BrainLAB
oncology solutions

User Guide

Revision 1.1

OEM Robotics

Contents

1 General Information

Overview

This guide provides an introduction and reference for the effective and correct use of BrainLAB's **OEM Robotics**. This guide is written for all members of the clinical team who use or handle the **OEM Robotics** or parts of it. You should read this guide carefully and acquaint yourself sufficiently with the system before use.

Support

If you cannot find the information you need in this guide, please contact BrainLAB support:

☎ United States and Canada	Tel: +1-800-597-5911 Fax: +1-708-409-1619
☎ Africa, Asia, Australia, Europe	Tel: +49-89-991568-44 Fax: +49-89-991568-811
☎ France & French-speaking regions	Tel: +33-800-67-60-30 support_fr@brainlab.com
☎ Latin America	Tel: +55-11-3256-8301 Fax: +55-11-3256-4968
☎ Japan	Tel: +81-3-5733-6275 Fax: +81-3-5733 6276
@ **Internet**, worldwide	support@brainlab.com www.brainlab.com

Copyright

Feedback

Despite careful review, errors may appear. We look forward to your comments and suggestions, and can be contacted at support@brainlab.com, or at the support phone numbers listed above.

Trademarks

Meliseptol® is a registered trademark of B. Braun.

CE Label

CE 0123

The CE0123 mark shows that BrainLAB's **OEM Robotics** complies with the essential requirements of the Medical Device Directive. According to the MDD (Council Directive 93/42/EEC), **OEM Robotics** is a Class IIb product.

Manufacturer

BrainLAB AG - Kapellenstr. 12 - 85622 - Feldkirchen - Germany

Language Information

All BrainLAB user guides are originally drafted in English. The corresponding reference number for this manual is 60911-29EN.

Disposal Instructions

Electrical and electronic equipment should only be disposed of in accordance with statutory regulations.

For information regarding the WEEE (Waste Electrical and Electronic Equipment) directive, visit: www.brainlab.com/weee

1.1 Symbols Used in this Manual

1.1.1 Symbols on the System Hardware Components

Hardware Symbols The following symbols may be found on the system or on accessory devices:

Symbol	Explanation
	Class I Type B equipment according to IEC 60601-1
	Attention! Consult accompanying documents
IPXO	The product is classified **IPX0** according to IEC 529.
SN	• Serial number of device: XXXX-**YY**-XX-XXXX-X • Serial number of workstation: **YY**-XXX-XXXXX **YY** specifies the manufacturing year of the device

1.1.2 Safety Information

Warning Symbol

Warnings are indicated by a triangular warning symbol. They always contain safety-critical information regarding possible injury, death or other serious consequences associated with misuse of the device.

Caution Symbol

Cautions are indicated by a circular caution symbol. They always contain safety-critical information regarding circumstances that could result in device malfunction, device failure, damage to the device or damage to property.

1.2 Important

1.2.1 Device Handling

Appropriate Use

OEM Robotics and accessory devices comprise precise mechanical parts which must be handled with care.

OEM Robotics and accessory devices may only be used by trained medical personnel.

Sales in the US

U.S. federal law restricts this device to sale by or on the order of a physician.

1.2.2 Indications for Use

OEM Robotics Robotics is an additional device for treatment tables used for radiation treatment. It enables a motorized table tilt around the lateral and longitudinal axis to compensate for patient rotation. In this fashion misalignments and shift of the patient can be precisely compensated.

1.3 System Compatibility

1.3.1 BrainLAB Systems

Medical Hardware

OEM Robotics is compatible with the following medical hardware products manufactured by BrainLAB AG:

BrainLAB Accessories	Comment
Imaging Couch Top (ICT) for Varian Exact	Imaging couch top for Varian Exact couch
Imaging Couch Top (Short) for Varian Exact	Short imaging couch top for Varian Exact couch
Anti-Skid Mat	Ensures comfortable patient positioning on the treatment table

Only medical hardware specified by BrainLAB may be used with OEM Robotics. Using unauthorized medical hardware may adversely affect the effectiveness of the system.

Only BrainLAB medical software specified by BrainLAB may be installed and used with OEM Robotics.

1.3.2 Non-BrainLAB Systems

Medical Hardware

OEM Robotics is compatible with the following non-BrainLAB medical hardware products:

Medical Device	Comment
Treatment table	The selected treatment table must fulfill the specifications for use with **OEM Robotics**.

Medical Software

OEM Robotics is compatible with the following non-BrainLAB medical software applications:

Software	Comment
Controller software	The controller software must fulfill the specifications for use with **OEM Robotics**.

Contact BrainLAB support for clarification regarding treatment table and controller software compatibility with **OEM Robotics**.

Only non-BrainLAB medical software specified by BrainLAB may be installed and used with OEM Robotics.

Only combinations with non-BrainLAB medical devices authorized by BrainLAB may be used together with OEM Robotics. Using medical device combinations that have not been authorized by BrainLAB may adversely affect the safety and/or the effectiveness of the medical device.

2 OEM Robotics

2.1 Overview

2.1.1 Background

OEM Robotics is a device that can automatically compensate for deviations in the patient's rotational (longitudinal and lateral) position. In combination with a controller software, a correction of the patient's appropriate treatment position can be determined. **OEM Robotics** can then automatically move the patient to the corrected position. Both automatic control with a controller software and manual operation (if supported by the controller software) are possible. For further details, refer to the instruction manual for the controller software.

2.1.2 General Information

Operating Conditions

- **OEM Robotics** must be operated at an ambient temperature of 10°C to 40°C (50°F to 104°F).

Cleaning

- **OEM Robotics** should be cleaned using a soft and dry cloth. Stubborn stains can be removed using a slightly moistened cloth. Do not use water, sharp objects, rough materials or caustic soaps to remove residue, especially not for the bellow.

Maintenance

Only remove the covers of OEM Robotics for maintenance purposes. In order to avoid injury or system damage due to clamping, do not operate OEM Robotics with the covers removed.

Warranty

- Warranties do not apply to products that have been damaged due to accident, misuse, misapplication, improper re-installation, or inadequate packaging in the case of return shipments. Warranties do not apply to products that have been modified or replaced without the written authorization of BrainLAB.
- Do not open the device. It does not contain user-serviceable parts. Only BrainLAB and authorized partners are allowed to repair or service the system and equipment.

Regulatory Information

OEM Robotics is a Class I / Type B product in accordance with IEC 60601-1 (Medical electrical equipment - General requirements for safety). This is indicated on the product label by an appropriate symbol in accordance with IEC 60878:2003.

OEM Robotics also complies with the requirements of IEC 60601-1-2 (Medical electrical equipment - General requirements for safety - Electromagnetic compatibility).

2.2 Supported Roll and Pitch Axes

2.2.1 Maximum Tilt Ranges

Overview

OEM Robotics is mounted between the selected treatment table and the BrainLAB **Imaging Couch Top for Varian Exact** (see illustrations below).

Tilt Ranges

When mounted beneath the couch top, **OEM Robotics** can tilt along two rotational axes of the treatment table (longitudinal and lateral). The maximum tilt ranges are:

- Maximum pitch (lateral tilt): ± 2.7°
- Maximum roll (longitudinal tilt): ± 4° (depending on software settings)
- Maximum roll when pitched to ± 2°: maximum ± 3°.

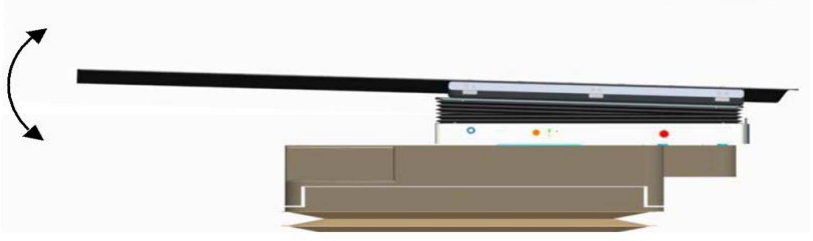

Figure 1: Lateral Tilt (Pitch)

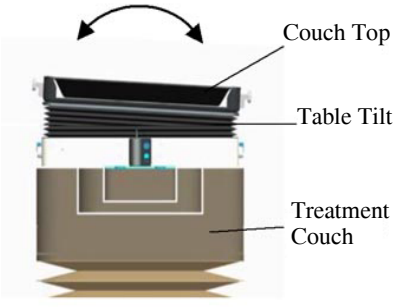

Figure 2: Longitudinal Tilt (Roll)

Safety Notes

During patient movement with OEM Robotics, you must have an unobstructed view of the patient.

Verify that the patient cannot become trapped between the treatment table and the gantry when OEM Robotics is moving. If the possibility of collision cannot be eliminated, reposition the patient.

Always use OEM Robotics in combination with the BrainLAB Imaging Couch Top for Varian Exact in order to avoid the risk of structural damage.

2.3 System Operation

2.3.1 Control Elements

Emergency Stop

An emergency stop function is provided by the treatment system manufacturer. **OEM Robotics** does not provide a separate emergency stop function.

To shut down the power and immediately stop the operation of **OEM Robotics**, activate the emergency stop function and follow the instructions provided by the treatment system manufacturer.

Robotics Controls

The following control elements are provided on the side of **OEM Robotics**:

- Fault LED
- Power LED
- Enable (LOCK ALL) LED
- Heavy Load Safety Lock

The Service Brake Release is provided at the foot end of the treatment table.

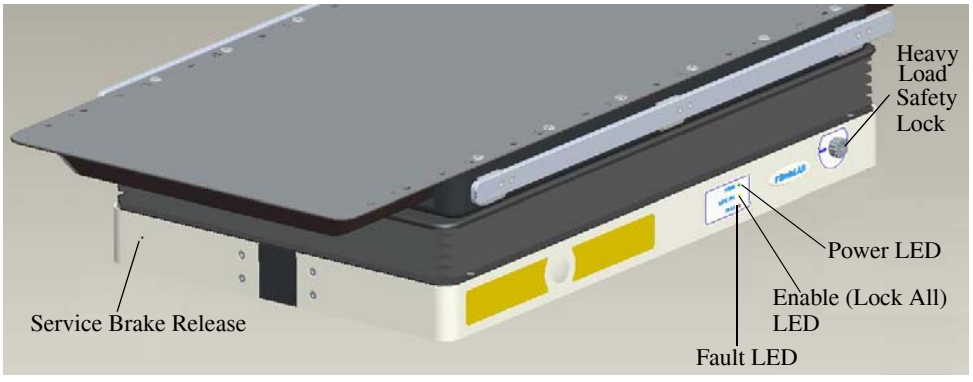

Figure 3: Available Controls

Heavy Load Safety Lock

A **Heavy Load Safety Lock** is located on both sides of **OEM Robotics**. The safety locks both drive a steady bolt, which only engages in the LOCK position (internal zero position) and manually locks the device.Once one of the safety locks is engaged, a sensor locks the device motor, so that further movement is no longer possible. In this case, both **LOCK ALL** LEDs are illuminated.

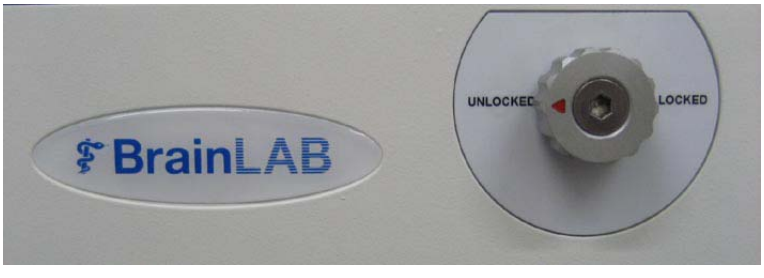

Figure 4: Heavy Load Safety Lock

If the treatment table must hold a person's weight in its cranial area, or if the tilting functionality of **OEM Robotics** is not used because the maximum operational load of 135kg is exceeded, both **Heavy Load Safety Locks** must be engaged. This is especially important when maintenance is being performed in the treatment room.

- Move the couch top into the LOCK position (internal zero position of **OEM Robotics**), e.g. by switching **OEM Robotics** on and off. Depending on the treatment room setup, this may not be equivalent to the room 0° position. However, the upper plate and base plate of **OEM Robotics** should be parallel to each other.
- Turn both **Heavy Load Safety Locks** to the **Locked** position to lock **OEM Robotics**.

The maximum load permitted on OEM Robotics combined with the BrainLAB Imaging Couch Top (no extension) is 135kg during OEM Robotics operation. If OEM Robotics is not in clinical use, the maximum load on OEM Robotics combined with the imaging couch top (no extension) is 185kg, provided that the Heavy Load Safety Locks are engaged.

The maximum load at the cranial end of the couch top (no extension) is 88kg.

Always lock the Heavy Load Safety Locks if the load on OEM Robotics combined with the couch top is greater than 135kg. The maximum load is 185kg.

If a person stands on the couch top (e.g. for maintenance purposes), the Heavy Load Safety Locks must be engaged.

Service Brake Release

The **Service Brake Release** button is located at the foot end of the treatment table (see Figure 3 on page 14). During normal operation, the brakes of **OEM Robotics** are always engaged. However, the brakes can be released, e.g. to manually move the treatment table into a horizontal position.

In order to release the device brakes, the **Service Brake Release** button must be held down.

- Remove the white plastic cap covering the **Service Brake Release** button.
- Insert a long thin object into the hole, and hold in position to activate the **Service Brake Release** button. **OEM Robotics** and the couch top can now be manually moved into the required position.
- While the **Service Brake Release** button is pressed, no drive command can be sent to **OEM Robotics**.

The Service Brake Release functionality enables the motor brakes to be unlocked. Be aware that sudden couch top movement, caused by gravity or spring retention force, can occur if you press the Service Brake Release button. Never activate the Service Brake Release button while a patient is lying on the treatment table.

Status LEDs

The LEDs on the OEM Robotics interface panel indicate:

- Power on (green LED)
- System lock enabled (yellow LED)
- System fault (red LED)

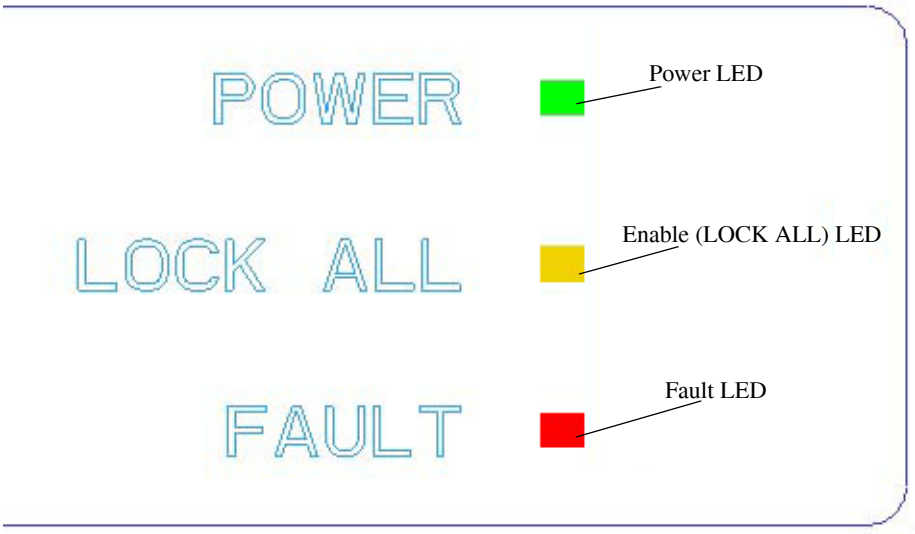

Figure 5: LEDs

- **Fault LED**.

This LED is illuminated (in red) in the event of an internal error. In this case, verify whether the locks are engaged. If this is not the case, send a drive command to **OEM Robotics**. If the **Fault LED** is still illuminated, switch the power off and on again.

If the **Fault LED** still remains illuminated, contact BrainLAB support.

- **Enable (LOCK ALL) LED**

An enable function is provided by the treatment system manufacturer. Activating this button enables movement of **OEM Robotics**.

To ensure safe patient treatment, the enable function must be locked once the patient is in the final treatment position. When the system lock is activated, this is indicated by the yellow LED.

Further information is provided in the instruction manual provided by the treatment system manufacturer.

The Enable (LOCK ALL) LED indicates that either the electrical motor brakes are engaged or that the Heavy Load Safety Lock has disabled movement.

2.4 Using the Anti-Skid Mat

Background

In order to enhance patient comfort when performing table tilting using **OEM Robotics**, the BrainLAB **Anti-Skid Mat** can be placed on the couch top beneath the patient.

Anti-Skid Mat

Figure 6: Anti-Skid Mat

Compliances

The BrainLAB **Anti-Skid Mat** has been tested for harmful substances and approved for skin contact in accordance with Oeko Tex Standard 100 (product class II).

Using the Anti-Skid Mat

Figure 7: Anti-Skid Mat on Couch Top

- Place the **Anti-Skid Mat** on the couch top as shown.

Washing the Anti-Skid Mat

The **Anti-Skid Mat** is machine washable up to 30°C using a mild detergent (a spin cycle should not be used).

- The **Anti-Skid Mat** can then be rolled up in a towel, in order to remove excess liquid.
- It should then be left to drip-dry naturally, and should not be placed in a spin or tumble dryer, or on a radiator.
- The mat should not be folded or used in patient treatment until is has dried completely.

Disinfection

- Standard surface disinfection can also be performed using a surface disinfectant such as Meliseptol. The recommendations of the disinfectant manufacturer should be observed.
- The mat can also be wiped clean using a soft, damp cloth. Paper should not be used.

Storage

The **Anti-Skid Mat** can be conveniently stored simply by rolling it up.

Dosimetric Properties

When irradiating through the **Anti-Skid Mat**, especially in combination with the BrainLAB **Imaging Couch Top**, attenuation and dose build-up should be verified experimentally using appropriate measurements.

Radiation attenuation will vary depending on beam energy and the beam entry angle through the Anti-Skid Mat.

Irradiating upwards through the Anti-Skid Mat with the gantry at the 6 o'clock position results in a dose attenuation equivalent to an estimated 1.4mm of water. This may not have been taken into account during treatment planning.

3 Maintenance of OEM Robotics

3.1 Safety Inspection Overview

3.1.1 General Inspection Guidelines

Interval A detailed inspection should be performed by BrainLAB support once a year.

The system should be maintained and inspected on a regular basis to ensure functionality and safety.

Authorized Persons Only BrainLAB and/or authorized partners are allowed to repair the system and the equipment.

Risk of electrical shock: There are no user-serviceable parts. All servicing is to be carried out by trained technicians or referred to BrainLAB.

3.1.2 Annual Inspection Requirements

Authorized Persons Only BrainLAB support specialists are authorized to perform annual inspections.

Arrangement

- If a service contract has been purchased, BrainLAB will automatically perform the annual inspection.
- If you do not have a service contract, contact BrainLAB support to arrange the inspection.

Scope This inspection covers all components and functions as well as the items described under “Performing Electrical Inspections”.

3.1.3 Weekly and Monthly Inspection Requirements

Authorized Persons Only qualified clinical personnel are authorized to perform weekly and monthly inspections.

Weekly Inspections Inspect the following components once a week:

Component	Inspection
Cabling	Visual control (twists, cracks)

Monthly Inspections

Inspect the following components once a month:

Component	Inspection
Labeling	Legibility

3.1.4 Safety Inspection Requirements

Interval

The safety inspection should be performed once a year.

Scope

The safety inspection must include all the items described under “Performing Electrical Inspections”.

Inspections by Non-BrainLAB Personnel

The safety inspection must be performed by a qualified engineer who:

- Is qualified for carrying out safety inspections on electrical medical equipment.
- Is familiar with the product safety information and product instructions, and has read and understood the user guides.
- Is up-to-date with current local regulations regarding industrial and non-industrial accident prevention.
- Informs BrainLAB immediately in writing if the equipment is deemed unsafe.

Inspections by BrainLAB Personnel

- If a suitably qualified person is not available at the customer site, BrainLAB’s support specialist will carry out this inspection for a set fee.
- If you require a BrainLAB support specialist, contact BrainLAB support.

Safety Inspection Record

- Make a copy of the instructions provided on the following pages.
- Make a note of the inspection results.
- Keep this as a record of the inspection.

3.2 Performing Electrical Inspections

3.2.1 Safety Inspection Form

Tests to be Performed

Measured Quantity	Instructions
Enclosure Leakage Current	Measure the enclosure leakage current from several points of the surface of **OEM Robotics** to the protective earth of the Linac. Use the test setup according to Figure 18.f of IEC 601-1. The test must be performed without the charging device connected to **OEM Robotics**.

Critical Values

	Normal Conditions	Single Fault Conditions
Enclosure Leakage Current	< 0.1 mA AC < 0.01 mA DC	

Reference Dimension

	Normal Conditions	Single Fault Conditions	Passed/ Not Passed
Enclosure Leakage Current		---	

Test performed (date): by:

3.3 Damaged Equipment

3.3.1 When the System Should Not Be Used

Detected Damage

Do not use the system or system components if:

- The power cable or plug is damaged or frayed.
- Liquid has been spilled into the device.
- The system does not operate normally when the operating instructions are followed.
- System components have been dropped or the cabinet has been damaged.
- System components exhibit a distinct decrease in performance, indicating the need for servicing.
- Liquids leak from the system.
- Smoke is emitted by the system.

What to do

- Switch off the system and immediately disconnect from the utility power.
- Contact BrainLAB support.
- Attach a suitable notice such as “DO NOT USE” to the equipment to prevent it from being used inadvertently.

If you continue to use equipment that has been found to be defective during an inspection, you risk causing injury to the patient.

3.3.2 Returning Damaged Equipment

Reporting Damaged Equipment

Any damaged equipment should be immediately reported to BrainLAB support.

BrainLAB support will ask you for the following information:

- System serial number (located on the system’s type plate)
- Serial number of the faulty component (inscribed on the component)
- A description of the problem

Repair and Replacement

The BrainLAB support specialist will

- provide you with cost estimate for repair or replacement.
- inform you when your system is expected to be operational again (usually within 48 hours).

Removing Damaged Equipment

Only remove defective components if instructed by BrainLAB support.

Return Instructions

- Use suitable packaging material and properly wrap and package each defective component in its original box, in the replacement product box, or in a suitable box so that it will not sustain further damage.
- Complete and return the Return Material Authorization form (RMA) that was faxed to you or accompanied the replacement part.
- Securely tape the box shut.
- Ship the defective product to one of the return addresses. If you are not sure where to return the product, contact your BrainLAB support specialist.

Return Addresses

BrainLAB AG
RMA Dept.
Kapellenstr. 12
85622 Feldkirchen
Germany

BrainLAB Inc.
RMA Dept.
3 Westbrook Corporate Center
Suite 400
Westchester, IL 60154
USA

BrainLAB KK
RMA Dept.
32 Shibakoen Bldg. 4F
3-4-30 Shibakoen,
Minato-ku,
Tokyo 105-0011
Japan

BrainLAB Ltd.
RMA Dept.
Unit 1307, 13/F
Lippo Sun Plaza
28 Canton Road
Tsim Sha Tsui
Hong Kong

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