

JMA^{Optic}



Hardware User Manual JMA-Optic

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Illustrations of this manual may differ.

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Please always provide the serial number of the product for inquiries!



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1 User information

1.1 Configuration of the instructions for use

The instructions for use of the JMA-Optic consists of several parts:

- I. Installation instructions for the WinJaw + software, also contains your license code,
- II. Technical specifications and instructions for use of the JMA-Optic Hardware,
- III. Instructions for use of the application software WinJaw +

The part technical specifications and instructions for use of the JMA-Optic Hardware primarily contains information on technical data and the operation of the JMA-Optic system as well as information on its safe operation in combination with the patient accessories such as bite fork or jaw attachment. Information concerning accessory components is limited to key safety and maintenance measures and/or hygiene measures.

The software and hardware usage instructions can be viewed in the WinJaw + software as online help (F1 key).

In addition, the documents are available on the enclosed installation media as well as online at <https://www.zebris.de/en/info-menu/downloads/>



Please read this instruction carefully before using the product for the first time to avoid operating errors and damage.

The exact adherence to the instructions in all sections of the operating Instructions for the measuring system is a precondition for its intended use.

1.2 Target Group

This document is intended for dentists, dentists, practice staff and service personnel.

1.3 Symbols used on products, packaging and instructions for use



Warning instructions designate a potential danger to the health and safety of users and/or patients. The instructions explain the type of danger and how it can be avoided.



Notices designate a potential danger that can cause damage to the device. The instructions explain the type of danger and how it can be avoided.



CE mark according to EC directive 93/42 Medical devices



Manufacturer



Type BF device corresponding to DIN EN 60601-1



HF-transmitter (WiFi)



USB port



Direct Current



This symbol shows that pursuant to the Directive on Waste Electrical and Electronic Devices (2012/19/EU) and national legislation, a product cannot be disposed of via the



Refer to instructions for use.



Item number



Serial number



Lot number



An accessory that is intended for one-off use on a single patient during a single treatment.

2 Area of use and safety

2.1 Intended use

The JMA-Optic system captures the individual mandibular movements of the patient by optical triangulation.

From the movement data, parameters are calculated and visualized, which serve to assist in the design of functional dentures and bite splints.

The JMA-Optic systems also is able to calculate functional parameters for the programming of virtual and mechanical articulators and export of data for further processing with CAD/CAM or DVT systems. Furthermore, the system allows the therapeutic positioning of the mandible in a jaw relation.

The JMA-Optic system must be used by trained dentists and its application environment is limited to dental facilities. A typical measurement is performed within 15 minutes.

Patients must be able to mentally follow the operators instructions exactly. The device must not be used on open wounds in the oral and head area.

2.1.1 Use

The system consists of face bow and lower jaw sensor. The face bow is placed on the patient's head and is supported on the nose. The lower jaw sensor is temporarily fixed with an accessory on the lower jaw. Subsequently, a measurement can be performed.

Through the visualization of positions and movements, disorders of the dental-oral-jaw system (stomatognathic system) can be determined.

Functional analysis can be used to determine both discoordinations and movement limitations as well as a neuromuscular jaw relation.

The system software calculation of adjustment data of fully adjustable articulators. It supports several well established articulators.

Interfaces for data export enable the use of the movement data recorded by the JMA-Optic in CAD / CAM systems and CBCT systems for the functional optimization of dental prostheses and bite splints.

The use of the JMA-Optic is only permitted as an additional diagnostic tool. Measurements must be verified by means of additional measures before invasive procedures are taken.

2.1.2 Data export

The XML export function allows the use of determined jaw movements in CAD/CAM systems and CBCT systems for functional optimization of dentures and occlusal splints. As a reference for data matching serves a bite fork. This carries reference marks which can be detected by imaging systems such as surface scanner or CBCT.

2.1.3 Product life

Provided that the software of the JMA-Optic and the operating system of the measurement PC are kept up to date, a product life of approx. 10 years can be expected.

2.2 Safety

2.2.1 Environmental conditions

The JMA-Optic is suitable for use in dry interior rooms, as can be found in clinics, medical practices and laboratories.

Temperature:	0°C to +45°C
Air pressure:	700 - 1100 hPa
Relative humidity	max. 85%, non condensing



The devices may not be operated in wet zones, damp areas, climatic chambers, under-pressure-, overpressure-, or height-chambers.

The system is not intended for use in areas where there is a risk of explosion, rooms used for medical purposes or in a flammable atmosphere (oxygen-enriched).

The devices should not be used near engines or transformers with a big connected load, for example, or heavy current power lines, as electrical or magnetic interference fields can distort the correct measurements and/or render them impossible.

Do not operate the device in the immediate vicinity of heat sources (radiators) or in direct sunlight, because IR radiation could affect the accuracy of the measurements.

2.2.2 Storage and transport

Storage and transport of the JMA-Optic should only be carried out in the original packaging (hard case) provided by the manufacturer.

Temperature:	-20°C to +70°C
Relative humidity:	max. 95%, non condensing
Protect from moisture	



The JMA-Optic contains lithium-ion batteries. When shipping the JMA-Optic, transport instructions for Li-ion batteries must be adhered to. Additionally: Labeling of the transport packaging according to valid regulations.

Storage at temperatures > 70 ° C can lead to premature aging of the installed batteries.

2.2.3 Obligations of the user



- The general guidelines and/or national legislation, national regulations and technical regulations pertaining to medical products are to be applied and fulfilled both during installation and operation of the product appropriate to the stated intended use.
- It is the obligation of the user:
 - To comply with all the safety instructions stated in the operating instructions.
 - To carry out all of the inspection and maintenance work regularly as specified in the operating instructions.
 - To only use fault free working equipment.
 - To ensure that the device is functionally safe and in a proper state prior to every use of the device.
 - To ensure all the provided operating instructions that which art part of the measurement system, are kept within close range of the measurement system and are accessible to users at all time.
 - To protect oneself, the patients and third parties against dangers.
 - To prevent a contamination occurring by the product.
- During use, it is necessary to comply with the legal regulations especially:
 - The current work safety regulations.
 - The current accident prevention measures.
- Responsibility for safety, reliability and effective performance of the JMA-Optic is assumed in case:
 - Assembly work, extensions, new setting, changes or repairs are carried out by trained technicians or dealers explicitly authorized by the manufacturer.
 - The product operated in compliance with the operating instructions.
 - The information technology components provided by the user comply with the technical requirements for hardware and software lined out in these operating instructions, and that they are installed and set up according to the applicable instructions for these components.
 - The place of installation corresponds with the specified environmental conditions for the measurement system and the current installation regulations.
 - Only the software made available by the manufacturer, as well as the components and accessory parts listed in these operating instructions are used with the system.

2.2.4 General safety information



- The use and operation of the system and the evaluation of measurement data and its interpretation should only be carried out by trained specialist personnel. The manufacturer assumes no liability for damage to persons or property, or the loss of data that may occur due to the improper use of the software, the device, or its accessory parts.
- Patients and measurement data may only be copied, moved or deleted with the help of the database function that is provided by the zebris software application. In the case of the deliberate changing of data without the database function, the user alone bears the full risk.
- Before reinstalling and updating the software, a backup of the database must be created. After data records have been imported, the integrity of the database must be validated by the user.
- All measurement and/or analysis results should always be interpreted by a trained specialist and checked for their relevance in consideration of the clinical medical history of the patient and in the context of the further diagnostic procedure. If invasive measures are taken, the measurement system should only be used as an additional assessment method. Under no circumstances can or should invasive surgery or measures that put the patient at risk be carried out based on the measurement results alone.
- The measuring system must be checked at regular intervals to make sure it is functioning properly. More details on this can be found in the section, "Maintenance of the Device" in this User Manual.
- Ensure that all power and connection cables are routed and protected so that nobody is able to trip over them. Check all cables and connection plugs regularly for damage. Damaged power supply units, plug connectors and cables must be replaced before further use.
- The measurement system is not protected against the penetration of fluids. If fluid penetrates the measurement system, switch it off and please contact the technical service team of your sales partner.
- Never insert objects into components of the measurement system.
- Before starting every measurement, it is necessary to ensure the correct choice and correct position of face bow and lower jaw sensor. The cables or the application aids can present a risk of injury to the patient. In this context, please consult the special instructions in the handbooks of the application software, and do not allow children or mentally impaired patients to enter the proximity of the device without supervision.

2.2.5 Safety information on heart pacemakers / defibrillators



- The magnetic coupling for attaching the lower jaw sensor to the lower jaw attachment contains strong permanent magnets (neodymium magnets) such as those that are used on headphones on MP3 players. Electronic implants such as e.g. Pacemakers or ICD's can switch to a maintenance mode when the magnetic field is strong. To exclude potential risks, patients with electronic implants should keep the lower jaw sensor at a minimum distance of 10 cm from the patient's chest and record with an upper body. Also, the lower jaw sensor should not be placed on the patient's upper body in patients with.
- The JMA-Optic can be operated wireless via WiFi as an interface to the evaluation PC. Although there are no indications of possible interference with electronic implants by WiFi transmitters, it is recommended for patients with electronic implants to keep the face bow of the JMA-Optic **at least 15 cm away from the patient's thorax.**

2.2.6 Prohibited use



- Improper and/or prohibited use of the measurement system is not permitted an express warning is herewith provided of such.
- Do not under any circumstances attempt to maintain or prepare the measurement system in any way other than as described in the operating instructions. This could cause the high sensitivity sensor technology to be in impaired terms of its measurement accuracy.
- In the case of malfunctions and/or defects being suspected and/or ascertained, the device has to be taken out of use immediately, labeled as 'Out of Use', and secured to prevent use, with the on/off switch being covered and secured with adhesive tape. Please contact your dealer before further use.
- Changing or modifying the measurement system or its accessory parts without the written permission of zebris Medical GmbH is not allowed. If the device is changed without permission, the operator is obliged to carry out suitable examinations and inspections in order to guarantee the secure use.
- It is not permitted to operate the systems under conditions different from those lined out in chapter "Environmental Conditions".
- Do not attempt to reprocess the disposable accessories. In addition to an infection risk associated with reprocessing, it can not be guaranteed that equivalent measuring accuracy will be obtained by using reprocessed components. Thus, the reprocessing eliminates the manufacturer's warranty for the disposable product.
- Parallel / simultaneous operation of other programs (SOUP) and WinJaw + on the same PC system is not permitted and is not provided for purpose. The manufacturer assumes no liability for hazards that occur in this context.

3 Product description

3.1 System components

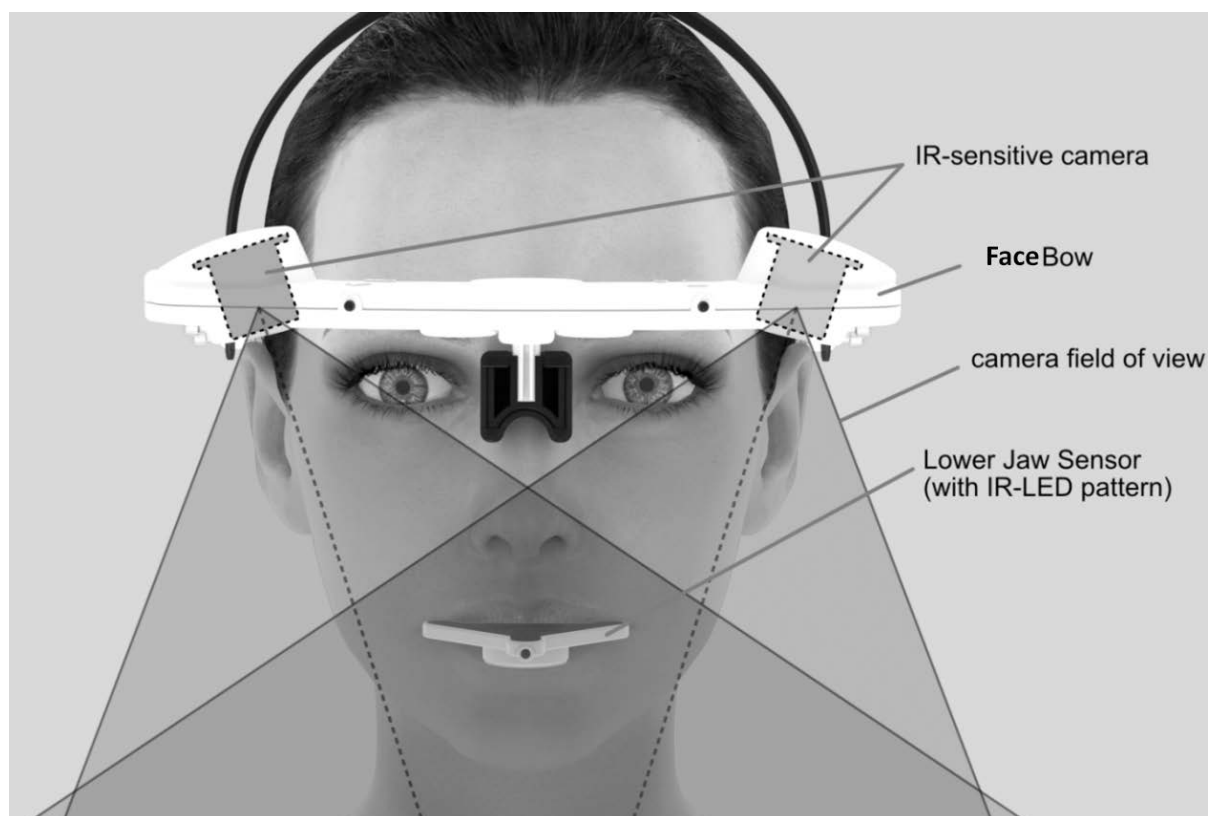
In the basic configuration, the JMA-Optic consists of the following components:

- JMA-Optic Face bow (receiver)
- Lower jaw sensor (transmitter)
- USB power supply for supplying the inductive charger and/or the face bow
- USB adapter with connector plug to the face bow (includes galvanic isolation)
- WinJaw + application software
- Accessories (IR foot switch, T-pointer, bite fork, attachments)

3.2 Functional principle of JMA-Optic system

The JMA-Optic is based on the technology of stereoscopy (optical triangulation). This technology principle is implemented by means of two cameras integrated in the Face Bow (receiving and control unit) at a defined distance and angle. The cameras record a pattern of infrared LED's which are integrated within the battery driven Lower Jaw Sensor (transmitting unit).

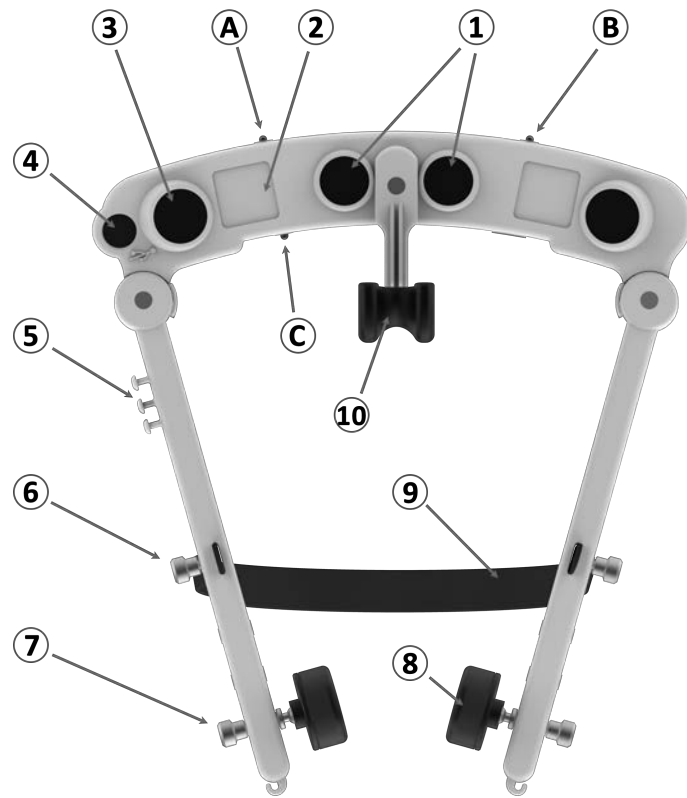
When the Lower Jaw Sensor is moved, the cameras register a slightly distorted picture of the Lower Jaw Sensor's LED pattern. These distortions are used to calculate the coordinates of the Lower Jaw Sensor in 3-dimensional space. The coordinates are transferred to a connected computer in a constant stream via either WiFi or USB interface. The application software on the computer carries out all further calculations as well as elimination of transients.



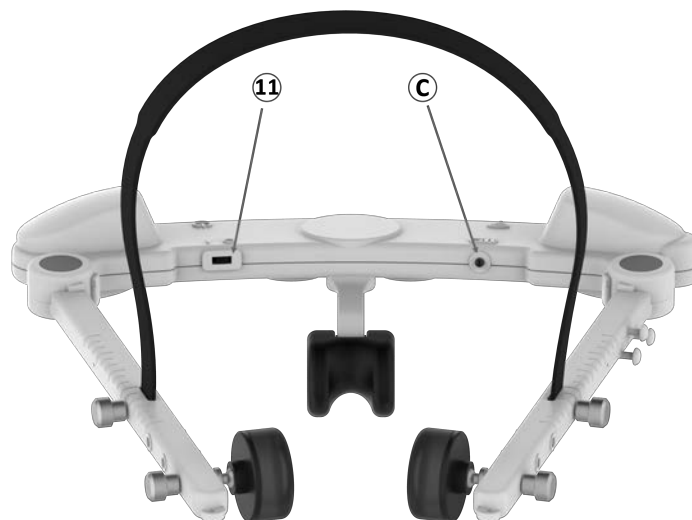
3.3 Elements of the JMA-Optic system

- 1 IR-Sync LED's, Face bow
 - 2 Product labeling: Label, Face bow
 - 3 Camera modules left / right
 - 4 Connection socket: external power supply / data transmission
 - 5 Cable guide / strain relief
 - 6 Knurled screw for locking: overhead band
 - 7 Knurled screw for locking: bearing seat
 - 8 Bearing cushions / Bearing seat
 - 9 Headband
 - 10 Nose Cushion
 - 11 Transport switch
 - 12 IR-Sync LED's, Lower jaw sensor
 - 13 Magnetic coupling for lower jaw attachment
 - 14 Product labeling: Label, Lower jaw sensor
 - 15 Power supply, USB socket, Inductive charger
 - 16 Product labeling: Label, Inductive charger
 - 17 Product labeling: Label, IR Foot switch
 - 18 Product labeling: Label, IR Remote Control
-
- A Status-LED, Face bow, "WiFi Connection" (blue)
 - B Status-LED, Face bow, "Measurement active" (green)
 - C Status-LED, Face bow, Power supply / battery charging (orange)
 - D Status-LED, Lower jaw sensor, "Measurement active" (green)
 - E Status-LED, Inductive charger, "Power supply" (green)
 - F Status-LED, IR Foot switch, "Device active" (green), "Battery low" (orange)
 - G Status-LED, IR Remote control, "Device active" (green)
 - H IR-Sync LED, IR Remote control

3.4 Face bow



Cleanliness / integrity of the optical components (1 & 3) must be checked before each use to ensure the accuracy of the measuring system.



The transport switch (11) disables the batteries to prevent accidental activation of the head bow and discharge of the batteries.

3.4.1 Technical data

Property	Value
REF	01170010
Dimension (W x H x L)	222 x 60 x 250 mm
Weight	208 g
Power supply	5V DC / 2,5W (USB for battery charging)
Max. recording rate	60 Hz
Measuring accuracy (occlusal)	± 0.05 mm (x, y, z); ROM 15 mm
Connector socket	device specific Push-Pull plug (USB)
PC interface	WiFi / USB



Device contains lithium-ion batteries. When shipping the device, comply with the transport instructions for Li-Ion batteries. In addition, a labeling of the transport packaging according to valid regulations is required.

The batteries in the face bow can only be replaced by trained service technicians. Therefore it is required to send the device to the manufacturer.

Never attempt to open the face bow or replace the batteries yourself, as this may affect the measurement accuracy and may result in an electric shock.

3.4.2 Type plate JMA Optic zebris



3.4.3 State LED's

LED Signal

State / Meaning

WiFi / (A)

Flashing, blue

WiFi not connected / active

Permanent on, blue

WiFi connected and active

Recording / (B)

Flashing, green

Face bow is switched on and ready for operation

Permanent on, green

Face bow is in operation.

Power Supply & Battery Charging / (C)

Flashing slow, orange

Warning: "Battery low"

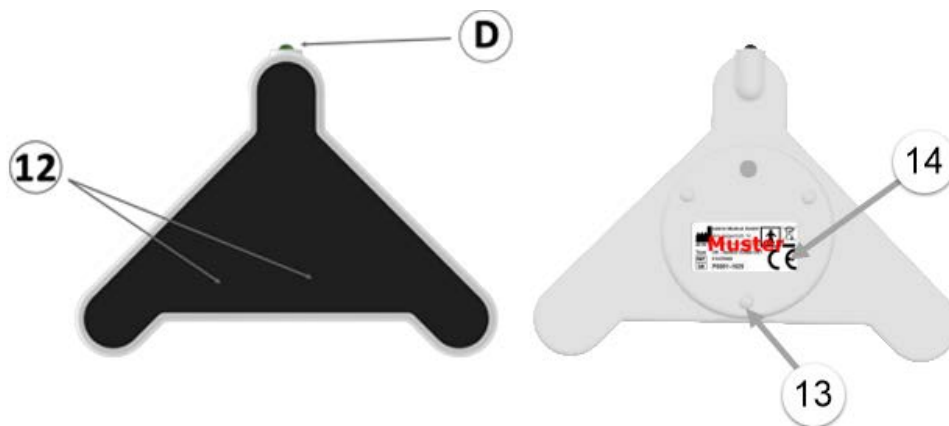
Permanent on, orange

Battery is charging

Flashing, Interval: 3s, duration: each flash 1/3s, orange

Battery is fully charged

3.5 Lower jaw sensor (UK-Sensor)



Cleanliness / integrity of the optical components (12) must be checked before each use to ensure the accuracy of the measuring system.

Deformation / wear of the magnetic coupling balls (13) between the UK sensor and Attachment may reduce the measurement accuracy of the system.

3.5.1 Technical data

Property	Value
REF	01470000
Dimensions (W x H x L)	67 x 15 x 45 mm
Weight	15 g
Battery	Lithium coin cell; type CR 1632
Energy consumption (recording active)	2 mA
Battery life	Recording: ~ 5 days Standby: ~ 17 month

3.5.2 State LED

LED-Signal (D)	State	Meaning
Permanent on	UK-Sensor is in operation	Battery condition good
Flashing	UK-Sensor is in operation	Warning: "Battery low"

3.5.3 Changing the battery

To replace the battery of the lower jaw sensor, proceed as follows:

Required Materials:

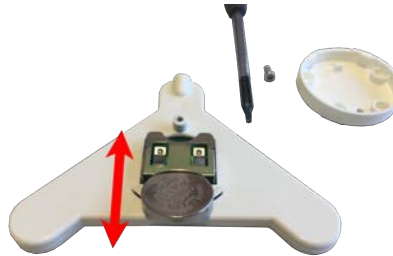
- Screw driver Type TX 06
- Coin Cell Type CR1632

Open the cover of the battery with a screwdriver TX06.



Remove the used battery.

Insert the new battery (type CR1632) into the battery holder and screw the cover back on.



Disposal of the used battery

Refer to chapter: [Disposal](#) ³⁵

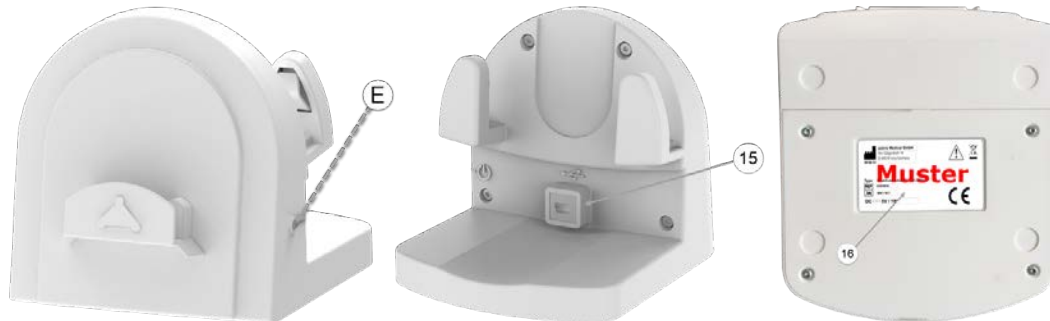


Only use CR1632 batteries within the lower jaw sensor.

3.6 Inductive charger

The inductive charger is used for wireless charging of the JMA-Optic head bow and for storing the head bow and the UK sensor.

The charging process starts automatically when the head bow is inserted into the charger and the USB socket (15) is connected to a power source.



3.6.1 Technical data

Property	Value
REF	01870010
Dimensions (W x H x L)	101 x 105 x 127 mm
Weight	340 g
Power source	USB socket type B
Permitted power sources	<ul style="list-style-type: none"> • USB power supply (included) • USB outlet of a computer • USB outlet of a USB-Hub
Standby current (face bow is not charging)	~ 12 mA
Max. charging current	~ 500 mA (5V / 1W)

3.6.2 Type plate JMA Optic zebris



3.6.3 State LED

LED-Signal (E)	State	Meaning
Permanent on	Device is charging	Normal operation, Power supply is active

3.7 IR foot switch

The foot switch provides wireless control of the WinJaw + software. Each activation of the foot switch triggers the "next" function in the WinJaw + software 1x and initiates the next step in the work flow.

The LED indicates the operation status of the foot switch. If the switch is pressed permanently for more than approx. 2 seconds, the electronics automatically switches off and the status LED shuts of.



3.7.1 Technical data

Property	Value
REF	01860020
Dimension (W x H x L)	84 x 35 x 120 mm
Weight	300 g
Battery	Bloc battery 9V, Type: 6LR91

3.7.2 State LED

LED Color	Function	Description
Permanent on / green	Device is in operation	Normal operation, Battery condition OK
Permanent on / orange	Device is in operation	Warning: Battery low

3.7.3 Changing the battery

To replace the battery of the IR foot switch, proceed as follows:

Required Materials:

- Screw driver type PH 0x40
- Battery type 6LR91/ 9Volt

Open the cover of the battery with a screwdriver PH 0x40.



Remove the used battery.



Insert the new battery (type 6LR91) into the battery holder and screw the cover back on.



Disposal of the used battery:

Refer to chapter: [Disposal](#)³⁵



Only use 6LR91 batteries within the IR foot switch.

3.8 IR remote control

The IR remote control is used for wireless control of the WinJaw + software.

Pressing the buttons emits an infra-red signal that allows control of the "next" and "back" functions within the WinJaw + software.



3.8.1 Technical data

Property	Value
REF	01860020
Dimensions (W x H x L)	27 x 14 x 141 mm
Weight	34 g
Battery	Lithium battery type CR2430

3.8.2 State LED

LED Signal (G)	State	Meaning
Permanent on	Remote control is active	Normal operation (button pressed)

3.8.3 Changing the batteries

To replace the battery of the IR remote control, proceed as follows:

Required Materials

- Screw driver type TX 06
- Lithium Battery type CR2430

Open the housing with a screwdriver TX 06.



Remove the used battery.



Insert the new battery (type CR2430) into the battery holder and close the housing



Disposal of the used battery:

Refer to chapter: [Disposal](#)³⁵⁾














Only use CR2430 batteries within the IR remote control.









4 Accessories and spare parts






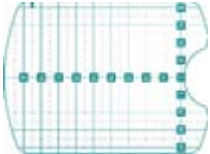


Multiple use of disposable items leads to an increased risk of infection for the patient and possibly to a falsification of the measurement and analysis results due to changes in shape of the products with multiple use of the sterilization process.









4.1 Hardware

REF	Description	Figure
01170010	JMA-Optic Face bow	
01960140	Bearing seat for JMA-Optic face bow	
11502501 (green)	Bearing cushions Package á 10 pieces, suitable for item 01960140	
11502503 (green)	Nose cushion Package á 10 pieces, suitable for JMA-Optic face bow	
11502508 (green)	Head band for JMA-Optic face bow	
01470000	Lower jaw sensor Battery powered	
01960260 	Para-occlusal Attachment for attachment to the anterior teeth suitable for gas and steam sterilization Note: Disposable, not intended for multiple use	
01960270 	Occlusal Attachment for attachment to the anterior teeth suitable for gas and steam sterilization Note: Disposable, not intended for multiple use	
01960271	Occlusal Adapter for attaching the lower jaw sensor to the occlusal attachment suitable for gas and steam sterilization	

REF	Description	Figure
01960320 	Bite fork type SD suitable for gas and steam sterilization Note: Disposable, not intended for multiple use	
01960400 	Bite fork adapter for attaching the lower jaw sensor to the bite fork suitable for gas and steam sterilization Note: Disposable, not intended for multiple use	
01970110	T-Pointer for determining the reference plane by means of the lower jaw sensor	
01870010	Inductive charger for wireless charging of the face bow	
01860417	USB-Adapter Connects the JMA-Optic face bow to the PC and charges the battery	
21030069	USB Cable Type A-B 0,90m black UL-certified For connecting the USB power supply to the inductive charger.	
33101120	USB power supply with localized adapter plug Charges / powers the JMA-Optic face bow	
33101121 + country code	Adapter plug for USB power supply available types: EU, UK, USA, AUS, IEC/World	
21030010	WiFi USB Adapter Required for wireless coupling of face bow and PC	

REF	Description	Figure
01860020	IR foot switch for wireless control of WinJaw + software	
01860020	IR remote control for wireless control of WinJaw + software	
01560050	Digital Model Transfer Allows the transfer of the jaw position into articulators with the Adesso Multisplit System. Includes protective case, 3x bite fork type SD with bolt thread, bite fork adapter, 1 set of position bolts (3 of each type), and 5x positioning foil.	
01960500	Model positioner Adesso Split Allows the transfer of the jaw position into ARTEX CR and Ivoclar Stratos articulators with the Adesso Multisplit System.	
01960501	Positioning screws set Set consisting of 3 positioning screws each, in lengths of 30mm, 45mm and 60mm. To set the coupling tray height for the digital model transfer.	
01960510	Positioning Films Set Positioning film for mounting on the model positioner to position transmission for digital model transmission. Package á 5 pieces,	

4.2 Software

REF	Description	Figure
07210200	WinJaw + application 3D-Analysis for 3D and function analysis.	
07210220	WinJaw + application Jaw Relation for designation of neuro muscular jaw relation.	
07210250	WinJaw + application EPA Electronic Position Analysis and determination of condyle positions.	
07210260	WinJaw + application CSV-Export enables the export of the report parameters as well as the movement data into export files to be opened with MS Excel.	
07210000	WinJaw + licence enhancement the basic version contains licences for installation on 3 PC's. Extension for installation on an additional computer. PC.	
07210290	WinJaw + option external database allows installation of zebris database in a freely configurable network path.	
79010230	Hardware user manual Printing edition is liable to be charged. Availability from 5 working days after receipt of order.	
79010240	Software user manual Printing edition is liable to be charged. Availability from 5 working days after receipt of order.	

5 Putting the system into operation

Commissioning the JMA-Optic system requires the USB adapter (REF 01860417), the WiFi USB adapter (REF 21030010) and the WinJaw + application software. All components are included with the JMA-Optic system.

5.1 Power supply and charging the batteries

There are three ways to charge the batteries in the face bow.

- Plug the USB power supply into a wall outlet and connect the turned-off face bow to the power supply using the supplied USB adapter (REF 01860417).
- Charging via inductive charger (REF 01870010).
- Charging or operation directly on the USB socket of a PC. To accomplish this, connect the face bow to the PC using the USB adapter (REF 01860417).

The batteries are fully charged after about 1.5 hours charging time.

A fully charged battery allows for about 10 applications per patient with an average recording time of 3 minutes.



Only connect the USB power supply that is approved and supplied by the manufacturer and arrange the measurement system such that the plug for the power socket is easily accessible at all times and the device can be easily disconnected from the mains.

Visually inspect the power supply unit, power supply cable and socket as well as protective contacts before connecting or operating the system. Damaged power supplies, cables or plug-in devices must be replaced immediately by a person authorized to do so.



The JMA-Optic system may only be connected with other electrical devices if they correspond with the requirements of DIN EN 60950 and/or DIN EN 60601-1, or have been designated as compatible by the manufacturer.

When connecting several devices to a single measurement station, it is necessary to ensure that no dangers can occur due to the accumulation of leakage currents.

Devices with that the patient comes directly into contact, and that are used together in a single medical electrical system, must comply in complete form with all the requirements of DIN EN 60601-1:2013, section 11.

Do not use multiple sockets to combine medical and non-medical devices. There is the risk of an electrical shock upon contact with devices that are not earthed separately. (also refer to chapter [multiple-sockets](#)^[37])



Before connecting the USB power supply to the mains, consult the type plate information on the USB power supply, checking that the voltage and frequency is consistent with the local data. Only connect if such consistency is given.

5.2 Lower jaw sensor

Before the lower jaw sensor is set into operation for the first time, the transport lock, which disconnects the battery from the electronics when it is delivered, must be removed.

Pull the safety tag in the direction of the arrow away from the housing to activate the battery.



5.3 IT security and software installation

If the system is not shipped with a computer and properly installed WinJaw + software, the operator is responsible to ensure that the safety of patients, operators and environment is not compromised by the computer. If in question please contact a dealer authorized by the manufacturer.

For the requirements of the WinJaw + Software with concern to a PC/laptop, please refer to the instructions for use on WinJaw + Software.

In order to provide easy integration into an existing system for data backup and to store personal data separately from the PC the data base of the application software can be installed on a network server.

If the database of the WinJaw + software is stored on a storage medium connected via an IT network, the following requirements have to be met:

- the data connection must be secured against interference by third parties,
- the data connection must be secured against disconnections,
- applicable data protection regulations must be adhered to for the data connection in the IT network as well as for the location in the IT network,
- access to the location in the IT network must be restricted to the authorized group of persons,
- the exchange of data between the WinJaw + database and the IT system is realized via the SMB protocol,
- the exchange of data with third party devices in the IT network is not provided.



If the requirements listed above are not met, the following hazardous situations may arise:

- Data loss due to disconnection during data transfer between WinJaw + software and IT network,
- Unauthorized access to personal data by third parties,
- Complete data loss due to missing data backup in the event of disruptions and / or damage to the IT network.



The manufacturer is unable to accept any liability for damage or functional errors that are caused by faulty software installation or unsuitable computer hardware. If the operator installs additional hardware or third party software, this occurs based on the sole responsibility of the operator and is not covered by the manufacturer's liability.

The computer needs to be CE-marked and needs to satisfy the requirements of DIN EN 60950 and/or DIN EN 60601-1.



Connecting the system to a network/data pool can cause unforeseen risks to the patient and third parties. If the database of the WinJaw + software is installed in a network/data pool, the operator is obliged to ascertain, analyze, evaluate and manage all of the associated risks. In this context, the aspects of data protection, virus safety, updates to the operating system and regular backups are of particular importance. The risk assessments also have to include the subsequent changes to the network/data pool, such as updates/upgrades to devices and components that are connected with the network.

The connection of the PC system to the Internet must take place via a professionally maintained IT network in conjunction with a hardware firewall in order to minimize risks due to the Internet connection. Never use the local computer with Internet access with administrator rights.



For the safe operation of the measuring system are the aspects of data protection, virus security, updates of the operating system and regular backups of the WinJaw + database on external data carriers of essential importance and to be implemented by the user as measures of IT security.

If the system is delivered without PC/laptop, please install the application software before connecting the JMA-Optic to the computer. Please find information on the installation in the user manual of the WinJaw + software.



Should problems with the hardware driver of the JMA-Optic system occur then disconnect and restart the PC



Installing a virus scanner on the PC can interfere with the proper functioning of the application software. The manufacturer is not liable for damages caused by such programs..

6 Decommission the system

To take the system out of service, first close the WinJaw + software and then shut down the PC.

Move the face bow transport switch to position (0) and store face bow in transport case.

After 2 minutes at rest, the face bow automatically shuts off.

Finally, if necessary, remove the charger from the mains socket and store all components of the JMA-Optic system in the carrying case.

7 Functional checks, preparation, disposal

- Regular maintenance of the system helps to prevent damage and guarantees its long-term safety. All of the procedures described in these instructions for use concerning maintenance and preparation of the system are to be carried out on a regular basis.
- If the system or accessory parts show damage, they should be sent to the manufacturer for a safety inspection. In the case of malfunctions and/or defects being suspected and/or ascertained, the device has to be taken out of use immediately, labeled as 'Out of Use'.
- All maintenance and servicing work on the system or individual parts that are extended beyond the activities described in the instructions for use may only be completed by the manufacturer or authorized organizations.
- Prior beginning the preparation, switch the measurement system off under all circumstances and disconnect it completely from the power supply.



The cleanliness and integrity of the optical components must be checked before each use to ensure the accuracy of the system.

7.1 Regular checks and safety checks

- To maintain the proper status of the electrical operating equipment, it is necessary to carry out repeated inspections and technical safety checks (e.g. in Germany according to BGV A3 accident prevention regulations as well as technical safety checks pursuant to the German Medical Products Operator Ordinance).
- For safety reasons, inspecting the proper state of all the connection cables, network cables, USB power supply and power sockets is recommended before every use of the measurement system. If parts are damaged it is necessary to replace them before using the measurement system again.
- Immediate servicing measures are to be carried out by the manufacturer if:
 - a) any liquids/fluids entered the device.
 - a) the cables or plug connectors show any damage.
 - a) parts of the sensor technology are damaged.
 - a) covers are damaged or have come off.
 - a) a defect or fault is either suspected or ascertained.
- If the name plate or other labeling (e.g. warning notices) on the machine are damaged or unreadable, these are to be replaced.



For face bow or UK sensor service, please always ship both components together in the original case to your dealer or manufacturer.

7.2 Checking the measurement function



The JMA-Optic system should be periodically checked by the user for proper operation to ensure patient safety on a permanent basis.

After hard knocks, or if the face bow or lower jaw sensor has fallen to the floor, a re-calibration by the manufacturer must be performed to ensure system high accuracy.

In the case of recognizable damage to system components (deformation, dents, cracks), no further recordings may be made.

If the surfaces of the IR filter discs on the JMA-Optic head bow and / or lower jaw sensor are scratched, use is prohibited. Correct results can not be guaranteed.

- To inspect the system, for known jaw functioning measurements (e.g. known maximum opening width, known condylar range of motion with protrusion, known horizontal condylar guidance inclination), the user can measure himself with the measurement system. These measurement results should correspond with the known values.
- When the sensors do not move, the WinJaw + software should show an unmoving image of the lower jaw. Possible deviations (spikes or jumps in the measurement curve in spite of unmoved markers, incorrect presentation of the lower jaw, etc.) indicate a faulty measurement and impair the evaluation.
- Should there be any doubts about the measurement accuracy, re-calibration of the JMA-Optic system by the manufacturer is recommended in order to ensure the specified accuracy.



In order to guarantee the high accuracy of ± 0.05 mm (x, y, z) permanently, the JMA-Optic system should be recalibrated at the latest after 3 years by the manufacturer.

7.3 Troubleshooting

In case of problems, please first check the following points:

- Is the JMA-Optic system switched on and powered? When the green status LED's on face bow and lower jaw sensor are lit, the batteries are charged or an external power source is connected and the system is ready for use.
- Is USB or WiFi connection between the system and the PC correctly established? If the WiFi connection is correct, the blue LED is permanently lit.



For further information on error messages and their rectification, please refer to the instructions for use of the WinJaw + software.



To be able to provide you with the optimum support in the case of operational faults of the JMA-Optic system, our service team requires the following information:

Checklist for the recording of error messages

- Serial numbers of face bow and the lower jaw sensor.
The serial numbers are on the type plates located on the bottom of face bow and lower jaw sensor.
- WinJaw + software version.
The version of the WinJaw + software can be found in the "Program Information" in the "About" dialog (question mark button) of the software.
- Operating system version of your measurement PC.
The version of the operating system can be found in the "System Information" in the "About" dialog (question mark button) of the software. e.g. Windows 10 Professional Build 1803
- Further components connected to the JMA-Optic system.
- List of all USB/WiFi devices connected to the system e.g. mouse, printer, other measuring systems, etc.
- Screen shot of the error message, or exact wording e.g. „Timeout reading from USB“
- Precise and detailed description of the procedure that has led to the error message.
e.g. Measurement "Type A" started, then clicked on button "B", afterwards carried out movement "C", switched to function "D", when switching back, the error message xyz occurred etc.

7.4 Processing methods



After every case of use of the JMA-Optic system, reprocessing is required according to DIN EN ISO 17664. All accessory parts that come into contact with the patient's mucosa have to be sterilized before use.



Before starting cleaning work or disinfection, switch the measurement system off under all circumstances and disconnect it completely from the USB connection and the USB power supply.

The following accessory parts are intended for single-off use on one patient only and should never be reprocessed after use.



- Para-occlusal attachment
- Occlusal attachment
- Bite forks of all types
- Bite fork adapter

Before use on the patient, these accessories are to be sterilized (see chapter [Sterilization](#)³⁴).

7.4.1 Manual disinfection

The disinfection of electrical components (face bow, lower jaw sensor, IR remote control, IR-foot switch) should only be carried out when the system is switched off and the USB power supply and/or USB cable are unplugged.

The electrical components of the system can be wipe-disinfected with suitable solutions. Disinfect all electrical components (face bow, lower jaw sensor, IR remote control, IR-Footswitch) with a cloth that has been dampened with a disinfection solution.

Recommended disinfectant solution

Composition approx. 25% ethanol, 35% propanol

e.g. Mikrozid Wipes (wipes impregnated with marcocide) / Schülke & Mayr, or comparable



When using a disinfectant solution, please comply with the recommendations stated by the manufacturer, especially the specified application time.



Due to the risk of possible mix-ups, chemicals that are required for the disinfection or cleaning must only be stored, prepared and kept ready in their intended containers.

7.4.2 Manual cleaning

Electrical components:

The cleaning of electrical components (face bow, lower jaw sensor, IR remote control, IR-foot switch) should only be carried out when the system is switched off and the USB power supply and/or USB cable are unplugged, and using a damp cloth.

Cleaning prior to sterilization:

- Prior to sterilization, clean the accessory parts by hand under running water (drinking water quality, $30\text{ °C} \pm 5\text{ °C}$, flow rate 2 liters/min.) with a medium strength toothbrush for 30 seconds.
- Complete the sterilization immediately subsequent to the cleaning.

7.4.3 Sterilization

All accessory parts that come into contact with the patient's mucosa have to be sterilized before use.



The sterilization is to be completed immediately subsequent to the cleaning.

Sterilize the bite-forks, bite fork adapters and lower jaw attachments with a fractionated pre-vacuum for four minutes at $134\text{ °C} \pm 1\text{ °C}$ and 2 bar (can be sterilized up to a max. of 138 °C).

7.5 Disposal

7.5.1 Packaging

All transport packaging's delivered by zebris Medical GmbH can be recycled within Germany via the local recycling depots. In order to provide the reuse of the recyclable material contained in the packaging, the zebris Medical GmbH takes part in the dual ZENTEK system that takes over the proper disposal of packaging.



7.5.2 Disposal of electronic waste

The adjacent symbol shows that pursuant to the EC Directive on Waste Electrical and Electronic Devices (2012/19/EU) and national legislation, a product cannot be disposed of via the household waste, and must be disposed of separately within Europe.

For this purpose, at the end of its product life, the measurement system can be returned by the customer to the manufacturer, and will then be forwarded by him at no extra cost and without reimbursement to the appropriate recycling companies.

Due to potentially dangerous substances that can often be found in electrical or electronic devices, the improper handling of old devices can have a negative impact on the environment and human health. In disposing of this product properly, you also contribute to an effective use of natural resources.



7.5.3 Accumulators and batteries

Batteries do not belong in the household waste! In the interest of protecting the environment, the end user is legally obliged (Battery Directive) to hand in old and used batteries. Used batteries and power packs can be handed in at the district collection points, or in all locations where such batteries are offered for sale. The batteries are accepted at no cost to the consumer.



The batteries in the face bow can only be replaced by trained service technicians. Therefore it is required to sent the device to the manufacturer.

Never attempt to open the face bow or replace the batteries yourself, as this may affect the measurement accuracy and may result in an electric shock.

8 Safety standards and system classification

8.1 Classification pursuant to appendix IX of the directive 93/42/EEC

The system is classified as a medical product of **Class I with a measuring function**.

8.2 Safety of medical electrical devices

The device fulfills the requirements of the standard DIN EN 60601-1:2013.

Classification according to DIN EN 60601-1

- Type BF
- Safety class II
- Steady state conditions
- Unsuitable for use in an oxygen-enriched atmosphere

8.2.1 Connecting the system to other electrical devices

(also refer to DIN EN 60601-1:2013 section 16 medical electrical systems)



The JMA-Optic system may only be coupled with other electrical devices if these conform to the provisions of DIN EN 60950 or DIN EN 60601-1 or the manufacturer has confirmed their compatibility.



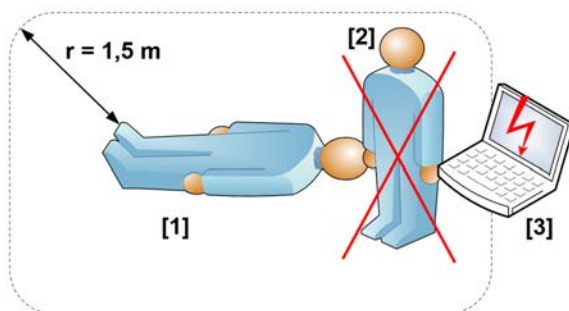
When coupling several devices to one measuring station, please note that no danger through summation of leakage currents can occur.

Devices that are in direct contact with the patient and that are commonly used in a medical electrical system, as a whole have to fulfill all requirements of DIN EN 60601-1:2013 section 16.

There is a potential danger of electric shock when touching devices that are not grounded separately.

8.2.2 Environment of the patient

In practice, as an empirical value a clearance of 1.5 m from the patient has proven effective for the determination of the patient environment.





When operating the JMA-Optic system, the user [2] must be sure never to touch the PC [3] and the patient [1] at the same time. The same applies to all other non-medical electrical components that are only to be used outside the patient environment.

Failure to comply can lead to the occurrence of dangerous leakage currents.

The following components of the JMA-Optic system may only be used within the patient environment:

- JMA-Optic system (face bow, lower jaw sensor, accessories)
- IR foot switch, IR remote control



The computer, the inductive charger and other non-medical electrical accessories have to be set up outside of the patient environment (1.5 m clearance).

8.2.3 Multiple Sockets



If multiple sockets are used for connecting the JMA-Optic system or its components (especially PC and inductive charger), the following safety regulations are to be observed:

It is extremely dangerous to use multiple sockets for combining the mains connection of components of Medical Electrical Equipment Systems with non medical components that. It is possible for excessive touch currents to occur if mains are connected without the user having any respective expert knowledge. In the worst case, the impedance of the protective conductor system limits the short-circuit current in such a way that the fuse does not trip.

The manufacturer advises to connect the power supply of the face bow always directly to a wall socket with a tested protective earth and separate fuse.

- If multiple sockets are used jointly for face bow and PC / inductive charger the multiple socket and complete interconnection of the system must adhere to all the requirements of DIN EN 60601-1:2013 Section 16. If necessary, an isolating transformer is to be used for an arrangement of this kind, and the ground leakage current in the protective earth conductor of the multiple sockets must not exceed 5 mA. The adherence to the maximum permissible patient leakage currents is to be verified by measuring. If a multiple socket was integrated after setting the system into operation for the first time, no additional device may be connected to it (use multiple sockets with locking covers for this purpose)
- Multiple sockets must not be placed on the floor to avoid accidentally penetration of liquids or mechanical damages.
- It is forbidden to use several multiple sockets connected in series.
- Multiple sockets can be used without causing any danger for connecting the PC and inductive charger outside the patients' vicinity.

8.3 Electromagnetic compatibility guideline

The JMA-Optic system complies with the requirements of the EN 60601-1-2 standard.

Detailed information on EMC values and information supplied by the manufacturer can be found in the tables in this section of the user manual.

Electrical equipment in the medical field is subject to particular precautionary measures as regards the EMC (Electromagnetic Compatibility) and must be installed and put into operation in accordance with the instructions given below.



Even though the JMA-Optic system fully complies with the requirements of the standard EN 60601-1 it cannot be totally guaranteed that portable and mobile RF communications equipment cant affect the system. If ever possible such devices should not be operated within close vicinity of the system during measurements



The use of accessories, particularly cables for connecting to the PC, that are not supplied by the manufacturer for use with the JMA-Optic systems, or explicitly recommended for use with the device, can lead to a reduced resistance to EMC interference of the JMA-Optic system.




The JMA-Optic system should not be operated in the vicinity of e.g. X-ray equipment, motors or transformers with a high connected load, as electrical or magnetic interference fields can influence the measurements. The same is applicable for neighbouring power lines and equipment without a CE mark. Should operation next to possible sources of interferences be necessary it is mandatory to check and verify the correct function of the system.

Guidelines and Manufacturer's Statement - Electromagnetic Emission		
The JMA-Optic system is intended for use in the electromagnetic environment described below . The customer or user of the JMA-Optic system should ensure that it is operated in such an environment.		
Emitted interference measurements	Compliance	Electromagnetic environment guidelines
RF emissions acc. to CISPR 11	Group 1	The JMA-Optic system uses RF energy exclusively for its internal functions. Therefore its RF emission is very low and it is unlikely that electronic equipment in close proximity will experience interference. The JMA-Optic system is intended for use in all facilities including those in residential areas and those directly connected to a public utility network also supplying buildings used for residential purposes.
RF emissions acc. to CISPR 11	class B	
Emission of harmonic oscillations acc. to IEC 61000-3-2	class B	
Emission of voltage fluctuations / flickers acc. to IEC61000-3-3	in compliance	

Guidelines and Manufacturer's Statement - Electromagnetic Interference Immunity			
The JMA-Optic system is intended for use in the electromagnetic environment described below. The customer or user of the JMA-Optic system should ensure that it is operated in such an environment.			
Interference immunity tests	IEC 60601 test levels	Compliance level	Electromagnetic environment guidelines
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV atmospheric discharge	± 6 kV contact discharge ± 8 kV atmospheric discharge	Flooring should be of wood or concrete or laid with ceramic tiles. If the flooring is made of synthetic material, the relative humidity must be at least 30%.
Fast transient electrical interferences/bursts acc. to IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines	± 2 kV for power lines ± 1 kV for input and output lines	The quality of the supply voltage should be the same as the voltage of a typical business or hospital environment.
Surges acc. to IEC 61000-4-5	± 1 kV differential mode voltage ± 2 kV common mode voltage	± 1 kV differential mode voltage ± 2 kV common mode voltage	The quality of the supply voltage should be the same as the voltage of a typical business or hospital environment.
Blackouts, brownouts and fluctuations of the power supply acc. to IEC 61000-4-11	< 5% UT (> 95% crash of the UT) for ½ period 40% UT (60% crash of the UT) for 5 periods 70% UT (30% crash of the UT) for 25 periods < 5% UT (> 95% crash of the UT) for 5 s	< 5% UT (> 95% crash of the UT) for ½ period 40% UT (60% crash of the UT) for 5 periods 70% UT (30% crash of the UT) for 25 periods < 5% UT (> 95% crash of the UT) for 5 s	The quality of the supply voltage should be the same as the voltage of a typical business or hospital environment. If the user of the jaw motion measuring system requires the continuation of functionality also after power interruptions/disruptions, it is recommended to provide the jaw motion measuring system with power from an uninterrupted power supply.
Magnetic field with supply frequency (50/60 Hz) acc. to IEC 61000-4-8	3 A/m	Not tested as no influence is possible on the device within the specified test level. (see Note B)	Magnetic fields of the mains power frequency should comply with the typical values of a business and hospital environment.
NOTE UT is the AC main voltage prior to applying the test levels.			

Guidelines and Manufacturer's Statement - Electromagnetic Interference Immunity

The JMA-Optic system is intended for use in the electromagnetic environment described below. The customer or user of the JMA-Optic system should ensure that it is operated in such an environment.

Interference immunity tests	IEC 60601 test levels	Compliance level	Electromagnetic environment guidelines
			Portable and mobile wireless sets should not be used in closer proximity to the jaw motion measuring system, including the cables, than the recommended safety distance, that is calculated on the basis of the formula suitable for the transmitting frequency. Recommended safety distance:
Conducted RF interference quantities acc. to IEC 61000-4-6	3 V _{eff} 150 kHz to 80 MHz	3 V _{eff}	$d = 1,2\sqrt{P}$
Radiated RF interference quantities acc. to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1,2\sqrt{P}$ 80 MHz to 800 MHz
			$d = 1,2\sqrt{P}$ 800 MHz to 2.5 GHz
			With P as the rated output of the transmitter in watts (W) according to the information provided by the manufacturer of the transmitter and d as the recommended safety distance in meters (m). The field strength from fixed RF transmitters as determined by an electromagnetic site survey a is less than the compliance level b in all the frequencies. Interference is possible in the proximity of devices featuring the following pictograph
NOTE 1	The higher value applies in the case of 80 MHz and 800 MHz		
NOTE 2 influenced	These guidelines may not be applicable in all situations. The spread of electromagnetic waves is influenced by absorption and the reflections of buildings, objects, and people		
a	The field strength of stationary transmitters, such as the base stations of mobile phones and land mobile services, ham radio stations, AM and FM radio and TV broadcasters is theoretically not 100% predictable. A site study is recommended to determine the electromagnetic environment as a result of stationary RF transmitters. If the measured field strength at the site of the measuring system exceeds the compliance levels listed above, the %MEASUREMENT_SYSTEM %> system must be monitored to document its proper functionality at every place of application. Additional measures might become necessary, e.g. modifying the orientation or moving the location of the %MEASUREMENT_SYSTEM %> system, if unusual performance characteristics are observed.		
b	The field strength is less than 3 V/m for the frequency range of 150 kHz to 80 MHz		

Recommended Safety Distances between Portable and Mobile RF Telecommunications Devices and the % MEASUREMENT_SYSTEM %> jaw motion measuring system

The JMA-Optic system intended for use in an electromagnetic environment where RF interference quantities are controlled. The customer or user of the JMA-Optic system can contribute towards preventing electromagnetic emissions by complying with the minimum distance between portable and mobile RF telecommunications devices (transmitters) and the jaw motion measuring system, as recommended below in accordance with the maximum output power of the communication device.

Rated output of the transmitter (W)	Safety distance based on the transmitting frequency (m)		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2,3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

The safety distance for transmitters with a rated output not listed in the table above, can be calculated by applying the formula corresponding to the respective column, whereby P is the rated output of the transmitter in watts (W) as specified by the transmitter manufacturer.

NOTE 1 For calculating the recommended safety distance of transmitters in the frequency range of 80 MHz to 2.5 GHz, an additional factor of 10/3 was used to reduce the probability of a mobile/portable telecommunications device taken unintentionally into the patient's area, causing interference.

NOTE 2 These guidelines may not be applicable in all situations. The spread of electromagnetic waves is influenced by absorption and the reflections of buildings, objects, and people.

