
Dräger
Dräger. Technology for Life®

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EN

1. General notes

This manual provides you with an overview of the necessary steps for commissioning and operating the computer system. Please read them even if you are familiar with the operation of computer systems.

The term "device" is used below to refer to the OR-PC® 21 or OR-PC® 24 manufactured by ACL GmbH for Dräger.

2. Classification and intended use

The device is designed for documentation purposes of data, such as patient-related information inside and outside operating rooms, intensive care units and similar areas of use. It supports the local software environment and can be part of the IT data network.

Based on IEC 60601-1:2020, Section 6, the following classification results:
6.2 Protection class I device
6.3 IP20
6.4 The device is not intended for sterilization.
6.5 Operation in an oxygen-enriched environment is not intended.
6.6 The device is suitable for continuous operation.

When connecting devices, it is not permitted to touch the patient and the contacts of connectors of the signal input or output parts at the same time.

The device is
- a professional ME device as defined in IEC 60601-1-2:2014, para. 3.23,
- suitable for use within the patient environment,
- not suitable for use with direct contact to the patient,
- not intended for operation or maintenance by the patient,
- not approved for use in private households,
- not equipped with fireproof enclosure features according to IEC 60601-1:2020, para. 11.2,
- not explosion-proof, and
- may only be started up, operated or serviced by qualified personnel familiar with the equipment and this manual.

No information is required on actions to avert dangerous conditions or situations for humans, animals or the environment.

The connection of third-party devices is permitted under consideration of the restrictions, explanations and case examples cited in Section 3.1.

3. Installation and commissioning

The device was thoroughly cleaned before leaving the factory. However, due to the transport conditions and the transport packaging, neither a sterile nor a disinfected product can be assumed upon delivery. For the initial cleaning, please observe the instructions provided in Section 5.1.

First check the device and accessories for completeness by comparing with the enclosed delivery bill.

The device may only be operated in an upright position; operation with an inclination of more than 30° from the normal in one direction is not permitted. Operation in inadmissible positions (upside down on its head, lying on its back or on its display) is not permitted and may result in damage to the device.

Only use the screws supplied. Always use all fastening points for safe mounting of the device.

Adequate ventilation is necessary for reliable and continuous operation of the device. Ventilation protects the device from overheating. Therefore, do not install the device in a location or under conditions where adequate ventilation of the housing surfaces is not possible. To avoid heat accumulation or interruption of air circulation and to protect the device mounting from possible overloads, it is not permitted to place objects or materials on the device or to hang them on the device.

To avoid the risk of injury and damage to the device, all connection cables should be routed so that no one can step on them, trip over them, or place heavy objects on them. When mounting, ensure a fixed position and/or stable suspension.

3.1 Cable and device connection

Use only the supplied connection cables.

First connect the potential equalization cable (special green-yellow marking) to ensure sufficient potential equalization between user and device. Operation in the medical field without connected potential equalization is not permitted.

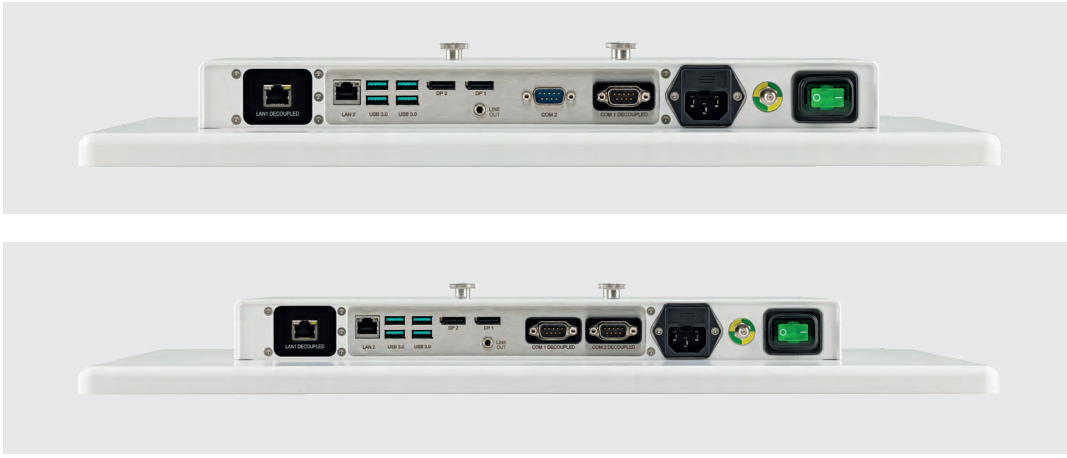
Before connecting to a supply network, check the correct voltage and frequency of your power supply network (see nameplate on the housing). Carefully connect all desired connection cables (power cable, keyboard, mouse, serial cable, network, etc.) to the device. To avoid the risk of electric shock, this device must only be connected to a supply network with a protective earth conductor. Finally, check the tight fit of all cable connections. It is not necessary for the end customer to attach strain reliefs to the device.

For complete disconnection from the mains, the system mains switch must be actuated or the mains plug must be pulled out of the socket. When disconnecting from the mains, always grasp the mains cable by the plug. Do not pull on the cable. Do not place the device in conditions that make it difficult to disconnect it from the mains power supply.

When establishing an electrical connection with other devices and when operating the device on a portable multiple socket outlet, ensure compliance with IEC 60601-1 in the currently valid version. To maintain conformity with the standard, so-called "decoupled interfaces" are provided for this case for the RJ-45 port (LAN1) and, depending on the configuration, one or both RS232 ports. Data can be transmitted via these galvanic isolators without a direct electrical connection. From an electrical point of view, the connection of medical devices is permitted at these decoupled interfaces.

At the same time, a functional unit is created when exchanging data with other devices. This applies in particular if this functional unit has a medical purpose (e.g. control of infusion pumps by the device, connection of application parts). The validity of any assured standard conformities and properties of the device would not extend to the new functional unit. Instead, the person placing the new functional unit on the market is responsible for its conformity to applicable regulations and standards.

Should the device be brought into contact with other devices, unforeseen interactions or even malfunctions may occur on one or both devices.



Illustrations: Connection panels on the underside of the device for different product versions

3.2 Device environment, safety and handling instructions

Please observe the safety instructions compiled below to avoid fire, electric shocks, injuries and damage to the device.

Protect the unit from
- exposure to strong infrared radiation, such as direct sunlight,
- strong magnetic fields, such as those occurring in the immediate vicinity of an MRI,
- the impact of strong electromagnetic radiation,
- exposure to strong ionizing radiation, such as occurs at the C-arm of an X-ray machine,
- as well as from strong shocks and vibrations over longer periods of time.

The device may only be operated under the following environmental conditions:

	Operation	**Storage**
Temperature	0 to 35 °C 32 to 104 °F	-10 to 60 °C 14 to 140 °F
Humidity	10 to 90% non-condensing	5 to 70% non-condensing
Height	0 to 3.048 m 0 to 10,000 ft	0 to 12.192 m 0 to 40,000 ft
Pressure	105 to 70 kPa	105 to 19 kPa

Store the device for three hours at its new operating location before commissioning if the temperature difference during transport is more than 10 °C. Rapid temperature changes can cause damage to the device, e.g. due to condensation.

Avoid displaying the same screen content for an extended period of time. Otherwise, TFT displays may show afterimages at least temporarily (image sticking effect).

3.3 Electromagnetic compatibility (EMC)

The use of cables and accessories other than those supplied may adversely affect EMC. Under certain circumstances, this may mean that compliance with the limit values assured at the time of delivery can no longer be assumed.

Output lines intended for direct connection to lines in the outdoor area are not covered within the scope of the warranted EMC properties of the device. Additional tests may be necessary for this purpose.

Stacking devices and mounting them in close proximity to other electrical devices may cause interference and malfunction of both devices. Ensure sufficient distance or appropriate shielding between the devices.

The device is intended for operation in an electromagnetic environment with controlled RF disturbances. Electromagnetic interference can be avoided by observing the distances to mobile HF telecommunication devices (transmitters) specified below to prevent performance degradations. These minimum distances depend on the output power of the communication device but must not be closer than 30cm between portable HF telecommunication devices and any point of the unit or its cables.

Interference emission measurements	**Matching**	**Electromagnetic environment - Guidelines**
HF emissions according to CISPR 11	Group 1	The device uses HF energy exclusively for its internal function. Therefore, its HF emission is very low and it is unlikely to interfere with adjacent electronic devices.
HF emissions according to CISPR 11	Class B	tested for both environmental conditions (IEC 60601-1-2/5.2.1.1)
Emissions of harmonics according to IEC 61000-3-2	Class D	The device is suitable for use in facilities other than residential and those directly connected to the public utility network, which also supplies buildings used for residential purposes.
Voltage fluctuation/flicker emissions according to IEC 61000-3-3	complies	

Nominal power of the transmitter in W	**Protective distance, depending on the transmitting frequency in m**		
	150 kHz to <80 MHz	80 MHz to <800 MHz	800 MHz to 2.7 GHz
	$d=\left[\frac{3,5}{U1}\right]\sqrt{P}$	$d=\left[\frac{3,5}{E1}\right]\sqrt{P}$	$d=\left[\frac{7}{E1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters whose maximum rated power is not specified in the above table, the recommended protective distance (d) in meters (m) can be determined using the equation associated with the respective column, where:

- P is the maximum rated power of the transmitter in watts (W) as specified by the transmitter manufacturer;
- U1 is the maximum permissible field strength according to IEC 61000-4-6 (3V RMS outside the ISM bands, 6V RMS in the ISM and amateur radio bands);
- E1 is the maximum permissible field strength according to IEC 61000-4-3.

Note:
These guidelines may not be applicable in all cases. The propagation of electromagnetic quantities are affected by absorption and reflection of the buildings, objects and people.

Electromagnetic immunity test	Test level
High frequency electromagnetic fields acc. 61000-4-3	IEC 60601-1-2:2014 table 4, home care; IEC 60601-1-2:2014 table 9
ESD (electrostatic discharge) acc. IEC 61000-4-2	IEC 60601-1-2:2014 table 4; IEC 60601-1-2:2014 table 8
Electrical fast transients / bursts acc. IEC 61000-4-4	IEC 60601-1-2:2014 Table 5
Surge acc. IEC 61000-4-5	IEC 60601-1-2:2014 Table 5
Conducted disturbances induced by RF fields acc. IEC 61000-4-6	IEC 60601-1-2:2014 Table 5, home care; IEC 60601-1-2:2014 Table 8, home care
Voltage dips and voltage interruptions acc. IEC 61000-4-11	IEC 60601-1-2:2014 Table 5
Rated power frequency magnetic fields acc. IEC 61000-4-8	IEC 60601-1-2:2014 Table 4
Electro surgery interference	IEC 60601-2-2 Annex BB, mono cut, monopolar coagulation – spray

3.3.1 FCC Statement

This unit has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This unit generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this unit does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Increase the separation between the unit and other devices even beyond the distances listed in section 3.3 if necessarry.
- Consult the manufacturer at the adress listed in section 6.

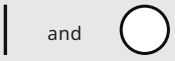
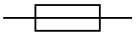
3.4 BIOS

The BIOS can be called up with the "Del" key when starting the device. The BIOS settings of the device are password-protected by default to prevent malfunctions caused by improper settings.

BIOS password ex works: asdf9

3.5 Graphic symbols

Depending on the equipment version of your product, the following symbols and notes may have been used on your device:

Symbol	Meaning	Source
	CE marking	2006/95/EC Annex III
	MEDICAL – GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1: A1:2012, C1:2009/I2012 und A2:2010/I2012, CSA CAN/CSA-C22.2 NO. 60601-1:14	Underwriter Laboratories LLC
	EAC mark	CU TR 004/2011
	This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. FCC ID: 2AUWB2	47 CFR Part 15
	Industrial protection	IEC 60529
	Observe manual instructions	ISO 7010-M002
	Do not open device	none
	AC voltage	IEC 60417-5032
 and	Connection to or disconnection from the supply network	IEC 60417-5007 resp. IEC 60417-5008
	Protective connection, grounding	IEC 60417-5019
	Potential equalization connection	IEC 60417-5021
	Fuse rated value	EN 60617-2/07-21-01
	Manufacturer	ISO 15223-1
	Date of manufacture	ISO 15223-1
	WEEE	2002/96/EC Annex IV

4. Operation

The standby button can be used to switch the device on and off. This function corresponds to the soft start switch of conventional PCs. This does not disconnect the power supply from the mains.

Your device has a capacitive keypad. It is enough to touch the glass pane on the key icon to trigger the function of the key. To avoid unintentional triggering of the keys during wipe disinfection, the keys must be pressed for at least 0.5 sec.
To switch off the device, the standby button must be pressed for at least 2.5 sec.

The device confirms all entries with a signal tone.

4.1 Keypad

The device is operated via the front keypad. The assignment of the function keys and LEDs varies depending on the selected equipment variant.

The following key functions are integrated:

Function keys		LED indicators	
	Switch on/off Shutdown in standby		Deactivate resp. reactivate the touch
	Device off; disconnected from the mains		Touch shutdown inactive
	Device in standby; connected to power grid		Touch shutdown active
	Device switched on		

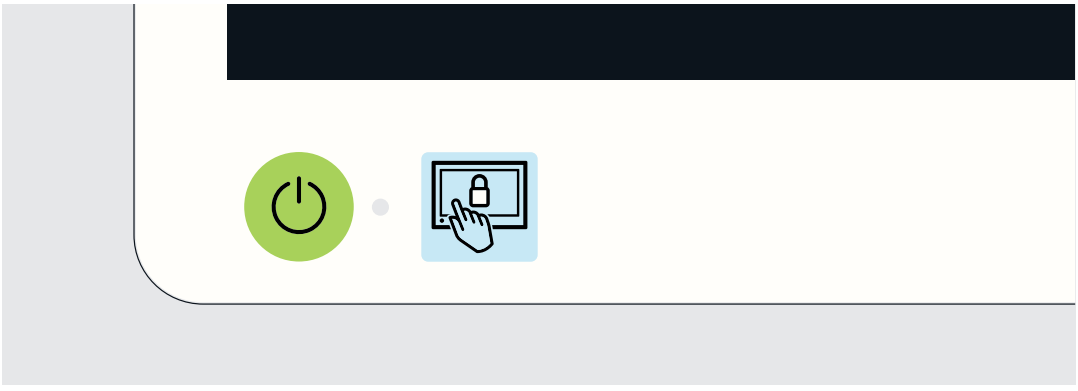


Illustration: Keypad

5. Maintenance

5.1 Care and hygiene instructions

The device cannot be sterilized.

Before starting disinfection on the running device, use the touch shutdown key to avoid unintentional incorrect entries.

All surface disinfectants on the RKI list are approved for cleaning (see: "List of disinfectants and disinfection methods tested and approved by the Robert Koch Institute," Federal Health Gazette 12/2013.) The complete list can also be viewed on the RKI website or requested from ACL.

The following table lists active ingredients that are considered harmless to the device within the specified limits. The table does not represent an evaluation of the disinfection success from a medical point of view.

Active ingredient	**max. concentration in %**	**max. exposure time in minutes**	**Example products**
Alcohol	100	360	Bacillol® 30 Foam Meliseptol
Biguanide	8	360	Incidin Plus
Chlorine, organic or inorganic substances with active chlorine	10	360	Incidin perfekt Optisept
Alkaline solution	8	360	Milk of lime
Per-compounds	8	360	Incidin active Terralin PAA
Phenol or phenol derivatives	6	360	Helipur

The manufacturer's instructions for the disinfectants must be observed. The use of disinfectants based on other active ingredients takes place at the user's own responsibility.

Please ensure that the device has been disinfected with a suitable cleaning agent before any repair work is carried out, especially when returning the device for repair. If this is not possible, clearly mark the contaminated product and seal it twice in safety film.

To protect the health of our employees, we reserve the right to refuse acceptance of contaminated equipment or to apply appropriate follow-up measures at the expense of the sender.

5.2 Maintenance intervals and wearing parts

All devices are designed for 24/7 use. The resulting load places the highest demands on the components and materials used.

To ensure reliable operation under these demanding operating conditions in the long term, preventive replacement of the following components is recommended:

Component	replacement after	Notes
Mass storage	30,000 operating hours[*1]	data backup before replacement is recommended
Panel	30,000 operating hours	No pretreatment required

[*1] The lifetime of flash memory depends on numerous external factors. High ambient temperatures, a high utilization of the memory capacity as well as numerous write operations, especially of many smaller files, puts additional stress on the memory. Depending on your device environment and the relevance of your locally stored data, other intervals may therefore make sense.

The device does not require any consumables for operation.

5.3 Malfunctions and alarm signals

If any mechanical damage to the housing, display and connection cables is detected, the device must be taken out of operation. In this case, the device must be checked by service personnel. Operation with damaged components can lead to further defects as well as data loss.

In the following cases, restart the device and check the device environment for strong sources of EMC interference and for non-compliance with the specified minimum distances from sources of interference provided in Section 3.3:

- Interference signals in the image
- Sporadic, brief intermittent image display
- Keypad triggers without user input

In the following cases, disconnect the device from the mains immediately and contact the manufacturer or authorized service technicians:

- Unusual emission of odor or smoke
- Strong heating of the device
- Damage to the power cable or plug
- Malfunctions of the device, although the operating instructions were followed
- Clear changes in the behavior of the device indicating the need for maintenance
- Mechanical damage to the device or the front pane (e.g. due to falling).
- Unusual noises emanating from the device during operation

There is no alarm system integrated in the device.

5.4 In-house repairs

The manufacturer guarantees that the device and accessories have been carefully checked before leaving the factory. The manufacturer is only responsible for safety-related properties within the scope of statutory regulations if all work on the product is carried out by service personnel authorized by the manufacturer and the device and accessories are used exclusively in accordance with their intended use. For this reason, you will find warranty seals on or inside your device. If a seal is broken, it must be assumed that the warranty is void. Authorized service personnel can only be trained and certified by ACL.

The equipment is designed so that the components listed in this section can be replaced by the customer's technical personnel who have completed training in the use of electrical equipment. Further replacement of components is only possible by ACL, Dräger, or other certified service partners. For service partner training, service manual, and repair assistance, please contact the manufacturer contact listed in Section 6.

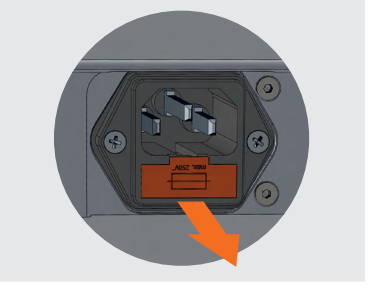
Improper repairs pose a safety risk. The use of your own setting or adjustment methods that do not comply with the device specifications or of components not supplied or approved by ACL is not permitted and may result in damage to the device. Any changes to the device without the manufacturer's permission, modifications or performance-enhancing measures beyond the original settings are not permitted.

If you want to reinstall your device as part of maintenance or repair work, you will find all the drivers you need for this on the ACL website after logging in with your customer login.

Your device requires the ACL driver set 16.

The device has one fuse per phase in the mains filter with the following characteristics:

Manufacturer:	Schurter AG
Type	5X20 mm SPT series
Operating voltage	250V AC
Current	4A
Release speed	T
Shutdown capacity	1.5kA @ 250V AC 10kA @ 125V AC



To change the fuse, remove the cover cap (orange) on the mains filter as shown in the picture. Then you can remove defective fuses and replace them with new ones of the same type.

5.5 Transport notes for ACL devices

To avoid transport damage, please use only the original ACL transport packaging. If you need suitable transport packaging, we will be happy to send you suitable materials for your device at short notice at cost price.

Improper packaging may result in damage to individual components. Therefore, ensure careful handling during transport and loading operations. Ensure compliance with the transport conditions as described in the device manual and on the package label.

Detailed instructions on how to pack your device, e.g. for return transport during a repair, can be found on the ACL website at: https://www.acl.de/en/rma-request

5.6 Environmentally sound disposal

The following section applies to the return of electrical and electronic devices in countries of the EU.

Users of electrical and electronic equipment are obligated to collect old equipment separately. Waste electrical and electronic equipment must not be disposed of together with unsorted municipal waste (household waste). Separate collection is a prerequisite for reuse, recycling and recovery of waste electrical and electronic equipment, thus conserving resources.

For equipment return, please contact the manufacturer's address given in Section 6, or an appropriately authorized disposal company. We will be happy to advise you on the options for disposing of your old equipment. Old equipment that poses a risk to human health or safety due to contamination during use may be refused for return.

According to the EU directive, electrical and electronic equipment marked with one of the following symbols must not be disposed of with household waste.

Return of batteries:
Batteries marked with one of these symbols must not be disposed of with household waste in accordance with the EU directive. For batteries containing harmful substances, the chemical symbol for the heavy metal contained is indicated below the waste garbage can.

Cd	Cadmium
Hg	Mercury
Pb	Lead

For Germany:
The end user is obliged to return defective or used batteries to the distributor or to the manufacturer's address listed in Section 6.

6. Manufacturer contact

We are at your disposal at the following address:

ACL GmbH
Apelsteinallee 5
04416 Markkleeberg
Germany

Phone: +49 (341) 23078 - 60 Monday to Friday 8:00 am to 5:00 pm CET
Fax: +49 (341) 23078 - 99

Email: service@acl.de
Internet: www.acl.de/en

7. Warranty and guarantee

We will be happy to provide you with all information on warranty conditions, types of warranty, repair procedures and exclusions of liability upon request. Our contact details can be found in Section 6.

8. Applicable law

The warranty shall be governed by and construed in accordance with the applicable law of the country in which the initial purchase of the product by the end customer from the dealer occurred. The Convention on Contracts for the International Sale of Goods does not apply.

9. Data protection

We would like to point out that data collected from you in the course of processing your order or preparing an offer will be electronically recorded, processed and evaluated for the purpose of quality assurance. We assure you that this data will be treated in accordance with the German General Data Protection Regulation (GDPR).

At your request, we will be happy to inform you free of charge whether and what personal data is stored about you.

If, in individual cases, you do not wish your personal data to be stored, used and/or transmitted within the scope of the aforementioned quality assurance measures beyond the immediate warranty processing, you can inform us of this at any time.

For our complete privacy policy, please visit the website mentioned in Section 6.