

STORZ

KARL STORZ—ENDOSKOPE

En **Directions for use**
OR1 Control Tablet 11"
WM400



12-2024

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DRAFT – For internal use only

1 General information

1.1 Read the instructions for use

If the instructions for use are not followed, patients, users and third parties may be injured or the product damaged.

- ▶ Read the instructions for use carefully and observe all safety instructions and warnings contained therein.
- ▶ Read the reprocessing instructions carefully and observe all safety instructions and warnings contained therein. The preparation instructions can be called up on www.karlstorz.com/ifu by quoting the article number.
- ▶ Keep the instructions for use and preparation instructions carefully.

1.2 Read the instructions for use of the combinable products

If the instructions for use of the combinable products are not followed, patients, users and third parties may be injured or the product damaged.

- ▶ Read the instructions for use of the combinable products carefully and observe all safety instructions and warnings contained therein.
- ▶ Read the preparation instructions of the combinable products carefully and observe all safety instructions and warnings contained therein.

1.3 Scope

Due to different approval requirements, the products listed may not be available in every country.

This instruction manual applies to:

Tablet

Product	Article
OR1 Cotrol Tablet 11"	WM400
OR1 Control Tablet 11" Extension	WM40000
OR1 Control Tablet 11" Power Supply	WM40001
OR1 Control Tablet 11" Halterung	WM40002
OR1 Control Tablet 11" Kabel-Set	WM40003

1.4 Applicable documents

The following documents must also be observed:

- Instruction manual OR1 CCS software

1.5 General Signs and Symbols

The signs and symbols used in this document have the following meanings:

Practical tip



This sign indicates useful and important information.

General information

Actions to be performed

Plot with several plot steps:

✓ Condition that must be fulfilled before an action is performed.

1. Step 1 ⇨ Intermediate result of an action
2. Step 2 ⇨ Result of a completed action

▶ Actions in a single action step: Step 1

Actions in safety instructions:

- ▷ Step 1
- ▷ Step 2

Enumerations

1. Numbered list
 - Unnumbered List, 1st Level
 - Unnumbered list, 2nd level

1.6 Warning Statement

To avoid personal injury and property damage, the warnings and safety instructions in the instructions for use must be observed. The warnings use the following hazard levels:

▲ WARNING

WARNING

Refers to a possible imminent danger. If it is not avoided, death or serious injury can result.

▲ CAUTION

CAUTION

Refers to a possible imminent danger. If it is not avoided, minor or minor injuries can result.

ATTENTION

ATTENTION

Refers to a potentially harmful situation. If it is not avoided, the products can be damaged.

Intended use

2 Intended use

2.1 Purpose

Tablet

The OR1 Control Tablet 11" is a touch-operated tablet that can be used as an execution platform for KARL STORZ (medical/non-medical) software applications. That OR1 Control Tablet 11" is used in the medical environment in the operating room and in rooms with the same or lower hygiene requirements. For this purpose, the tablet is mounted in a suitable way on an operating tower, cart or trolley. The OR1 Control Tablet 11" is not intended for mobile use outside a holder and is not intended for use in sterile areas.

2.2 User Target Groups

The medical device may only be used by doctors and medical assistants who have the appropriate professional qualifications.

2.3 Patientenpopulation

There are no restrictions on patient groups for this product.

The product is not in direct contact with patients.

3 Safety and Warning

⚠ WARNING

Danger due to non-observance of warnings and safety instructions!

This chapter contains warnings and safety advisories organized by hazards and risks.

- ▷ Read and observe all warnings and safety instructions carefully.
- ▷ Follow the instructions.

3.1 Serious incidents

A "serious incident" includes events that have had, could have had or could have, directly or indirectly, any of the following:

- Death of a patient, user or other person
 - Temporary or permanent serious deterioration in the health of a patient, user or other person
 - A serious threat to public health
- ▶ Report all serious incidents to the manufacturer and the competent authority.

3.2 Proper handling and product testing

If the product is not handled properly, patients, users and third parties can be injured.

- ▶ Only allow people who have the necessary medical qualifications and who are familiar with the use of the product to work with the product.
- ▶ Before the procedure, check whether the product is suitable for the procedure.
- ▶ Check the product before and after each application for the following properties, for example:
 - Functionality
 - Damage
 - Modification of the surface
 - In the case of multiple components: completeness and correct assembly Do not reuse damaged products.
- ▶ Dispose of the product properly, see chapter *Disposing of the product*.

3.3 Combination with other components

The use of unapproved equipment and components may result in injury.

- ▶ Ensuring that additional equipment connected to electrical medical equipment complies with relevant IEC or ISO standards.
- ▶ Ensure that all configurations meet the requirements for medical electrical systems.
- ▶ Combine the product only with devices and components that are approved by the manufacturer for joint use, see chapter *Combination options*.

3.4 Dangers of electric current

Improper power supply can lead to electric shock and injure patients, users and third parties.

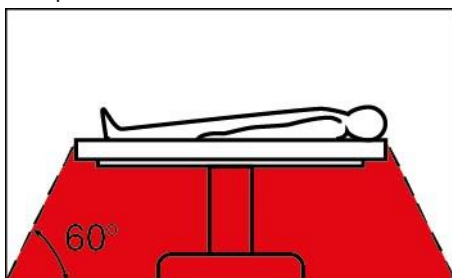
Security and Warning

- ▶ For reliable grounding, connect the product to a properly installed outlet that is approved for use in the OR. Check plugs and cables regularly and do not use them if damaged.
- ▶ Unplug before cleaning and maintenance work.

3.5 Risk of explosion and fire

The product can generate sparks that ignite or explode flammable or ignitable gases and liquids. This can injure patients, users or third parties.

- ▶ When using explosive anesthetic gases: The product outside the danger zone prosecute.



- ▶ Do not use the product in the presence of flammable anesthetics.
- ▶ Do not operate the product in an oxygenated environment.
- ▶ Plug in or unplug the mains plug only outside of potentially explosive atmospheres.

3.6 Comply with environmental conditions

If the product is stored, transported, operated or reprocessed in unsuitable conditions, patients, users or third parties may be injured or the product may be damaged.

- ▶ Comply with the environmental conditions listed in the instructions for use and preparation.

4 Product Description

4.1 Functional description

The OR1 Control Tablet 11" serves as a central user interface

- for the execution of specified software applications
- for web-based applications from KARL STORZ that can be used to operate building management systems, documentation (network-based recording), communication and audio/video management.

4.2 Product Overview



OR1 Cotrol Tablet 11" Front and Back

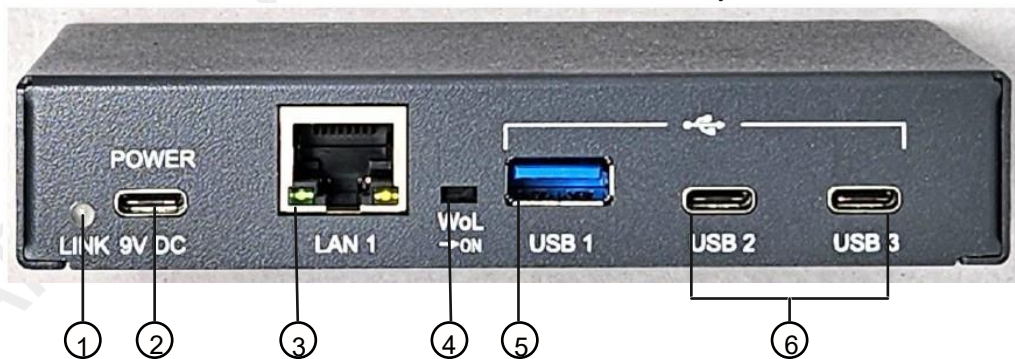
1	Brightness sensor	5	Rear camera
2	Touchscreens	6	VESA 75 Mounting Thread
3	Front camera	7	Cable cover
4	OK LED (tablet, power supply)	4	Microswitch Wake-onLAN
5	Power connector (USB C)	5	1x USB-A port
6	Ethernet RJ45	6	2x USB-C port
		4RFID	8
			1 W speaker



OR1 Cotrol Tablet 11" Side View

- 1 Button ON/OFF
2 Volume button

- 3 USB C connector
4 3.5 mm jack socket



OR1 Cotrol Extension 11" Front



OR1 Cotrol Extension 11" Back

- 1 Data and power connection to the tablet

- 2 Control port to the tablet (3.5 mm LCD)

(USB C)

Wed)

4.3 Possible combinations

It is recommended to check the suitability of the products for the planned procedure before use. Please note that the products listed in this medium may not be available in every country due to different approval requirements.

The product consists of the items listed in the scope and is used exclusively in combination with them.

4.4 Technical Data

Designation	Value
System	
System-on-Chip (SoC)	Snapdragon™ QCS8250
CPU	Qualcomm® Kryo™ 585
Graphics card	Qualcomm® Adreno™ 650
Digital Signal Processor (DSP)	Qualcomm® Hexagon™ DSP with quad Hexagon Vector eXtensions (HVX).
Video Encoder	
Video Decoder	
Memory	8 GB LPDDR5 DRAM
Display	
Screen diagonal (inches)	11" TFT color LCD with LED backlight
Screen resolution	1,600 x 2,176
Brightness	300 cd/m2
Touchscreen	10-point PCAP with Gorilla Glass ver 3.0 and anti-glare protection with anti-fingerprint coating
Camera	
Front camera	1 x 16 Megapixel CMOS Auto Focus
Rear camera	1 x 16 Megapixel CMOS Auto Focus
Audio	
Designation	Value
Microphone	2x digital

Loudspeaker	2x 1 W
Case	
Material	Plastic (PC-ABS)
Color	Schiefergrau (RAL7015, matt)
Degree of protection according to IEC 60259	IP54
Dimensions (L x H x W)	543 x 348 x 90 mm
Weight	approx. 802 g
Assembly	
VESA	75

4.5 Explanation of symbols

4.5.1 Symbols on the packaging

OR1 Control Tablet 11"

Symbol	Meaning
	Manufacturer
	Manufacture
SN	Serial number
	Follow the instructions for use. The color may vary on the product. On the packaging label, the symbol is black and white.
	CE marking With this marking, the manufacturer declares the conformity of the product with the applicable EU legislation. If the CE mark is followed by an identification number, this identifies the competent notified body. The EU legislation applicable to the product can be found in the EU Declaration of Conformity, which can be requested from KARL STORZ.
	Preventing pollution from electronic devices
	FCC Marking

Symbol	Meaning
	Preventing pollution from electronic devices
	Data Matrix Code (illustration as an example) Information about the product, e.g. UDI
	RFID tag, general
	Separate collection of electrical and electronic equipment. Do not dispose of in household waste.

OR1 Control Tablet 11" Extension

Symbol	Meaning
	USB port

OR1 Control Tablet 11" Power Supply

Symbol	Meaning
	UL recognized component. The power supply is considered to be part of the CCS Tablet WM400 system.
	FCC Marking
	CE marking With this marking, the manufacturer declares the conformity of the product with the applicable EU legislation. If the CE mark is followed by an identification number, this identifies the competent notified body. The EU legislation applicable to the product can be found in the EU Declaration of Conformity, which can be requested from KARL STORZ.

	Test mark for electromagnetic compatibility
Symbol	Meaning
	Indoor use
	Protection class II
	Preventing pollution from electronic devices
	Separate collection of electrical and electronic equipment. Do not dispose of in household waste.

4.5.2 Symbols on the product

OR1 Cotrol Tablet 11"

Symbol	Meaning
	ON/OFF (Standby)
	RFID tag, general

OR1 Cotrol Tablet 11" Extension

Symbol	Meaning
	USB port

4.5.3 Symbols on the nameplate

OR1 Control Tablet 11"

Symbol	Meaning
	Manufacturer
	Manufacture
	Article
SN	Serial number

	Follow the instructions for use. The color may vary on the product. On the packaging label, the symbol is black and white.
Symbol	Meaning
	Direct current
	NRTL mark for USA and Canada With this marking, the manufacturer declares compliance with the certification requirements.
	FCC Marking
	Non-ionizing electromagnetic radiation
	CE marking With this marking, the manufacturer declares the conformity of the product with the applicable EU legislation. If the CE mark is followed by an identification number, this identifies the competent notified body. The EU legislation applicable to the product can be found in the EU Declaration of Conformity, which can be requested from KARL STORZ.
	Preventing pollution from electronic devices
	Data Matrix Code (illustration as an example) Information about the product, e.g. UDI
	Separate collection of electrical and electronic equipment. Do not dispose of in household waste.

OR1 Control Tablet 11" Extension

Symbol	Meaning
	Manufacturer
	Manufacture
	Article
SN	Serial number
	Direct current

	Follow the instructions for use. The color may vary on the product. On the packaging label, the symbol is black and white.
	NRTL mark for USA and Canada With this marking, the manufacturer declares compliance with the certification requirements.
Symbol	Meaning
	FCC Marking
	CE marking With this marking, the manufacturer declares the conformity of the product with the applicable EU legislation. If the CE mark is followed by an identification number, this identifies the competent notified body. The EU legislation applicable to the product can be found in the EU Declaration of Conformity, which can be requested from KARL STORZ.
	Preventing pollution from electronic devices
	Separate collection of electrical and electronic equipment. Do not dispose of in household waste.

OR1 Control Tablet 11" Halterung

Symbol	Meaning
	Manufacturer
	Manufacture
	Article
SN	Serial number
	Direct current
	Follow the instructions for use. The color may vary on the product. On the packaging label, the symbol is black and white.
	NRTL mark for USA and Canada With this marking, the manufacturer declares compliance with the certification requirements.

	FCC Marking
Symbol	Meaning
	CE marking With this marking, the manufacturer declares the conformity of the product with the applicable EU legislation. If the CE mark is followed by an identification number, this identifies the competent notified body. The EU legislation applicable to the product can be found in the EU Declaration of Conformity, which can be requested from KARL STORZ.
	Preventing pollution from electronic devices
	Separate collection of electrical and electronic equipment. Do not dispose of in household waste.

OR1 Control Tablet 11" Power Supply

Symbol	Meaning
	Direct current
	Alternating current
	UL recognized component. The power supply is considered to be part of the CCS Tablet WM400 system.
	FCC Marking
	CE marking With this marking, the manufacturer declares the conformity of the product with the applicable EU legislation. If the CE mark is followed by an identification number, this identifies the competent notified body. The EU legislation applicable to the product can be found in the EU Declaration of Conformity, which can be requested from KARL STORZ.
	Test mark for electromagnetic compatibility
	Indoor use
	Protection class II

	Preventing pollution from electronic devices
	Separate collection of electrical and electronic equipment. Do not dispose of in household waste.

4.6 Environmental conditions

Transport conditions and storage conditions	
Temperature	-18 °C ... +60 °C (-0.4 °F ... +140 °F)
Relative humidity (non-condensing)	10 – 85 %
Atmospheric pressure	500 – 1,080 hPa
Conditions	
Temperature	0 °C ... 40 °C (32 °F ... 104 °F)
Relative humidity (non-condensing)	5 – 90 %
Atmospheric pressure	700 – 1,080 hPa

5 Preparation

5.1 Unboxing the product

1. Carefully remove the product and accessories from the packaging.
2. Check the delivery for any damage.
3. In the event of detected damage, hidden defects and underdeliveries, document the type and extent and contact the manufacturer or supplier immediately.
4. Keep the packaging material for further transport.

5.2 Setting up the product

▲ CAUTION

Fragile glass! Injury!

The glass of the screen will shatter if the product is dropped or receives a significant impact. Broken glass can injure patients, users and third parties.

- ▷ Do not touch broken glass.
 - ▷ Do not touch the glass parts of the product.
 - ▷ Do not remove glass parts from the product.
 - ▷ Have the glass replaced by qualified service personnel.
- ▶ Place the product and its components out of the reach of patients.

6 Operation

6.1 Instructions for use

⚠ WARNING

Wrong diagnosis! Injury!

The components and monitors of the are not diagnostic or therapeutic devices> use for diagnostic or therapeutic purposes.

Do not

⚠ CAUTION

Unplugged in! Risk of injury due to product failure!

The product will turn off when the power plug is unplugged. This can disrupt the operation and injure the patient.

- ▷ Do not loosen or plug any cable connections during operation.

6.2 Launch Product

1. Press the ON/OFF button until the splash screen appears to start the boot process.
 - ⇒ The home screen appears.
2. For more information on how to use each application, see the OR1 CCS Software Instructions for Use.

6.3 Turn off the product

1. Press and hold the ON/OFF button for 3 seconds or more.
 - ⇒ A shutdown menu will appear.
2. Tap the **Power off** button . ⇒ A shutdown message appears and the system shuts down

Maintenance, repair, servicing and disposal

7 Maintenance, repair, servicing and disposal

7.1 Maintaining the product

⚠ WARNING

Product defects! Injury!

Defects in the product and accessories can injure patients, users and third parties.

- ▷ Decommission the product.
- ▷ Have the defects professionally repaired by persons authorized by KARL STORZ.

Maintenance activities, unless further carried out, may only be carried out by KARL STORZ or a company authorized by KARL STORZ.

7.1.1 Maintenance

The following maintenance intervals are recommended:

Interval	Activity	To carry out
annual	Security Testing	KARL STORZ Service Technician

7.1.2 Safety testing according to IEC 62353

Regardless of country-specific accident prevention regulations and inspection intervals for medical devices, safety tests must be carried out and recorded once a year by a qualified electrician as repeat tests in accordance with IEC 62353. Detailed information on the scope and execution of the safety test can be found in the service manual.

7.2 Repairing the product

Repair measures may only be carried out by KARL STORZ or a company authorized by KARL STORZ. Excluded are interventions described in this instruction manual.

- Contact the responsible KARL STORZ branch or the responsible specialist dealer (see branch list).

Contaminated products must not be shipped. To avoid contact infections and airborne infections, the products must be decontaminated beforehand. KARL STORZ reserves the right to return contaminated products.

7.3 Disposing of the product

The product meets the requirements of the Waste Electrical and Electronic Equipment (WEEE) Directive.

Within the scope of the Directive, KARL STORZ SE & Co. KG is responsible for the proper disposal of the product.

1. Dispose of the product in accordance with country-specific laws and regulations at a suitable disposal point for the processing of electrical and electronic equipment.
2. The responsible collection point can be obtained from KARL STORZ SE & Co. KG, a KARL STORZ branch or a specialist dealer.

Accessories and spare parts

8 Accessories and spare parts

8.1 Accessories

Article	Order No.
OR1 Control Tablet 11" Extension	WM40000
OR1 Control Tablet 11" Power Supply	WM40001
OR1 Control Tablet 11" Halterung	WM40002
OR1 Control Tablet 11" Kabel-Set	WM40003

9 Electromagnetic compatibility

9.1 General Notes on the Operating Environment

The product is suitable for use in professional healthcare facilities. Professional healthcare facilities include doctors' offices, dental offices, limited care facilities, freestanding surgical centers, freestanding birthing centers, multiple treatment facilities, hospitals (emergency rooms, patient rooms, intensive care units, operating rooms, outside the HF-shielded room of an ME system for magnetic resonance imaging).

-  The emission characteristics of this product make it suitable for use in industrial sectors as well as in hospitals (CISPR 11 Class A) and other professional healthcare facilities. If used in a residential environment (which normally requires CISPR 11 Class B), this product may not provide sufficient protection for radio transmission operations. The user may need to take action, such as relocating or reorienting the product.

WARNING

Electromagnetic interference! Malfunction!

Using this device immediately next to or stacked on top of other equipment may result in faulty operation.

- ▷ Avoid this situation.
- ▷ If such use is necessary: Ensure that this device and the other devices are operating normally.

WARNING

Performance! Malfunction!

Portable RF communication devices (including peripherals such as antenna cables and external antennas) may affect the performance of the product.

- ▷ Use portable communication devices, including their cables, no closer than 12 inches (30 cm) to any part of the product.

10 branches

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This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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. These limits are

designed to provide reasonable protection against harmful interference in a residential installation. This equipment 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 equipment does cause harmful interference to radio or television reception, 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:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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. These limits are

designed to provide reasonable protection against harmful interference in a residential installation. This equipment 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.

Any changes or modifications not expressly approved by the party responsible for compliance could void the authority to operate equipment.

This device and its antenna must not be co-located or operating in conjunction with any other antenna or transmitter.

FCC RF Radiation Exposure Statement:

This product is based on SAR assessment and the user manual must have the following warnings “This device meets the government’s requirements for exposure to radio waves. This device is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government.

The exposure standard employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6 W/kg. Tests for SAR are conducted using standard operating positions accepted by the FCC with the EUT transmitting at the specified power level in different channels. The FCC has granted an Equipment Authorization for this device with all reported SAR levels evaluated as in compliance with the FCC RF exposure guidelines. SAR information on this device is on file with the FCC and can be found under the Display Grant section of www.fcc.gov/oet/ea/fccid.”



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