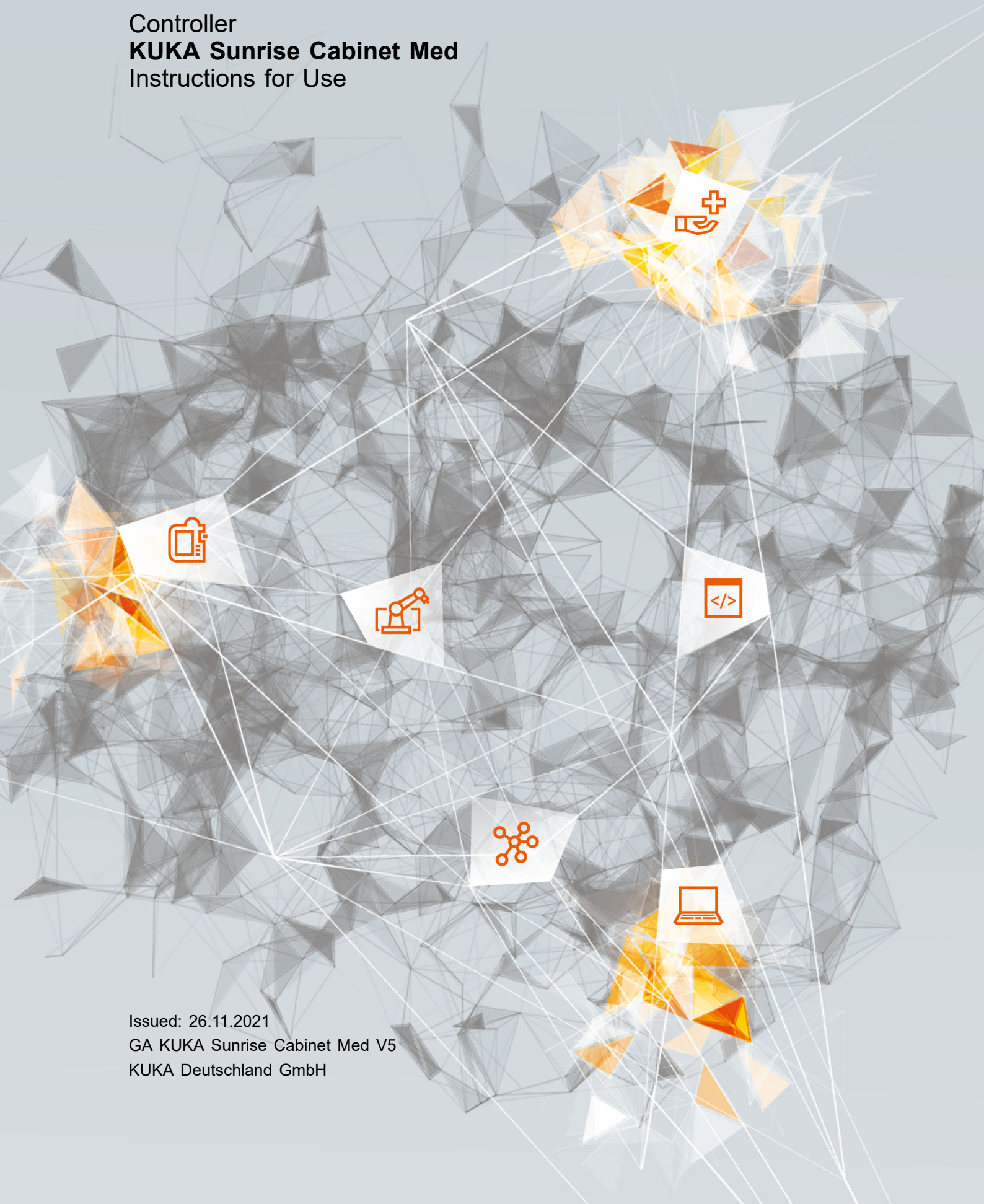
KUKA

Controller
KUKA Sunrise Cabinet Med
Instructions for Use



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GA KUKA Sunrise Cabinet Med V5
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Contents

1 Introduction

1.1 LBR Med documentation

The documentation consists of the following parts:

- Instructions for Use of LBR Med:
  Instructions for Use of LBR Med 7 R800 and LBR Med 14 R820
- Instructions for Use of KUKA Sunrise Cabinet Med:
  Information about operating the robot controller
- Documentation for the smartPAD-2 (if used)
- Instructions for Use of KUKA Sunrise.OS Med:
  Operating and Programming Instructions for System Integrators
- Instructions for options and accessories
- Spare parts in KUKA.Xpert

Each set of instructions is a separate document.

For integration of the LBR Med into a medical product, additionally supplied documents are available to the medical product manufacturer, which must be taken into consideration.
(>>> *13 "Appendix" Page 107*)

1.2 Target group

This documentation is aimed at medical product manufacturers. The medical product manufacturer must ensure that the LBR Med is only handled by appropriately trained skilled personnel with the following knowledge and skills:

- Advanced knowledge of mechanical engineering
- Advanced knowledge of electrical engineering
- Knowledge of the robot controller system

This documentation may not be forwarded to the medical product manufacturer's customer as Instructions for Use.

For optimal use of KUKA products, we recommend the training courses offered by KUKA College. Information about the training program can be found at www.kuka.com or can be obtained directly from our subsidiaries.

1.3 Representation of warnings and notes

Safety

These warnings are provided for safety purposes and **must** be observed.

DANGER

These warnings mean that it is certain or highly probable that death or severe injuries **will** occur, if no precautions are taken.

WARNING

These warnings mean that death or severe injuries **may** occur, if no precautions are taken.

CAUTION

These warnings mean that minor injuries **may** occur, if no precautions are taken.

NOTICE

These warnings mean that damage to property **may** occur, if no precautions are taken.

These warnings contain references to safety-relevant information or general safety measures.
These warnings do not refer to individual hazards or individual precautionary measures.

This warning draws attention to procedures which serve to prevent or remedy emergencies or malfunctions:

SAFETY INSTRUCTION

The following procedure must be followed exactly!

Procedures marked with this warning **must** be followed exactly.

Notices

These notices serve to make your work easier or contain references to further information.

Tip to make your work easier or reference to further information.

1.4 Trademarks

- **Windows** is a trademark of Microsoft Corporation.
- **EtherCAT®** is a registered trademark and patented technology, licensed by Beckhoff Automation GmbH, Germany.

1.5 Terms used

Term	Description
B	Body
BF	Body Floating
CBTC	Certified body test certification: CB Test Certificate
CBTR	Certified body test report: CB Test Report
CCU_SR	Cabinet Control Unit, Small Robot
CF	Cardial Floating
CIB_SR	Cabinet Interface Board, Small Robot

Drape	Sterile sleeve in medicine for covering non-sterile devices or components.
Dual NIC	Dual Network Interface Card Dual-port network card
EDS	Electronic Data Storage (memory card)
EMC	Electromagnetic compatibility
End user	Customer of the medical device manufacturer (user, e.g. medical personnel)
Main switch	The term “main switch” used in this documentation refers to a device switch as defined by relevant standards, as it has no grid isolation function.
KCB	KUKA Controller Bus
KEI	KUKA EtherCAT Interface
KLI	KUKA Line Interface Ethernet interface of the robot controller for external communication.
KOI	KUKA Operator Panel Interface
KONI	KUKA Option Network Interface Interface for KUKA options
KSB	KUKA System Bus Field bus for internal networking of the controllers
KSI	KUKA Service Interface Interface on the CSP on the control cabinet or robot controller The WorkVisual PC can either connect to the robot controller via the KLI or it can be plugged into the KSI.
KSS	KUKA System Software
KUKA smartPAD	see “smartPAD”
KUKA smartPAD-2	see “smartPAD”
KUKA Sunrise Cabinet	Control hardware for operating robots. Hereinafter called “robot controller” in these Instructions for Use.
KUKA Sunrise.OS	KUKA Sunrise.Operating System System Software for robots which are operated with the robot controller KUKA Sunrise Cabinet

LBR	Lightweight robot Robot as part of a robotic component There are 2 robot variants available: • LBR Med 7 R800 • LBR Med 14 R820 Hereinafter called “robot” for both variants in these Instructions for Use.
LBR Med	A robotic component for integration into a medical device by a medical device manufacturer. The LBR Med includes all assemblies, such as the robot (robot arm and the associated electrical installations), robot controller and connecting cables. Hereinafter also called “robot system” in these Instructions for Use.
Med	Identifier for KUKA products that are supplied to medical device manufacturers.
ME sytems	Medical electrical systems
ME devices	Medical electrical devices
MOOP	Means of Operator Protection: measure for operator protection Protective measure that is intended to reduce the risk to the operator of an electric shock.
MOP	Means of Protection: safety measure Measures for reducing the risk of an electric shock acc. to IEC 60601-1. Umbrella term for MOOP and MOPP.
MOPP	Means of Patient Protection: measure for patient protection Protective measure that is intended to reduce the risk to the patient of an electric shock.
Medical device manufacturer (distributor, customer)	The customer is the manufacturer of the medical device. In their capacity as medical device manufacturer/system integrator, they integrate the robotic component into their medical device and market the overall system as a medical device.
System integrator (plant integrator)	System integrators are people who safely integrate the LBR Med into a medical device and commission it.
End user	Customer of the medical device manufacturer (user, e.g. medical personnel)
PDS	Power Drive System
PMB_SR	Power Management Board, Small Robot
SATA connections	Data bus for exchanging data between the processor and the hard drive Transmission request signal

smartPAD	Teach pendant The smartPAD is the teach pendant for the robot. It provides all the operator control and display functions required by the distributor and the system integrator (in the medical environment) for operating the robot during start-up, maintenance and diagnosis. 2 models exist: • smartPAD • smartPAD-2 In turn, for each model there are variants, e.g. with different lengths of connecting cables. The designation “KUKA smartPAD” or “smartPAD” refers to both models unless an explicit distinction is made.
SSD	Solid State Drive Hard drive
KUKA Sunrise.OS	KUKA Sunrise.Operating System System Software for robots which are operated with the robot controller KUKA Sunrise Cabinet
USB	Universal Serial Bus Bus system for connecting additional devices to a computer
Tool	Applied part or medical instrument mounted on the robot via the media flange.
EA	External axis (linear unit, Posiflex)

2 Product description

2.1 Overview of the robot system

The robot system (>>> *Fig. 2-1*) includes all assemblies, such as the robot (robot arm and the associated electrical installations), robot controller and connecting cables.

The robot system consists of the following components:

- Robot (with media flange Inside electrical Med)
- KUKA Sunrise Cabinet Med robot controller
- KUKA smartPAD teach pendant (optional)
- Connecting cables
- KUKA Sunrise.OS Med software
- Options, accessories

Detailed information about the components of the robot system can be found in the supplied documentation.
(>>> *13 "Appendix" Page 107*)

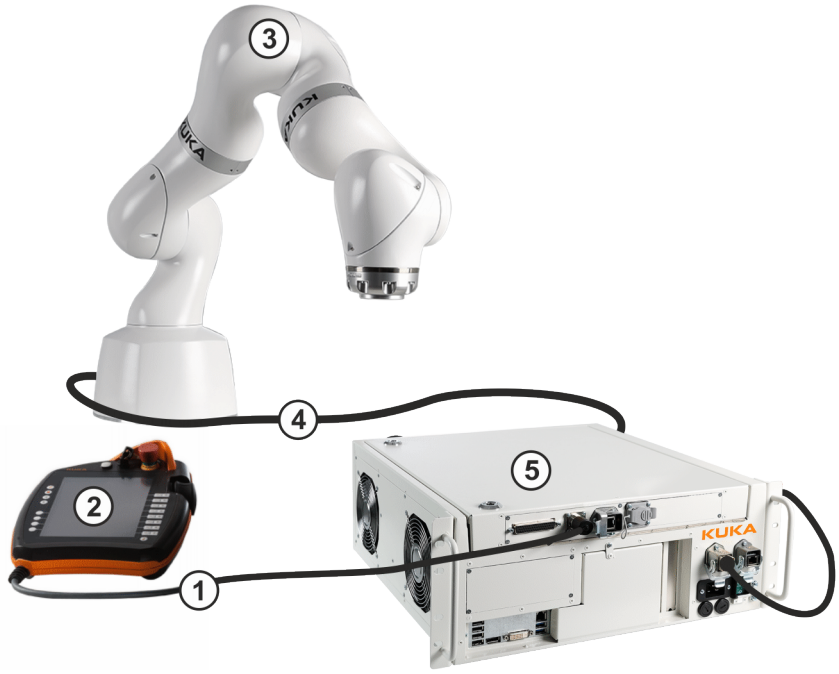


Fig. 2-1: Overview of robot system (LBR Med)

1 Connecting cable to KUKA smartPAD
2 KUKA smartPAD teach pendant
3 Robot
4 Connecting cable to KUKA Sunrise Cabinet Med robot controller
5 KUKA Sunrise Cabinet Med robot controller

2.2 KUKA Sunrise Cabinet Med

Overview

The KUKA Sunrise Cabinet Med robot controller consists of the following components:

- Control PC
- smartPAD control panel
- Connection panel

The robot controller can be installed in a 19" rack.

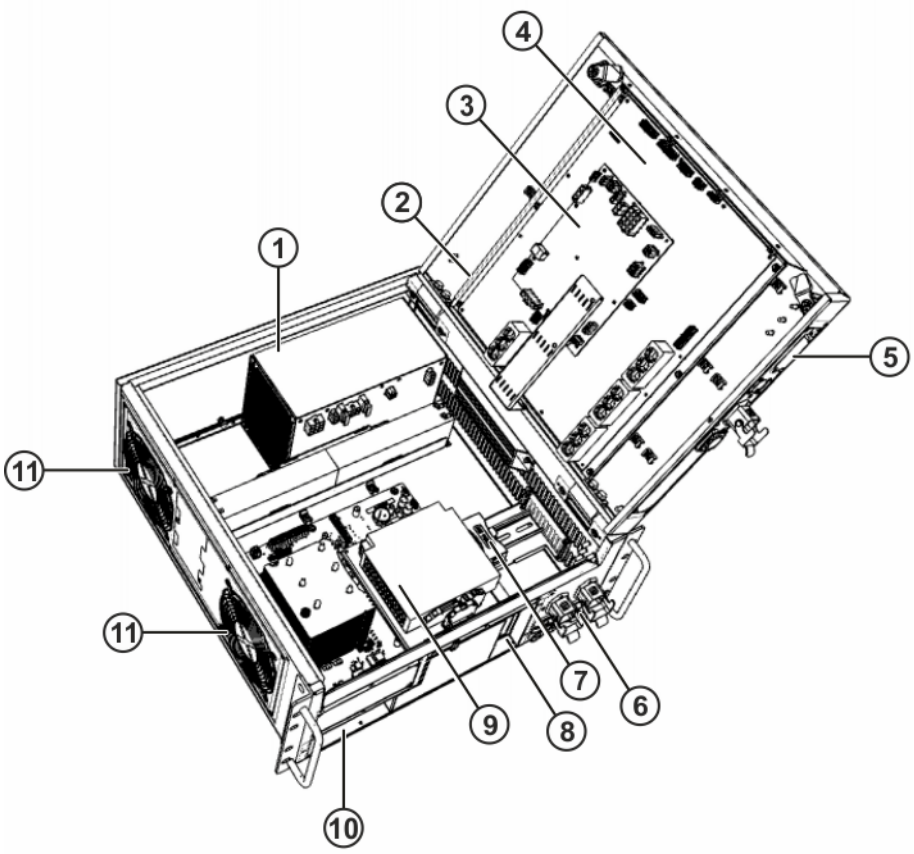


Fig. 2-2: Overview of the robot controller

1	Low-voltage power supply unit
2	Memory card (EDS)
3	Power Management Board, Small Robot (PMB_SR)
4	Cabinet Interface Board, Small Robot (CIB_SR)
5	Interfaces
6	Device switch, interfaces, fuses
7	Network insulator
8	Network connections cover
9	DC/DC converter
10	Motherboard D3445-K interfaces
11	Fan

2.3 Control PC

Components

The control PC includes the following components:

- Motherboard
- Processor
- Heat sink
- Memory modules
- Hard drive
- LAN Dual NIC network card (not present on all motherboard variants)

2.4 Cabinet Control Unit, Small Robot

Description

The Cabinet Control Unit, Small Robot (CCU_SR) is the central power distributor and communication interface for all components of the robot controller. The CCU_SR consists of the Cabinet Interface Board, Small Robot (CIB_SR) and the Power Management Board, Small Robot (PMB_SR). All data are transferred via this internal communication interface to the controller for further processing. If the mains voltage fails, the control components continue to be powered by batteries until the position data are saved and the controller has shut down. The charge and quality of the batteries are checked by means of a load test.

The CCU_SR also incorporates sensing, control and switching functions. The output signals are provided as electrically isolated outputs.

Functions

- Communication interface for the components of the robot controller
- Safe inputs and outputs
  - Contactor activation
  - 3 floating outputs
  - 7 safe inputs
  - Teach pendant connected
- Power supply fan monitoring
- Control box internal temperature
- The following components are connected to the KPC via the KUKA Controller Bus:
  - Power Drive System
- The following operator panels and service devices are connected to the control PC via the KUKA System Bus:
  - KUKA Operator Panel Interface
- Diagnostic LEDs
- Electronic Data Storage interface

Power supply with battery backup

- KUKA smartPAD
- Control PC quad-core processor
- Power Drive System

Power supply without battery backup

- Motor brakes

- Customer interface

2.5 Low-voltage power supply

Description

The low-voltage power supply unit provides power to the components of the robot controller and supplies the robot drives with 48 V DC.

Two green and two red LEDs indicate the operating state of the low-voltage power supply unit.

2.6 Batteries

In the event of a power failure, or if the power is switched off, the batteries enable the robot controller to be shut down in a controlled manner. The batteries are charged via the CCU_SR and the charge is checked and indicated.

2.7 Description of interfaces

Overview

The connection panel of the KUKA Sunrise Cabinet Med robot controller consists as standard of connections for the following cables:

- Device connection cable
- Robot cable
- smartPAD cable
- Peripheral cables

The configuration of the connection panel varies according to the customer-specific version and the options required.

Connection panel

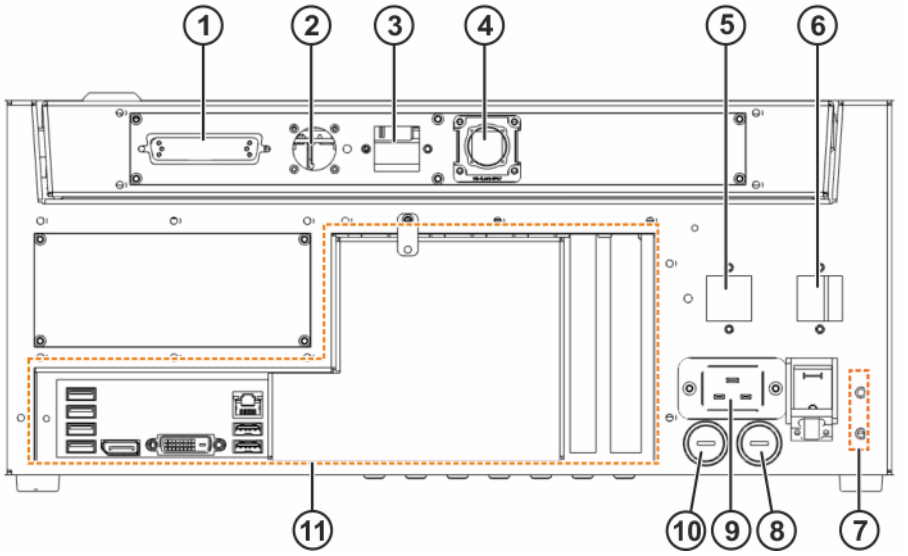


Fig. 2-3: KUKA Sunrise Cabinet Med interfaces

Item	Interface	Item	Interface
1	X11 interface	7	2 PE connections
2	X19 smartPAD interface	8	F2
3	X65 Extension interface	9	X1 Power supply connection
4	X69 Service interface	10	F1
5	X21 Robot interface (Med variant)	11	Control PC interfaces
6	X66 KUKA Line Interface		

All contactor, relay and valve coils that are connected to the robot controller by the user must be equipped with suitable suppressor diodes. RC elements and VCR resistors are not suitable.

NOTICE

Only devices that meet the minimum requirements for separation from the mains voltage according to IEC 60601-1 may be connected to the robot controller:

- 2 x MOOP
- 1 x MOPP

  (based on the maximum mains voltage of 230 V AC)

This minimum requirement corresponds to a separation of at least 3.4 mm clearance, 5.0 mm creepage distance and 3000 V dielectric strength.

When connecting devices to the interfaces of the robot controller, the medical product manufacturer must verify compliance with the permissible limit values for leakage currents according to IEC 60601-1. In addition to this, the requirements of IEC 60601-1 for ME systems must be taken into consideration.

NOTICE

In its risk management process, the medical product manufacturer must evaluate the overall system, including all devices connected to the interfaces.

2.7.1 Motherboard D3445-K PC interfaces

Overview

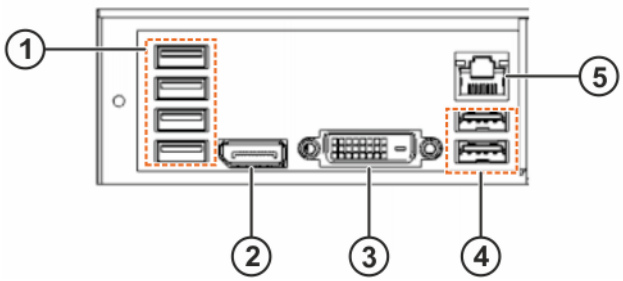


Fig. 2-4: Motherboard D3445-K interfaces

1 4 USB 2.0 ports
2 Display port
3 DVI-D

4 2 USB 3.0 ports

5 LAN Onboard – KUKA Option Network Interface

KUKA Deutschland GmbH has assembled, tested and supplied the motherboard with an optimum configuration. No liability will be accepted for modifications to the configuration that have not been carried out by KUKA Deutschland GmbH.

The USB interfaces can be used for integrating the controller into the medical product. The medical product manufacturer must ensure that the functionality of the medical product cannot be adversely affected, e.g. by a test for malware or by restriction of the USB devices that may be connected.

2.8 Cooling

Description

The components of the control and power electronics are cooled with ambient air by 2 fans.

NOTICE

Upstream installation of filter mats at the ventilation slits causes an increase in temperature, leading to a reduction in the service life of the installed devices!

Cooling circuit, control box

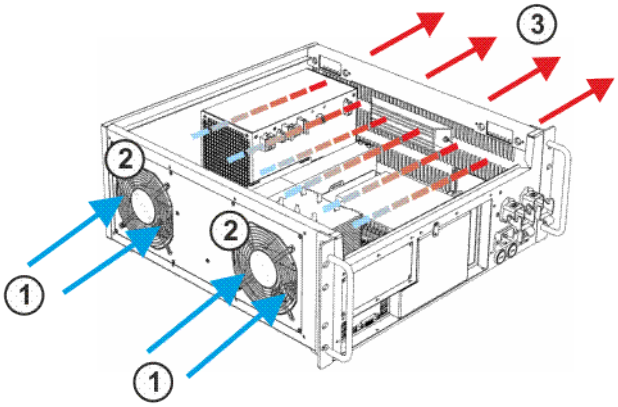


Fig. 2-5: Cooling circuit, control box

1 Air inlet
2 Fan
3 Air outlet

2.9 Intended use

Use

The KUKA Sunrise Cabinet Med robot controller is intended solely for operating the LBR Med. The KUKA Sunrise Cabinet Med robot controller is integrated into a medical device by a medical device manufacturer.

Misuse

Any use or application deviating from the intended use is deemed to be misuse and is not allowed. KUKA Deutschland GmbH is not liable for any damage resulting from such misuse. The risk lies entirely with the medical device manufacturer/user.

Examples of such misuse include:

- Use other than in medical applications (e.g. industry)
- Operation outside the specified operating parameters
- Operation in potentially explosive environments
- Outdoor operation
- Direct use in sterile environments

Operating life

The operating life of the robot system is 10,000 hours of operation.

3 Safety

3.1 General

3.1.1 Disclaimer

The robot system described in this document is a robotic component for integration into a medical device (hereinafter called “LBR Med”):

The LBR Med includes:

- Robot
- Robot controller
- Teach pendant
- Connecting cables
- Software
- Options, accessories

The LBR Med is built using state-of-the-art technology and in accordance with the recognized safety rules. Nevertheless, misuse may constitute a risk to life and limb or cause damage to the LBR Med and to other material property.

The LBR Med may only be used in perfect technical condition in accordance with its intended use and only by safety-conscious persons who are fully aware of the risks involved in its operation. Use is subject to compliance with this document and with the documentation provided with the robot upon delivery (Important information on LBR Med). Any functional disorders, especially those affecting safety, must be rectified immediately.

The LBR Med meets the requirements of the standards named in the CB Test Certificate. All requirements deviating from the CB Test Certificate are not met.

All uses deviating from the CB Test Certificate have not been considered, examined and tested. The medical product manufacturer must evaluate these uses in its risk management process and take the necessary measures for the medical product / overall system.

Examples of such uses include:

- Integration into a portable or hand-held medical device
- Integration of the LBR Med into medical devices which are intended for sale to the general public
- Operation in domestic environments
- Operation in the vicinity of emergency response operations
- Operation in the vicinity of strong magnetic fields
- Operation in combination with the use of defibrillators (the robot is not defibrillator-safe)
- Unsupervised operation of the LBR Med or the medical device (e.g. by the medical device manufacturer or end user)
- Operation of the medical device by non-medical personnel, patients or third parties.
- Operation of the robot as an applied part
- Connection of type BF or CF applied parts according to IEC 60601-1 directly to the robot without suitable intermediate insulation
- Power supply to an applied part via the data cables of the integrated energy supply system (e.g. Power over Ethernet)
- Operation by persons without the relevant training

Safety information

Information about safety may not be construed against KUKA Deutschland GmbH. Even if all safety instructions are followed, this is not a guarantee that the LBR Med will not cause personal injuries or material damage.

No modifications may be carried out on the LBR Med without the authorization of KUKA Deutschland GmbH. Additional components (tools, software, etc.) not supplied by KUKA Deutschland GmbH may be integrated into the LBR Med. The user is liable for any damage these components may cause to the LBR Med or to other material property.

In addition to the Safety chapter, this document contains further safety instructions. These must also be observed.

3.1.1.1 CB Test Certificate and CB Test Report

The LBR Med is tested according to the CB Scheme and delivered with a CB Test Certificate.

Through the CB Test Certificate, it is declared that the LBR Med has been produced in accordance with the standards named in the CB Test Certificate.

Only the software components named in the CB Test Report in the specified versions are compatible with one another and may be jointly installed. If software components deviating from the CB Test Report are installed, the CB Test Report is no longer valid.

3.1.1.2 EC declaration of conformity and declaration of incorporation

The LBR Med constitutes partly completed machinery as defined by the EC Machinery Directive. The LBR Med supplied may only be put into operation if the following preconditions are met:

- The LBR Med is integrated into a medical device.
- The medical device complies with Medical Device Directive/Regulation. This has been confirmed by means of a conformity assessment procedure.

EC declaration of conformity

The system integrator must issue an EC declaration of conformity in accordance with the EU Directive/Regulation for the medical device. The EC declaration of conformity forms the basis for the CE mark for the medical device. The LBR Med must always be operated in accordance with the applicable national laws, regulations and standards.

The robot controller has a CE mark in accordance with the EMC Directive and the Low Voltage Directive.

Declaration of incorporation

The partly completed machinery is supplied with a declaration of incorporation in accordance with Annex II B of the Machinery Directive 2006/42/EC. The assembly instructions and a list of essential requirements complied with in accordance with Annex I are integral parts of this declaration of incorporation.

The declaration of incorporation declares that the start-up of the partly completed machinery is not allowed until the partly completed machinery has been incorporated into a medical device, or has been assembled with other parts to form a medical device, and this medical device complies with the terms of the Medical Device Directive/Regulation, and the EC declaration of conformity is present.

3.1.2 Terms in the “Safety” chapter

Term	Description
Axis range	Range within which the axis may move The axis range must be defined for each axis.
Stopping distance	Stopping distance = reaction distance + braking distance The stopping distance is part of the danger zone.
Workspace	Area within which the robot may move. The workspace is derived from the individual axis ranges.
Automatic (AUT)	Operating mode for program execution. The robot moves at the programmed velocity.
User	The user of the medical device can be the management, employer or delegated person responsible for use of the medical device.
ESD	Electrostatic sensitive devices
Service life	The service life of a safety-relevant component begins at the time of delivery of the component to the customer. The service life is not affected by whether the safety-relevant component is used in a robot controller or elsewhere or not, as safety-relevant components are also subject to aging during storage.
Danger zone	The danger zone consists of the workspace and the stopping distances.
CRR	Controlled robot retraction CRR is an operating mode to which the system can be switched when the robot is stopped by the safety controller for one of the following reasons: • Robot violates an axis-specific or Cartesian monitoring space. • Orientation of a safety-oriented tool is outside the monitored range. • Robot violates a force or torque monitoring function. • A position sensor is not mastered or referenced. • A joint torque sensor is not referenced. Once the operating mode has been switched to CRR, the robot can be moved again. **Note:** This operating mode can only be selected in conjunction with the smartPAD.
KUKA smartPAD	see “smartPAD”
KUKA smartPAD-2	see “smartPAD”
Safety zone	The safety zone is situated outside the danger zone.

Safety stop	The safety stop is triggered by the safety controller, interrupts the work procedure and causes all robot motions to come to a standstill. The program data are retained in the case of a safety stop and the program can be resumed from the point of interruption. The safety stop can be executed as a Stop category 0, Stop category 1 or Stop category 1 (path-maintaining). **Note:** In this document, a safety stop of Stop category 0 is referred to as safety stop 0, a safety stop of Stop category 1 as safety stop 1 and a safety stop of Stop category 1 (path-maintaining) as safety stop 1 (path-maintaining).
smartPAD	Teach pendant The smartPAD is the teach pendant for the robot. It provides all the operator control and display functions required by the distributor and the system integrator (in the medical environment) for operating the robot during start-up, maintenance and diagnosis. 2 models exist: • smartPAD • smartPAD-2 In turn, for each model there are variants, e.g. with different lengths of connecting cables. The designation “KUKA smartPAD” or “smartPAD” refers to both models unless an explicit distinction is made.
Stop category 0	The drives are deactivated immediately and the brakes are applied.
Stop category 1	The robot is braked and deviates from the programmed path. The robot is brought to a standstill with the drives. As soon as an axis is at a standstill, the drive is switched off and the brake is applied. The internal electronic drive system of the robot performs safety-oriented monitoring of the braking process. Stop category 0 is executed in the event of a fault. **Note:** Stop category 1 is currently only supported by the LBR Med. For other manipulators, Stop category 0 is executed.
Stop category 1 (path-maintaining)	The robot is braked and stays on the programmed path. At standstill, the drives are deactivated and the brakes are applied. If Stop category 1 (path-maintaining) is triggered by the safety controller, the safety controller monitors the braking process. The brakes are applied and the drives are switched off after 1 s at the latest. Stop category 1 is executed in the event of a fault.
System integrator (plant integrator)	System integrators are people who safely integrate the LBR Med into a medical device and commission it.
T1	Test mode, Manual Reduced Velocity (<= 250 mm/s) **Note:** With manual guidance in T1, the velocity is not reduced, but rather limited through a safety-oriented velocity monitoring in accordance with the safety configuration. **Note:** This operating mode can only be selected in conjunction with the smartPAD.

T2	Test mode, Manual High Velocity (> 250 mm/s permissible) **Note:** This operating mode can only be selected in conjunction with the smartPAD.

3.2 Groups of persons

The operating and programming instructions for system integrators contain information for the medical device manufacturer and are not intended for the end user (e.g. medical personnel).

The following persons or groups of persons are defined for the LBR Med:

- System integrator / medical device manufacturer
- User
- Personnel

All persons working with the LBR Med must have read and understood the LBR Med documentation, including the safety chapter.

System integrator

The LBR Med must be safely integrated into the medical product by the system integrator.

The following list gives an indication as to the tasks for which the system integrator is responsible:

- Installing the LBR Med
- Connecting the LBR Med
- Conducting risk management for the medical product
- Use of the required safety equipment and safeguards
- Issuing the EC declaration of conformity
- Attaching the CE mark
- Creating the Instructions for Use for the medical product and the corresponding components for the overall system for the user and end user

User

The user must observe the labor laws and regulations. This includes e.g.:

- The user must comply with his monitoring obligations.
- The user must carry out briefing at defined intervals.
- The user must comply with the regulations relating to personal protective equipment (PPE).

The user must ensure that the robot controller is inaccessible to unauthorized personnel. The user is responsible for the storage and issuing of keys for the system (e.g. robot controller, smartPAD).
The user must issue keys in accordance with the applicable laws, regulations and standards.

Personnel

Personnel must be instructed, before any work is commenced, in the type of work involved and what exactly it entails as well as any hazards which may exist. Instruction must be carried out regularly. Instruction is also required after particular incidents or technical modifications.

Personnel includes:

- System integrator
- Operators, subdivided into:
  - Start-up, maintenance and service personnel
  - Operating personnel
  - Cleaning personnel

Installation, exchange, adjustment, operation, maintenance and repair must be performed only as specified in the Instructions for Use for the relevant component of the LBR Med and only by personnel specially trained for this purpose.

Operators

The operator must meet the following preconditions:

- The operator must be trained for the work to be carried out.
- Work on the LBR Med must only be carried out by qualified personnel. These are people who, due to their specialist training, knowledge and experience, and their familiarization with the relevant standards, are able to assess the work to be carried out and detect any potential hazards.

Work on the electrical and mechanical equipment of the robot may only be carried out by KUKA Deutschland GmbH.

3.3 Workspace, safety zone and danger zone

Workspaces are to be restricted to the necessary minimum size in order to prevent danger to persons or the risk of material damage. Safe axis range limitations required for personnel protection are configurable.

Further information about the configuration of safely monitored axis limits is contained in the “Safety configuration” chapter of the operating and programming instructions for system integrators.

The danger zone consists of the workspace and the stopping distances of the robot. In the event of a stop, the robot is braked and comes to a stop within the danger zone. The safety zone is the area outside the danger zone.

The danger zone must be protected by means of physical safeguards, e.g. by light barriers, light curtains or safety fences. If there are no physical safeguards present, the requirements for collaborative operation must be examined and met where applicable in accordance with EN ISO 10218.

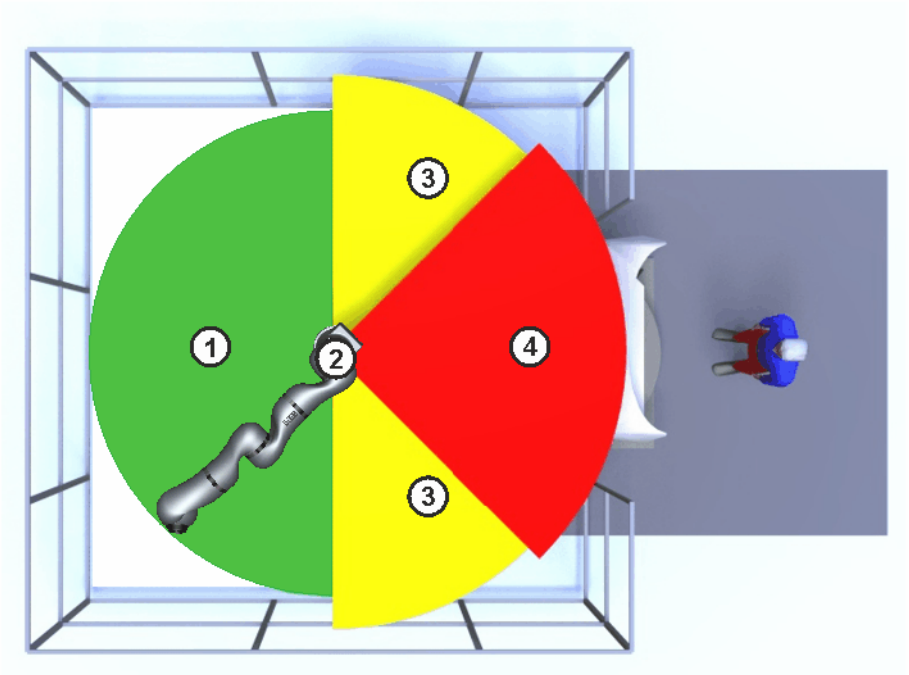


Fig. 3-1: Example: axis range A1

1	Workspace	3	Stopping distance
2	Manipulator	4	Safety zone

3.4 Triggers for safety-oriented stop reactions

Stop reactions are triggered in response to operator actions or as a reaction to monitoring functions and errors. The following tables show the different stop reactions according to the operating mode that has been set.

Overview

In Sunrise.OS a distinction is made between the following triggers:

- Permanently defined triggers

  Permanently defined triggers for stop reactions and the associated stop category are preset by the system and cannot be changed. However, it is possible for the implemented stop reaction to be stepped up in the user-specific safety configuration.
- User-specific triggers

  In addition to the permanently defined triggers, the user can also configure other triggers for stop reactions including the associated stop category.

Further information about configuring the safety functions is contained in the “Safety configuration” chapter of the operating and programming instructions of the system software for system integrators.

Permanently defined triggers

The following triggers for stop reactions are permanently defined:

Trigger	T1, T2, CRR	AUT
Operating mode changed during operation	Safety stop 1 (path-maintaining)	
Enabling switch released	Safety stop 1 (path-maintaining)	-
Enabling switch pressed fully down (panic position)	Safety stop 1 (path-maintaining)	-
Local E-STOP pressed	Safety stop 1 (path-maintaining)	
Error in safety controller	Safety stop 1	

User-specific triggers

When creating a new Sunrise project, the system automatically generates a project-specific safety configuration. This contains the following user-specific stop reaction triggers preconfigured by KUKA (in addition to the permanently defined triggers):

Trigger	T1, CRR	T2, AUT
Safety gate opened (operator safety)	-	Safety stop 1 (path-maintaining)
External E-STOP pressed	Safety stop 1 (path-maintaining)	
External safety stop	Safety stop 1 (path-maintaining)	

This default safety configuration is valid for the system software without additionally installed option packages or catalog elements. If additional option packages or catalog elements have been installed, the default safety configuration may be modified.

Triggers for manual guidance

If an enabling device is configured for manual guidance, the following additional triggers for stop reactions are permanently defined:

Trigger	T1, CRR	T2, AUT
Manual guidance enabling switch released	Safety stop 1 (path-maintaining)	-
Manual guidance enabling switch pressed fully down (panic position)	Safety stop 1 (path-maintaining)	-
Maximum permissible velocity exceeded while manual guidance enabling signal is set	Safety stop 1 (path-maintaining)	

A maximum permissible velocity of 250 mm/s is preconfigured for manual guidance. The maximum permissible velocity can be adapted.

The medical product manufacturer must evaluate the maximum permissible velocity in its risk management process and take the appropriate measures.

3.5 Safety functions

Safety functions are distinguished according to the safety requirements that they fulfill:

- Safety-oriented functions for the protection of personnel

  The safety-oriented functions of the LBR Med meet the following safety requirements:

  – **Category 3** and **Performance Level d** in accordance with EN ISO 13849-1
  – **SIL 2** according to EN 62061

  The requirements are only met on the following condition, however:

  – All safety-relevant mechanical and electromechanical components of the LBR Med are tested for correct functioning during start-up and at least once every 12 months, unless otherwise determined in accordance with a workplace risk assessment. These include:
    – Local EMERGENCY STOP device on the teach pendant
    – Enabling device on the teach pendant
    – Enabling device on the hand guiding device (if present)
    – External enabling devices (if present)
    – Mode selector switch on the smartPAD (if used as teach pendant)
    – Safety-oriented outputs of the discrete safety interface

Details about safety parameters (e.g. PFH, SIL, Performance Level) are also available as a SISTEMA library. The library can be downloaded from the KUKA website.

- Non-safety-oriented functions

  The non-safety-oriented functions of the LBR Med do not meet specific safety requirements.

DANGER

Risk of fatal injury due to non-operational safety functions or external safeguards
In the absence of operational safety functions or safeguards, the robot can cause death, severe injuries or damage to property.

- If safety functions or safeguards are dismantled or deactivated, do not operate the robot.

Integrate robot into safety system of medical device
During the integration of the LBR Med, the safety functions of the medical device must also be planned and designed. Death, severe injuries or damage to property may otherwise result.

- The LBR Med must be integrated into the safety system of the medical device.

3.5.1 Safety-oriented functions

The following safety-oriented functions are present and permanently defined in the LBR Med:

- EMERGENCY STOP device
- Enabling device

The following safety-oriented functions are preconfigured and can be integrated via the safety interface of the robot controller:

- Operator safety (= connection for the monitoring of physical safeguards)

- External EMERGENCY STOP device
- External safety stop 1 (path-maintaining)

Other safety-oriented functions may be configured, e.g.:

- External enabling device
- External safe operational stop
- Axis-specific workspace monitoring
- Cartesian workspace monitoring
- Cartesian protected space monitoring
- Velocity monitoring
- Standstill monitoring
- Axis torque monitoring
- Collision detection

Further information about configuring the safety functions is contained in the “Safety configuration” chapter of the operating and programming instructions of the system software for system integrators.

The preconfigured safety functions are described in the following sections on safety.

3.5.1.1 EMERGENCY STOP device

As standard, the EMERGENCY STOP device for the manipulator is the EMERGENCY STOP device on the smartPAD. The device must be pressed in the event of a hazardous situation or emergency.

Reaction of the LBR Med if the EMERGENCY STOP device is pressed:

- The robot stops with a safety stop 1 (path-maintaining).

Before operation can be resumed, the EMERGENCY STOP device must be turned to release it.

WARNING

Danger to life and limb due to tools and equipment without EMERGENCY STOP
If tools and other equipment connected to the robot are not integrated into the EMERGENCY STOP circuit, this can result in death, severe injuries or damage to property.

- Integrate tools and other equipment into the EMERGENCY STOP circuit if they could constitute a potential hazard.

If a holder is used for the teach pendant and conceals the EMERGENCY STOP device on the teach pendant, an external EMERGENCY STOP device must be installed that is accessible at all times.

If the smartPAD is unplugged, an external EMERGENCY STOP device must be installed that is accessible at all times.

(>>> *3.5.1.4 "External EMERGENCY STOP device" Page 32*)

3.5.1.2 Enabling device

The enabling devices of the robot are the enabling switches on the smartPAD teach pendant as standard.

- **smartPAD**: 3 enabling switches
- **smartPAD-2**: 4 enabling switches

The enabling switches have 3 positions:

- Not pressed
- Center position
- Fully pressed (panic position)

In operating modes T1, T2 and CRR, the robot can only be moved if one of the enabling switches is held in the center position.

It is possible to hold several enabling switches in the center position simultaneously. This makes it possible to adjust grip from one enabling switch to another one.

In operating modes T1, T2 and CRR, the manipulator can be stopped in the following ways:

- Press at least one enabling switch down fully.

  Fully pressing an enabling switch triggers a safety stop 1 (path-maintaining).
- Or release all enabling switches.

  Releasing all (!) enabling switches held in the center position triggers a safety stop 1 (path-maintaining).

WARNING

Danger to life and limb due to lack of reaction when an enabling switch is released
Releasing one of multiple enabling switches held in the center position does not trigger a stop reaction.
If multiple switches are held in the center position, the robot controller cannot distinguish whether one of them was intentionally released or if it was unintentionally released as the result of an accident.

- Create awareness for the hazard.

If an enabling switch malfunctions (e.g. jams in the center position), the LBR Med can be stopped using the following methods:

- Press another enabling switch down fully.
- Actuate the EMERGENCY STOP device.
- Release the Start key.

WARNING

Danger to life and limb due to manipulation of enabling switches
The enabling switches must not be held down by adhesive tape or other means or tampered with in any other way. Death, severe injuries or damage to property may result.

- Carry out a visual inspection of the enabling switches.
- Rectify tampering or remove any foreign bodies.

3.5.1.3 “Operator safety” signal

The “operator safety” signal is used for monitoring physical safeguards, e.g. safety gates. In the default configuration, T2 and automatic operation are not possible without this signal. Alternatively, the requirements for collaborative operation must be examined and met where applicable in accordance with EN ISO 10218.

Reaction of the robot in the event of a loss of signal during T2 or automatic operation (default configuration):

- The robot stops with a safety stop 1 (path-maintaining).

By default, operator safety is not active in the modes T1 (Manual Reduced Velocity) and CRR, i.e. the signal is not evaluated.

WARNING

Following a loss of signal, automatic operation must not be resumed merely by closing the safeguard; the signal for operator safety must first be set by an additional device, e.g. by an acknowledge button. It is the responsibility of the system integrator to ensure this. This is to prevent automatic operation from being resumed inadvertently while there are still persons in the danger zone, e.g. due to the safety gate closing accidentally.

- This additional device must be designed in such a way that an actual check of the danger zone can be carried out first. Devices that do not allow this (e.g. because they are automatically triggered by closure of the safeguard) are not permitted.
- Failure to observe this may result in death to persons, severe injuries or considerable damage to property.

3.5.1.4 External EMERGENCY STOP device

Every operator station that can initiate a robot motion or other potentially hazardous situation must be equipped with an EMERGENCY STOP device. The system integrator is responsible for ensuring this.

Reaction of the LBR Med if the external EMERGENCY STOP device is pressed (default configuration):

- The robot stops with a safety stop 1 (path-maintaining).

External EMERGENCY STOP devices are connected via the safety interface of the robot controller. External EMERGENCY STOP devices are not included in the scope of supply of the LBR Med.

3.5.1.5 External safety stop 1 (path-maintaining)

The external safety stop 1 (path-maintaining) can be triggered via an input on the safety interface (default configuration). The state is maintained as long as the external signal is FALSE. If the external signal is TRUE, the robot can be moved again. No acknowledgement is required.

3.5.1.6 External enabling device

External enabling devices are required if it is necessary for more than one person to be in the danger zone of the LBR Med.

Multiple external enabling devices can be connected via the safety interface of the robot controller. External enabling devices are not included in the scope of supply of the LBR Med.

An external enabling device can be used for manual guidance of the robot. When enabling is active, the robot may only be moved at reduced velocity.

For manual guidance, safety-oriented velocity monitoring with a maximum permissible velocity of 250 mm/s is preconfigured. The maximum permissible velocity can be adapted.

The value for the maximum permissible velocity must be determined as part of a risk management process.

3.5.1.7 External safe operational stop

The safe operational stop is a standstill monitoring function. It does not stop the robot motion, but monitors whether the robot axes are stationary.

The safe operational stop can be triggered via an input on the safety interface. The state is maintained as long as the external signal is FALSE. If the external signal is TRUE, the robot can be moved again. No acknowledgement is required.

3.5.2 Non-safety-oriented functions

3.5.2.1 Mode selection

The LBR Med can be operated in the following modes:

- Manual Reduced Velocity (T1)
- Manual High Velocity (T2)
- Automatic (AUT)
- Controlled robot retraction (CRR)

Operating mode	Use	Velocities
T1	Programming, teaching and testing of programs.	• Program verification: reduced programmed velocity, maximum 250 mm/s • Jog mode: jog velocity, maximum 250 mm/s • Manual guidance: no limitation of the velocity, but safety-oriented velocity monitoring in accordance with the safety configuration
T2	Testing of programs	• Program verification: programmed velocity • Jog mode: not possible
AUT	Automatic execution of programs For robots with and without a higher-level controller	• Program mode: programmed velocity • Jog mode: not possible
CRR	CRR is an operating mode to which the system can be switched when the robot is stopped by the safety controller for one of the following reasons: • Robot violates an axis-specific or Cartesian monitoring space. • Orientation of a safety-oriented tool is outside the monitored range. • Robot violates a force or torque monitoring function. • A position sensor is not mastered or referenced. • An axis torque sensor is not referenced. Once the operating mode has been switched to CRR, the robot can be moved again.	• Program verification: reduced programmed velocity, maximum 250 mm/s • Jog mode: jog velocity, maximum 250 mm/s • Manual guidance: no limitation of the velocity, but safety-oriented velocity monitoring in accordance with the safety configuration

Mode selector switch

The user can change the operating mode via the connection manager. The connection manager is a view that is called by means of the mode selector switch on the smartPAD.

The mode selector switch for LBR Med:

- With key
  It is only possible to change operating mode if the key is inserted.

3.5.2.2 Velocity monitoring in T1

The reduced velocity in T1 does not constitute a safety-rated reduced speed in the standard safety configuration, i.e. the maximum permissible velocity of 250 mm/s in T1 is not subjected to safety-oriented monitoring.

If the application requires safety-oriented velocity monitoring in T1, this can be added in the safety configuration. The safety option KUKA Sunrise.SafeOperation provides the monitoring function *Cartesian velocity monitoring* for this purpose.

Further information about configuring safety-oriented velocity monitoring for T1 is contained in the “Safety configuration” chapter of the operating and programming instructions of the system software for system integrators.

3.5.2.3 Software limit switches

The axis ranges of all axes on the robot are limited by means of non-safety-oriented software limit switches. These software limit switches only serve as protection for the robot and are preset in such a way that the robot is stopped under servo control if the axis limit is exceeded, thereby preventing damage to the mechanical system.

3.6 Service phases of the robot system

The following service phases have been defined for the robot system:

- **Transportation**
- **Start-up** and **recommissioning**
- **Normal operation**
- **Malfunction**
- **Cleaning**
- **Maintenance**
- **Repair**
- **Decommissioning**
- **Storage**
- **Disposal**

Full responsibility for the service phases indicated lies with the medical product manufacturer.

The medical product manufacturer must provide the end customer the necessary information for operation of the medical product (overall system) during the service phases of normal operation, malfunction, cleaning and maintenance.

3.7 Additional protective equipment

3.7.1 Jog mode

In the operating modes T1 (Manual Reduced Velocity), T2 (Manual High Velocity) and CRR, the robot controller can only execute programs in jog mode. This means: It is necessary to hold down an enabling switch and the start key in order to execute a program.

- Releasing the enabling switch on the smartPAD triggers a safety stop 1 (path-maintaining).
- Pressing the enabling switch on the smartPAD fully down triggers a safety stop 1 (path-maintaining).
- Releasing the Start key triggers a stop of Stop category 1 (path-maintaining).

3.7.2 Labeling on the LBR Med

All plates, labels, symbols and marks constitute safety-relevant parts of the LBR Med.

CAUTION

If the plates and labels are removed for integration into a medical product, the medical product manufacturer must evaluate this in its risk management process and take the necessary measures.

Labeling on the LBR Med consists of:

- Identification plates
- Warning labels
- Safety symbols
- Designation labels
- Cable markings
- Rating plates

Further information is contained in the technical data of the Instructions for Use for the components of the LBR Med.

3.7.3 External safeguards

The medical product manufacturer must evaluate the selection of external safeguards in its risk management process and take the necessary measures for the medical product / overall system.

Access of persons to the danger zone of the LBR Med must be prevented by means of safeguards. Alternatively, the requirements for collaborative operation must be examined and met where applicable in accordance with EN ISO 10218. It is the responsibility of the system integrator to ensure this.

Physical safeguards must meet the following requirements:

- They must be examined according to requirements and meet EN ISO 14120 where applicable.
- They prevent access of persons to the danger zone and cannot be easily circumvented.

- They are sufficiently fastened and can withstand all forces that are likely to occur in the course of operation, whether from inside or outside the enclosure.
- They do not, themselves, represent a hazard or potential hazard.
- The prescribed minimum clearance from the danger zone is maintained.

Safety gates (maintenance gates) must meet the following requirements:

- They are reduced to an absolute minimum.
- The interlocks (e.g. safety gate switches) are linked to the configured operator safety inputs of the robot controller.
- Switching devices, switches and the type of switching conform to the requirements of Performance Level d and category 3 according to EN ISO 13849-1.
- Depending on the hazard situation: the safety gate is additionally safeguarded by means of a locking mechanism that only allows the gate to be opened if the robot is safely at a standstill.
- The device for setting the signal for safety, e.g. the button for acknowledging the safety gate, is located outside the space limited by the safeguards.

Further information is contained in the corresponding standards and regulations. These also include EN ISO 14120.

Other safety equipment

Other safety equipment must be integrated into the system in accordance with the corresponding standards and regulations.

3.8 Safety measures

3.8.1 General safety measures

The LBR Med may only be used in perfect technical condition in accordance with its intended use and only by safety-conscious persons. Operator errors can result in personal injury and damage to property.

It is important to be prepared for possible movements of the robot even after the robot controller has been switched off and locked. Incorrect installation (e.g. overload) or mechanical defects (e.g. brake defect) can cause the robot to sag. If work is to be carried out on a switched-off LBR Med, the robot must first be moved into a position in which it is unable to move on its own, whether the payload is mounted or not. If this is not possible, the robot must be secured by appropriate means.

DANGER

Risk of fatal injury due to non-operational safety functions or external safeguards

In the absence of operational safety functions or safeguards, the robot can cause death, severe injuries or damage to property.

- If safety functions or safeguards are dismantled or deactivated, do not operate the robot.

DANGER

Danger to life and limb of persons under the robot arm
Standing underneath the robot arm can lead to death, serious injuries or damage to property. Especially if objects are being moved that can become detached.

- The system integrator must evaluate the risk from standing under the robot arm in his risk management process and implement the appropriate measures.

HRC

In the case of collaborative operation (HRC), the system must be equipped with a visual display indicating when the robot is in collaborative operation.

Implants

DANGER

Danger to life due to malfunction of implants caused by motors and magnets
Electric motors and magnets generate electric and magnetic fields. The fields can cause malfunctions in implants, e.g. pacemakers.

- The integrator / medical device manufacturer must evaluate this through its risk management and take the appropriate measures.

smartPAD

The medical device manufacturer must ensure that the LBR Med is only operated with the smartPAD by authorized persons.

The smartPAD may only be used as intended by the system integrator for start-up and recommissioning (e.g. after maintenance).
The smartPAD is not intended for operation of the medical device by the end user (e.g. medical personnel).

If more than one smartPAD is used in a medical device, it must be ensured that each smartPAD is unambiguously assigned to the corresponding LBR Med. It must be ensured that 2 smartPADs are not interchanged.

The medical device manufacturer must configure the smartPAD as unpluggable.

WARNING

Risk of fatal injury due to non-operational EMERGENCY STOP device
If the smartPAD is disconnected, the medical device can no longer be switched off by means of the EMERGENCY STOP device on the smartPAD.
Death, injuries or damage to property may otherwise result.

- If the smartPAD is configured as unpluggable, at least one external EMERGENCY STOP device must be installed that is accessible at all times.

Modifications

After modifications to the LBR Med, checks must be carried out to ensure the required safety level. The valid national or regional work safety regulations must be observed for this check. The correct functioning of all safety functions must also be tested.

New or modified programs must always be tested first in Manual Reduced Velocity mode (T1).

After modifications to the LBR Med, existing programs must always be tested first in Manual Reduced Velocity mode (T1). This applies to all components of the LBR Med and includes modifications to the software and configuration settings.

The robot may not be connected and disconnected when the robot controller is running.

Faults

The following procedure must be followed in the case of faults on the LBR Med:

- Switch off the robot controller and secure it (e.g. with a padlock) to prevent unauthorized persons from switching it on again.
- Indicate the fault by means of a label with a corresponding warning (tagout).
- Keep a record of the faults.
- Eliminate the fault and carry out a function test.

3.8.2 IT security

KUKA products must only be used in perfect technical condition in accordance with their intended use and only by safety-conscious persons.

In particular, safety-conscious use includes being operated in an IT environment which meets the current security-relevant standards and for which there is an overall concept for IT security.

Take measures to ensure IT security
IT security involves not only aspects of information and data processing as such, but also affects at least the following areas:

- Technology, organization, personnel, infrastructure

KUKA urgently recommends that users implement an information security management system for their products which designs, coordinates and monitors the tasks related to information security.

Sources for information about IT security for companies include:

- Independent consulting firms
- National cyber security authorities

National authorities often make their recommendations available on the Internet. In addition to their official language, some national authorities provide their information in English.

3.8.3 Transportation

Robot

The prescribed transport position of the robot must be observed. Transportation must be carried out in accordance with the Instructions for Use for the LBR Med.

Avoid vibrations and impacts during transportation in order to prevent damage to the manipulator.

Robot controller

The prescribed transport position of the robot controller must be observed. Transportation must be carried out in accordance with the Instructions for Use for the robot controller.

Avoid vibrations and impacts during transportation in order to prevent damage to the robot controller.

Contamination

Seemingly or actually contaminated products constitute a health hazard to persons who come into contact with the returned goods due to infectious biomaterials or hazardous substances.

A template for declaration of the hygiene status can be found in the supplied documentation. The declaration must be filled out and attached to the goods being returned.

Further information can be found on the website of BVMed - Bundesverband Medizintechnologie e. V.

3.8.4 Start-up and recommissioning

Before starting up the LBR Med and the medical device for the first time, a check must be carried out to ensure that the LBR Med and the medical device are complete and operational, that they can be operated safely and that any damage is detected.

The valid national or regional work safety regulations must be observed for this check. The correct functioning of all safety functions must also be tested.

Prior to start-up, the passwords for the user groups must be modified by the administrator, transferred to the robot controller in an installation procedure and activated. The passwords must only be communicated to authorized personnel.

Do not impair safety functions
Additional components (e.g. cables and hoses) not supplied by KUKA may be integrated into the LBR Med or the medical device.
The medical device manufacturer is responsible for ensuring that these components do not impair or disable safety functions. Non-compliance can result in death, serious injury or damage to property.

- Additional components must not impair or disable safety functions.

NOTICE

Damage to property due to condensation
If the internal cabinet temperature of the robot controller differs greatly from the ambient temperature, condensation can form. This may result in damage to property.

- Wait until the internal cabinet temperature has adapted to the ambient temperature in order to avoid condensation.

Function test

The following tests must be carried out before start-up and recommissioning:

General test:

It must be ensured that:

- The LBR Med is correctly installed and fastened in accordance with the specifications in the documentation.
- There are no foreign bodies, or defective or loose parts on the LBR Med.

- All required safety equipment is correctly installed and operational.
- The power supply ratings of the LBR Med correspond to the local supply voltage and mains type.
- The equipotential bonding cable is sufficiently rated and correctly connected.
- The connecting cables are correctly connected and the connectors are locked.

Test of the safety functions:

A function test must be carried out for all the safety-oriented functions to ensure that they are working correctly.

Test of the safety-relevant mechanical and electromechanical components:

The following tests must be performed prior to start-up and at least once every 12 months unless otherwise determined in accordance with a workplace risk assessment:

- Function of all connected EMERGENCY STOP devices

  Press the EMERGENCY STOP device. A message must be displayed on the teach pendant indicating that the EMERGENCY STOP has been actuated. At the same time, no error message may be displayed about the EMERGENCY STOP device.
- Function of the enabling switches of all connected enabling devices

  Move the robot in Test mode and release the enabling switch. The robot motion must be stopped. At the same time, no error message may be displayed on the teach pendant about the enabling device.

  The test must always be carried out for all enabling switches of a connected enabling device.

  If the state of the enabling device is configured at an output, the test can also be performed via the output.
- Panic function of the enabling switches of all connected enabling devices

  Move the robot in test mode, press the enabling switch down and hold in the panic position for 3 seconds. The robot motion must be stopped. At the same time, no error message may be displayed on the teach pendant about the enabling device.

  The test must always be carried out for all enabling switches of a connected enabling device.

  If the state of the enabling device is configured at an output, the test can also be performed via the output.
- Function of the mode selector switch on the smartPAD (if used as teach pendant)

  Turn the mode selector switch to the right and then back again. There must be no error message displayed on the smartPAD.
- Switch-off capability of the safety-oriented outputs

  Switch robot controller off and then on again. After it is switched on, no error message relating to a safety-oriented output may be displayed on the teach pendant.

In the case of incomplete start-up of the medical device, additional substitute measures for minimizing risk must be taken and documented, e.g. installing a safety fence, attaching a warning sign, locking the main switch. Start-up is incomplete, for example, if not all safety functions have yet been implemented, or if a function test of the safety functions has not yet been carried out.

Test of the functional capability of the brakes:

For the LBR Med, a brake test is available which must be used to check whether the brake of each axis applies sufficient braking torque.

The brake test ensures that any impairment of the braking function is detected, e.g. due to wear, overheating, fouling or damage, thereby eliminating avoidable risks.

The brake test cannot be switched off by the system integrator. The system forces regular brake tests and stops the system if these are not carried out.

- The brake test must be carried out for each axis during start-up and recommissioning of the LBR Med.

Inspection before start-up:

- Carry out a visual inspection of the robot and robot controller to check for damage.
- Check the fastening screws with the torque wrench.
- Carry out a visual inspection of the connecting cables and connectors to check for damage. Shake gently by hand. Secure any loose cables and connectors.

3.8.5 Manual mode

General

Manual mode is the mode for setup work. Setup work comprises all the tasks that have to be carried by the system integrator on the LBR Med to enable automatic operation. Setup work includes:

- Jog mode
- Teaching
- Program verification

The following must be taken into consideration in manual mode:

- New or modified programs must always be tested first in Manual Reduced Velocity mode (T1).
- The robot and its tooling must never touch or project beyond the safety fence.
- Workpieces, tooling and other objects must not become jammed as a result of the robot motion, nor must they lead to short-circuits or be liable to fall off.
- All setup work must be carried out, where possible, from outside the safeguarded area.

Setup work in T1

If it is necessary to carry out setup work from inside the safeguarded area, the following must be taken into consideration in the operating mode **Manual Reduced Velocity (T1)**:

- If it can be avoided, there must be no other persons inside the safeguarded area.

  If it is necessary for there to be several persons inside the safeguarded area, the following must be observed:

  – Each person must have an enabling device.
  – All persons must have an unimpeded view of the LBR Med.
  – Eye-contact between all persons must be possible at all times.
- The system integrator must be so positioned that he can see into the danger area and get out of harm's way.

- Unexpected motions of the manipulator cannot be ruled out, e.g. in the event of a fault. For this reason, an appropriate clearance must be maintained between persons and the manipulator (including tool). Guide value: 50 cm.

  The minimum clearance may vary depending on local circumstances, the motion program and other factors. In his risk assessment, the medical device manufacturer must assess the minimum clearance that is to apply for the specific application and take appropriate measures.

Setup work in T2

If it is necessary to carry out setup work from inside the safeguarded area, the following must be taken into consideration in the operating mode **Manual High Velocity (T2)**:

- This mode may only be used if the application requires a test at a velocity higher than that possible in T1 mode.
- Teaching is not permissible in this operating mode.
- Before commencing the test, the system integrator must ensure that the enabling devices are operational.
- The system integrator must be positioned outside the danger zone.
- There must be no-one present inside the safeguarded area. It is the responsibility of the system integrator to ensure this.

3.8.6 Automatic mode

Automatic mode is only permissible in compliance with the following safety measures:

- All safety equipment and safeguards are present and operational.
- There are no persons in the system, or the requirements for collaborative operation have been examined and met where applicable in accordance with EN ISO 10218.
- The defined working procedures are adhered to.

If the robot comes to a standstill for no apparent reason, the danger zone must not be entered until an EMERGENCY STOP has been triggered.

3.8.7 Maintenance and repair

No maintenance and repair work may be carried out during operation.

After maintenance and repair work, checks must be carried out to ensure the required safety level. The valid national or regional work safety regulations must be observed for this check. The correct functioning of all safety functions must also be tested.

The purpose of maintenance and repair work is to ensure that the system is kept operational or, in the event of a fault, to return the system to an operational state. Repair work includes troubleshooting in addition to the actual repair itself.

The following safety measures must be taken when working on the LBR Med:

- Carry out work outside the danger zone. If work inside the danger zone is necessary, the user must define additional safety measures to ensure the safe protection of personnel.
- Switch off the LBR Med and secure it (e.g. with a padlock) to prevent it from being switched on again. If it is necessary to carry out work

with the robot controller switched on, additional safety measures must be defined to ensure the safe protection of personnel.

- If it is necessary to carry out work with the robot controller switched on, this may only be done in operating mode T1.
- Label the system with a sign indicating that work is in progress. This sign must remain in place, even during temporary interruptions to the work.
- The EMERGENCY STOP devices must remain active. If safety functions or safeguards are deactivated during maintenance or repair work, they must be reactivated immediately after the work is completed.

DANGER

Danger to life and limb due to live parts
The robot system must be disconnected from the mains power supply prior to work on live parts. It is not sufficient to trigger an EMERGENCY STOP or safety stop, because parts remain live. Death or severe injuries may result.

- Before commencing work on live parts, turn off the main switch and secure it against being switched on again.

  If the controller variant in question does not have a main switch (e.g. KR C5 micro), turn off the device switch then disconnect the power cable and secure it so it cannot be reconnected.
- Then check to ensure that the system is deenergized.
- Inform the individuals involved that the robot controller is switched off. (e.g. by affixing a warning sign)

Faulty components must be replaced using new components with the same article numbers or equivalent components approved by KUKA Deutschland GmbH for this purpose.

Cleaning and preventive maintenance work is to be carried out in accordance with the Instructions for Use.

Robot controller

Even when the robot controller is switched off, parts connected to peripheral devices may still carry voltage. The external power sources must therefore be switched off if work is to be carried out on the robot controller.

The ESD regulations must be adhered to when working on components in the robot controller (electrostatic sensitive devices).

Voltages in excess of 60 V can be present in various components for several minutes after the robot controller has been switched off! To prevent life-threatening injuries, no work may be carried out on the LBR Med in this time.

Various components may have elevated temperatures after the robot controller has been switched off. To prevent burns, wait until the components have cooled off.

On robot controllers with transformers, the transformers must be disconnected before working on components in the robot controller.

Water and dust must be prevented from entering the robot controller.

Robot

In connection with maintenance and repair work, KUKA Deutschland GmbH must be informed beforehand as to the application for which the LBR Med was used and under what conditions. Information must also be provided as to the possible types of contamination.

3.8.8 Decommissioning, storage and disposal

The LBR Med must be decommissioned, stored and disposed of in accordance with the applicable national laws, regulations and standards.

3.8.9 Safety measures for “single point of control”

Overview

If certain components are used on the LBR Med, safety measures must be taken to ensure full implementation of the principle of “single point of control” (SPOC).

Components:

- Tools for configuration of bus systems with online functionality

The implementation of additional safety measures may be required. This must be clarified for each specific application and is the responsibility of the medical product manufacturer. The medical product manufacturer must evaluate this in its risk management plan and take the appropriate measures.

Since only the system integrator knows the safe states of actuators in the periphery of the robot controller, it is his task to set these actuators to a safe state.

T1, T2, CRR

In modes T1, T2 and CRR, a robot motion can only be initiated if an enabling switch is held down.

Tools for configuration of bus systems

If these components have an online functionality, they can be used with write access to modify programs, outputs or other parameters of the robot controller, without this being noticed by any persons located inside the system.

Such tools include:

- KUKA Sunrise.Workbench
- WorkVisual from KUKA
- Tools from other manufacturers

Safety measure:

- In the test modes, programs, outputs or other parameters of the robot controller must not be modified using these components.

3.9 Risk management

Following the integration of the LBR Med, the medical product manufacturer must evaluate its risk management for the medical product or the overall system and take the appropriate measures. The following list provides a rough guideline. The risk management process must also take the attached documentation (Important information on LBR Med) into consideration:

- Suitability of the drape used:

  For use in a sterile environment, a drape can be used to avoid the risk of contamination and infection. The suitability of the drape used

must be evaluated in the risk management process for the medical product. The drape used must meet the following requirements as it concerns intended use:

- Unrestricted robot mobility
- Manual guidance mode must not be adversely affected: A stretched drape must not cause any additional external loads.
- The drape must not be damaged or relocated during robot motions, e.g. by lifting.
- The medical product manufacturer must provide the model and type designations for the approved drape to the end user (customer).
- The drape used must not lead to overheating. The ambient conditions and the surface temperatures must be taken into account.

- Avoidance of the risk of contamination and infection due to liquids:

  On account of its design, the robot exhibits gaps and open cavities in which liquids could collect. The medical product manufacturer must evaluate the appropriate measures to avoid the risk of contamination and infection in its risk management process and implement these measures. Possible measures:

  - Preventing liquids from collecting (e.g. condensation)
  - Using a drape
- Parts that come in contact with the patient:
  - The robot and the media flange are not applied parts:

    According to IEC 60601-1, cl. 4.6, the medical product manufacturer must evaluate in its risk management process whether the parts that could come into contact with the patient (but are not applied parts) must meet the requirements for applied parts. The medical product manufacturer must determine whether these components must comply with the requirements for type B, BF or CF applied parts.

    The robot and the media flange meet the requirements for type B applied parts.

    The medical product manufacturer must finally evaluate the following in its risk management plan:

    - Which parts of the robot and the media flange could come in contact with a patient.
    - Location, probability and duration of contact with the robot and the media flange by a patient.
    - Responsiveness and the necessity of protecting a patient in the case of contact with the robot and the media flange by a patient.
  - The robot controller must not be touched by the patient:

    The medical product manufacturer must ensure that the robot controller is not accessible to unauthorized personnel or patients, e.g. by using an additional cover. The robot controller must only be accessible to maintenance personnel through the use of tools.

    The robot controller is not intended for direct operation in a sterile environment. If the intended use requires this, the medical product manufacturer must evaluate this in its risk management and take corresponding measures (e.g. additional housing).
- Leakage currents in the overall system:

  The medical product manufacturer must ensure that the limit values for leakage currents are not exceeded. The leakage currents must be

measured for the overall system in accordance with the classification of the applied part.

- Hazard due to vibrations:

  Vibrations may occur on the robot during operation. The transmission of vibrations can lead to “discomfort” for patients or end users. The medical product manufacturer must minimize the occurrence of vibrations on the overall system. The medical product manufacturer must evaluate this through its risk management and take the appropriate measures.

- Unexpected stopping:

  The medical product manufacturer must ensure that unexpected stopping of the robot does not lead to an unacceptable risk.

  The medical product manufacturer must define and implement appropriate measures which eliminate the corresponding risk or reduce it to an acceptable level.

- Stopping of the robot in the event of a fault

  In its risk management, the medical product manufacturer must evaluate what behavior is required of the robot when stopping due to a fault. If the risk management permits it, a safety stop 1 for stopping the robot in an emergency is to be preferred to stopping using the holding brakes (safety stop 0) in order to prevent unnecessary wear of the holding brakes.

- Single fault safety:

  To ensure single fault safety for the robot, the medical product manufacturer must correctly configure the safety configuration in Sunrise Workbench based on its own, application-specific risk management process.

  The functions described in the “Operating and Programming Instructions for System Integrators” are available to the medical product manufacturer for this.

- Setting up alarm systems:

  To meet the requirements from the standard IEC 60601-1-8, the medical product manufacturer can set up alarm systems which are based on the data of the LBR Med. The medical product manufacturer must define suitable alarm conditions and the selection of the values to be monitored.

- Integration of the PEMS from the medical product manufacturer into the user’s IT network:

  The medical product manufacturer must analyze the associated hazard that could arise from integration of the LBR Med into IT networks. The information must be made available to the user by the system integrator according to IEC 60601-1, cl. 14.13.

  The following hazards can arise when integrating the LBR Med into an IT network:

  – Incorrect flow of data between the system of the integrator and the robot controller.

    Possible remedies:

    – Secure sequence control prevents misinterpretations of incorrect commands via the data flow
    – Secure communications protocol (CRC, time stamp, packet counter)
    – Standard protocol for starting, pausing and restarting the application

  – Excessive loading of the IT network via network nodes.

    Possible remedies:

  - Asynchronous information between the system of the integrator and the robot controller
  - Watchdogs for time-critical sequences
  - Cyclical sequences with requirements for hard real time only in the real-time part of the controller
- Brakes as a safety measure:

  The brakes of the robot are considered as a safety measure and are only applied during operation in the event of a fault. The integrity of the brakes is ensured through a cyclical brake test.

Further information about the brake test is contained in the “Operating and Programming Instructions for System Integrators”.

  The reduction of the holding torque is detected in good time before reaching the minimum permissible holding torque for the brakes and signaled by the system using the **Warning** message. The medical product manufacturer must take the cyclical execution of the brake test into account in the development and planning of the application.
- Trapping hazard:

  In its risk management, the medical product manufacturer must evaluate the hazard to the operator (e.g. medical personnel) due to crushing at potential trapping points. The medical product manufacturer must take appropriate measures to ensure that the robot motion is stopped if a trapping hazard point is reached.

  The safety functions must be configured accordingly for this.
- Properties of the sensor system:

  For applications with high requirements in terms of accuracy, it must be ensured that all measured values are assigned defined tolerances (e.g. for space monitoring). For further information concerning tolerance values, please contact KUKA Customer Support.
- Use of an applied part with an additional energy supply system:

  In the case of installation of an applied part with an additional energy supply system, the medical product manufacturer must ensure that the maximum rated payload is not exceeded on account of the additional weight.

  The medical product manufacturer must evaluate the use of an applied part with an additional energy supply system in respect of the following in its risk management process:

  - The impact on safety-oriented monitoring functions (e.g. collision detection).
  - The impact on manual guidance.
  - The impact on motions which use impedance functions.
- Risk resulting from strong magnets: Operation in the vicinity of magnetic fields can lead to faults, system failure or damage to the robot.

  The medical product manufacturer must evaluate this through its risk management and take the appropriate measures.

4 Technical data

Basic data

Cabinet type	KUKA Sunrise Cabinet (19" housing)
Color	Med white
Weight	23 kg
Protection rating	IP 20
Sound level according to DIN 45635-1	Average: 54 dB (A)

Power supply connection

The robot controller may only be connected to grounded-neutral power supply systems.

Rated supply voltage	110 V/230 V AC, single-phase
Permissible tolerance of rated supply voltage	Rated supply voltage ±10%
Mains frequency	50 Hz ± 1 Hz or 60 Hz ± 1 Hz
Rated power input	1 kVA, see rating plate
Mains-side fusing	2x 16 A slow-blowing (1x phase; 1x neutral conductor (optional))
Device-side fusing	2x 10 A, slow-blowing
Equipotential bonding	The common neutral point for the equipotential bonding conductors and all protective ground conductors is the reference bus of the power unit.

Environmental conditions

Ambient temperature during operation	+5 ... 45 °C (278 ... 318 K)
Ambient temperature during storage/transportation with batteries	-25 ... +40 °C (248 ... 313 K)
Ambient temperature during storage/transportation without batteries	-25 ... +70 °C (248 ... 343 K)
Relative air humidity	5% ... 85%
Temperature change	max. 1.1 K/min
Humidity class	3k3 acc. to DIN EN 60721-3-3; 1995
Installation altitude	• up to 1000 m above mean sea level with no derating • up to a maximum of 3000 m above mean sea level with a derating of 5%/1000 m
Air pressure during storage and transportation	500 hPa to 1060 hPa

NOTICE

Destruction of the batteries due to exhaustive discharge
To prevent exhaustive discharge and thus destruction of the batteries, the batteries must be recharged at regular intervals according to the storage temperature.

- If the storage temperature is +20 °C or lower, recharge the batteries every 9 months.
- If the storage temperature is between +20 °C and +30 °C, recharge the batteries every 6 months.
- If the storage temperature is between +30 °C and +40 °C, recharge the batteries every 3 months.

NOTICE

The fuses are liable to corrode during longer transportation or storage times at temperatures below 0 °C and with high air humidity. The correct functioning of the fuses must be checked following transportation and storage.

Vibration resistance

Type of loading	During transportation	During continuous operation
r.m.s. acceleration (sustained oscillation)	0.37 g	0.1 g
Frequency range (sustained oscillation)	4...120 Hz	
Acceleration (shock in X/Y/Z direction)	10 g	2.5 g
Waveform/duration (shock in X/Y/Z direction)	Half-sine/11 ms	

CAUTION

If more severe mechanical stress is expected, anti-vibration measures must be adopted.

Control unit

Supply voltage	DC 27.1 V ± 0.1 V

Main processor	Quad-core
DIMM memory modules	See shipping version (min. 2 GB)
Hard drive	SSD

KUKA smartPAD

Supply voltage	20 … 27.1 V DC
Dimensions (WxHxD)	approx. 33x26x8 cm
Display	Touch-sensitive color display 600x800 pixels
Display size	8.4"
Interfaces	USB
Weight	1.1 kg

KUKA smartPAD-2

Further information about the smartPAD-2 is contained in the operating instructions of the smartPAD-2.

Cable lengths

For cable designations, standard lengths and optional lengths, please refer to the Instructions for Use of the robot.

When using smartPAD cable extensions, only two extensions may be used. An overall cable length of 50 m must not be exceeded.

4.1 Cabinet Interface Board, Small Robot

The power contacts must only be fed from a safely isolated PELV power supply unit.

CIB_SR outputs

Operating voltage, power contacts	≤ 30 V
Current via power contact	min. 10 mA < 750 mA
Cable lengths (connection of actuators)	< 50 m cable lengths < 100 m wire length (outgoing and incoming lines)
Cable cross-section (connection of actuators)	≥ 1 mm^2
Switching cycles CIB_SR	Service life: 20 years < 100,000 (corresponds to 13 switching cycles per day)

The module must be exchanged when the number of switching cycles is exceeded.

CIB_SR inputs

Switching level of the inputs	The state for the inputs is not defined for the voltage range from 5 V to 11 V (transition range). Either the ON state or the OFF state is set. OFF state for the voltage range from -3 V to 5 V (OFF range). ON state for the voltage range from 11 V to 30 V (ON range).
Load current with 24 V supply voltage	> 10 mA
Load current with 18 V supply voltage	> 6.5 mA
Max. load current	< 15 mA
Cable length, terminal - sensor	< 50 m, or < 100 m wire length (outgoing and incoming lines)
Cable cross-section, test output - input connection	> 0.5 mm^2

Capacitive load for the test outputs per channel	< 200 nF
Resistive load for the test outputs per channel	< 33 Ω

Test outputs A and B are sustained short-circuit proof.
The specified currents flow via the contact element connected to the input. This must be rated for the maximum current of 15 mA.

4.2 Dimensions

The dimensions of the robot controller are indicated in the diagram (>>> *Fig. 4-1*).

Dimensions: mm

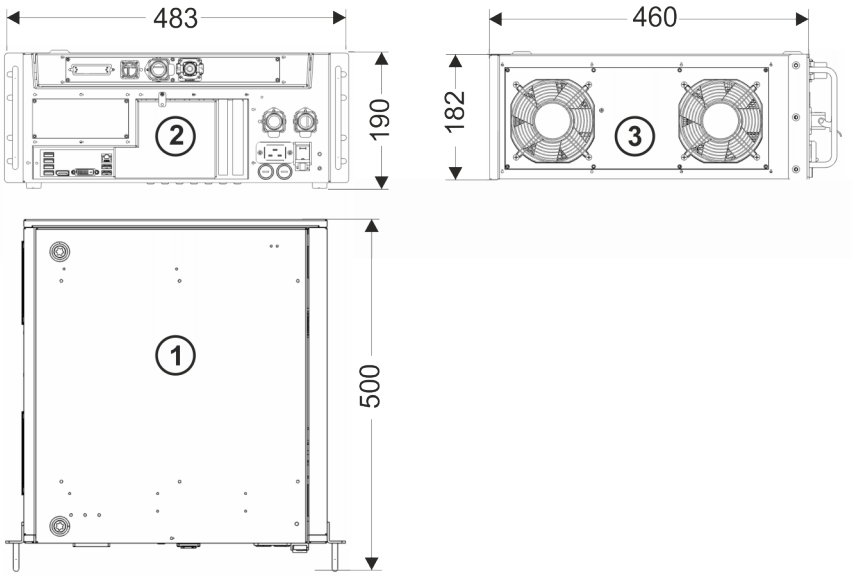


Fig. 4-1: Dimensions

1 Top view
2 Front view
3 Side view

4.3 Dimensions of handle brackets

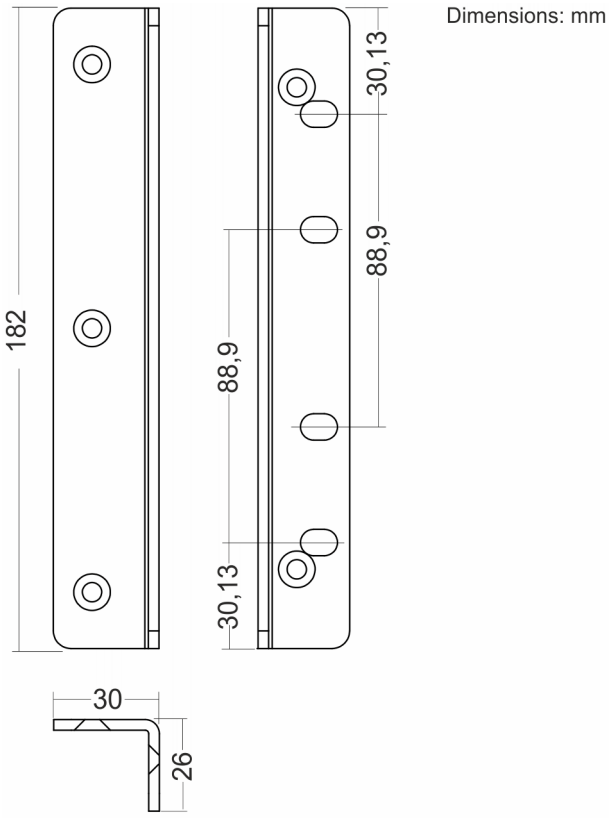


Fig. 4-2: Dimensions of handle brackets

4.4 Dimensions of the smartPAD holder (optional)

The diagram shows the dimensions and drilling locations for mounting on the safety fence.

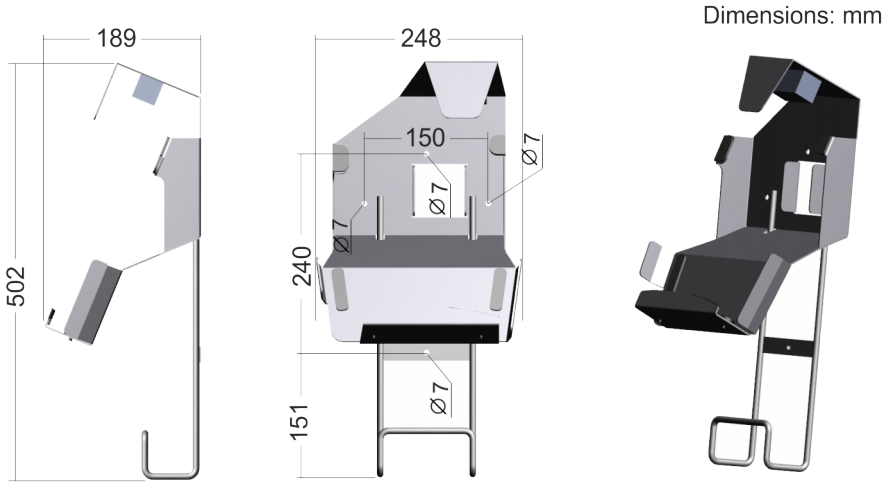


Fig. 4-3: Dimensions and drilling locations for smartPAD holder

4.5 Plates and labels

Designations

The following plates and labels are attached to the robot controller. They must not be removed or rendered illegible. Illegible plates and labels must be replaced.

CAUTION

If the plates and labels are removed for integration into a medical product, the medical product manufacturer must evaluate this in its risk management process and take the necessary measures.

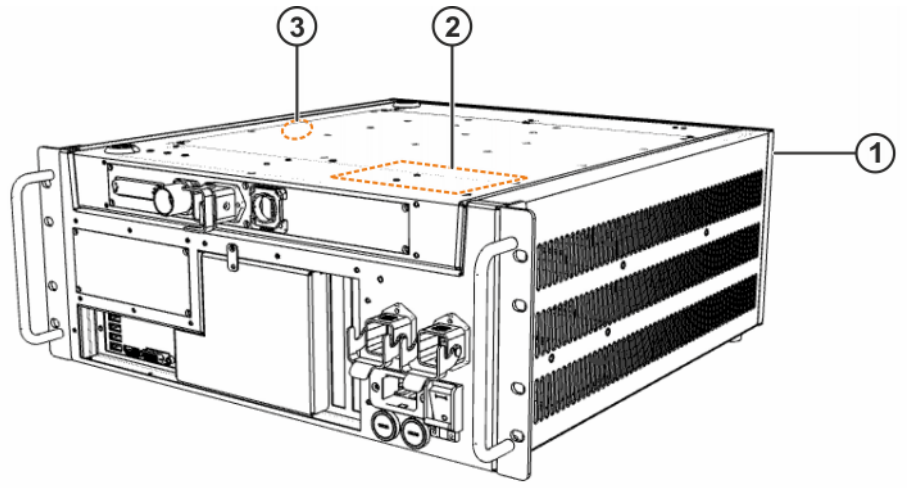
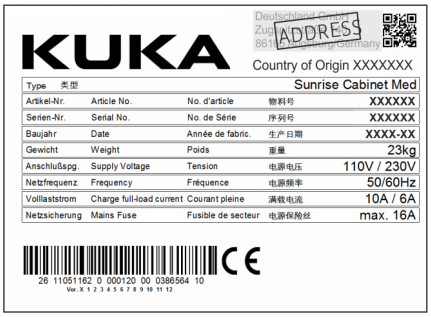
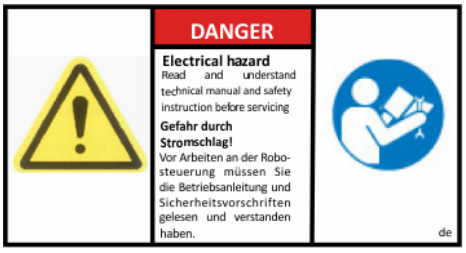


Fig. 4-4: Plates and labels

Item	Description
1	 Example of **identification plate for robot controller**Content according to Machinery Directive. The QR code contains a link to product information in KUKA Xpert.
2	 **Electric shock hazard** The Instructions for Use and safety regulations must be read and understood before work is carried out on the robot controller.

Item	Description
3	 **Remove mains connector** Unplug mains connector before opening the housing.

The plates may vary slightly from the examples illustrated above depending on the specific cabinet type or as a result of updates.

4.6 REACH duty to communicate information acc. to Art. 33 of Regulation (EC) 1907/2006

On the basis of the information provided by our suppliers, the following components of this product contain substances included on the Candidate List of Substances of Very High Concern (SVHCs) in a concentration exceeding 0.1 percent by mass. None of these substances are released under normal and reasonably foreseeable conditions of use.

Product	REACH candidate/SVHC substance name	CAS number
CR 2032 button cell	1,2-Dimethoxyethane; Ethylene glycol dimethyl ether (EGDME)	110-71-4
2.5 inch SSD hard drive; SATA	Silicic acid, lead salt	11120-22-2

5 Planning

5.1 Overview

This is an overview of the most important planning specifications. The precise planning depends on the application, the robot type, the technology packages used and other customer-specific circumstances.
For this reason, the overview does not claim to be comprehensive.

Step	Description	Information
1	Electromagnetic compatibility (EMC)	(>>> *5.2 "Electromagnetic compatibility (EMC)" Page 57*)
2	Installation conditions for robot controller	(>>> *5.3 "Installation conditions" Page 58*)
3	Connection conditions	(>>> *5.4 "Connection conditions" Page 59*)
4	Power supply connection	(>>> *5.5 "Power supply connection" Page 60*)
5	Safety interface X11	(>>> *5.6.1 "Interface X11" Page 61*)
6	Safety interface X11 default connector pin allocation	(>>> *5.6.1.2 "X11 safety interface" Page 62*)
7	KUKA Extension Bus interface X65	(>>> *5.6.2 "KUKA Extension Bus X65" Page 66*)
8	KUKA Line Interface X66	(>>> *5.6.3 "KUKA Line Interface X66" Page 67*)
9	Service interface X69	(>>> *5.6.4 "X69 KUKA Service Interface" Page 68*)
10	Equipotential bonding	(>>> *5.6.6 "PE equipotential bonding" Page 70*)

5.2 Electromagnetic compatibility (EMC)

Description

If connecting cables (e.g. field buses, etc.) are routed to the control PC from outside, only shielded cables with an adequate degree of shielding may be used.

The robot controller corresponds to EMC class B, group 1 in accordance with EN 55011.

In order to achieve EMC class B, group 1 in accordance with EN 55011 for the robot system, a PE equipotential bonding conductor must be connected to the robot.

NOTICE

Damage to property due to radio interference
If the smartPAD-2 is connected, emissions class B is not achieved. Radio interference can occur during residential use.

- Create awareness for the hazard.

5.3 Installation conditions

Dimensions

The robot controller can be installed in a 19" rack or as a standalone device. The specifications in the “Technical data” chapter must be observed. If the robot controller is to be installed in a 19" rack, the depth must be at least 600 mm.

If the robot controller is to be installed in a 19" rack, it must be fastened in the rack by appropriate means (preferably angle plates) along the entire side edge in order to prevent distortion of the housing.

CAUTION

The medical product manufacturer must ensure that the robot controller is not accessible to unauthorized personnel or patients, e.g. by using an additional cover. The robot controller must only be accessible to maintenance personnel through the use of tools.

The robot controller has protection rating IP20 in accordance with IEC 60529 and may be operated in an environment with pollution degree 2. If the robot controller is to be operated in an environment with pollution degree 3, the medical product manufacturer must take additional safety measures, e.g. additional housing with protection rating IPX4.

During installation, the following must be taken into consideration:

- Both sides of the robot controller must be accessible to the cooling air. Clearance of 70 mm on each side.
- In the case of a vertical mounting position, the openings of the fans and the ventilation slots may not be on top.
- In the case of a vertical mounting position of the robot controller, fastening by means of screws is required.

Dimensions: mm

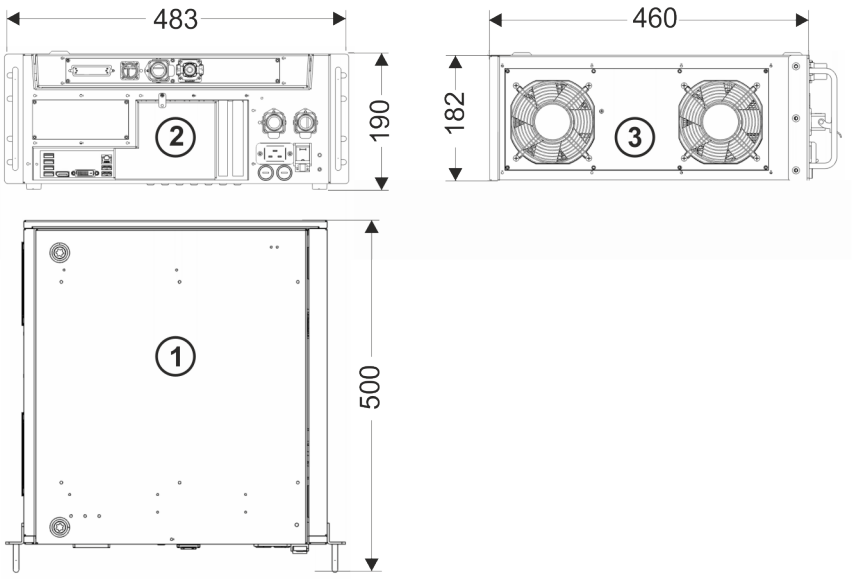


Fig. 5-1: Dimensions

1	Top view	3	Side view
2	Front view		

Handle brackets

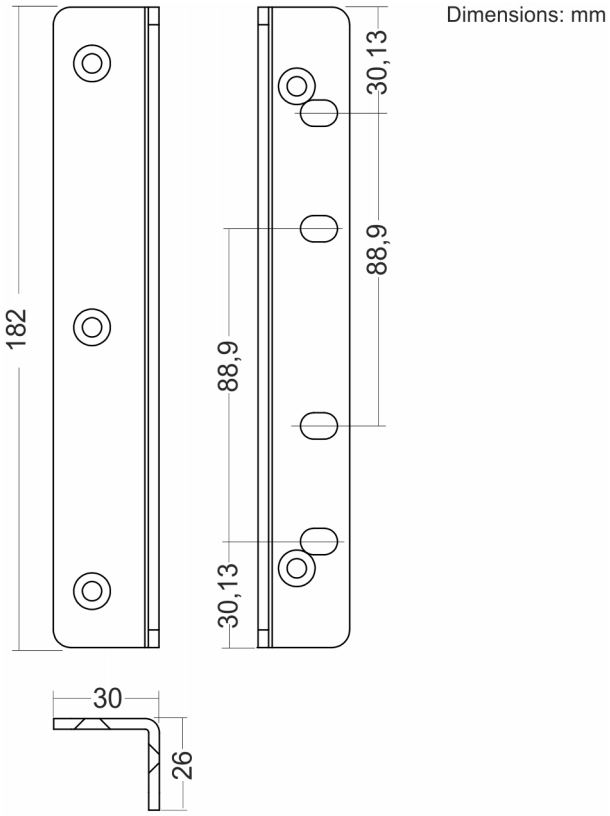


Fig. 5-2: Dimensions of handle brackets

5.4 Connection conditions

Power supply connection

The robot controller may only be connected to grounded-neutral power supply systems.

Rated supply voltage	110 V/230 V AC, single-phase
Permissible tolerance of rated supply voltage	Rated supply voltage ±10%
Mains frequency	50 Hz ± 1 Hz or 60 Hz ± 1 Hz
Rated power input	1 kVA, see rating plate
Mains-side fusing	2x 16 A slow-blowing (1x phase; 1x neutral conductor (optional))
Equipotential bonding	The common neutral point for the equipotential bonding conductors and all protective ground conductors is the reference bus of the power unit.

CAUTION

Risk of injury due to malfunctions

If the robot controller is connected to a power system **without** a grounded neutral, this may cause malfunctions in the robot controller. Injuries due to electrical voltage and material damage to the power supply units may result.

- Operate the robot controller only on a grounded-neutral power supply system.

WARNING

The robot controller is a protection class I device. To avoid the risk of an electric shock, the robot controller must only be connected to a supply network with a ground conductor.

If use of a residual-current circuit-breaker (RCCB) is planned, we recommend the following RCCB: trip current difference 300 mA per robot controller, universal-current sensitive, selective.

Cable lengths

For cable designations, standard lengths and optional lengths, please refer to the Instructions for Use of the LBR Med.

When using smartPAD cable extensions, only two extensions may be used. An overall cable length of 50 m must not be exceeded.

5.5 Power supply connection

Description

For connection to the mains, the robot controller is equipped with a 3-pole socket for non-heating appliances. The robot controller must be connected to the mains via the device connection cable included in the scope of supply.

The robot controller can be connected to the mains via the following device connection cables:

- with mains connector
- without mains connector

Infeed

- 110 V/230 V AC, single-phase, two-phase (with grounded neutral (as symmetrical as possible) between the phases used)
- 50 Hz ± 1 Hz or 60 Hz ± 1 Hz

Fusing

- 2x 16 A slow-blowing, type C (1 (2)x phase; 1x neutral conductor (optional))

5.6 Interface and connector pin allocation

NOTICE

Only devices that meet the minimum requirements for separation from the mains voltage according to IEC 60601-1 may be connected to the robot controller:

- 2 x MOOP
- 1 x MOPP

  (based on the maximum mains voltage of 230 V AC)

This minimum requirement corresponds to a separation of at least 3.4 mm clearance, 5.0 mm creepage distance and 3000 V dielectric strength.

When connecting devices to the interfaces of the robot controller, the medical product manufacturer must verify compliance with the permissible

limit values for leakage currents according to IEC 60601-1. In addition to this, the requirements of IEC 60601-1 for ME systems must be taken into consideration.

NOTICE

In the robot controller, the interfaces have the following separation from the mains voltage:

- 2 x MOOP
- 1 x MOPP

  (based on the maximum mains voltage of 230 V AC)

Only devices for which measures for operator protection (MOOP) are sufficient may be connected to the interfaces. Devices requiring measures for patient protection (MOPP) must not be connected to the interfaces of the robot controller.

NOTICE

In its risk management process, the medical product manufacturer must evaluate the overall system, including all devices connected to the interfaces.

5.6.1 Interface X11

Description

EMERGENCY STOP devices must be connected via interface X11 or linked together by means of higher-level controllers (e.g. PLC).

Wiring

Take the following points into consideration when wiring interface X11:

- System concept
- Safety concept

5.6.1.1 Contact diagram, connector X11

Description

The counterpart to interface X11 is a 50-contact D-Sub connector with a male insert, type Harting F-95972.

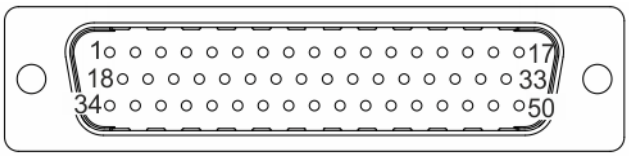


Fig. 5-3: Contact diagram, view from connection side

Outer diameter of cable: max. 12 mm

Recommended wire cross-section: AWG 20 (0.75 mm^2)

In the cabling for the input signals and test signals in the system, suitable measures must be taken to prevent a cross-connection between the voltages (e.g. separate cabling of input signals and test signals).

In the cabling for the output signals and test signals in the system, suitable measures must be taken to prevent a cross-connection between the output signals of a channel (e.g. separate cabling).

5.6.1.2 X11 safety interface

The X11 safety interface is wired internally to the CCU_SR.

Connector pin allocation

			Default settings		
Signal	**Pin**	**Designation**	**Assignment**	**Description**	**Remarks**
Test output A	1	Safe input 1 (CIB_SR.1)	External E-STOP, channel A	For 2-channel connection of an EMERGENCY STOP device max. 24 V	Triggers an EMERGENCY STOP
Input 1 A	2				
Test output B	10		External E-STOP, channel B		
Input 1 B	11				
Test output A	3	Safe input 2 (CIB_SR.2)	Operator safety, channel A	For dual-channel connection of a safety gate locking mechanism max. 24 V	Triggers a safety stop 1
Input 2 A	4				
Test output B	12		Operator safety, channel B		
Input 2 B	13				
Test output A	5	Safe input 3 (CIB_SR.3)	Safety stop 1, channel A	Input, safety stop 1	Triggers a safety stop 1 of all axes
Input 3 A	6				
Test output B	14		Safety stop 1, channel B		
Input 3 B	15				
Test output A	7	Safe input 4 (CIB_SR.4)	-	-	-
Input 4 A	8				
Test output B	16		-	-	-
Input 4 B	17				
Test output A	18	Safe input 5 (CIB_SR.5)	-	-	-
Input 5 A	19				
Test output B	28		-	-	-
Input 5 B	29				
Test output A	20	Safe input 6 (CIB_SR.6)	-	-	-
Input 6 A	21				
Test output B	30		-	-	-
Input 6 B	31				
Test output A	22	Safe input 7 (CIB_SR.7)	-	-	-
Input 7 A	23				
Test output B	32		-	-	-
Input 7 B	33				

			Default settings		
Signal	**Pin**	**Designation**	**Assignment**	**Description**	**Remarks**
Output 12 A	34	Safe output 12 (CIB_SR.12)	E-STOP local channel A	Output, floating contacts from internal EMERGENCY STOP	The contacts are closed if the following conditions are met: • E-STOP on smartPAD not actuated • Controller switched on and operational The contacts open if any condition is not met.
	35				
Output 12 B	45		E-STOP local channel B		
	46				
Output 13 A	36	Safe output 13 (CIB_SR.13)	Test mode, channel A	Output, floating contacts for Test mode	The contacts are open when Test mode is selected.
	37				
Output 13 B	47		Test mode, channel B		
	48				
Output 14 A	38	Safe output 14 (CIB_SR.14)	Automatic mode, channel A	Output, floating contacts for Automatic mode	The contacts are open when Automatic mode is selected.
	39				
Output 14 B	49		Automatic mode, channel B		
	50				

The assignments of the inputs and outputs are freely configurable. The assignments specified in the table correspond to the default settings of the safety configuration.

In the cabling for the input signals and test signals in the system, suitable measures must be taken to prevent a cross-connection between the voltages (e.g. separate cabling of input signals and test signals).

In the cabling for the output signals and test signals in the system, suitable measures must be taken to prevent a cross-connection between the output signals of a channel (e.g. separate cabling).

The voltage switched with the safe outputs must be generated by a power supply unit. The power supply unit must meet the requirements of 2 x MOOP for safe isolation according to EN 61010-1.

5.6.1.3 Wiring example for E-STOP circuit and safeguard

Description

The EMERGENCY STOP devices are connected to X11 in the robot controller.

EMERGENCY STOP

WARNING

Risk of fatal injury due to missing EMERGENCY STOP device
Missing or disconnected EMERGENCY STOP devices can cause death, injury or property damage.

- EMERGENCY STOP devices on the robot controller must be integrated into the EMERGENCY STOP circuit of the system by the system integrator.

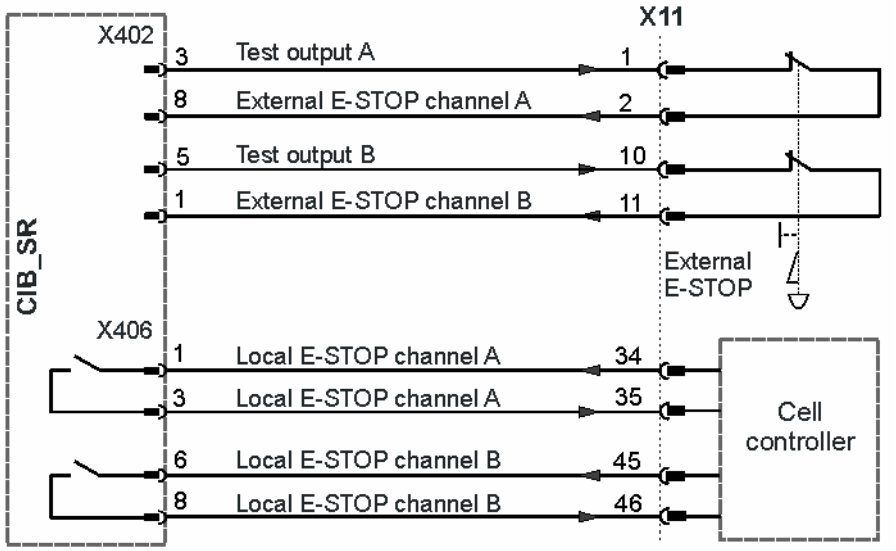


Fig. 5-4: Wiring example: EMERGENCY STOP

5.6.1.4 Wiring example for safe inputs and outputs

Safe input

The switch-off capability of the inputs is monitored cyclically.

The inputs of the CIB_SR are of dual-channel design with external testing. The dual-channel operation of the inputs is monitored cyclically.

The following diagram illustrates the connection of a safe input to a floating contact provided by the customer.

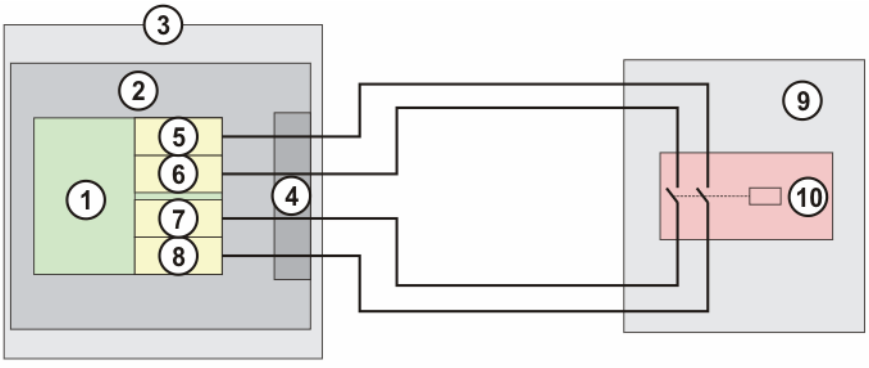


Fig. 5-5: Connection schematic for safe input

1 Safe input CIB_SR
2 CIB_SR
3 Robot controller
4 Interface X11

5 Test output channel B
6 Test output channel A
7 Input X, channel A
8 Input X, channel B
9 System side
10 Floating contact

Test outputs A and B are fed with the supply voltage of the CIB_SR. Test outputs A and B are sustained short-circuit proof. The test outputs must only be used to supply the CIB_SR inputs, and for no other purpose.

The wiring example can be used to achieve compliance with SIL2 (DIN EN 62061) and Cat. 3 (DIN EN 13849).

Dynamic testing

- The switch-off capability of the inputs is tested cyclically. For this, the test outputs TA_A and TA_B are switched off alternately.
- The switch-off pulse length is defined for the CIB_SRs as t1 = 625 µs (125 µs – 2.375 ms).
- The duration t2 between two switch-off pulses on one channel is 106 ms.
- The input channel SIN_x_A must be supplied by the test signal TA_A. The input channel SIN_x_B must be supplied by the test signal TA_B. No other power supply is permissible.
- It is only permitted to connect sensors which allow the connection of test signals and which provide floating contacts.
- The signals TA_A and TA_B must not be significantly delayed by the switching element.

Switch-off pulse diagram

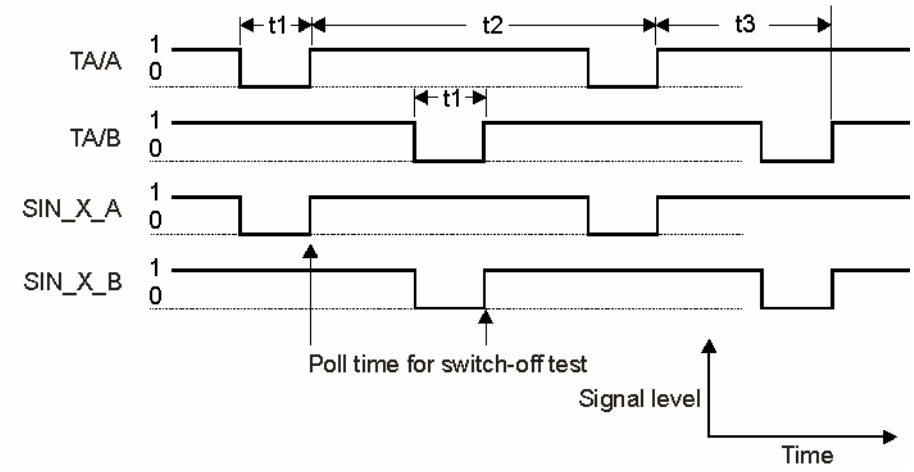


Fig. 5-6: Switch-off pulse diagram, test outputs

t1 Switch-off pulse length
t2 Switch-off period per channel (106 ms)
t3 Offset between switch-off pulses of both channels (53 ms)
TA/A Test output channel A
TA/B Test output channel B
SIN_X_A Input X, channel A
SIN_X_B Input X, channel B

Safe output

On the CIB_SR, the outputs are provided as dual-channel floating relay outputs.

The following diagram illustrates the connection of a safe output to a safe input provided by the customer with external test facility. The input used by the customer must be monitored externally for cross-connection.

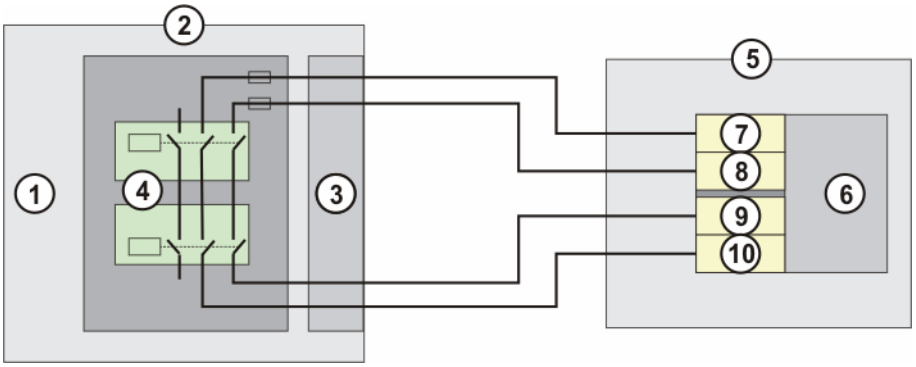


Fig. 5-7: Connection schematic for safe output

1 CIB_SR
2 Robot controller
3 Interface X11, safe output
4 Output wiring
5 System side
6 Safe input (Fail Safe PLC, safety switching device)
7 Test output channel B
8 Test output channel A
9 Input X, channel A
10 Input X, channel B

The wiring example shown can be used to achieve compliance with SIL2 (DIN EN 62061) and Cat. 3 (DIN EN 13849).

5.6.2 KUKA Extension Bus X65

Description

Connector X65 is intended for connecting EtherCAT slaves outside the robot controller. The EtherCAT line is routed out of the robot controller.

The devices in the EtherCAT line must be configured with WorkVisual and transferred to the controller using Sunrise Workbench.

Necessary equipment

- RJ45 connector

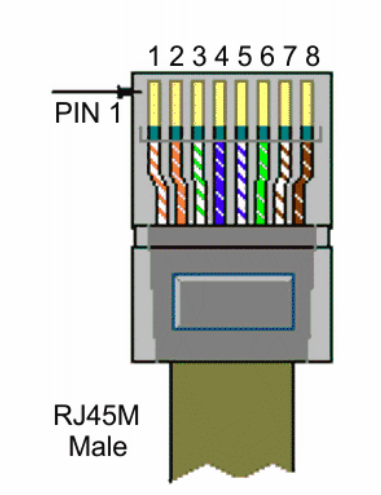


Fig. 5-8: Pin assignment

- Recommended connecting cable: Ethernet-compatible, min. category CAT 5
- Maximum cable cross-section: AWG22

Connector pin allocation X65 via CIB

Pin	Description
1	TPFO_P
2	TPFO_N
3	TPFI_P
6	TPFI_N

5.6.3 KUKA Line Interface X66

Description

Connector X66 is intended for connecting an external computer for the purpose of installation, programming, debugging and diagnosis.

Interface X66 can also be used for Profinet/ProfiSafe as well as for the Automatic External connection via UDP.

Necessary equipment

- Connector RJ45

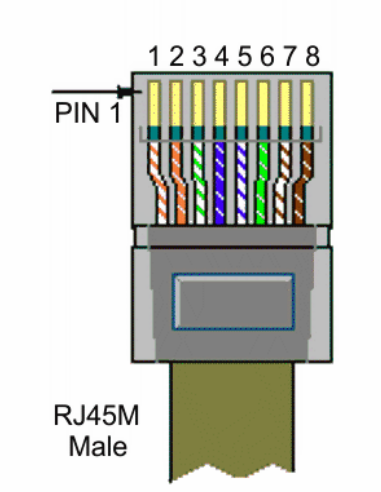


Fig. 5-9: Pin assignment

- Recommended connecting cable: Ethernet-compatible, min. category CAT 5e
- Maximum cable cross-section: AWG22

Connector pin allocation X66

Pin	Description
1	TD+
2	TD-
3	RD+
6	RD-
4	C+
5	C-
7	D+
8	D-

5.6.4 X69 KUKA Service Interface

Description

Interface X69 is intended for connecting a notebook for the purpose of diagnosis, WorkVisual configuration, update, etc., via the KSI (KUKA Service Interface). The service notebook does not have to be connected to the shop network for this.

Interface X69 has no function.

Necessary equipment

- Connector RJ45

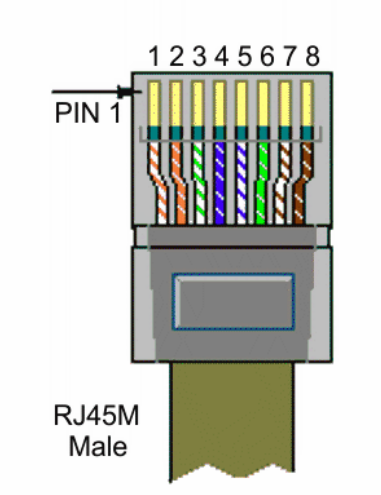


Fig. 5-10: Pin assignment

- Recommended connecting cable: Ethernet-compatible, min. category CAT 5e
- Maximum cable cross-section: AWG22

Connector pin allocation X69

Pin	Description
1	TFPO_P
2	TFPO_N
3	TFPI_P
6	TFPI_I
-	PE

5.6.5 X55 External power supply (optional)

Description

The Sunrise Cabinet Med internally generates a direct voltage of 27 V. An external device can be supplied with the internally generated voltage via the optional connector X55.

Necessary equipment

- Male insert, HAN 8D

Fig. 5-11: Contact diagram, view from contact side

- Cable clamping range: Ø9 ... Ø13 mm
- Recommended wire cross-section: 1 mm^2

Connector pin allocation X55

Pin	Description
7	27 V DC, maximum 7 A
8	0 V internal
-	PE

The power supply for external devices may only be used for devices for which measures for operator protection are sufficient. This secondary power circuit is separated from the voltage supply by 2 MOOPs.

5.6.6 PE equipotential bonding

Description

The robot controller can be grounded by means of the PE equipotential bonding rail at the installation site.

6 Transportation

6.1 Transportation by trolley

Preconditions

- The housing of the robot controller must be closed.
- No cables may be connected to the robot controller.

Procedure

- Transport the robot controller horizontally on the device feet on a trolley.

NOTICE
The robot controller must be protected from excessive shock loads during transportation. The load limits must not be exceeded during transportation.

6.2 Transportation without trolley

Preconditions

- The housing of the robot controller must be closed.
- No cables may be connected to the robot controller.

Procedure

- Transport the robot controller using the carrying handles.

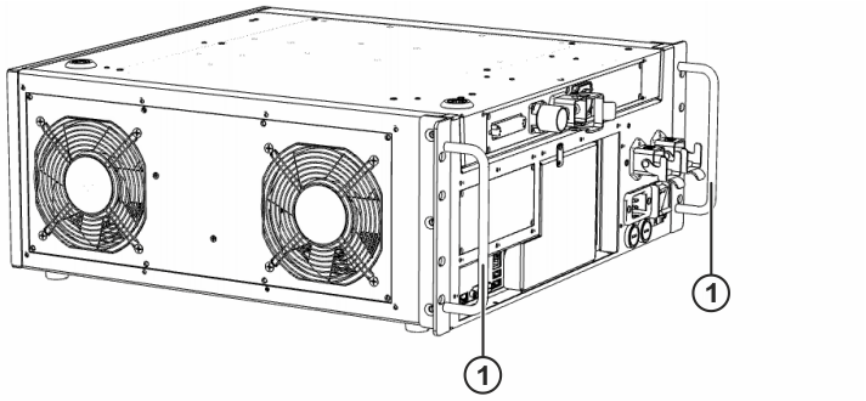


Fig. 6-1: Transportation without trolley

1 Carrying handles

7 Start-up and recommissioning

7.1 Overview

This is an overview of the most important steps during start-up. The precise sequence depends on the application, the robot type, the technology packages used and other customer-specific circumstances.

For this reason, the overview does not claim to be comprehensive.

This overview refers to start-up of the LBR Med. Start-up of the medical product is not part of the scope of this documentation.

Robot

Step	Description	Information
1	Carry out a visual inspection of the robot.	Detailed information is contained in the Instructions for Use of the robot, in the “Start-up and recommissioning” chapter.
2	Install the robot mounting base (mounting base, machine frame mounting or booster frame).	
3	Install the robot.	

Electrical equipment

Step	Description	Information
4	Carry out a visual inspection of the robot controller.	-
5	Make sure that no condensation has formed in the robot controller.	-
6	Ensure that the fuses function.	-
7	Install the robot controller.	(>>> *7.2 "Installing the robot controller" Page 74*)
8	Connect the connecting cables.	(>>> *7.3 "Connecting the connecting cables" Page 74*)
9	Plug in the KUKA smartPAD.	
10	Connect the equipotential bonding.	(>>> *7.5 "Connecting the PE equipotential bonding" Page 75*) This connection is only required if requested by the customer.
11	Reverse the battery discharge protection measures.	(>>> *7.6 "Reversing the battery discharge protection measures" Page 75*)
12	Configure and connect interface X11.	(>>> *7.7 "Configuring and connecting connector X11" Page 76*)
13	Connect the robot controller to the power supply.	(>>> *7.8 "Connecting the robot controller to the power supply" Page 76*)
14	Switch on the robot controller.	(>>> *7.9 "Switching on the robot controller" Page 77*)
15	Check the safety equipment.	Detailed information can be found in the “Safety” chapter.
16	Configure the inputs/outputs between the robot controller and the periphery.	Detailed information can be found in the field bus documentation.

7.2 Installing the robot controller

Description

The robot controller can be installed in a 19" rack or as a standalone device.

Preconditions

- If the robot controller is to be installed in a 19" rack, the depth must be at least 600 mm.
- Both sides of the robot controller must be accessible to the cooling air.

Procedure

1. Check the robot controller for any damage caused during transportation.
2. Install the robot controller, preferably in the horizontal position. If the robot controller is installed in the vertical position, both sides must always be accessible to the cooling air. In the case of a vertical mounting position, the openings of the fans and the ventilation slots may not be on top.

CAUTION

The robot controller must not be touched by the patient or unauthorized personnel.
The medical product manufacturer must ensure that the robot controller is not accessible to unauthorized personnel or patients, e.g. by using an additional cover. The robot controller must only be accessible to maintenance personnel through the use of tools.
The robot controller is not intended for direct operation in a sterile environment. If the intended use of the medical product requires this, the medical product manufacturer must take corresponding measures (e.g. additional housing).

7.3 Connecting the connecting cables

Overview

A standard cable set with the following basic equipment is supplied with the robot system:

- Connecting cable
- Device connection cable

  The following cables may be provided for additional applications:
- Peripheral cables

Procedure

- Plug connecting cable connector X21 into the control box.

Connector pin allocation X21

Pin	Description
1	48 V DC out1
2	0 V
3	48 V DC out2
4	0 V

Pin	Description
5	+24V network
6	GND
9	TPFO_P
10	TPFI_P
11	TPFO_N
12	TPFI_N

7.4 Plugging in the KUKA smartPAD

Procedure

- Plug the KUKA smartPAD into X19 on the robot controller.

If the smartPAD is disconnected, an EMERGENCY STOP is triggered.

NOTICE

Damage to property due to radio interference
If the smartPAD-2 is connected, emissions class B is not achieved. Radio interference can occur during residential use.

- Create awareness for the hazard.

Connector pin allocation X19

Pin	Description
11	TD+
12	TD-
2	RD+
3	RD-
8	smartPAD plugged in (A) 0 V
9	smartPAD plugged in (B) 24 V
5	24 V PS2
6	GND

7.5 Connecting the PE equipotential bonding

Procedure

The PE connections on the robot controller can be used to connect the robot system to the reference point of the equipotential bonding conductors for the medical product.

7.6 Reversing the battery discharge protection measures

Description

To prevent the batteries from discharging before the controller has been started up for the first time, the robot controller is supplied with connector X305 disconnected from the CCU_SR.

Procedure

- Plug connector X305 into the CCU_SR.

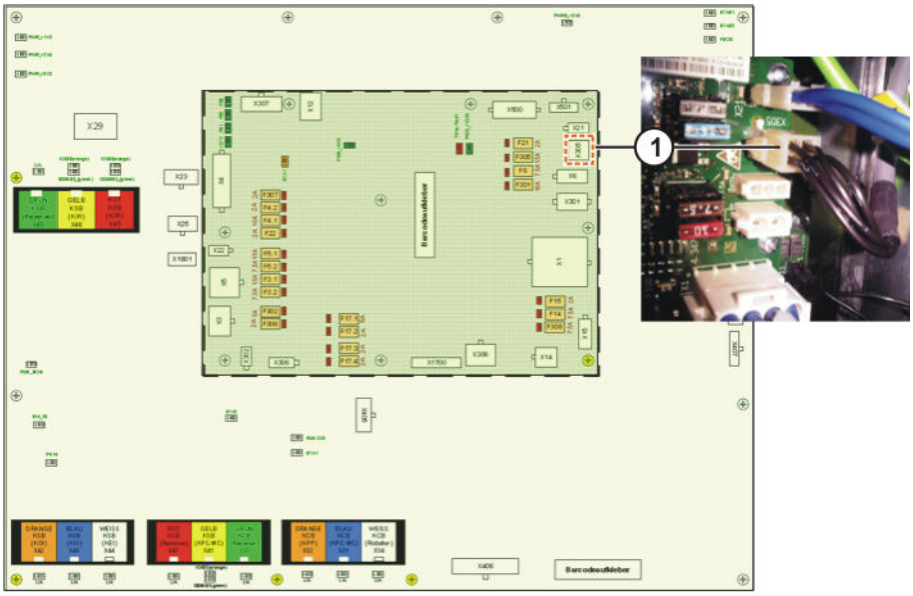


Fig. 7-1: Battery discharge protection X305

1 Connector X305 on the CCU_SR

7.7 Configuring and connecting connector X11

Precondition

- The robot controller is switched off.

Procedure

1. Configure connector X11 in accordance with the system and safety concepts.
2. Connect interface connector X11 to the robot controller.

NOTICE

Damage to property due to plugging or unplugging of live connectors

Connector X11 may only be plugged in or unplugged when the robot controller is switched off. If connector X11 is plugged in or unplugged when energized, damage to property may occur.

- Switch off the robot controller.

7.8 Connecting the robot controller to the power supply

7.8.1 Connecting the robot controller to the power supply with a mains connector

Precondition

- The robot controller is switched off.
- The power cable is de-energized.

Procedure

1. On the robot controller, plug in the connector for non-heating appliances for the device connection cable.
2. Connect the robot controller to the mains via the mains connector.

7.8.2 Connecting the robot controller to the power supply without a mains connector

Precondition

- The robot controller is switched off.
- The power cable is de-energized.
- Connection to the power supply must be carried out in accordance with the applicable national regulations.
- The power supply connection and the mains connector must be designed in accordance with the power data of the robot controller.

Procedure

1. On the robot controller, plug in the connector for non-heating appliances for the device connection cable.
2. Connect the robot controller to the mains via the mains connector.
3. Connect the robot controller to a grounded-neutral power supply system in accordance with (>>> *Fig. 7-2*) .
   - Green/yellow (GNYE) to the PE of the power supply system
   - Light blue (BU) to the neutral conductor of the power supply system
   - Black (BK) to the live cable of the power supply system

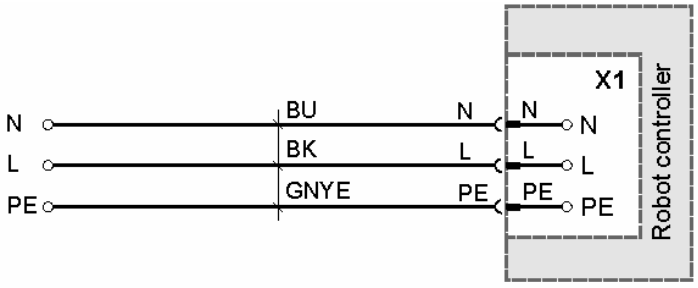


Fig. 7-2: Power supply connection

7.9 Switching on the robot controller

Preconditions

- The robot has been installed in accordance with the Instructions for Use.
- All electrical connections are correct and the energy levels are within the specified limits.
- The housing of the robot controller must be closed.
- The peripheral devices are correctly connected.
- It must be ensured that no persons or objects are present within the danger zone of the robot.
- All safety devices and protective measures are complete and fully functional.

- The internal temperature of the robot controller must have adapted to the ambient temperature.

Procedure

1. Release the EMERGENCY STOP device on the smartPAD.
2. Switch on the main switch.
   The control PC begins to run up (load) the operating system and the control software.

Information about operator control of the robot using the smartPAD can be found in the operating and programming instructions for system integrators.

8 Operation

8.1 KUKA smartPAD teach pendant

Description

The smartPAD is the teach pendant for the robot. The smartPAD has all the operator control and display functions required for operating and programming the robot.

2 models exist:

- **smartPAD**
- **smartPAD-2**

In this documentation, the designation “KUKA smartPAD” or “smartPAD” refers to both models unless an explicit distinction is made.

The USB interfaces can be used for integrating the controller into the medical product. The medical product manufacturer must ensure that the functionality of the medical product cannot be adversely affected, e.g. by a test for malware or by restriction of the USB devices that may be connected.

Use

In accordance with the intended use, the smartPAD may only be used for start-up and recommissioning (e.g. after maintenance), for maintenance and for troubleshooting by the system integrator or medical product manufacturer.

The smartPAD is not intended for operation of the medical product by the end user (e.g. medical personnel).

Misuse

Any use or application deviating from the intended use is deemed to be misuse and is not allowed. It will result in the loss of warranty and liability claims. KUKA is not liable for any damage resulting from such misuse.

8.1.1 smartPAD

8.1.1.1 Front view

The smartPAD has a touch screen: the smartHMI can be operated with a finger or stylus. An external mouse or external keyboard is not necessary.

Overview

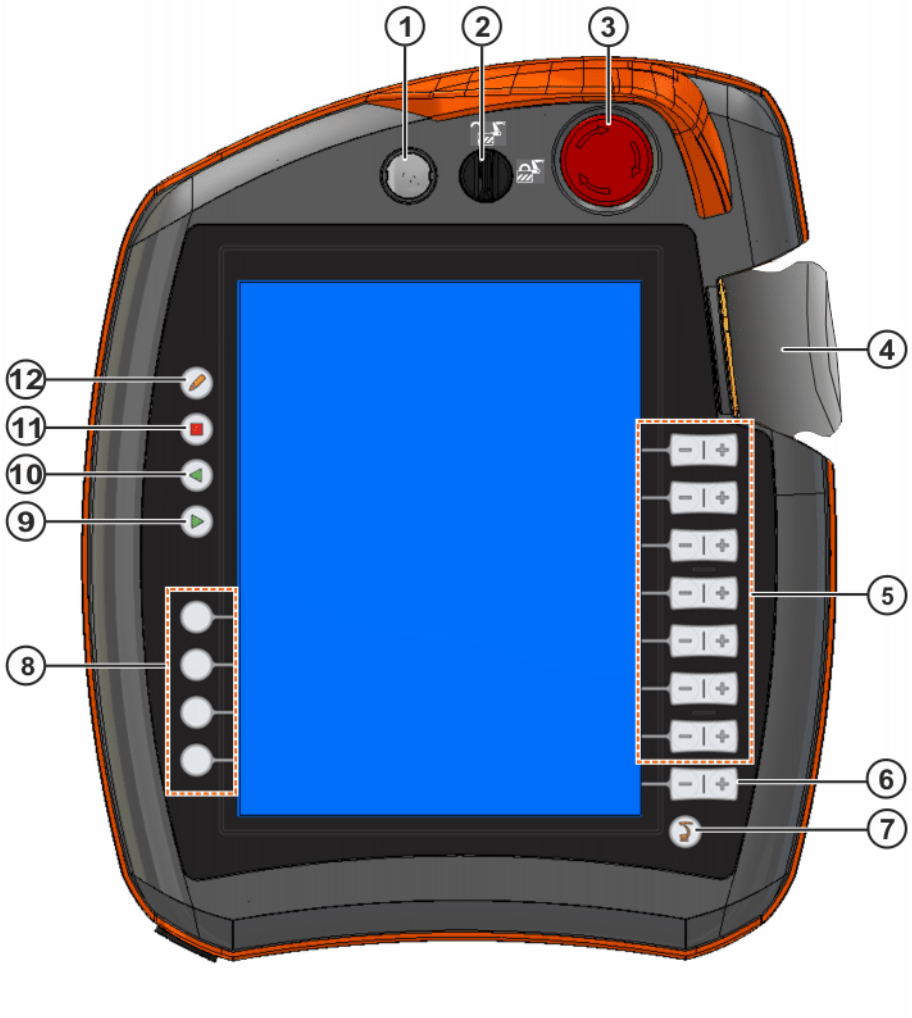


Fig. 8-1: Front of smartPAD

Item	Description
1	Button for disconnecting the smartPAD
2	Keyswitch The connection manager is called by means of the keyswitch. The switch can only be turned if the key is inserted. The connection manager is used to change the operating mode.
3	EMERGENCY STOP device The robot can be stopped in hazardous situations using the EMERGENCY STOP device. The EMERGENCY STOP device locks itself in place when it is pressed.
4	Space Mouse No function
5	Jog keys The jog keys can be used to move the robot manually.
6	Key for setting the override

Item	Description
7	Main menu key The main menu key shows and hides the main menu on the smartHMI.
8	User keys The function of the user keys is freely programmable. Possible uses of the user keys include controlling peripheral devices or triggering application-specific actions.
9	Start key The Start key is used to start a program. The Start key is also used to manually address frames and to move the robot back onto the path.
10	Start backwards key No function
11	STOP key The STOP key is used to stop a program that is running.
12	Keyboard key No function

The following applies to the jog keys, the user keys and the Start, Start backwards and STOP keys:

- The current function is displayed next to the key on the smartHMI.
- If there is no display, the key is currently without function.

8.1.1.2 Rear view

Overview

Fig. 8-2: Rear of smartPAD

1	Enabling switch	4	USB connection
2	Start key (green)	5	Enabling switch
3	Enabling switch	6	Identification plate

Description

Element	Description
Identification plate	Identification plate
Start key	The Start key is used to start a program. The Start key is also used to manually address frames and to move the robot back onto the path.

Element	Description
Enabling switch	The enabling switch has 3 positions: • Not pressed • Center position • Fully pressed (panic position) The enabling switch must be held in the center position in operating modes T1, T2 and CRR in order to be able to jog the robot. As standard, the enabling switch has no function in Automatic mode.
USB connection	The USB connection is used for archiving data, for example. Only for FAT32-formatted USB sticks.

8.1.2 smartPAD-2

KUKA smartPAD-2

Further information about the smartPAD-2 is contained in the operating instructions of the smartPAD-2.

6D mouse on the smartPAD-2 has no function.

The firmware update for operation with the smartPAD-2 may only be carried out by KUKA Service.
This update is only possible from KUKA Sunrise.OS Med 1.15.3 onwards.

8.1.3 Disconnecting and connecting the smartPAD

Description

The information is applicable for both the smartPAD and the smartPAD-2.

WARNING

Risk of fatal injury due to non-operational EMERGENCY STOP device
If the smartPAD is disconnected, the system can no longer be switched off by means of the EMERGENCY STOP device on the smartPAD. Measures must be taken to prevent operational and non-operational EMERGENCY STOP devices from being mixed up.
Death, injuries or damage to property may result.

- Connect an external EMERGENCY STOP to the robot controller.
- Remove the disconnected smartPAD from the system immediately.

From KUKA Sunrise.OS Med 1.15.3 onwards, the “smartPAD” and “smartPAD-2” models are compatible with one another, i.e. if one model has been disconnected, the other model can then be plugged in.

Procedure

Disconnection:

The smartPAD can also be disconnected while the robot controller is running.

1. Press the disconnect button on the smartPAD.

   A message and a counter are displayed on the smartHMI. The counter runs for 25 s. During this time, the smartPAD can be disconnected from the robot controller.

   If the counter expires without the smartPAD having been disconnected, this has no effect. The disconnect button can be pressed again at any time to display the counter again.
2. Disconnect the smartPAD from the robot controller.

If the smartPAD is disconnected without the counter running, this triggers an EMERGENCY STOP. The EMERGENCY STOP can only be canceled by plugging the smartPAD back in.

Connection:

A smartPAD can be connected at any time.

1. Connect the smartPAD to the robot controller.
   - The EMERGENCY STOP and enabling switches are operational again 30 s after connection.
   - The smartHMI is automatically displayed again. (This may take longer than 30 s.)
   - The connected smartPAD assumes the current operating mode of the robot controller.
2. Check the functions. The following checks must be performed:
   - Function test of EMERGENCY STOP
   - Function test for the enabling switches
   - Check whether the smartHMI is displayed again. (This may take longer than 30 s.)

WARNING

Risk of fatal injury due to non-operational EMERGENCY STOP device

If a non-operational smartPAD remains connected, there is the danger that the user will attempt to activate a non-operational EMERGENCY STOP. Death, injuries or damage to property may result.

- Disconnect a non-operational smartPAD and remove it from the system immediately.

9 Maintenance

Description

Maintenance work must be performed at the specified maintenance intervals after commissioning at the customer's plant.

Maintenance symbols

Tighten screw/nut

Check component, visual inspection

Clean component

Exchange battery

Precondition

- The robot controller must be switched off and secured to prevent unauthorized persons from switching it on again.
- Power supply lead disconnected.

NOTICE

Damage to or destruction of components due to electrostatic discharge (ESD)
Electrostatic discharge during installation or removal work can result in destruction or partial damage to electronic components.

- Observe the ESD guidelines.

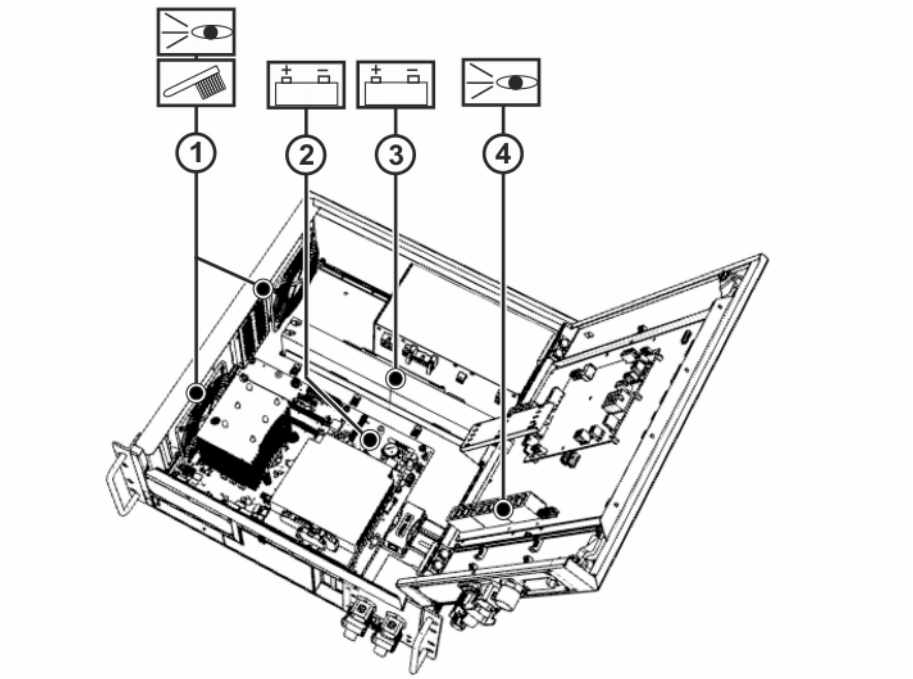


Fig. 9-1: Maintenance points

Interval	Item	Activity
Test of the safety functions:		
1 year	4	Check the utilized relay outputs of the CCU_SR for correct functioning. (>>> *9.1 "Checking CCU_SR relay outputs" Page 86*)
General maintenance work:		
1 year at the latest	1	Depending on installation conditions and degree of fouling, clean the protective grille and fan with a brush.
5 years	2	Exchange the motherboard battery. (>>> *10.3 "Exchanging the motherboard battery" Page 90*)
5 years (with 3-shift operation)	1	Exchange the fan. (>>> *10.6 "Exchanging the fans" Page 94*)
According to display of battery monitoring; 2 years at the latest	3	Exchange the batteries. (>>> *10.5 "Exchanging the batteries" Page 92*)

Once an activity from the maintenance list has been carried out, a visual inspection must be made, with special attention to the following points:

- Check that fuses, contactors, plug-in connections and boards are fitted securely.
- Check cabling for damage.
- Check PE equipotential bonding connection.
- Check all system components for wear and damage.

9.1 Checking CCU_SR relay outputs

Activity

Check the function of output 12 (default: “Local E-STOP”).

Procedure

- Actuate the configured function of output 12 (default: Press the local EMERGENCY STOP device).

Activity

Check the function of output 13 (default: “Test mode”).

Procedure

- Actuate the configured function of output 13 (default: Actuate Test mode).

Activity

Check the function of output 14 (default: “Automatic mode”).

Procedure

- Actuate the configured function of output 14 (default: Actuate Automatic mode).

If no error message is displayed, the relay outputs are OK.

9.2 Cleaning the robot controller

Precondition

- The robot controller must be switched off and secured to prevent unauthorized persons from switching it on again.
- The power cable is deenergized.

Work safety

WARNING

Risk of fatal injury from mains voltage
Cables routed from power supply connection X1 to the main switch are energized even when the main switch is switched off. Death, severe injuries or damage to property may result.

- Before starting work, deenergize the incoming power cable.
- Before starting work, ensure that the system is deenergized.

NOTICE

Damage to or destruction of components due to electrostatic discharge (ESD)
Electrostatic discharge during installation or removal work can result in destruction or partial damage to electronic components.

- Observe the ESD guidelines.

Work regulations

- The manufacturer's instructions must be observed when using cleaning agents for cleaning work.
- It must be ensured that no cleaning agents enter electrical components.
- Do not use compressed air during cleaning work.
- Do not spray with water.

Procedure

1. Loosen and vacuum up any dust deposits.
2. Clean the housing of the robot controller with a cloth soaked with a mild cleaning agent.
3. Clean cables, plastic parts and hoses with a solvent-free cleaning agent.
4. Replace damaged, illegible or missing identifications, labels and plates.

10 Repair

10.1 Repair and procurement of spare parts

Repair

Repairs to the robot controller may only be carried out by KUKA Customer Support personnel or by customers who have taken part in a relevant course of training.

Repairs within modules may only be carried out by specially trained KUKA Customer Support personnel.

Procurement of spare parts

The article numbers of the spare parts are listed in the spare parts catalog. Only spare parts from the spare parts catalog may be used.

KUKA Customer Support supplies the following types of spare parts for repairs to the robot controller:

- New parts

  Once the new part has been installed, the part that has been removed can be disposed of.
- Exchange parts

  Once the exchange part has been installed, the part that has been removed is returned to KUKA Customer Support.

NOTICE

If the robot controller is not operated with OEM replacement parts, this may cause damage, premature wear and failure of modules.
For safety reasons, the robot controller may only be equipped and operated with genuine OEM replacement parts.

A “Robot Repair Card” is supplied with the exchange parts. The Repair Card must be completed and returned to KUKA Customer Support.

10.2 Opening the housing cover

Precondition

- The robot controller must be switched off and secured to prevent unauthorized persons from switching it on again.
- Power supply lead disconnected.

Work safety

WARNING

Risk of fatal injury from voltage
The device switch on the robot controller does not have a grid isolation function. Failure to take this into consideration may result in severe injuries or even death.

- Before undertaking work on the robot controller, the power cable on the robot controller must be disconnected.
- Store the disconnected power cable out of sight and reach of personnel working on the robot controller.
- Use a sign to inform the individuals involved that the robot controller is switched off (e.g. by affixing a warning sign).

NOTICE

Damage to or destruction of components due to electrostatic discharge (ESD)
Electrostatic discharge during installation or removal work can result in destruction or partial damage to electronic components.

- Observe the ESD guidelines.

Procedure

1. Unscrew the housing cover screws.
2. Open the housing cover.

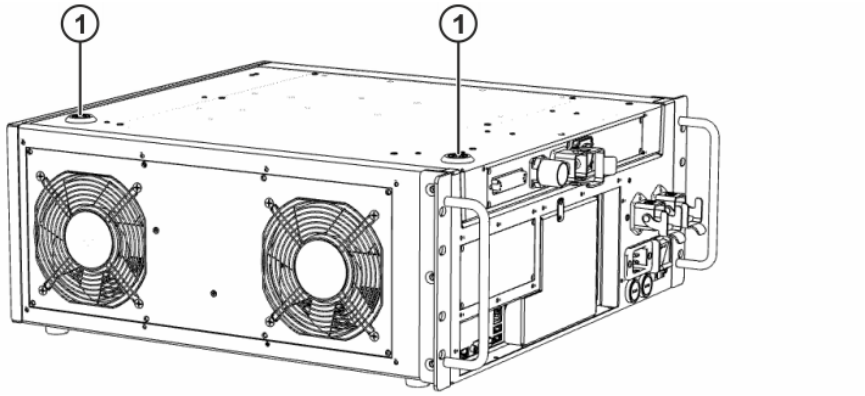


Fig. 10-1: Housing cover screws

1 Housing cover screws

10.3 Exchanging the motherboard battery

Precondition

- The robot controller must be switched off and secured to prevent unauthorized persons from switching it on again.
- Power supply lead disconnected.

Work safety

WARNING

Risk of fatal injury from voltage
The device switch on the robot controller does not have a grid isolation function. Failure to take this into consideration may result in severe injuries or even death.

- Before undertaking work on the robot controller, the power cable on the robot controller must be disconnected.
- Store the disconnected power cable out of sight and reach of personnel working on the robot controller.
- Use a sign to inform the individuals involved that the robot controller is switched off (e.g. by affixing a warning sign).

NOTICE

Damage to or destruction of components due to electrostatic discharge (ESD)
Electrostatic discharge during installation or removal work can result in destruction or partial damage to electronic components.

- Observe the ESD guidelines.

Procedure

1. Open the housing cover.
2. Unlock the locking mechanism of the lithium button cell and remove the button cell.

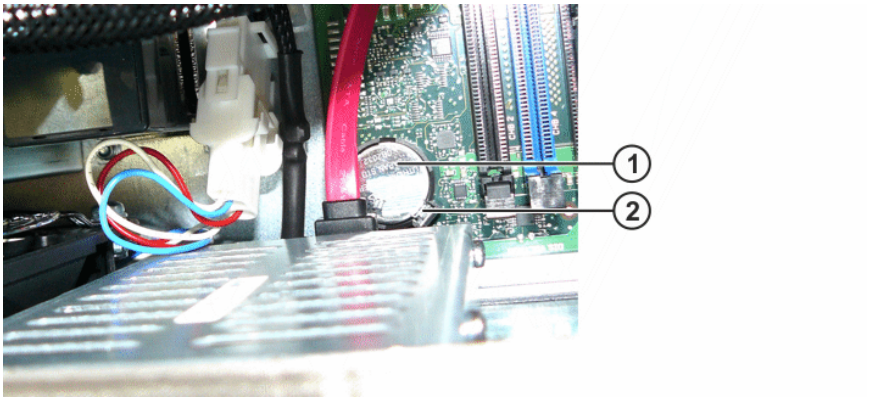


Fig. 10-2: Lithium button cell

1 Battery
2 Retaining spring and battery holder

3. Insert the new lithium button cell and click the locking mechanism into place.
4. Close the housing cover.

10.4 Exchanging the hard drive

Precondition

- The robot controller must be switched off and secured to prevent unauthorized persons from switching it on again.
- Power supply lead disconnected.

Work safety

WARNING

Risk of fatal injury from voltage
The device switch on the robot controller does not have a grid isolation function. Failure to take this into consideration may result in severe injuries or even death.

- Before undertaking work on the robot controller, the power cable on the robot controller must be disconnected.
- Store the disconnected power cable out of sight and reach of personnel working on the robot controller.
- Use a sign to inform the individuals involved that the robot controller is switched off (e.g. by affixing a warning sign).

NOTICE

Damage to or destruction of components due to electrostatic discharge (ESD)
Electrostatic discharge during installation or removal work can result in destruction or partial damage to electronic components.

- Observe the ESD guidelines.

Procedure

1. Open the housing cover.
2. Unplug the hard drive connections (power supply and data cable).

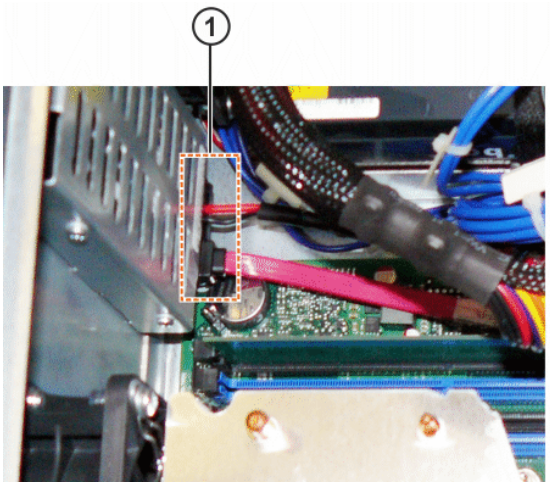


Fig. 10-3: Connections

1 Hard drive connections

3. Remove the hard drive retaining screws.

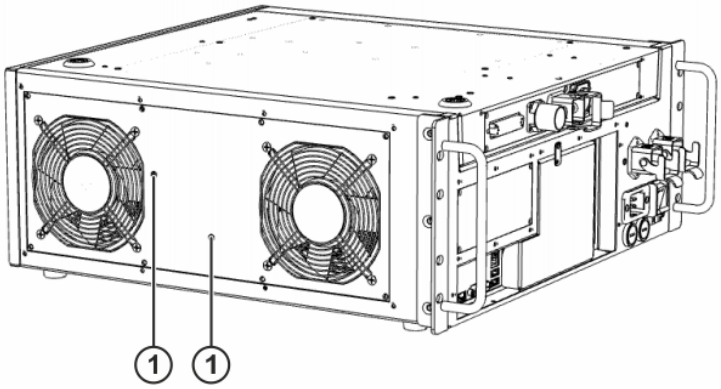


Fig. 10-4: Hard drive fastening

1 Hard drive fastening

4. Remove the hard drive.
5. Plug the connections to the new hard drive.
6. Fasten the new hard drive to the housing.
7. Close the housing cover.

10.5 Exchanging the batteries

Precondition

- The robot controller must be switched off and secured to prevent unauthorized persons from switching it on again.
- Power supply lead disconnected.

Work safety

WARNING

Risk of fatal injury from voltage
The device switch on the robot controller does not have a grid isolation function. Failure to take this into consideration may result in severe injuries or even death.

- Before undertaking work on the robot controller, the power cable on the robot controller must be disconnected.
- Store the disconnected power cable out of sight and reach of personnel working on the robot controller.
- Use a sign to inform the individuals involved that the robot controller is switched off (e.g. by affixing a warning sign).

NOTICE

Damage to or destruction of components due to electrostatic discharge (ESD)
Electrostatic discharge during installation or removal work can result in destruction or partial damage to electronic components.

- Observe the ESD guidelines.

Procedure

1. Open the housing cover.
2. Unfasten the Velcro strips.
3. Unplug the battery connection cables.

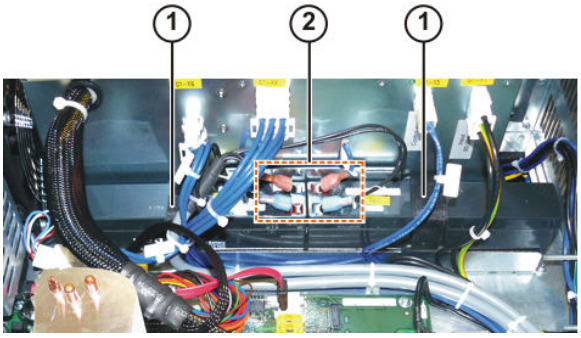


Fig. 10-5: Fastening and connections of the battery blocks

1 Velcro strip for battery fastening
2 Battery connection cables

4. Take out both battery blocks.

The battery blocks must both be exchanged together.

5. Insert new battery blocks.
6. Fasten the Velcro strips.
7. Plug in the battery connection cables in accordance with the cable labels.

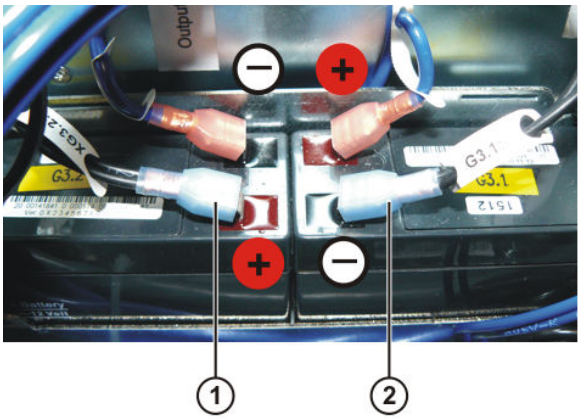


Fig. 10-6: Battery polarity

1 Connection G3.2
2 Connection G3.1

8. Close the housing cover.

Storage

NOTICE

Destruction of the batteries due to exhaustive discharge
To prevent exhaustive discharge and thus destruction of the batteries, the batteries must be recharged at regular intervals according to the storage temperature.

- If the storage temperature is +20 °C or lower, recharge the batteries every 9 months.
- If the storage temperature is between +20 °C and +30 °C, recharge the batteries every 6 months.
- If the storage temperature is between +30 °C and +40 °C, recharge the batteries every 3 months.

10.6 Exchanging the fans

Precondition

- The robot controller must be switched off and secured to prevent unauthorized persons from switching it on again.
- Power supply lead disconnected.

Work safety

WARNING

Risk of fatal injury from voltage
The device switch on the robot controller does not have a grid isolation function. Failure to take this into consideration may result in severe injuries or even death.

- Before undertaking work on the robot controller, the power cable on the robot controller must be disconnected.
- Store the disconnected power cable out of sight and reach of personnel working on the robot controller.
- Use a sign to inform the individuals involved that the robot controller is switched off (e.g. by affixing a warning sign).

NOTICE

Damage to or destruction of components due to electrostatic discharge (ESD)
Electrostatic discharge during installation or removal work can result in destruction or partial damage to electronic components.

- Observe the ESD guidelines.

Procedure

1. Open the housing cover.
2. Remove the fastening screws from the fan holder.

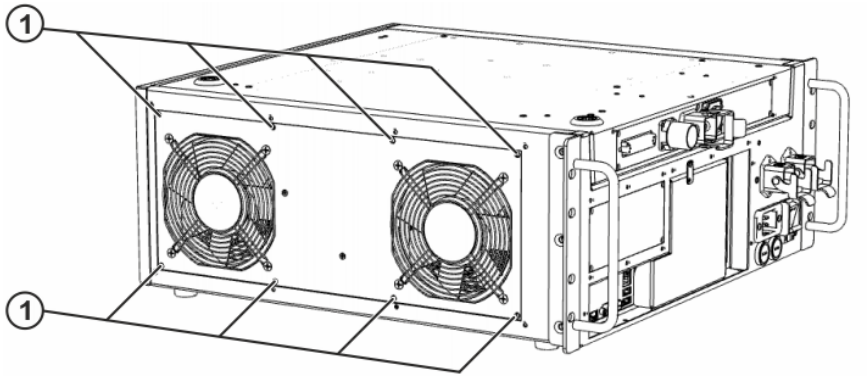


Fig. 10-7: Fan holder

1 Fastening screws of fan holder

3. Unplug the fan connections.

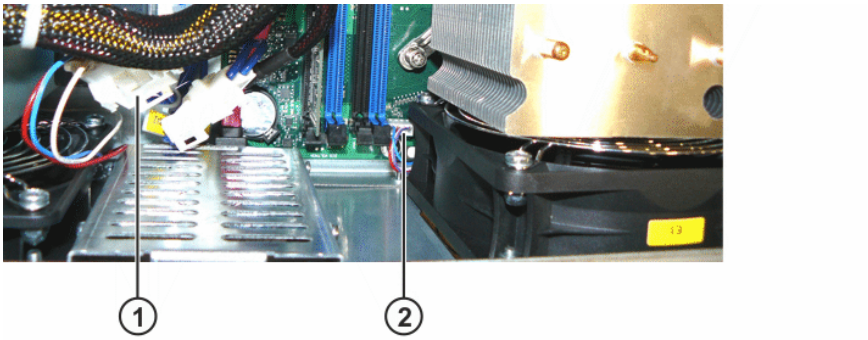


Fig. 10-8: Connections for fans

1 Connector for fan
2 Connector for motherboard CPU fan

4. Remove the fan holder with the fans.
5. Unscrew the inner and outer fan grilles and screw them to the new fans.
6. Install and fasten the new fans with the fan holder.
7. Plug in the connecting cables.

10.7 Installation of KUKA Sunrise.OS Med

Further information is contained in the operating and programming instructions for KUKA Sunrise.OS Med.

11 Troubleshooting

11.1 LED display on Cabinet Control Unit, Small Robot

Overview

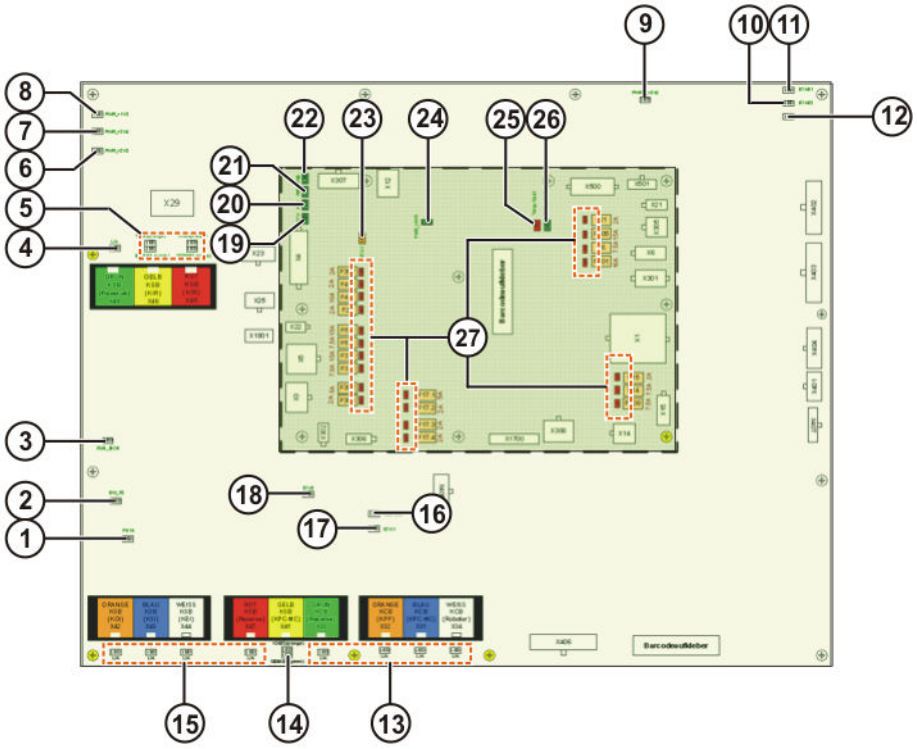


Fig. 11-1: CCU_SR LED display

Item	Designation	Color	Description	Remedy
1	PHY4	Green	Off = fault	Exchange CCU_SR module.
			On = OK	-
			Flashing = OK	-
2	SW_P0	Green	Off = fault	Exchange CCU_SR module.
			On = OK	-
			Flashing = OK	-
3	RUN SION EtherCat Safety nodes	Green	Off = Init (after switching on)	-
			On = operational (normal state)	-
			Flashing at 2.5 Hz = Pre-Op (intermediate state on startup)	-
			Single signal = Safe Op	-
			Flashing at 10 Hz = boot (for firmware update)	-

Item	Designation	Color	Description	Remedy
4	L/A KSB	Green	• Off = no physical connection. Network cable not plugged in • On = physical connection. Network cable plugged in • Flashing = data traffic on the line	-
5	L/A KSB KPC-MC	Green 100 Mbit Orange 1 Gbit		
6	PWR/3.3V Power for the CIB_SR	Green	Off = no supply voltage present	• Check fuse F17.3. • Jumper plug X308 present. • Check fuse F308. • With external supply via X308: check the external power supply (rated voltage 24 V).
			On = supply voltage present	-
7	PWR/2.5V Power for the CIB_SR	Green	Off = no supply voltage present	• Check fuse F17.3. • Jumper plug X308 present. • Check fuse F308. • With external supply via X308: check the external power supply (rated voltage 24 V).
			On = supply voltage present	-
8	PWR/1.2V Power for the CIB_SR	Green	Off = no supply voltage present	• Check fuse F17.3. • Jumper plug X308 present. • Check fuse F308. • With external supply via X308: check the external power supply (rated voltage 24 V).
			On = supply voltage present	-
9	PWRS/3.3V	Green	Off = no supply voltage present	• Check fuse F17.3. • If the LED PWR/3.3V lights up, exchange the CCU_SR module.
			On = power supply present	-

Item	Designation	Color	Description	Remedy
10	STAS2 Safety node B	Orange	Off = no supply voltage present	• Check fuse F17.3. • If the LED PWR/3.3V lights up, exchange the CCU_SR module.
			Flashing at 1 Hz = normal state	-
			Flashing at 10 Hz = boot phase	-
			Flashing = fault code (internal)	Check cabling at X309, X310, X312. For test purposes, disconnect the cables at X309, X310, X312 and switch the controller off and back on again. If the error recurs, exchange the module.
11	STAS1 Safety node A	Orange	Off = no supply voltage present	• Check fuse F17.3. • If the LED PWR/3.3V lights up, exchange the CCU_SR module.
			Flashing at 1 Hz = normal state	-
			Flashing at 10 Hz = boot phase	-
			Flashing = fault code (internal)	Check cabling at X309, X310, X312. For test purposes, disconnect the cables at X309, X310, X312 and switch the controller off and back on again. If the error recurs, exchange the module.
12	FSoE Safety protocol of the EtherCat connection	Green	Off = not active	-
			On = operational	-
			Flashing = fault code (internal)	-
13	L/A KCB	Green	• Off = no physical connection. Network cable not plugged in. • On = physical connection • Flashing = data traffic on the line	-
14	KSB smartPAD_MC	Green 100 Mbit		
		Orange 1 Gbit		
15	L/A KSB	Green		

Item	Designation	Color	Description	Remedy
16	RUN CIB_SR EtherCat ATμC I/O node	Green	Off = Init (after switching on)	-
			On = operational (normal state)	-
			Flashing at 2.5 Hz = Pre-Op (intermediate state on startup)	-
			Single signal = Safe Op	-
			10 Hz = boot (for firmware update)	-
17	STA1 (CIB_SR) μC I/O node	Orange	Off = no supply voltage present	• Check fuse F17.3. • If the LED PWR/3.3V lights up, exchange the CCU_SR module.
			Flashing at 1 Hz = normal state	-
			Flashing at 10 Hz = boot phase	-
			Flashing = fault code (internal)	Exchange CCU_SR module.
18	STA2 FPGA node	Orange	Off = no supply voltage present	• Check infeed at X1. • If the LED PWR/3.3V lights up, exchange the CCU_SR module.
			Flashing at 1 Hz = normal state	
			Flashing at 10 Hz = boot phase	
			Flashing = fault code (internal)	Exchange CCU_SR module.
19	27 V Voltage, main power supply unit, without battery back-up	Green	Off = no supply voltage present	Check infeed at X1 (rated voltage 27.1 V).
			On = power supply present	-
20	PS1 Voltage, Power Supply 1 (short battery backup)	Green	Off = no supply voltage present	• Check infeed at X1 (rated voltage 27.1 V). • Drive bus switched off (BusPowerOff state)
			On = power supply present	-
21	PS2 Voltage, Power Supply 2 (medium battery backup)	Green	Off = no supply voltage present	• Check infeed at X1. • Controller in Sleep state
			On = power supply present	-

Item	Designation	Color	Description	Remedy
22	PS3 Voltage, Power Supply 3 (long battery backup)	Green	Off = no supply voltage present	On = power supply present
			On = power supply present	-
23	STA1 (PMB_SR) µC USB	Orange	Off = no supply voltage present	• Check infeed at X1. • If the LED PWR/5V lights up, exchange the CCU_SR module.
			Flashing at 1 Hz = normal state	-
			Flashing at 10 Hz = boot phase	-
			Flashing = fault code (internal)	Exchange CCU_SR module.
24	PWR/5V Power supply for PMB_SR	Green	Off = no supply voltage present	Check infeed at X1 (rated voltage 27.1 V).
25	Temp Fault	Red	Off = no overtemperature at ballast resistor R1	-
			On = overtemperature at ballast resistor R1	• Check connector X501. • Check control box cooling. • Check temperature sensor (central position on ballast resistor R1 on the right-hand inner wall).
26	PWR_+12V5	Green	Off = brake chopper power supply not present	• Check connector X500. • Check connector on the low-voltage power supply unit.
			On = brake chopper power supply present	-
27	Fuse LEDs The LEDs indicate the status of the fuses.	Red	Off = fuse OK	-
			On = fuse defective	Exchange defective fuse.

11.2 Fuses on the Cabinet Control Unit, Small Robot

Overview

A defective fuse is indicated by a red LED next to the fuse. Once the cause of the fault has been eliminated, defective fuses must be replaced with fuses with the value specified in the Instructions for Use or printed on the module.

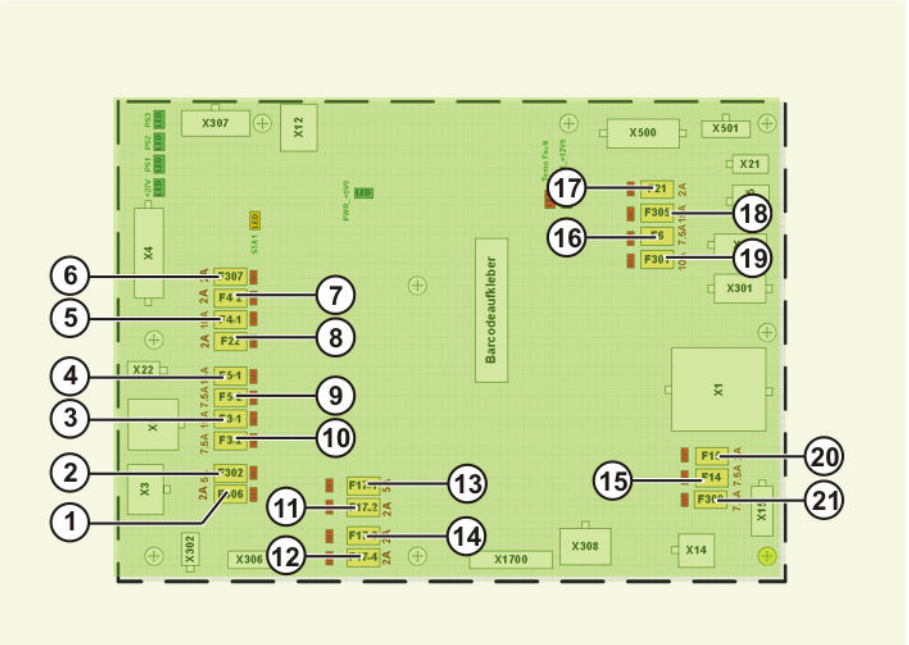


Fig. 11-2: Arrangement of the fuses

The fuse ratings printed on the board must be observed.

Item	Designation	Description	Fusing
1	F306	smartPAD power supply	32 V/2 A
2	F302	Not used	32 V/5 A
3	F3-1	Not used	32 V/15 A
4	F5-1	Not used	32 V/15 A
5	F4-1	KPC with battery backup	32 V/10 A
6	F307	Not used	32 V/2 A
7	F4-2	Not used	32 V/2 A
8	F22	Not used	32 V/7.5 A
9	F5-2	Not used	32 V/7.5 A
10	F3-2	Not used	32 V/7.5 A
11	F17-2	Inputs CCU_SR	32 V/2 A
12	F17-4	Safe inputs and relays CCU_SR	32 V/2 A
13	F17-1	Contactor outputs 1 … 4 CCU_SR	32 V/5 A
14	F17-3	Logic CCU_SR	32 V/2 A
15	F14	Not used	32 V/7.5 A
16	F6	24 V without battery backup (optional)	32 V/7.5 A
17	F21	PDS power supply	32 V/3 A
18	F305	Battery infeed	32 V/15 A
19	F301	Without battery backup, spare	32 V/10 A
20	F15	Power supply unit fan	32 V/2 A
21	F308	External power supply	32 V/7.5 A

11.3 Power supply connection fuses

Overview

Once the cause of the fault has been eliminated, defective fuses must be replaced with fuses with the value specified or printed on the module.

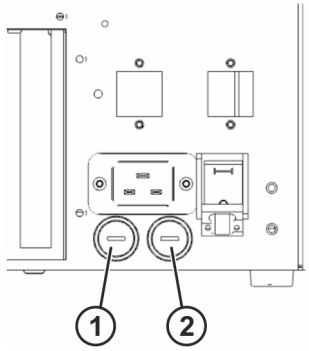


Fig. 11-3: Fuses

Item	Designation	Description	Fusing
1	F1	Power supply connection fuse	10 A slow-blowing / 250 V AC
2	F2	Power supply connection fuse	10 A slow-blowing / 250 V AC

11.4 Fuse, DC/DC converter

Overview

Once the cause of the fault has been eliminated, defective fuses must be replaced with fuses with the value specified or printed on the module.

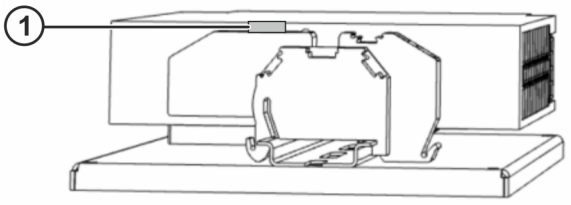


Fig. 11-4: Fuses

Item	Designation	Description	Fusing
1	F21.1	Secondary-side fuse, DC/DC converter	3 A / 32 V DC

11.5 Low-voltage power supply unit fuses

Overview

A defective fuse is indicated by a red LED under the fuse. Once the cause of the fault has been eliminated, defective fuses must be replaced with fuses with the value specified or printed on the module.

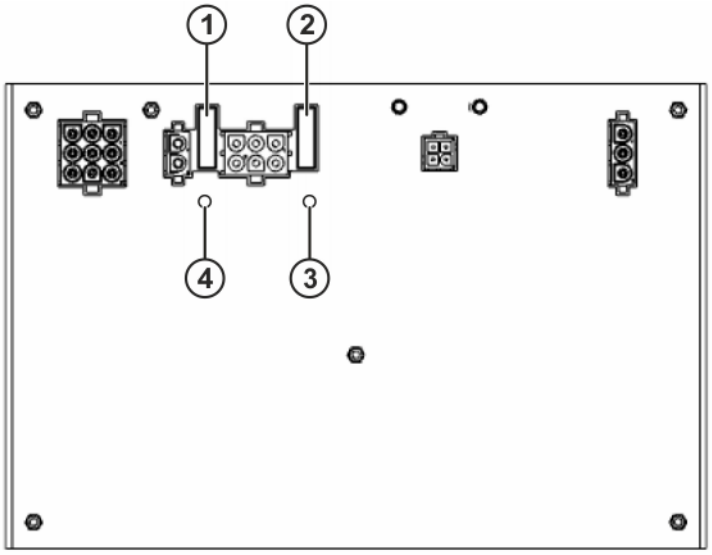


Fig. 11-5: Fuses

Item	Designation	Description	Fusing
1	F1	-	5 A / 80 V
2	F2	-	7.5 A / 80 V
3	LED F2	Status indicator (red) for fuse F2 • Off: fuse OK • On: fuse defective	-
4	LED F1	Status indicator (red) for fuse F1 • Off: fuse OK • On: fuse defective	-

12 Decommissioning, storage and disposal

12.1 Decommissioning

Description

This section describes all the work required for decommissioning the robot controller if the robot controller is to be removed from the system. After decommissioning, it is prepared for storage or for transportation to a different location.

Procedure

1. Release and unplug all peripheral connections.
2. Release and unplug the motor cable and control cable connectors.
3. Unscrew the ground conductor.
4. Prepare the robot controller for storage.

12.2 Storage

Precondition

If the robot controller is to be put into long-term storage, the following points must be observed:

- The storage location must be as dry and dust-free as possible.
- Avoid temperature fluctuations.
- Avoid wind and drafts.
- Avoid condensation.
- Observe and comply with the permissible temperature ranges for storage.
- Select a storage location in which the packaging materials cannot be damaged.
- Only store the robot controller indoors.

Procedure

1. Clean the robot controller. No dirt may remain on or in the robot controller.
2. Inspect the robot controller, both internally and externally, for damage.
3. Remove batteries and store in accordance with the manufacturer's instructions.
4. Remove any foreign bodies.
5. Remove any corrosion expertly.
6. Attach all covers to the robot controller and check that the seals are correctly in place.
7. Seal off electrical connections with suitable covers.
8. Cover the robot controller with plastic sheeting and seal it against dust.

   Provide an additional desiccant inside the sheeting if necessary.

12.3 Disposal

When the robot controller reaches the end of its useful life, it can be dismantled, and the materials can be disposed of properly by type.

The following table provides an overview of the materials used in the robot controller. Some of the plastic components are marked with a material designation and must be disposed of accordingly.

As the end user, the customer is legally required to return depleted batteries. Used batteries can be returned to the vendor or brought to the designated collection points (e.g. in communal refuse collection facilities or commercial centers) free of charge. The batteries can also be sent to the vendor by post.
The following symbols can be found on the batteries:

- Crossed-out garbage can: battery must not be disposed of with ordinary household refuse.

- Pb: battery contains more than 0.004 lead by weight.
- Cd: battery contains more than 0.002 cadmium by weight.
- Hg: battery contains more than 0.0005 mercury by weight.

Material	Subassembly, component	Additional information
Metals		
CuZn (gold-plated)	Connectors, contacts	Dispose of without dismantling
Copper	Cables, wires	
Steel (ST 52-3)	Allen screws, washers	
Steel-plate components	Screws and washers, robot controller housing	
Electrical parts		
	Bus modules, boards, sensors	Dispose of as electrical scrap without disassembling
	Electronics	
	Fans	
Lithium battery	Backup batteries	Must be disposed of as hazardous waste.
Lead battery		
Plastics		
EPDM	Seals, covers	
PE	Cable straps	
PUR	Cable sheaths	
	Flexible tube	
	Adhesive labels	

13 Appendix

13.1 Applied standards and directives

Name/Edition	Definition
2006/42/EC:2006	**Machinery Directive:** Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast)
2014/30/EU:2014	**EMC Directive:** Directive 2014/30/EC of the European Parliament and of the Council dated 26 February 2014 on the approximation of the laws of the Member States concerning electromagnetic compatibility
ANSI/RIA R15.06-2012	**Industrial Robots and Robot System**
CAN/CSA C22.2 No. 301-16	**Industrial electrical machinery**
CAN/CSA-C22.2 No. 61010-1:2012 + A1:2018	**Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use** Part 1: General requirements
CAN/CSA-C22.2 No. 61010-2-201:2018	**Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use** Part 2-201: Particular Requirements for Control Equipment
CAN/CSA-Z434-14	**Industrial Robots and Robot Systems:** General Safety Requirements
EN 614-1:2006+A1:2009	**Safety of machinery:** Ergonomic design principles - Part 1: Terms and general principles
EN 60204-1:2018	**Safety of machinery:** Electrical equipment of machines – Part 1: General requirements
EN 61000-6-2:2005	**Electromagnetic compatibility (EMC):** Part 6-2: Generic standards; Immunity for industrial environments
EN 61000-6-4:2007 + A1:2011	**Electromagnetic compatibility (EMC):** Part 6-4: Generic standards; Emission standard for industrial environments
EN 61010-1:2010 + A1:2019	**Safety requirements for electrical equipment for measurement, control and laboratory use** Part 1: General requirements
EN 62061:2005 + A1:2013 + A2:2015	**Safety of machinery:** Functional safety of safety-related electrical, electronic and programmable electronic control systems

EN IEC 61010-2-201:2018	**Safety requirements for electrical equipment for measurement, control and laboratory use** Part 2-201: Particular requirements for control equipment
EN ISO 10218-1:2011	**Industrial robots – Safety requirements:** Part 1: Robots
EN ISO 12100:2010	**Safety of machinery:** General principles of design, risk assessment and risk reduction
EN ISO 13849-1:2015	**Safety of machinery:** Safety-related parts of control systems - Part 1: General principles of design
EN ISO 13849-2:2012	**Safety of machinery:** Safety-related parts of control systems - Part 2: Validation
EN ISO 13850:2015	**Safety of machinery:** Emergency stop - Principles for design
EN ISO 14971:2012	**Medical devices** Application of risk management to medical devices
EN ISO 14971:2019	**Medical devices** Application of risk management to medical devices
IEC 60601-1:2005 + A1:2012	**Medical electrical equipment** Part 1: General requirements for basic safety and essential performance
IEC 62304:2006 + AMD1:2015	**Medical device software** Software life cycle processes
NFPA 79:2018	**Electrical Standard for Industrial Machinery**
UL 1740:2018	Robots and Robotic Equipment
UL 61010-1:2018	**Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use** Part 1: General Requirements
UL 61010-2-201:2018	**Safety requirements for electrical equipment for measurement, control, and laboratory use** Part 2-201: Particular requirements for control equipment

14 KUKA Service

14.1 Requesting support

Introduction

This documentation provides information on operation and operator control, and provides assistance with troubleshooting. For further assistance, please contact your local KUKA subsidiary.

Information

The following information is required for processing a support request:

- Description of the problem, including information about the duration and frequency of the fault
- The greatest possible amount of information about the hardware and software components of the overall system

  The following list gives an indication of the information which is relevant in many cases:

  – Model and serial number of the kinematic system, e.g. the manipulator
  – Model and serial number of the controller
  – Model and serial number of the energy supply system
  – Designation and version of the system software
  – Designations and versions of other software components or modifications
  – System Software diagnosis package

    Additionally for KUKA Sunrise: Existing projects including applications

    For versions of KUKA System Software older than V8: Archive of the software (Diagnosis package is not yet available here.)
  – Application used
  – External axes used

14.2 KUKA Customer Support

The contact details of the local subsidiaries can be found at:
www.kuka.com/customer-service-contacts

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