

Manual

OR-PC® series



Congratulations on purchasing your new ACL OR-PC®.

Since 1997 ACL develops and manufactures in Germany optimized IT hardware for use in the medical sector that meets the special requirements in hygiene-critical areas.

Our intelligent solutions set trends and we are always a step ahead of the competition. Those who use ACL products receive the highest stringent reliability in tough routine operations, outstanding quality, durability and ergonomics. The pursuit of innovation at the highest technical standards and the realization of your individual wishes is our incentive to always deliver excellent products. All ACL OR-PC® have a sturdy aluminum housing, which supports the highest performance requirements. Moreover, the material is completely recyclable and can be repeatedly returned for material recycling without loss of value or quality.

The manufacturing process is environmentally friendly, as our production is powered by our own solar energy on the way to a climate neutral manufacturing process.

If there is any complaint about this product, our Service Team from ACL will always kindly support you. We hope you enjoy your new ACL OR-PC®.

Thomas Wollesky



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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.

We will use the term "unit" to designate the OR-PC® xx model manufactured by ACL GmbH. xx is used to identify the display size between 09 and 55 inches.

2. Classification and intended use

The unit is designed for documenting data such as patient information inside and outside of operating theaters, intensive-care wards and similar areas of application. It is supporting the local software environment and it may be part of the IT network.

Following Section 6 of IEC 60601-1:2012 the unit is classified as below:

- 6.2 protective class I unit
- 6.3 see IP label on your unit, depending on your model IP20 or IP31 An optional IP65 upgrade is available on request for all models.
- 6.4 This unit is not intended for sterilization.
- 6.5 It is not intended for operating in an environment with enriched oxygen.
- 6.6 This unit is suited for permanent operation.

The unit is considered as professional ME-Equip according to IEC 60601-1-2:2014, paragraph 3.23.

It not is allowed to simultaneously touch the patient and pins of signal input/output components when connecting the unit to other devices.

The unit can be used within the patient environment.

This unit is not suited to be used in direct contact with the patient.

The patient is not supposed to operate or maintain the unit.

It is not allowed to use this unit in private households.

The unit is not protected against explosions.

Only qualified expert personnel, which is familiar with the unit and its manual, may install, operate and maintain the unit.

There is no information required for activities that should avoid damage to humans, animals or environment.

Third-party equipment may be connected in consideration of the restrictions in Section 3.1.

3. Installation and commissioning

The unit was cleaned before leaving our production facilities. However, the units are neither sterile nor disinfected on arrival due to transport conditions and packing. Advices for initial cleaning can be found at Section 5.1.

Make sure that the unit and its accessories are complete according to the attached delivery note.

Keep the original transport box and packaging for the event that it might have to be transported back (this does not apply to units with on-site service).

The integrated VESA-100 interface on the rear can be used to flexibly attach the unit to mounting solutions and other devices. Various manufacturers offer a whole series of adapters or installation solutions for this. We would be pleased to offer customized installation solutions on your request.

The unit may only be operated in an upright position (do not operate it in any direction at an inclination of more than 30° from the norm). The only units that may be operated with a screen rotated at 90° (portrait mode) are those specially designated as such (i.e., portrait models). It is not allowed to operate it in impermissible positions (reversed and lying on its head, back or display) because this may damage the unit.

Only use the screws supplied and always use all fastening screws (orange) for correct and save assembly.

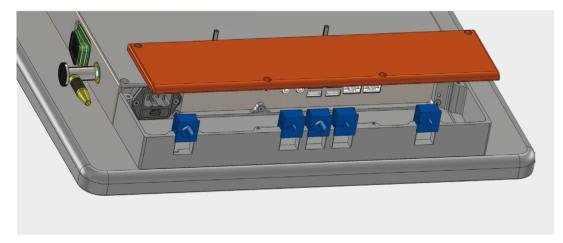




Furthermore, appropriate ventilation is necessary to protect the unit from overheating and to ensure reliable and continuous operation. This is the reason why the unit should not be put in a place or under conditions where it is impossible to offer sufficient ventilation for the unit's housing surfaces. Finally, it is not allowed to place or suspend objects or materials on the unit to prevent heat accumulation or an interruption of the air circulation and to protect the unit's mounting from excessive loads.

All service cables should be laid to make sure that nobody steps on them, trips over them or can put heavy objects on them to prevent the hazard of injury and damage to the unit. Make sure that there is a fixed location and/or stable suspension.

The industrial protection class of your unit can be upgraded up to IP65. If you have chosen this optional upgrade, one of the central elements of the IP65-sealing is the cover for the connector interface on the lower side of the unit. Connect all the required cables to the unit and insert them into the rubber sealings (blue) delivered with the unit. Insert the sealings into the cover. Finally, fix the cover to the unit's housing like indicated on the drawings below (orange).





3.1 Cable and device connection

Use the supplied connection cables only.

Start off by connecting the potential equalization cable (greenish-yellow marking) to ensure a sufficient potential equalization between the unit and the user. The unit should not be operated in medical areas without connecting up potential equalization.

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Check to see whether your power grid has the correct voltage and frequency before connecting the unit to the mains (refer to the nameplate on the housing). Afterwards, connect all of the needed cable connectors (such as mains cable, keyboard, mouse, serial cables, USB and network) to the unit. To prevent the risk of electrical shock, this unit may only be connected to a supply system with a protective earth. Attaching strain reliefs to the unit is not necessary for the customer.

If you want to completely disconnect the unit from the power system, turn off the mains switch or pull the power plug from the outlet. Never pull on the cable and always hold onto the plug of the cable when disconnecting the power system connections. Do not set up the unit under conditions that impede the disconnection from the mains.

When creating an electrical connection with other devices or when operating the unit at a mobile multiple outlet, compliance to the latest version of IEC 60601-1 has to be ensured. To maintain conformity in this case so-called "decoupled connectors" are available for connections via RJ45, RS232 or USB optionally. Data can be transferred through this galvanic isolation without any direct electrical contact. From the electrical point of view the connection of medical equipment on these decoupled connectors is admissible.

Furthermore, a functional unit is created by exchanging data with other devices, especially if this functional unit is intended to be used for medical purpose (i.e. unit is controlling infusion pumps or applied parts are connected). Validity of any assured properties nor conformity to standards for the unit cannot be expanded to the newly created functional unit. Instead, the party which is placing this unit on the market or in the clinical environment is responsible for its conformity with all applicable standards..

There might be unforeseeable interactions or even malfunctions on one or both units if the unit is connected to other units.

We would be glad to provide technical support and resolve unanswered questions.



Illustration: Example of a connector interface on the lower side of your OR-PC® Available connectors will vary depending on the configuration you have chosen for your unit.

3.2 Device environment, safety and handling instructions

Please comply with the safety instructions compiled below to prevent fire, electrical shocks, injuries and damage to the unit.

Protect the unit from exposure to strong infrared radiation like i.e. direct impact of sunlight.

Protect the unit from strong magnetic fields like the field close to a MRI.

Protect the unit from exposure to strong electromagnetic radiation. Operation close to HF surgery equipment is allowed for units with optional cable cover as long as the minimum distances listed in Section 3.3 are maintained.

Protect the unit from exposure to strong ionizing radiation like i.e. the radiation at a C-arm on X-ray devices.

Furthermore, the unit shall be protected from strong impacts and ongoing vibrations.

The unit may only be operated under the following ambient conditions:

	Operation	Storage
Temperature	0 to 40 °C*1 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

^{*1} If you have ordered upgrades for additional cards like i.e. framegrabber cards an operating temperature of 35°C shall not be exceeded.

Store the unit for three hours at the new operating location before commissioning if a difference in temperature of 10°C is exceeded. The unit might be damaged due to fast changes in temperature (i.e. by condensed water).

Prevent the unit from showing the same screen content over a longer period of time because TFT displays might have after images due to the image-sticking effect.

Use the "Display Off" function key to turn the display off if you do not use the unit for a longer period of time (this does not have any impact on the running programs or functions of the unit). A LED in the operating panel indicates the fact that the display is deactivated. Alternatively, a screen-saver could be used.

3.3 Electromagnetic compatibility (EMC)

Using other cables than the original ones may affect the EMC. It may also affect the compliance of limiting values assured on delivery.

Output cables, intended for a direct connection to outdoor wiring, are not covered by the assured EMC characteristics of the unit. Therefore, additional inspections might be necessary.

Stacking units or mounting the unit close to other electrical devices may cause interference effects on both devices. A sufficient distance or shielding between these devices shall be ensured.

The unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the unit can help to prevent electromagnetic interference by maintaining a minimum distance between portable mobile RF communications equipment (transmitters) and the unit, according to the maximum output power of the communications equipment, as shown below.

Emissions Test	Compliance Level	Electromagnetic environment - Guidelines
RF emissions CISPR 11	Group 1	The unit uses RF energy only for is internal function. Therefore, is RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	tested for both environments (IEC 60601-1-2/5.2.1.1)
Harmonic emissions IEC 61000-3-2	Class D	The unit is suitable for other use than in domestic establishments. The unit is suitable to be directly connected to the public low-voltage power supply network.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	complies	

Transmitter maximum output in W	Separation distance according to frequency of the transmitter 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 rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where:

- P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer;
- U1 is the maximum strength of frequency fields according to IEC 61000-4-6 (3V RMS outside the ISM band, 6V RMS in the ISM- and amateur radio band);
- E1 is the maximum strength of frequency fields according to IEC 61000-4-3.

Note:

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

3.4 BIOS

You can call up the BIOS by pressing "Del" during start up. The BIOS settings of the unit are protected by a password in standard operation to prevent malfunctions from incorrect settings.

BIOS password ex works: asdf9

You can call up the BIOS by pressing "Del" during start up. The BIOS settings of the unit are protected by a password in standard operation to prevent malfunctions from incorrect settings.

3.5 Graphic symbols

These signs and symbols below may have been used on your unit depending upon the configuration of your product:

Symbol	Meaning	Source
((CE symbol	2006/95/EC Annex III or 93/42/EEC Annex XII
	MEDICAL – GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHA- NICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1: A1:2012, C1:2009/I2012 and A2:2010/I2012, CSA CAN/CSA-C22.2 NO. 60601-1:14	Underwriter Laboratories LLC

C UL US	EDICAL – GENERAL MEDICAL EQUIPMENT 5 TO ELECTRICAL SHOCK, FIRE AND MECHA- ICAL HAZARDS ONLY IN ACCORDANCE WITH NSI/AAMI ES60601-1: A1:2012, C1:2009/I2012 Id A2:2010/I2012, CSA CAN/CSA-C22.2 NO. 1601-1:14	
ERC	EAC mark	CU TR 004/2011
IPN ₁ N ₂	international protection code	IEC 60529
&	instructions available in the manual	ISO 7010-M002
	do not open the unit	none
===	direct current	IEC 60417-5031
\sim	alternating current	IEC 60417-5032
and O	connection to or disconnection from the mains	IEC 60417-5007 resp. IEC 60417-5008
	protective earth	IEC 60417-5019
\downarrow	potential equalization connection	IEC 60417-5021
	fuse specification	EN 60617-2/07-21-01
	manufacturer	ISO 15223-1
	date of manufacturing	ISO 15223-1
<u> </u>	WEEE	2002/96/EG Annex IV
	barcode scanner	-
RFID	RFID scanner	

4. Operation

You can use the Standby button to turn the unit on and off. This function is equivalent to the soft-start switch of conventional PC's. This does not disconnect the power supply from the mains though.

Your unit is equipped with a capacitive operating panel. You can simply touch the glass pane above the symbol to trigger the key. To prevent the panel from trigger events during wipe disinfection you need to hold your finger on a key for at least 0.3s.

Input will be confirmed by a short audio signal.

4.1 Keypad

The unit operates with the operating panel on the front. The key and LED layout varies according to the equipment you chose for your unit.

The following key functions can be included:

Function keys			indicat	ors			
	Unit on/off – standby no separation from the mains	(\$)	₩				LED indicators in the key panel
**	Brightness control: brighter	×	X	X	X	X	Unit disconnected from the mains
*	Brightness control: darker	×	X	₩	X	X	Unit in standby
	Turn display and touch screen on/off		V	V		V	Unit operating
scan	Barcode reader is activated for 10s				V		Access mass storage
	Volume regulation: louder		(1)				min./max. brightness set
•	Volume regulation: quieter						



Illustration: example of a keypad on the OR-PC®

5. Maintenance

5.1 Care and hygiene instructions

The unit cannot be sterilized.

All kind of wipe disinfectants that are listed below can be used for cleaning the unit. The complete list with all active substances and product names is available on the Website of the "Robert Koch-Institut" with the title "Liste der vom Robert Koch-Institut geprüften und anerkannten Desinfektionsmittel und –verfahren" (source: Bundesgesundheitsblatt 10/2017) or from ACL in German.

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The active substances in the following table are expected to be harmless for the unit as long as the listed limits are observed. The table does not represent a medical evaluation of the effectiveness of these substances.

Active substance	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
lye	-	-	Lime milk
Per-compounds	8	360	Incidin active Terralin PAA
Phenol or phenol derivatives	6	360	Helipur

The following detergents and agents are unsuitable for cleaning:

- acetone
- · citric acid
- cleaning liquids basing on crude oil like petroleum, turpentine or oil

Using cleaning pads, rough sponges and cloths might damage surfaces and sealing material.

Please make sure that the unit is cleaned and disinfected with an appropriate cleanser every time it is sent back for repair. If you are not able to do so, mark the unit as contaminated and use safety foil to seal it twice.

To ensure the necessary health conditions for our employees we reserve ourselves the right to initiate suitable measures on contaminated units at your costs or to refuse the unit at all.

5.2 Maintenance intervals and wearing parts

All units are designed for 24/7-operation. This results in highest requirements to components and materials. To ensure the reliable operation under these harsh conditions we recommend to replace the following components prophylactically:

Component	Replacement after	Notes
Mass storage	30.000 hours of operation*1	data backup is recommended
Display panel	30.000 hours of operation	no pretreatment required
Grommets in cable cover	if necessary	clearly visible abrasion indicates the need to change the grommets

^{*1} The lifetime of your flash memory depends on various external aspects. High ambient temperature, a high storage utilization as well as a large number of writing operations, especially when writing lots of smaller files, will strain your memory additionally. Depending on your operation environment other intervals might be reasonable. We would be glad to submit an offer for these maintenance tasks.

No consumables are required.

5.3 Malfunctions and alarm signals

Shut the unit down if you discover any mechanical damage to the housing, display or service cables. The unit should be checked by a qualified service partner in this case because operating the unit with damaged components can cause further damage.

Disconnect the unit from the network immediately in the following cases and get in contact with the manufacturer or authorized service technician:

- · unusual odor or smoke
- · a high level of heat escaping from the unit
- · damage to the power cable or plug
- faulty unit functioning although you followed the operating instructions
- substantial changes in the unit's behavior that indicate that it needs service
- mechanical damage to the unit or to its frontal glass plate (such as due to a fall)
- unusual noises from the unit during operation

Restart the unit in the following situations and check the environment for strong sources of EMC radiation and for any non-conformities with the minimum distances from transmitters listed in Section 3.3:

- picture interferences
- short sporadic signal loss
- key panel triggered without user interaction

The unit does not have an alarm system.

5.4 In-house repairs

Diligent testing of the unit is guaranteed by the manufacturer. He is responsible for safety-related characteristics within the legal limits only if repairs and modifications are performed by personnel authorized and trained or supervised by ACL and if the unit and its accessory are used according to the rules of the intended use. Therefore, there are warranty seals on or in your unit. Once a seal is broken an expiring warranty has to be assumed. Service personnel may be trained and certified by ACL only.

The units are designed to enable the customers' technical personnel that is capable to deal with electrical installations to exchange the components listed in this section. Other components shall be exchanged by ACL GmbH or certified service partners only. Please contact the manufacturer at the address in Section 6 for training and advisory as well as for the service manual.

Incorrect repairs are a safety risk. You should not apply your own setting or adjusting methods if they do not comply with the unit's specifications or use components not supplied or approved by ACL GmbH because that might damage the unit. Finally, it is not allowed to make any changes or modifications in the unit or take actions to boost performance beyond the original settings without the manufacturer's permission.

If you are about to do a fresh installation on your unit due to maintenance or repairs you can find all necessary drivers after login in with your customer access data on the ACL website. Information about the required ACL driver set can be found on the side of your unit next to the download symbol. You can also ask for the correct driver set at the contact data in Section 6 with your units' serial number.

There is one fuse for every phase within the mains filter of your unit. Its characteristics are:

Manufacturer	Schurter AG
Model	5X20 mm SPT series
Operating voltage	250V AC
Ampere rating	4A
Characteristic	Т
Breaking capacity	1.5kA @ 250V AC 10kA @ 125V AC



To change a fuse, remove the cover (orange) on your mains filter like indicated on the picture. Thereafter, you can remove and replace your fuse.

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 unit, 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

This section applies for returning old electrical and electronic equipment in the countries of the European Union.

Users of electrical and electronic equipment are obliged to collect old equipment separately. Old electrical or electronic equipment may not be disposed of together with the unsorted domestic refuse (residential waste) because separate collection is the prerequisite for re-use, recycling and using old electrical or electronic equipment to drive down resource utilization.

Please get in contact with the manufacturer at the address given in Section 6 or with an authorized disposal company for returning your old units. We would be glad to advise you as to the options for disposing of your ACL unit. Return can be refused for old equipment that constitutes a risk to human health or safety due to contamination during usage.

The directive of the European Union states that electrical or electronic units designated with one of the symbols below may not be disposed with residential 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

This guarantee shall be subject to the applicable law in the country where the final customer first purchased the product from the dealer and it shall be interpreted in agreement with it. The convention on treaties for the international sale of goods shall 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.

Imprint

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Climate neutral printed on certified FSC® recycling paper in Leipzig, Germany.



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Here you can find the documents of your device.

BIOS password (default): asdf9

The device drivers and the digital manual can be downloaded from the login area on the ACL website:

www.acl.de/en

One-time registration required.

