500 Hz for pulse sequences (depending on the clinical application settings)</b>
	Polarity	Two-phase, positive and negative square-wave pulse
	Pulse width	50 - 2000 $\mu$ s
	Pulse sequence	1 - 10 pulses
	Type	Constant current
Nr. 7.	<b>Stimulation current</b> Stimuliavimo srovė	<b>0.01 – 25 mA</b> Reguliavimo ribos nuo 0,01mA iki 25mA
	Stimulation voltage	$V_{\max} = 100$ V
	Load impedance	0 - 10 k $\Omega$
	DC offset potential	0 V
	Current sensor	Display of the current flow (confirm current)

Table 24: Stimulator

## 8.6 SOFTWARE LICENCED

The C2 Xplore software contains the software component “Google Japanese Input Method (Mozc)” which is used for Japanese keyboard input. The following license applies to this software component:

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LIMITED TO, PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES; LOSS OF USE, DATA, OR PROFITS; OR BUSINESS INTERRUPTION) HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, STRICT LIABILITY, OR TORT (INCLUDING NEGLIGENCE OR OTHERWISE) ARISING IN ANY WAY OUT OF THE USE OF THIS SOFTWARE, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

## 8.7 OPERATING SYSTEM

C2 Xplore uses the operating system Microsoft® Windows® 10 IoT Enterprise LTSC 2016 1607 32 Bit.

The licence sticker is attached to the underside of the C2 Xplore.

## 8.8 ELECTROMAGNETIC PROPERTIES

The product fulfils all requirements of IEC 60601-1-2:014 + IEC 60601-2-40:2016. All therein-referred base standards are met. More specifically, C2 Xplore complies with the following:

- Emissions class and group and
- Immunity test levels.

The customer or user should ensure that the system is used in this kind of environment.

## 8.9 ELECTROMAGNETIC EMISSION

### Guidelines and manufacturer's declaration – electromagnetic emission

The C2 Xplore is intended for use in an electromagnetic environment as specified below.

Emissions measurements	Compliance level	Electromagnetic environment - guidelines
RF emissions according to CISPR 11	Group 1	C2 Xplore only uses RF energy for its internal function. This means that its RF emission is very low, and it is unlikely that neighboring electronic devices will be affected.
RF emissions according to CISPR 11	Class A	The emissions characteristics of this equipment make it suitable for use in industrial areas and

Emissions of harmonics to IEC 61000-3-2	Class A	hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.  This device/system is only intended for use by specialist medical staff.  Intended environment is <u>professional healthcare facility</u> .
Emissions of voltage fluctuations / flicker pursuant to IEC 61000-3-3	Compliant	

Table 25 Electromagnetic emission

## 8.10 ELECTROMAGNETIC IMMUNITY

### Guidelines and manufacturer's declaration – electromagnetic immunity

Deviations from the basic EMC standard / collateral standard and part two standard: N/A.

Moreover, required test conditions and declared compliance level for each immunity test are identical. The essential performance of C2 Xplore is maintained during the interference immunity conditions below.

#### **i Note:**

Excessive electrical fast transient interference / bursts may cause temporary screen flickering.

Interference immunity tests	IEC 60601-1-2:2014 IEC 60601-2-40:2016 Test conditions and compliance level	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) IEC 61000-4-2: 2008	Signal input/output parts port Patient coupling port ME equipment Contact: $\pm 8$ kV Air: $\pm 2$ kV, $\pm 4$ kV, $\pm 8$ kV, $\pm 15$ kV	Floors should be made of wood or concrete or be provided with ceramic tiles. If the floors are covered with synthetic material, the relative humidity must be at least 30%.
RF electromagnetic fields IEC 61000-4-3: 2006 +A1: 2007 +A2: 2010	I) 3 V/m 80 MHz to 2700 MHz  II) Proximity fields from RF wireless communications EQUIPMENT:  385 MHz (18 Hz Pulse Modulation) 27 V/m  450 MHz (FM+/-5KHz deviation 1 kHz sine or 18 Hz Pulse Modulation) 28 V/m  710 MHz (217Hz PM) 9 V/m  745 MHz (217Hz PM) 9 V/m	See warnings:  Adjacent and stacked use PORTABLE RF communications equipment

	<p>780 MHz (217Hz PM) 9 V/m</p> <p>810 MHz (18Hz PM) 28 V/m</p> <p>870 MHz (18Hz PM) 28 V/m</p> <p>930 MHz (18Hz PM) 28 V/m</p> <p>1720 MHz (217Hz PM) 28 V/m</p> <p>1845 MHz (217Hz PM) 28 V/m</p> <p>1970 MHz (217Hz PM) 28 V/m</p> <p>2450 MHz (217Hz PM) 28 V/m</p> <p>5240 MHz (217Hz PM) 9 V/m</p> <p>5500 MHz (217Hz PM) 9 V/m</p> <p>5785 MHz (217Hz PM) 9 V/m</p>	
<p>Electrical fast transient interference / bursts</p> <p>IEC 61000-4-4: 2012</p>	<p>Power supply lines <math>\pm 2</math> kV 100 kHz repetition frequency</p> <p>Input and output lines <math>\pm 1</math> kV 100 kHz repetition frequency</p>	<p>Mains power supply quality should comply with that of a typical commercial- or hospital environment.</p>
<p>Surges</p> <p>IEC 61000-4-5:2014</p>	<p>Power supply lines</p> <p>Line-to-ground</p> <p><math>\pm 0.5</math> kV, <math>\pm 1</math> kV, <math>\pm 2</math> kV</p> <p>Line-to-line</p> <p><math>\pm 0.5</math> kV, <math>\pm 1</math> kV</p>	<p>Mains power supply quality should comply with that of a typical commercial- or hospital environment.</p>
<p>Conducted disturbances induced by RF fields</p> <p>IEC 61000-4-6:2013</p>	<p>Input a.c. power ports</p> <p>Signal input/output ports</p> <p>Patient coupling ports</p> <p>3 V<sub>RMS</sub> 0.15 MHz – 80 MHz</p> <p>6 V<sub>RMS</sub> in ISM bands between 0.15 MHz – 80 MHz</p> <p>80 % AM at 1 kHz</p>	<p>See warnings:</p> <p>Adjacent and stacked use</p> <p>PORTABLE RF communications equipment</p>
<p>Voltage dips, short interruptions and voltage variations of the power supply</p> <p>IEC 61000-4-11:2004</p>	<p>Input a.c. power port 100Vac &amp; 230Vac</p> <p>0 % <math>U_T</math>; 0.5 cycle</p> <p>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°</p> <p>0 % <math>U_T</math>; 1 cycle and 70 % <math>U_T</math>; 25/30 cycles</p> <p>Single phase: at 0°</p> <p>Input a.c. power port 100Vac &amp; 230Vac</p> <p>0 % <math>U_T</math>; 250/300 cycle</p>	<p>Mains power supply quality should comply with that of a typical commercial- or hospital environment.</p> <p>If the user of C2 Xplore requires continued operation even when there are interruptions to the power supply, we recommend supplying the system from an uninterruptible power supply or a battery.</p>

Power frequency magnetic field (50/60 Hz) IEC 61000-4-8: 2009	ME equipment 30 A/m 50 Hz and 60 Hz	Power frequency magnetic fields should be at typical levels which are characteristic of a commercial or hospital environment.
ISO 7637-2	N/A	Standard is not applicable for professional healthcare facility environment.

Table 26 Electromagnetic immunity

## 9 CLEANING AND MAINTENANCE

The following instructions apply to:

C2 Xplore, foot switch, mute sensor, tube connection cable and adapter boxes

### 9.1 CLEANING AND DISINFECTION



#### **WARNING!**

- Electric shock!

All maintenance work must only be performed by inomed Medizintechnik GmbH or by an agent authorised by inomed to carry out such work.

- Electric shock!

Never make any modifications or repairs to the device or remove parts of it.



#### **CAUTION!**

- Incorrect measurement!

Do not saturate the device with water or cleaning agents. Always clean the device only in accordance with the cleaning information in the Instructions for Use.

- Incorrect measurement!

Do not saturate the adapter boxes with water or cleaning agents. Always clean the adapter boxes only in accordance with the cleaning information in the Instructions for Use.

#### **Recommended equipment and materials**

- Personal protective equipment in accordance with the recommendations of the disinfectant supplier.
- Soft, lint-free cloth
- Only disinfect with cleaning agents or alcohol.

#### **Wiping down the products**

1. Disconnect the mains cable from the power supply of the device.
2. Wipe down all outside surfaces of the device with a soft, lint-free cloth that has been wetted with a non-abrasive hospital disinfectant.
3. To remove visible, coarse soiling use a clean cloth wetted with the disinfectant and wipe down all surfaces. The surfaces must remain visibly damp at room temperature for at least the minimum time stated in the instructions for use of the disinfectant manufacturer.

4. Remove excess disinfectant solution with a soft, lint-free cloth moistened with water if this is required according to the instructions of the disinfectant manufacturer.
5. Check the equipment.

Component	Cleaning
C2 Xplore	Cleaning and wipe disinfection with alcohol or hospital disinfectant The C2 Xplore is non-sterilisable and must be stored outside of sterile areas.
Adapter box and connecting cables	Cleaning and wipe disinfection with alcohol or hospital disinfectant The products must be adequately dried before they are stored.
Mute sensor	
Foot switch	

Table 27 Cleaning of the components

## 9.2 MAINTENANCE



### WARNING!

- Electric shock!  
All maintenance work must only be performed by inomed Medizintechnik GmbH or by an agent authorised by inomed to carry out such work.



### CAUTION!

- Damage to the device!  
Have a yearly safety check and a technical inspection carried out by inomed Medizintechnik GmbH.
- Incorrect adjustment of the device!  
Empty battery. If the battery has been discharged and the device was restarted, a pop-up window will be displayed. Contact an inomed service engineer to set the correct time.

The recommended yearly safety check is performed by inomed Medizintechnik, your dealer or other persons authorised to carry out this work by inomed Medizintechnik. The following checks are performed during this safety check:

- Visual inspection and check of the device
- Function test
- Maintenance of the data memory
- Measurement of leakage currents

- Measurement of the protective conductor resistance
- Checking and replacement of the internal battery (battery type: CR2032, 3V)

In addition, the following steps must be carried out every time before using the device:

- Visual inspection and function check of the recording electrodes and cables.
- Visual inspection and function check of the stimulation cables and probes.

We recommend performing a data backup once a month or at the latest after 20 applications. The data can be saved via the export function and the USB port.

### 9.3 DISPOSAL

When the device needs to be decommissioned and disposed of, please get in touch with inomed Medizintechnik GmbH.

Connecting cables and reusable accessories should be disposed of as hospital waste.

	<p>Environmental pollution! Do not dispose of this product as domestic waste. All C2 Xplore electronic components must be sent to a WEEE recycling centre or disposed according to the local regulations.</p>
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## 10 C2 XPLORE – ACCESSORIES

This section contains an overview of suitable accessories. The C2 Xplore must only be operated with inomed accessories, which have been explicitly tested and approved by inomed.

Concerning further compatible accessories, please contact inomed Medizintechnik GmbH or your responsible dealer.

Nr. 13.1.1.	<b>REF</b>	<b>Neuromonitor</b>
	Kodas	Neurostimulatorius - neuromonitoringas
	<b>508288</b>	<b>C2 Xplore</b>
		Valdymo konsolė, kiekis 1 vnt.
Nr. 13.1.2.	<b>REF</b>	<b>Adapter boxes</b>
	Kodas	Adapterio dėžutės
	<b>540430</b>	<b>Head Box for C2 Xplore</b>
	540431	Body Box for C2 Xplore
	540432	SEP Box for C2 Xplore
	540433	plOM Box for C2 Xplore
	<b>REF</b>	<b>Software modules</b>
	508530	Cortical Stimulator Software Module for C2 Xplore
	508531	Thyroid and ENT Software Module for C2 Xplore
	508532	SEP Software Module for C2 Xplore
	508533	plOM Software Module for C2 Xplore
	508534	Spine Software Module for C2 Xplore
	508535	Cortical Software Module for C2 Xplore
Nr. 13.1.3.	<b>REF</b>	<b>Tube connecting cables</b>
	Kodas	Intubacinių vamzdelių jungiamieji laidai:
	530665	Connecting cable S Touchproof for adhesive laryngeal electrodes for tube
	530667	Connecting cable Redel for adhesive laryngeal electrodes for tube
	530668	Connecting cable F Touchproof for adhesive laryngeal electrodes for tube
	530669	Connecting cable M Touchproof for adhesive laryngeal electrodes for tube
	<b>530867</b>	<b>Connecting cable Redel for Select adhesive laryngeal electrodes for tube</b>
		Jungiamasis laidas „Redel“, skirtas „Select“ lipniems gerklų elektrodams klijuojamiems ant vamzdelių, kiekis 1 vnt.
	530869	Connecting cable F 2-channel for Select adhesive laryngeal electrodes for tube
	530866	Adapter cable Touchproof for Select adhesive laryngeal electrodes for tube
	530658	Adapter cable for laryngeal electrodes

REF	Adhesive laryngeal electrodes for the tube, set of 10 units
530655	Adhesive laryngeal electrodes for tubes with an internal diameter of 6-7 mm
530656	Adhesive laryngeal electrodes for tubes with an internal diameter of 7.5-9mm
530855	Select adhesive laryngeal electrodes for tubes with an internal diameter of 6-7 mm
530856	Select adhesive laryngeal electrodes for tubes with an internal diameter of 7-9mm

REF	ALM tube, set of 10 units
530843	ALM tube internal diameter 6.0
530845	ALM tube internal diameter 7.0
530846	ALM tube internal diameter 7.5
530847	ALM tube internal diameter 8.0

REF	DELTA electrode, set of 5 units
522623	DELTA electrode with direct connecting cable
522620	DELTA electrode
520037	Connecting cable for DELTA electrodes
520038	Connection cable Touchproof for DELTA Electrodes

REF	Subdermal needle electrodes, set of 10 units
530626	SDN electrodes RD/BK 20/1200, stainless steel
530627	SDN electrode GN 20/1200, stainless steel
530666	Single use vocalis electrode 15 mm bipolar, with neutral electrode;
532621	SDN electrode Trigon BU 15/1000, stainless steel
532622	SDN electrode Trigon BN 15/1000, stainless steel
532623	SDN electrode Trigon YE 15/1000, stainless steel
532624	SDN electrode Trigon GY 15/1000, stainless steel
532625	SDN electrode Trigon GN 15/1000, stainless steel
532626	SDN electrode Trigon RD 15/1000, stainless steel
532627	SDN electrode Trigon SW 15/1000, stainless steel
532628	SDN electrode Trigon VT 15/1000, stainless steel
532629	SDN electrode Trigon WH 15/1000, stainless steel
533621	SDN electrode BU 15/1000, stainless steel
533622	SDN electrode BN 15/1000, stainless steel
533623	SDN electrode YE 15/1000, stainless steel
533624	SDN electrode GY 15/1000, stainless steel
533625	SDN electrode GN 15/1000, stainless steel
533626	SDN electrode RD 15/1000, stainless steel
533627	SDN electrode BK, 15/1000, stainless steel
533628	SDN electrode VT 15/1000, stainless steel
533629	SDN electrode WH 15/1000, stainless steel

532651	SDN electrode Trigon GN 20/1500, stainless steel
532653	SDN electrode Trigon GN 20/3000, stainless steel
533651	SDN electrode GN 20/1500, stainless steel
533653	SDN electrode GN 20/3000, stainless steel
532631	SDN electrodes Trigon BU/BK 15/1000, stainless steel
532633	SDN electrodes Trigon YE/BK 15/1000, stainless steel
532634	SDN electrodes Trigon GY/BK 15/1000, stainless steel
532636	SDN electrodes Trigon RD/BK 15/1500, stainless steel
532637	SDN electrodes Trigon RD/BK 15/2000, stainless steel
532638	SDN electrodes Trigon VT/BK 15/1000, stainless steel
532641	SDN electrodes Trigon RD/BK/GN 15/1500, stainless steel
532657	SDN electrodes Trigon RD/BK 20/2000, stainless steel
532646	SDN electrodes Trigon coloured 15/2000, stainless steel
532666	SDN electrodes Trigon coloured 20/2000, stainless steel
532671	SDN electrodes Trigon RD/BK 30/2000, stainless steel
532675	SDN electrodes Trigon RD/BK 40/2000, stainless steel
533631	SDN electrodes BU/BK 15/1000, stainless steel
533633	SDN electrodes YE/BK 15/1000, stainless steel
533634	SDN electrodes GY/BK 15/1000, stainless steel
533636	SDN electrodes RD/BK 15/1500, stainless steel
533637	SDN electrodes RD/BK 15/2000, stainless steel
533638	SDN electrodes VT/BK 15/1000, stainless steel
533641	SDN electrodes RD/BK/GN 15/1500, stainless steel
533657	SDN electrodes RD/BK 20/2000, stainless steel
533646	SDN electrodes coloured 15/2000, stainless steel
533666	SDN electrodes coloured 20/2000, stainless steel
533671	SDN electrodes RD/BK 30/2000, stainless steel
533675	SDN electrodes RD/BK 40/2000, stainless steel
532656	SDN electrodes Trigon RD/BK 20/1500, stainless steel
532720	SDN electrodes RD/BK 6/1500, stainless steel
532722	SDN electrodes RD/BK 12/1500, 90°, stainless steel
533656	SDN electrodes RD/BK 20/1500, stainless steel

REF	Double needles
534641	Double needle, 2-channel set 12/1500, 2.5 mm, stainless steel
534643	Double needle, 4-channel set 12/1500, 2.5 mm, stainless steel
534671	Double needle, 2-channel set 12/1500, 2.5 mm, stainless steel
534645	Double Needle Electrode Set, 12/1500, 2.5mm, Stainless Steel
534646	Double Needle Electrode Set, 18/1500, 2.5mm, Stainless Steel
534673	Double Needle Electrode, 2 channel set, 12/1500, 2.5mm, Stainless Steel

REF	Needle electrodes
529500	SDN electrode WH 12/1500 platinum/iridium
530036	3 needle electrodes blue for facial nerve recording
530037	3 needle electrodes yellow for facial nerve recording,
530038	3 needle electrodes blue for facial nerve recording
530039	3 needle electrodes yellow for facial nerve recording
530050	SDN electrodes RD/BK 20/1200, stainless steel
530101	Hooked-Wire Applicator curved, for diagnostic,
530102	Flexible guide tube for Hooked Wire Applicator.
530103	Hooked-Wire-Applicator straight
530106	Hooked-Wire Recording cable Cable length 1.2m
530121	Vocalis Electrode Applicator for 9 mm needles, with handle,
530224	SDN electrode bipolar with ground needle 30mm, OD 0.7mm
530227	Electrode for vocal muscle, bipolar, 15 mm
530228	Electrode for vocal muscle, bipolar, 25 mm
530600	Hook Wire Electrode 2,5/300, in disposable cannula
530602	Hook Wire Electrode 13/400, in disposable cannula
530603	Hook Wire Electrodes 30/400, in disposable cannula
530607	SDN electrodes RD/RD 20/1200, stainless steel, 90°
530680	SDN electrodes RD/BK 25/1200, stainless steel
530683	SDN electrodes RD/BK 15/2000, stainless steel
530751	Corkscrew electrode set spiral needle 0.6 mm with tip
530770	EP-Cap helping tool for 10-20-System
530870	Rectal Electrode for Sphincter EMG recording
532609	SDN electrode pair peek WH/WH 9/1500, stainless steel
532610	SDN electrodes BN/BN 9/1500, stainless steel
532611	SDN Electrodes VT/VT 9/1500, stainless steel
532661	SDN electrodes Trigon RD/BK/GN 20/1500, stainless steel
532710	Oculomotorius electrode bipolar, needle 30 mm
532711	Oculomotor electrode bipolar, needle 20 mm
532730	SDN hooked electrodes 30/1500,35°, stainless steel
533661	SDN electrodes RD/BK/GN 20/1500, stainless steel

REF	Stimulation probes, set of 10 units
522600	BCS probe 90 mm straight
522601	BCS probe 90 mm angled 30°
522603	BCS probe 45mm angled 30°
522605	BCS probe 130 mm bayonet, angled 30°
522606	BCS probe 130 mm bayonet
522610	Microfork probe 45 mm straight
522624	Fork probe 45 mm straight, ball tip
522629	BCS probe 130mm straight
522630	BCS probe 130mm angled 30°

525603	Stimulation probe 45 mm monopolar, angled 30°
525608	Stimulation probe 85 mm monopolar, straight, flexible
525615	Stimulation probe 130 mm monopolar, bayonet, ball tip
525616	Stimulation probe 85 mm monopolar, straight, ball tip

REF	Stimulation probes, reusable
522002	Fork probe 130mm bayonet
522003	Fork probe 130mm bayonet, ball tip
522010	Micro fork probe 45 mm straight
522011	Micro hook probe 45mm straight
522014	Micro fork probe 130mm bayonet, ball tip
522017	Fork probe 25mm straight, flexible, ball tip
522018	stimulation probe 90mm bipolar, angled 20°
522019	Stimulation probe 90mm bipolar, angled 10°
522021	Hook probe 22mm bipolar, straight
522022	Hook probe 25mm tripolar, straight
522023	Micro hook probe 70mm tripolar, hook angled 90°
522024	Fork probe 10mm straight, ball tip
522100	BCS probe 90mm straight
522101	BCS probe 90mm angled 30°
522102	BCS probe 45mm straight
522103	BCS probe 45mm angled 30°
522104	BCS probe 130mm bayonet, angled 30°
522105	BCS probe 130mm bayonet, angled 30°
522106	BCS probe 130mm bayonet
522109	BCS probe 130mm bayonet, ball tip
522128	BCS probe 310mm straight
522130	Bipolar pedicle stimulation probe
522618	Stimulation probe 90mm bipolar, angled 20°
522625	hook probe 22mm bipolar, straight
522626	hook probe 25mm tripolar, straight
522627	BCS probe 230mm
525003	Stimulation probe 130mm monopolar, bayonet
525200	Stimulation probe 90mm monopolar, angled 30°
525203	Stimulation probe 90mm monopolar, straight
525206	Stimulation probe 130mm monopolar, bayonet
525207	Stimulation probe 25mm monopolar, straight, flexible
525208	Stimulation probe 90mm monopolar, straight, flexible
525209	Stimulation probe 130mm monopolar, straight, ball tip
525210	Stimulation probe 60mm monopolar, straight, flexible
525211	Stimulation probe 310mm monopolar, straight
525310	Surgical instrument 85mm needle, monopolar, straight
525311	Surgical instrument 85mm needle, monopolar, angled 30°

525312	Surgical instrument 85mm raspatory, monopolar
525313	Surgical instrument 85mm roundknife, monopolar, straight
525315	Surgical instrument 85mm monopolar, angled 90°,ball tip
525316	Surgical instrument 85mm Dissector, monopolar, curved
525317	Surgical instrument 85mm dissector, monopolar, curved
525318	Surgical instrument 85mm dissector, monopolar, curved
525319	Surgical instrument 135mm monopolar, angled 45°,ball tip
525320	Surgical instrument 85mm Rhizotomy dissector, monopolar
525600	Stimulation probe 90mm monopolar, angled 30°
525612	Surgical instrument 85mm raspatory, monopolar

REF	Accessories for spinal surgery
525615	Stimulation probe 130mm monopolar, bayonet, ball tip
525616	Stimulation probe 85 mm monopolar, straight, ball tip
535640	Spinal surgery set EMG recording, posterior access
540730	EMG adapter for colour-coded accessories
522130	Bipolar pedicle stimulation probe
520070	Stimulation adapter cable, cable length 0.7 m
520027	Stimulation probe cable, cable length 4 m

REF	Accessories for vascular surgery
533657	SDN electrodes RD/BK 20/2000, stainless steel
520040	Adapter cable, cable length 2 m
530750	Corkscrew electrode set with spiral needle 0.6 mm, cable 1 m
533651	SDN electrode GN 20/1500, stainless steel
533623	SDN electrode YE 15/1000, stainless steel

REF	Accessories for rectal surgery
520335	plOM set with SDN electrodes
520336	plOM set with rectal electrode
520332	Catheter connection set for bladder pressure measurement

REF	Accessories for neurosurgery
525650	Raabe mapping suction probe 120 mm, monopolar
522624	Fork probe 45 mm straight, ball tip
533646	SDN electrodes coloured 15/2000, stainless steel
611014	Cortex strip electrode, 4 contacts – 1 strip with cable
611016	Cortex strip electrode, 6 contacts – 1 strip with cable
611018	Cortex strip electrode, 8 contacts – 1 strip with cable

<b>REF</b>	<b>Accessories for stimulation cables and probes</b>
520024	Stimulation probe cable Cable length 4m
520025	Stimulation probe cable Cable length 6m
520036	Adapter cable Cable length 1.5m
520077	Stimulation adaptor cable Cable length 0.7m
520078	Stimulation adaptor cable Cable length 0.7m
520091	Extension cable Cable length 2m

<b>REF</b>	<b>General accessories</b>
510063	Foot switch black with 4 m PVC hose
510025	Mute sensor for suppression of HF interference signals
508335	Laser printer set
508565	C2 Xplore WiFi Stick
508566	C2 Xplore WiFi set for use in operating theatres
508520	GDT network connection software module for C2
508521	HL7 network connection for C2 NerveMonitor
508400	Ultra Mini Keyboard German
508410	Ultra Mini Keyboard English
508420	Ultra Mini Keyboard French
504365	Sterile cover for iPad
508562	Holder for iPad
508312	Transport case for C2 Xplore
508313	Transport cover for C2 Xplore
508301	Equipment trolley for C2 Xplore

## 11 SYMBOLS

The following symbols are utilised for usage of the device:

Measurement screen	
	Patient. Management of the patient database.
	Comments. Recorded EMG responses can be commented on during the stimulation. If no stimulation has been performed yet then the button is grey, and it is not available. Five comments are available in each program.
	Printer. Direct access to the examination of the current patient. If no stimulation has been performed yet then the button is grey and it is not available.
	Settings. The parameters for the stimulation and recording can be changed and are saved immediately.
	Programs. Selection from predefined programs.
	Help. Opens the Help function. Application information is displayed here.
	Standard zoom. Restores the original scaling on the measurement screen.
	Baseline. Sets the baseline based on the current signal.
	Impedance. Performs an impedance measurement.
	Loudspeaker. Displays the volume setting of the device. Use the middle rotary knob for adjustment.
	Electrode impedance bad. Displays a poor connection of the recording electrodes after the impedance measurement.
	Electrode impedance good. Displays a good connection of the recording electrodes after the impedance measurement.
	Save. Recorded signal curves are being saved for future review. It is enough memory space available.
	No saving. Recorded signal curves are not being saved for future review. The memory space is not sufficient.

Patient	
	New. To create a new patient in the database.
	Select. Select already existing patients from the database for further recordings.
	Analysis. Analysis of the recorded data of previous patients.
	Delete. Remove a patient from the database.
	Export data. Report data is available and can be exported to a USB stick. This is displayed if USB_STICK_CACHED has been selected as the printer and no USB stick was connected when a report was generated. To carry out the export, simply connect a USB stick to the device and check the export. If no data is available, the symbol is grey, and it is not available.
	Hard disk space free. Patient data can be saved.
	Hard disk space is not sufficient. No more patient data can be saved. Delete patients data to free up hard disk space.
	Back. Return to the previous menu. Available in all menus.

New patient	
	Save. Confirm the selected action.
	Cancel. Cancel the selected action.

Analysis	
	Print. Patient data can be selected in the review in order to generate reports. A print preview is available.
	Scroll: 100 steps upwards.
	Scroll: 100 steps downwards.

Settings	
	Advanced settings. Settings for the current program.
	System. Provides information about the device and basic settings for the device.
	Service. Access to remote access, licence updates and the import/export function of the system configuration and log files
	Trend settings. Settings for the trend thresholds.

Advanced settings	
	Channel settings. Settings for the channel assignment of the current program.
	Comments settings. Settings for the Comments menu of the current program.
	Dealer setup.
	Overwriting default factory settings.
	Saving the program. Saving the current program configuration as a program.

System	
	Programs. Changing the Program menu.
	Printer. Printer settings.
	Memory. Access for exporting, deleting and repairing the database. Memory space overview.
	Network. Network settings for connection to the hospital network and WIFI settings.
	General. Date and time settings. The brightness of the display and the name of the hospital can be changed.

Service	
	Starting remote access.
	Licence and upgrades. Overview of the current licence. Upgrades are installed here.
	Export. Export of the system configuration (program and application configuration)
	Import. Import of the system configuration (program and application configuration)
	Export log files. Export of the log files to a USB stick.
Database	
	Export database. Export all patient database information to an external USB stick. Password-protected.
	Delete database. Delete all patient database information. Password-protected.

## 12 WARRANTY

A full warranty for materials and processing is offered for devices manufactured by inomed Medizintechnik GmbH ("the Company") for a period of one year from the date of shipment, except for the items listed below. The Company reserves the right to carry out guaranteed services in its own factory, in an authorised repair workshop or at the customer's point of installation.

The following points are excluded from this warranty.

- The obligations arising for the Company from this warranty are limited to the free repair or replacement of defective parts if the defects occur during routine maintenance.
- Single-use electrodes are deemed to be free of faults if used. Sterility is assured, provided the packaging is undamaged, and the product is within its service life, which is indicated by the sterilisation date printed on the label.
- Claims for damages during transport must be asserted immediately against the transport company. All correspondence relating to the device must state the model name and/or model number as well as the serial number, which are indicated on the invoice.
- Improper use, incorrect handling, manipulation or operation of the device in a way that conflicts with the explanations set out in these Instructions for Use will render the warranty null and void and free the Company from any further warranty obligations.

The Company will only accept responsibility for the safety, reliability, and performance of the devices if:

- Modifications or repairs are carried out by persons authorised by the Company.
- the electrical installation of the room in which the device is used satisfies the locally applicable rules and regulations.
- the device is used in accordance with these Instructions for Use.
- the devices is only used by specially trained personnel.
- only original accessories is used.

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C2 Xplore:



Adapter boxes:



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