zebris

JMA Optic



User manual and technical data

Hardware User Manual

JMA Optic

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The operating instructions are valid for all versions of the JMA-Optic (REF 015700xx).

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Illustrations of this manual may differ.

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

CE 2797

Table of content

1 User information 6

1.1. Configuration of the user manual 6

1.2. Target group 6

1.3. Symbols used on products, packaging and user manual 7

2 Area of use and safety 8

2.1. Intended use 8

2.1.1. Use 8

2.1.2. Data export 8

2.1.3. Product life 8

2.2. Safety 9

2.2.1. Environmental conditions 9

2.2.2. Storage and transport 9

2.2.3. Obligations of the user 10

2.2.4. General safety information 11

2.2.5. Safety information on heart pacemakers / defibrillators 12

2.2.6. Prohibited use 12

3 Produkt description 13

3.1. System components 13

3.2. Funktional principle of the JMA-Optic system 13

3.3. Operating modes 14

3.3.1. Operating mode 1: Data connection via USB 14

3.3.2. Operating mode 2: Data connection via WiFi 14

3.3.3. Operating mode 3: Charging the Facebow 15

3.4. Elements of the JMA-Optic system 16

3.4.1. JMA-Optic Facebow 17

3.4.2. Technical data 18

3.4.3. Product label of the JMA-Optic Facebow 18

3.4.4. JMA-Optic USB-S 19

3.4.5. Technical data 20

3.4.6. Product label JMA-Optic Facebow USB-S 20

3.4.7. State LEDs 21

3.5. UK-sensor OJM-UK1 22
3.5.1. Technical data 22
3.5.2. State LED 22
3.5.3. Changing the battery 23
3.5.4. Product label UK-sensor OJM-UK1 23
3.6. Induktive Charger JMA-Optic 24
3.6.1. Technical data 24
3.6.2. State LED 24
3.7. IR-FS / IR Foot Switch 25
3.7.1. Technical data 25
3.7.2. State LED 25
3.7.3. Changing the battery 26
3.8. IR-RC / Remote Control 27
3.8.1. Technical data 27
3.8.2. State LED 27

4 System components, accessories and spare parts 28
4.1. Hardware 28
4.1.1. System components 28
4.1.2. Accessories 29
4.1.3. Spare parts 31

5 Putting the system into operation 33
5.1. Power supply and charging the batteries 33
5.2. UK-sensor OJM-UK1 34
5.3. IT security and software installation 34

6 Decommission the system 36

7 Funktional checks and disposal 36
7.1. Periodic inspections and safety inspections 36
7.2. Controlling the measurement function 37
7.3. Troubleshooting 38
7.4. Checklist for the recording of error messages 38
7.5. Disposal 39
7.5.1. Packaging 39
7.5.2. Disposal of electronics 39
7.5.3. Batteries and Rechargeable batteries 40

8 Preparation 41
8.1. Manual pretreatment 41
8.2. Manual cleaning and disinfection 42
8.3. Mechanical cleaning and disinfection 44
8.4. Inspection 45
8.5. Packaging 46
8.6. Sterilization 46
8.7. Reusability 46
8.8. Overview table 47

9 Safety standards and system classification 48
9.1. Classification pursuant to appendix IX of the directive 93 / 42 / EEC 48
9.2. Safety of medical electrical devices 48
9.2.1. Connecting the system to other electrical devices 48
9.2.2. Environment of the patient 48
9.2.3. Multiple sockets 49
9.3. Electromagnetic compatibility, guidelines 50

1 User information

1.1. Configuration of the user manual

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

1. Installation instructions for the WINJAW+ software, also contains your license code,
2. Technical specifications and instructions for use of the JMA-Optic hardware,
3. 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 attachment.
Information concerning accessory components is limited to key safety and maintenance measures and / or hygiene measures.
The software and hardware instructions for use 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.



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.



All serious events occurring in relation to the product must be reported to the manufacturer and the competent authority of the member state, in which the user and / or patient resides.

1.2. Target Group

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

1.3. Symbols on the Product, Packaging, and in the Instructions for Use



Warnings indicate a potential hazard to the health and safety of users and/or patients. The warnings explain the nature of the hazard and how it can be avoided.



Notes indicate a potential hazard that may result in damage to the device. The notes explain the nature of the hazard and how it can be avoided.



CE marking in accordance with EC Directive 93/42 on medical devices



Manufacturer



Date of manufacture



Type BF device in accordance with DIN EN 60601-1



HF transmitter (Wi-Fi interface)



USB port



DC voltage



Do not dispose of with household waste



Follow the instructions for use / Follow the electronic instructions for use

REF

Part number

SN

Serial number

LOT

Lot number

HIBC

UDI with HIBC code

MD

Medical device



Consumable intended for single use on a single patient during a treatment.



In accordance with U.S. federal law, this device may only be used by a physician, a dentist and authorized healthcare professionals.



Sterilizable in a steam sterilizer (autoclave) at the temperature specified in ISO 7000-2868.

CH REP

Indicates the authorized representative in Switzerland.

IP31

Digit 3: Protected against the ingress of solid foreign objects ≥ 2.5 mm in diameter and larger. Digit 1: Protected against vertically falling water droplets

IPX1

Digit X: Rating not specified Digit 1: Protected against vertically falling water droplets



Packaging REF acc. to PPWR

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 JMA-Optic system allows the therapeutic positioning of the mandible in a jaw relation. The JMA-Optic system must be used by trained dentists and it's 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.



US Federal law restricts this device to sale by or on the order of a healthcare professional / dentist. For dental use only.

2.1.1. Use

The JMA-Optic system consists of facebow and UK-sensor. The facebow is placed on the patient's head and is supported on the nose. The UK-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 software calculates the 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 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 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 DVT.

2.1.3. Product life

Provided that the WINJAW+ software and the operating system of the measurement PC are kept up to date, a product life of about 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 + 42°C
Maximum device temperature:	51.7°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, underpressure-, 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 USB / WiFi version of the JMA-Optic system contains Lithium-Ion batteries (Li-Ion batteries). When shipping the JMA-Optic system, transport regulations for Li-Ion batteries must be observed. Additionally: Marking of the transport packaging according to valid regulations.

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



To prevent deep discharge of the Li-ion battery, the system must be fully charged at least every 4 months.

2.2.3. Obligations of the user



It is the obligation 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.
- 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 settings, 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 measurement system must be checked at regular intervals to make sure it is functioning properly. More details on this: see chapter *7 Functional checks and disposal, p.39.* 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 support 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 facebow and UK-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 fastening the UK-sensor contains powerful permanent magnets (neodymium magnets). Electronic implants such as cardiac pacemakers or implantable cardioverter defibrillators (ICD) can switch to a maintenance mode in the presence of strong magnetic fields. To avoid possible risks, the UK-sensor should be held at a minimum distance of 10 cm from the patient‘s chest in patients with electronic implants, and the recording should be performed with the patient in an upright position.The UK-sensor should also not be placed on the patients with electronic implants, the UK-sensor should not be placed on the patient‘s upper body.
- 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 facebow 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. This is hereby explicitly pointed out.
- 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 impaired in terms of its measurement accuracy.
- In the case of malfunctions and / or defects being suspected and / or determined, 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, see chapter *2.2.1. Environmental conditions, p. 9*.
- 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+ software 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

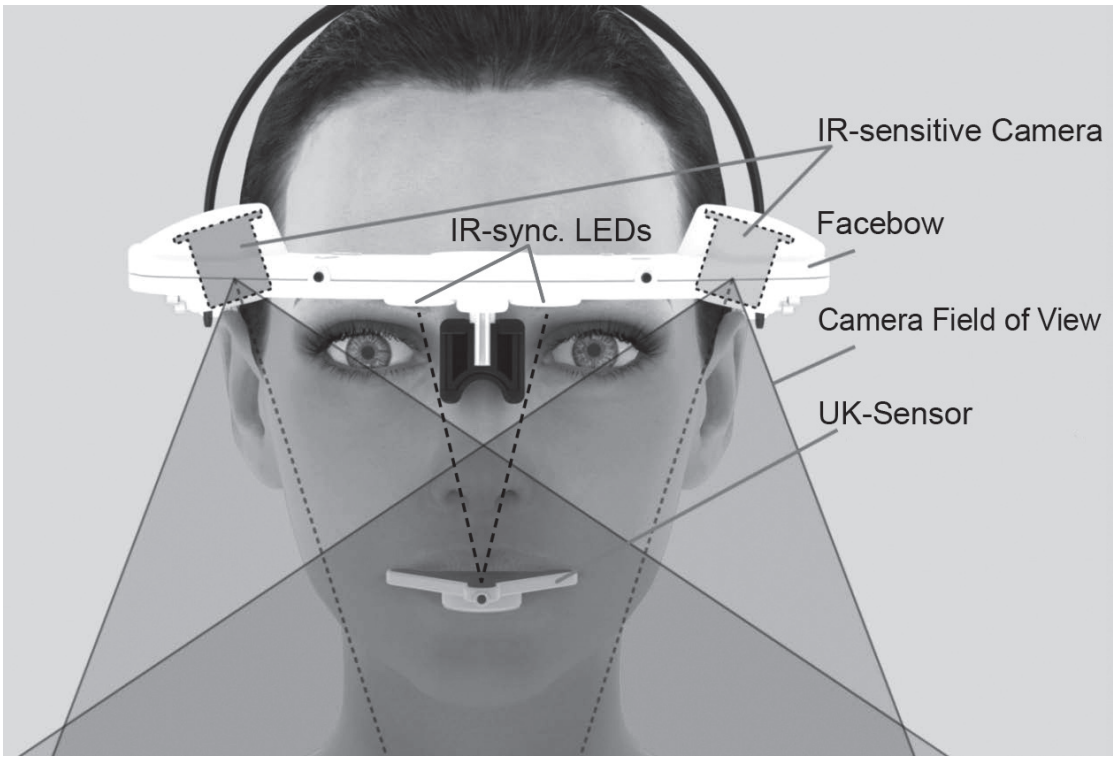
3.1. System components

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

- JMA-Optic facebow (receiver)
- UK-sensor (transmitter)
- USB power supply for supplying the inductive charger (optional)
- USB adapter with connector plug to the facebow
- WINJAW+ application software
- Accessories

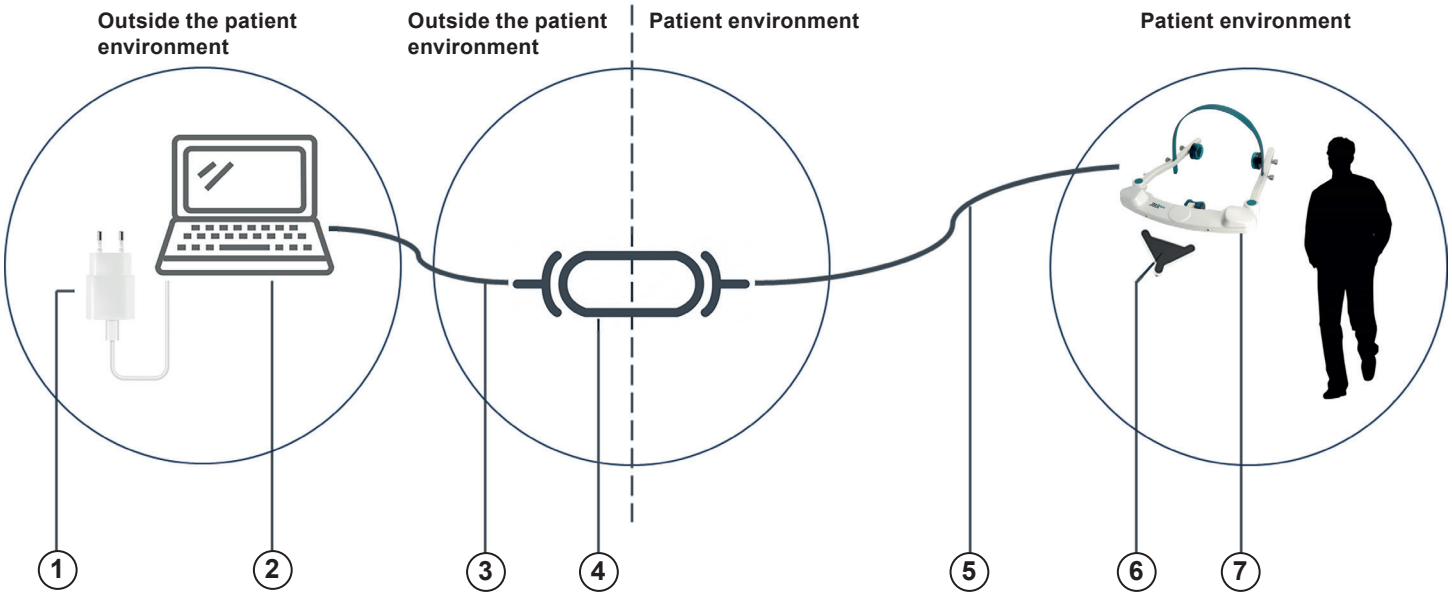
3.2. Functional principle of JMA-Optic system

The JMA-Optic system is a 3D coordinate measuring system. It consists of a facebow (receiver and control unit), the UK-sensor (transmitter unit) and an table stand.
The table stand is used for storing the system and also serves as an inductive charging station for the USB / WiFi system. The UK-sensor is powered by a button cell. It contains several LEDs that are activated during measurement by an infrared signal from the facebow.
During a measurement, the movements of the UK-sensor - attached to the lower teeth - are recorded by the cameras integrated in the facebow.
The position of the luminous points of the LEDs are determined by the two cameras in the facebow and sent it to the PC via USB connection or optionally via WiFi connection.
The WINJAW+ software uses this data to determine the position of the mandibular sensor relative to the facebow. The application software on the PC is used to store and analyze the measurement data.

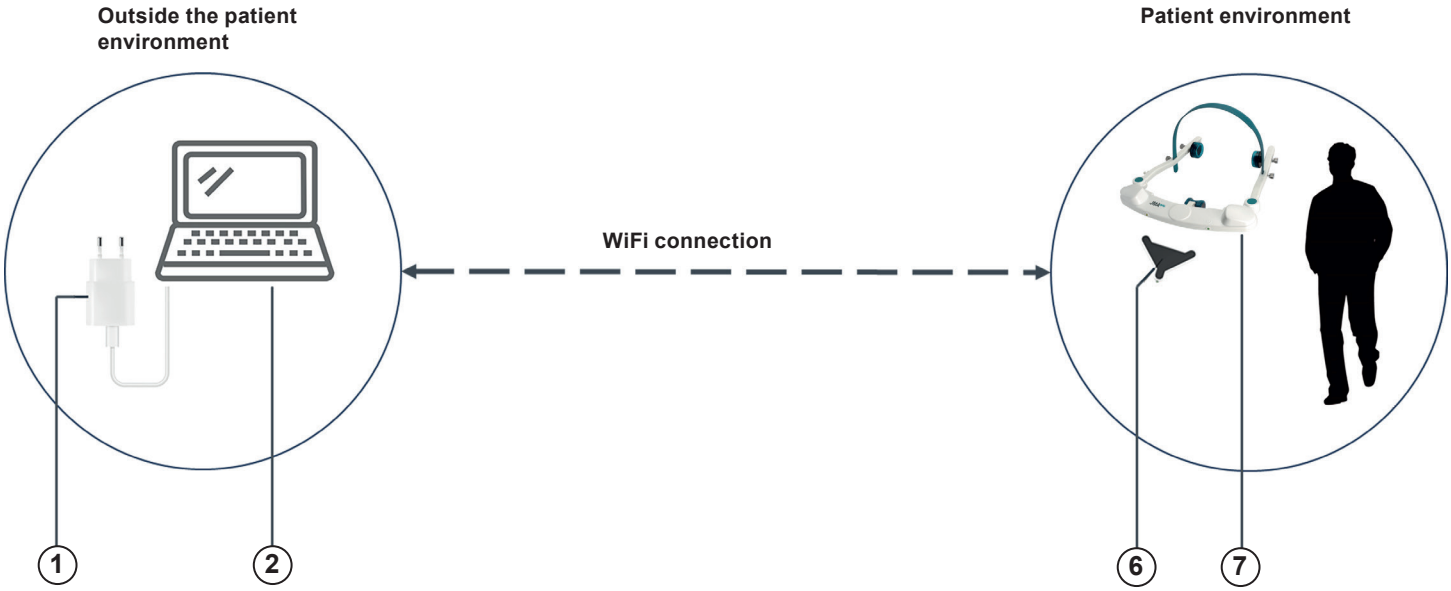


3.3. Operating modes

3.3.1. Operating mode 1: Data connection via USB



3.3.2. Operating mode 1: Data connection via WiFi



1 PC power supply unit in accordance with EN 62368-1 (1 MOOP / 1 MOPP)

2 PC system in accordance with EN 62368-1

3 USB adapter OJM-UA1 (REF 01860417, PC side with USB connection)

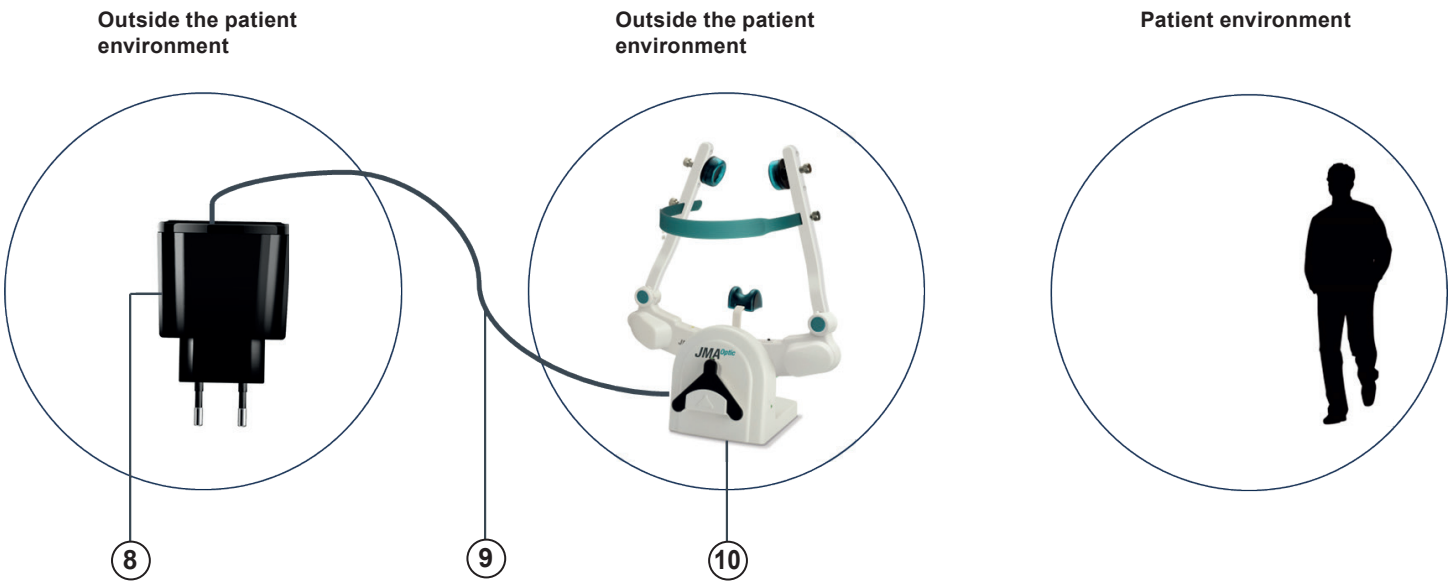
4 Isolator in accordance with IEC 60601-1 (2 MOOP / 2 MOPP)

5 USB adapter OJM-UA1 (REF 01860417, patient side with special plug)

6 UK-sensor (REF 014700xx, internal battery in accordance with IEC 60086-4)

7 Facebow (REF 011700xx, internal battery in accordance with IEC 62133)

3.3.3. Operating mode 3: Charging the facebow (only possible with the WiFi / USB version)



8 Power supply unit in accordance with IEC 60601-1 (protection class II, 2 MOOP / 2 MOPP)

9 Adapter cable (USB 2.0 cable A / B)

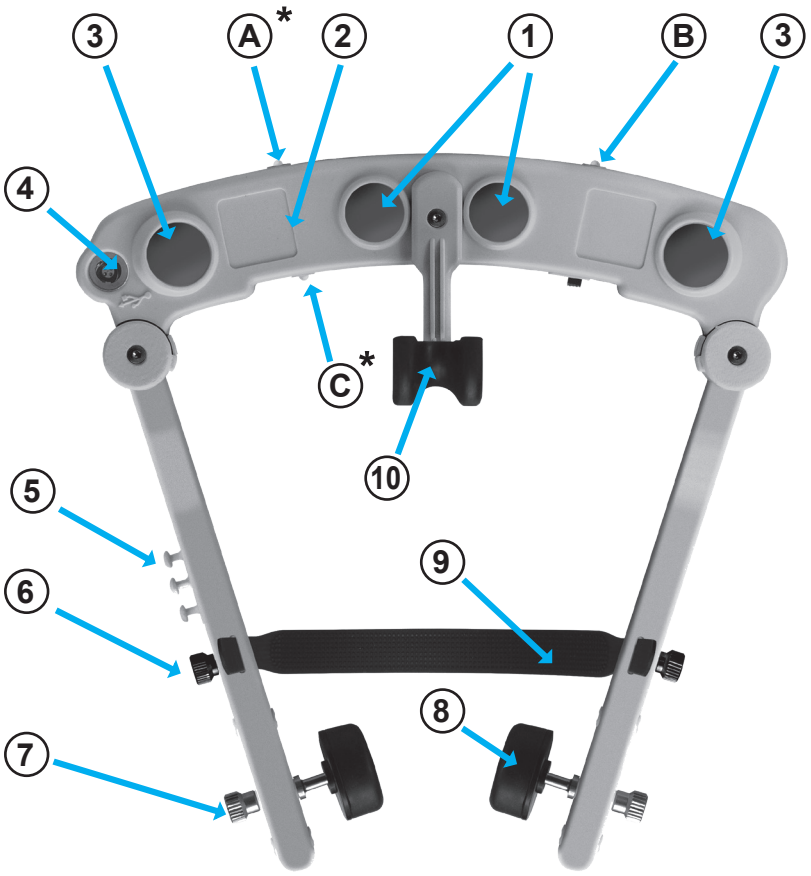
10 Inductive charger with facebow and UK-sensor

3.4. Elements of the JMA-Optic system

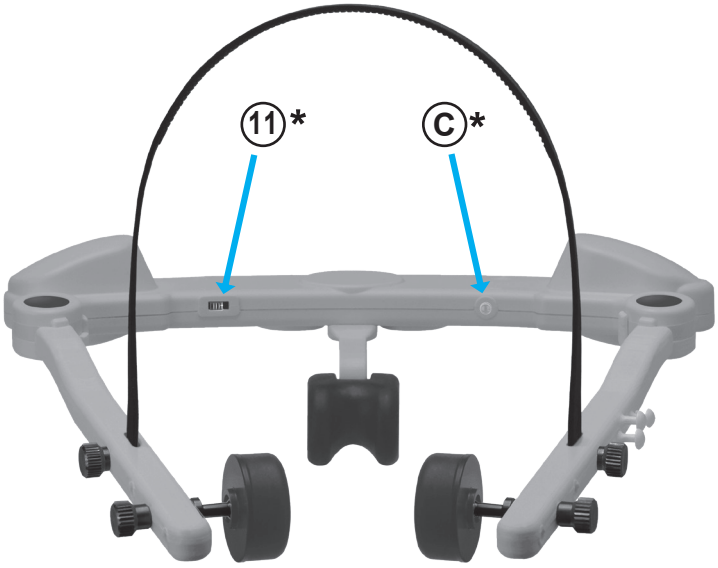
1 IR-Sync LEDs
2 Product label
3 Camera modules left / right
4 Connection socket: external power supply / data transmission
5 Cable guide / strain relief
6 Knurled screw for locking: overhead band
7 Knurled screw for locking: bearing seat
8 Bearing cushions / bearing seat
9 Headband
10 Nose cushion
11 Transport switch
12 IR-Sync LEDs, (UK-sensor)
13 Magnetic coupling (UK-sensor)
14 Product label, (UK-sensor)
15 Power supply, USB socket, (inductive charger)
16 Product label, (inductive charger)
17 Product label, (IR foot switch)
18 Clip-on headband
19 Product label, (IR-Remote Control)

A Status-LED, Facebow, ”WiFi Connection” (blue)
B Status-LED, Facebow, ”Measurement active” (green)
C Status-LED, Facebow, Power supply / battery charging (orange)
D Status-LED, UK-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)

3.4.1. JMA-Optic Facebow



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



* Available only in USB / WiFi version (REF 01170010)

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

3.4.2. Technical data

Property	Value
Dimensions (W x H x L)	222 x 60 x 250 mm
Weight	208 g
Power supply	5V DC / 2.5W
Max. recording rate	60 Hz
Measuring accuracy (occlusal)	± 0.05 mm (x, y, z); ROM 15 mm
Connector socket	Push-Pull plug / USB
PC interface	WiFi / USB

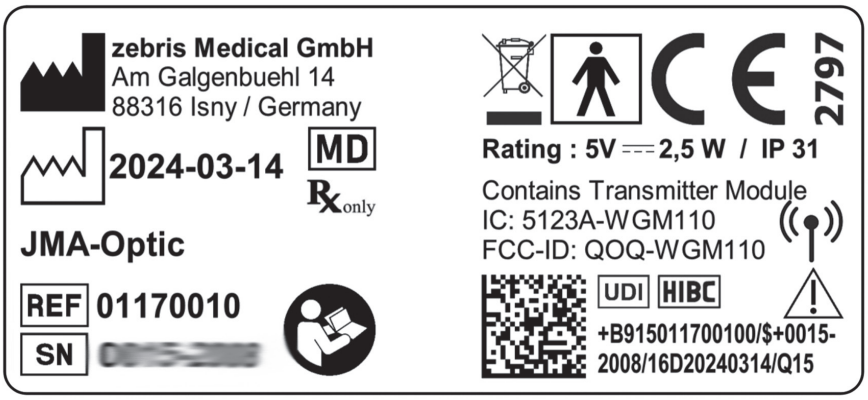
Device contains Li-Ion batteries. When shipping the device, comply with the transport instructions for Li-Ion batteries. In addition, a labeling of the transport packaging according to valid regulations is required.

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

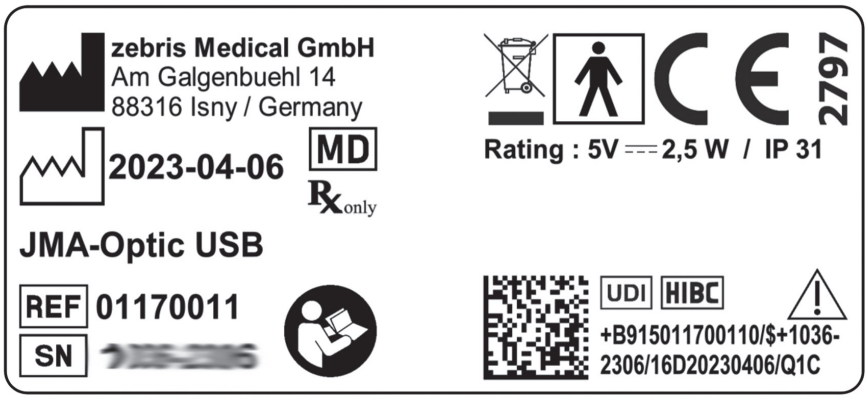
Never attempt to open the facebow or replace the batteries yourself, as this may affect the measurement accuracy and may result in an electric shock.

3.4.3. Product label JMA-Optic Facebow

Version USB / WiFi

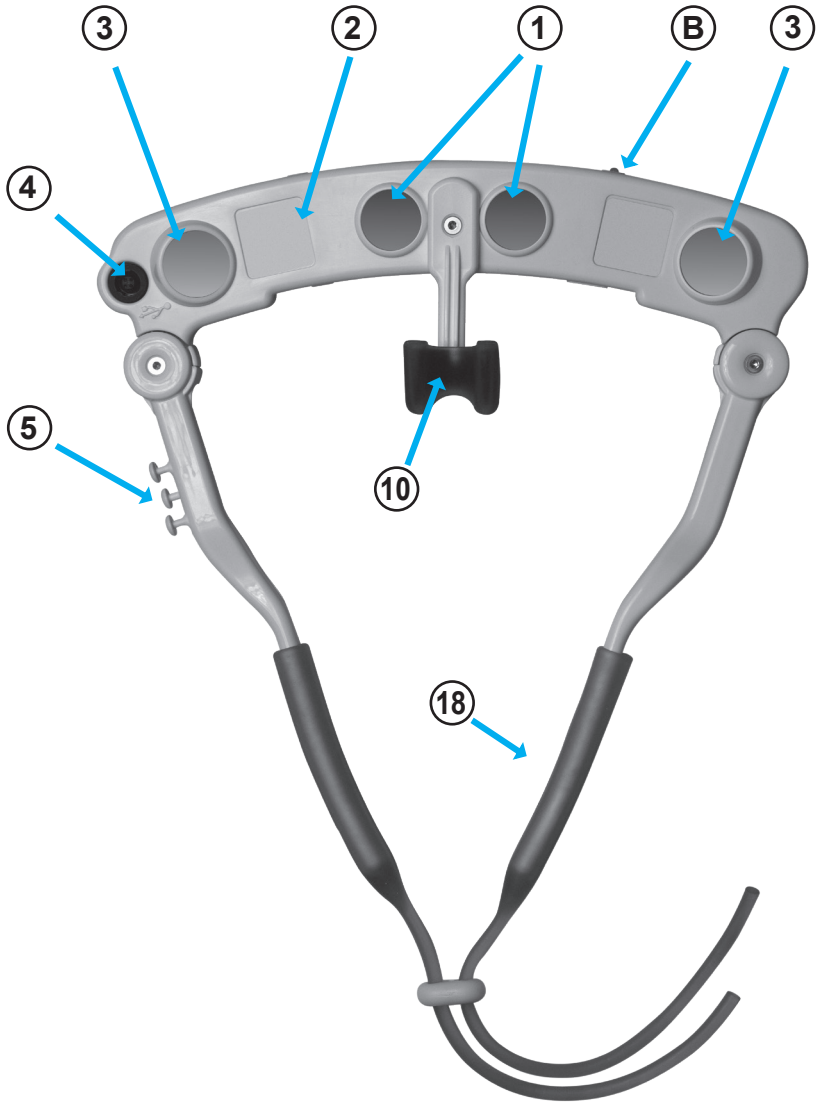


Version USB



3.4.4. JMA-Optic USB-S

with clip-on headband (REF 01170012)

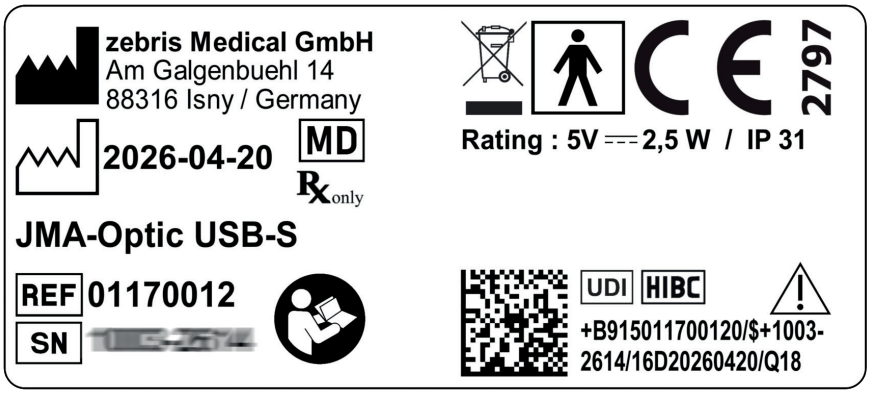


Cleanliness / integrity of the optical components (1 and 3) must be checked before each use to ensure the accuracy of the measuring system.

3.4.5. Technical data

Property	Value
Dimensions (W x H x L)	222 x 70 x 240 mm
Weight	157 g
Power supply	5V DC / 2.5W
Max. recording rate	60 Hz
Measuring accuracy (occlusal)	± 0.05 mm (x, y, z); ROM 15 mm
Connector socket	Push-Pull plug / USB
PC interface	USB

3.4.6. Product label JMA-Optic Facebow USB-S



3.4.7. State LEDs

LED Signal	State / Meaning
WIFI connection (status-LED, A)	
Flashing, blue	WiFi not connected / active
Permanent on, blue	WiFi connected and active
Recording activ (status-LED, B)	
Flashing, green	Facebow is switched on and ready for operation
Permanent on, green	Facebow is in operation
Power Supply / Battery Charging (status LED, 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

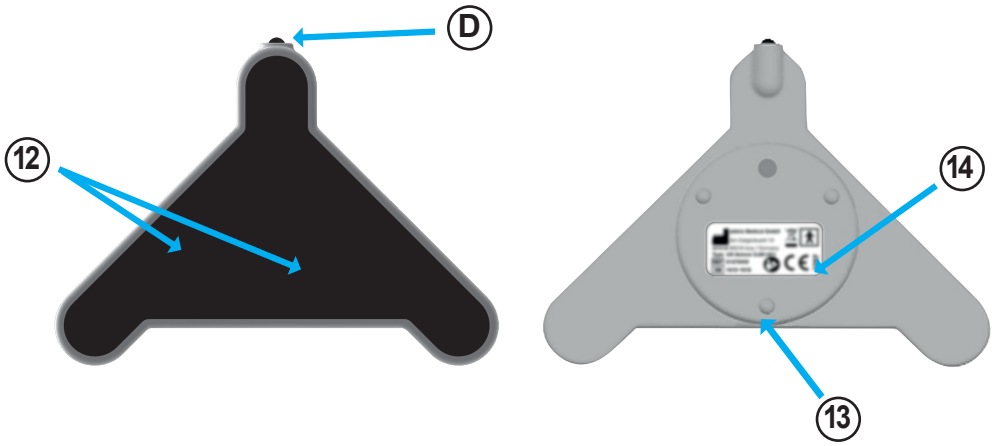
3.5. UK-sensor OJM-UK1

12 IR-Sync LEDs, UK-sensor

13 Magnetic coupling for attachments

14 Product label UK-sensor

D Status-LED, ”Measurement active” (green)



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.

The UK-sensor must be stored in the holder provided on the inductive charger/ table stand. This is the only way to prevent the battery from discharging prematurely and causing scratches on the top of the sensor.

3.5.1. Technical data

Property	Value
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 color	Function	Description
Flashing, green	UK-sensor is in operation	Warning: ”Battery low”
Permanent on, green	UK-sensor is in operation	Battery condition good

3.5.3. Changing the battery

To replace the battery of the UK-sensor, proceed as follows:

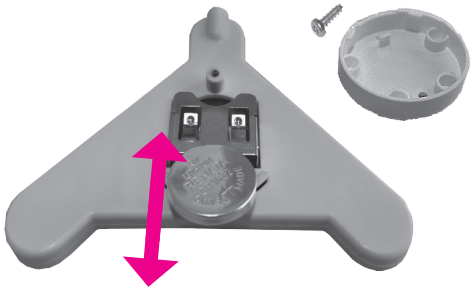
Required materials:

- Screwdriver 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 see chapter:
7.5. Disposal, p.39.

In the UK-sensor, use only CR1632 button cells that are certified according to IEC 60086-4 and/or UL 1642.

3.5.4. Product label UK-sensor OJM-UK1



3.6. Induktive Charger JMA-Optic

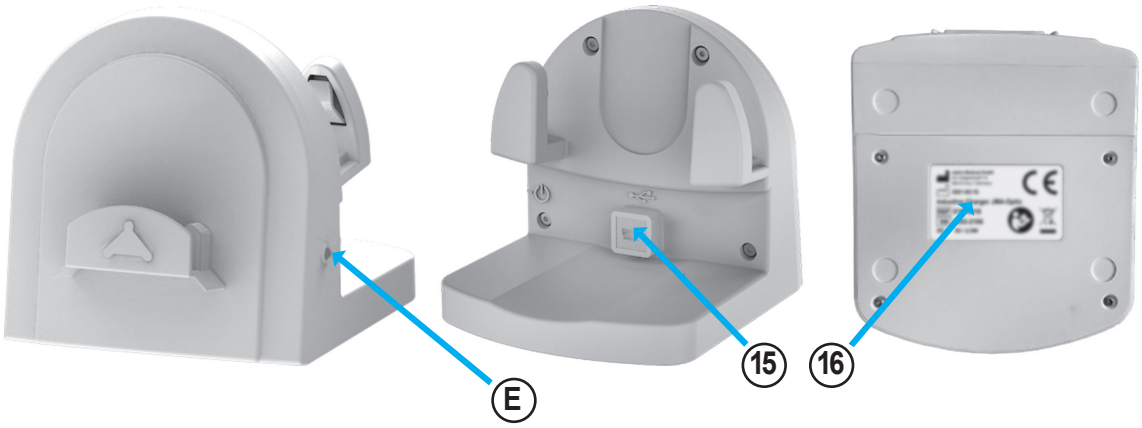
The inductive charger is used for wireless charging of the facebow and for storing the facebow and the UK-sensor.

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

15 Power supply, USB socket, Inductive charger

16 Product label, Inductive charger

E Status-LED, Inductive charger, ”Power supply” (green)



3.6.1. Technical data

Property	Value
Dimensions (W x H x L)	101 x 105 x 127 mm
Weight	340 g
Power source	USB socket type B
Permitted power sources	■ USB power supply (included) ■ USB outlet of a computer ■ USB outlet of a USB-Hub
Standby current (Facebow is not charging)	~ 12 mA
Max. charging current	~ 500 mA (5V/1W)

3.6.2. State LED

LED color	Function	Description
Permanent on, green	Device is charging	Normal operation, Power supply is active

3.7. IR-FS / IR Foot Switch

The IR foot switch provides wireless control of the WINJAW+ software.
Each activation of the IR 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 IR foot switch.
If the IR foot switch is pressed permanently for more than approx. 2 seconds, the electronics automatically switches off and the status LED shuts of.

17 Product label IR foot switch

F Status-LED, IR foot switch, ”Device active” (green), ”Battery low” (orange)



3.7.1. Technical data

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

3.7.2. State LED

LED color	Function	Description
Permanent on, green	Device is in operation	Normal operation, Battery condition good
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:

- Screwdriver type PH 0 x 40
- 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 see chapter:
7.5. Disposal, p.369

Only use 6LR91 batteries within the IR foot switch.

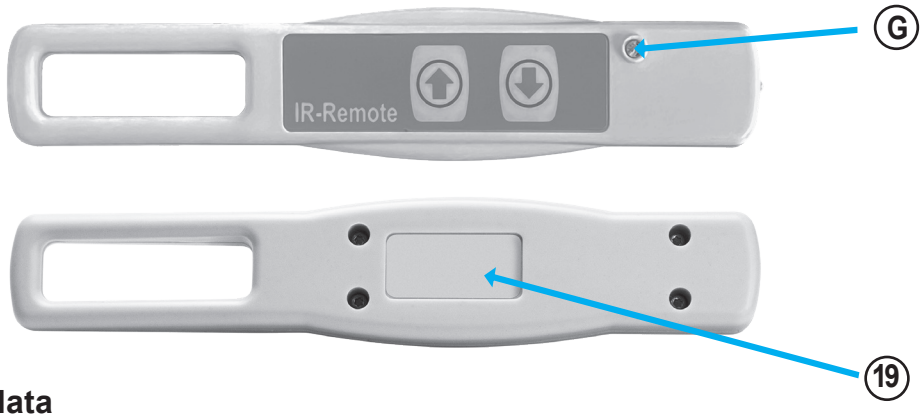
3.8. IR-RC / Remote Control

The IR Remote Control allows for wireless control of the WINJAW+ software.
Each press of the left button triggers the ”next” function once in the WINJAW+ software and initiates the next step in the workflow. Each press of the right button triggers the ”back” function in the WINJAW+ software and initiates the previous step in the workflow.

The LED (G) indicates the operating status of the IR remote control.

19 Product labeling: Label, IR remote control

G Status LED, IR remote control, ”Device active” (green)



3.8.1. Technical data

Property	Value
Dimension (W x H x L)	27 x 14 x 141 mm
Weight	33,5 g
Battery	Lithium coin cell; type CR 2032(3V)

3.8.2. Status-LED

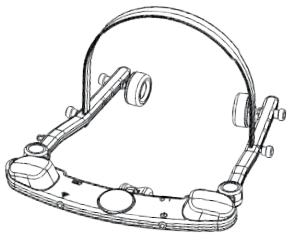
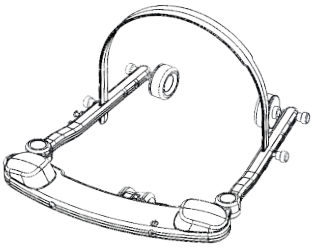
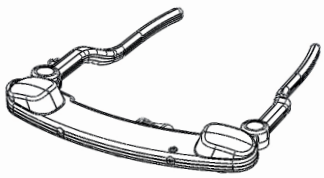
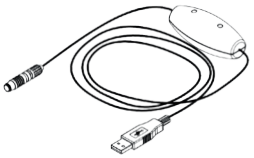
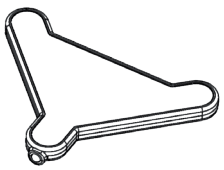
LED color	Function	Description
Permanent on, green	Device is in operation	Normal operation, Battery condition good

In the IR-RC / Remote Control, use only CR2032 button cells certified to IEC 60086-4 and/or UL 1642.

4 System components, accessories and spare parts

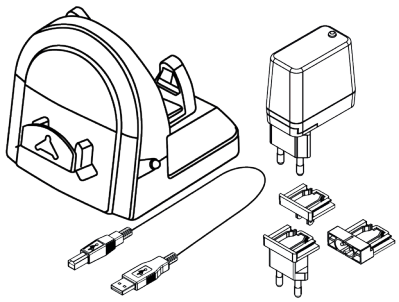
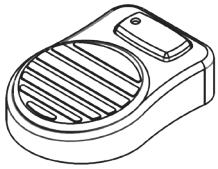
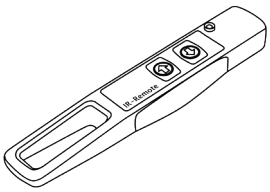
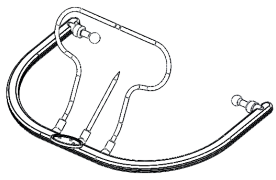
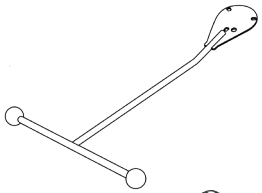
4.1. Hardware

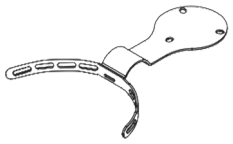
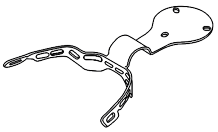
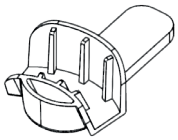
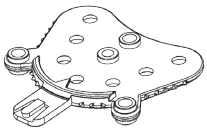
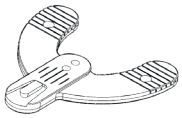
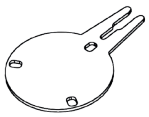
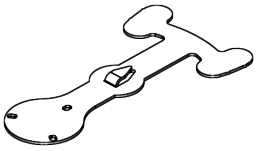
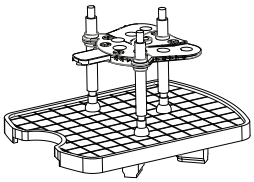
4.1.1. System components

REF	Description	Picture
01170010	**JMA-Optic Facebow**	
01170011	**JMA-Optic Facebow USB**	
01170012	**JMA-Optic Facebow USB-S**	
01860417	**USB-Adapter OJM-UA1** To connect the facebow to the PC and to charge the battery	
01470000	**UK-sensor OJM-UK1** UK-sensor with magnetic coupling	

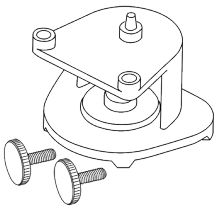
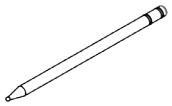
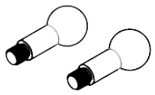
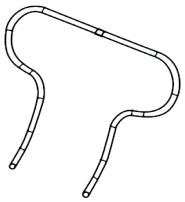
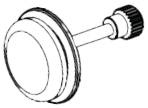
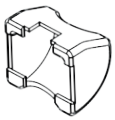
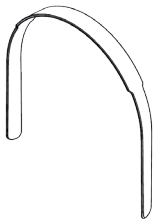
4.1.2. Accessories

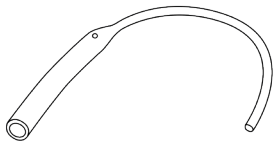
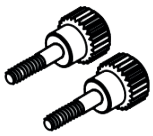
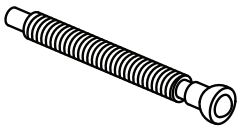
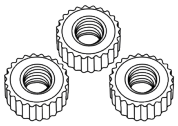
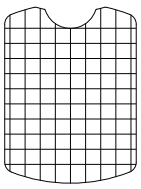
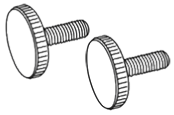
Multiple use of disposable items leads to an increased risk of infection for the patient and possibly to a falsification of the measurement and analysis results due to changes in shape of the products with multiple use of the sterilization process.

REF	Description	Picture
01870011	**Table Stand JMA-Optic** Without charging function	
01570510	**Inductive Charger JMA-Optic** Charger with charging cable, power supply and primary adapter	
01860020	**IR-FS / IR Foot Switch** For wireless remote control of the JMA-Optic system	
01860010	**IR-RC / Remote Control** For wireless remote control of the system	
01570212	**C-Positioner Set** To determine reference planes and the bipupillary line	
01970110	**T-Pointer** To determine reference planes	
01870100	**Wireless Link Adapter** For wireless coupling of facebow and PC	

REF	Description	Picture
01960250	**Para-occlusal Attachment with Lip Arch** For temporary fixation to the teeth	
	Para-occlusal Attachment with Support Surface For gingiva-supported fixation of the UK-sensor	
01960255	Size M	
01960254	Size L	
01960280	**Occlusal Attachment UN** For temporary fixation to the teeth	
01960360	**Bite Fork UN** For temporary fixation to the teeth, contains thread for screws	
01960341	**Bite Fork PS1** For temporary fixation to the teeth	
01960420	**Bite Fork Adapter UN** For mounting the UK-sensor	
01960430	**Alignment Fork** To determine the bite position	
	Digital Model Transfer Enables the transfer of the jaw position in articulators, incl. 3 x bite forks with screw thread, bite fork adapter, screw set, 3 x fixing nuts and positioning foil set, incl. brief instructions	
01560050	Multisplit	
01560053	Artex (Splitex)	
01560054	Protar	
01560055	SAM	
01560056	Panadent	

4.1.3. Spare parts

REF	Description	Picture
	Model Transfer with ZFT- zebris Fast Transfer Enables the transfer of the OK position to articulators using the UN bite fork, including 2 knurled screws	
01560063	Splitex	
01560064	Protar	
01560065	SAM	
01560066	Panadent	
01910025	**Pointer Pin 80** For use with the C-Positioner	
01960160	**Porion Buttons** For use with the C-Positioner	
01970120	**Bracket Bipupillary Position** For use with the C-Positioner	
01960140	**Retainer for Facebow** For use with the facebow	
11502501	**Bearing Cushion** Green opaque, á 10 pieces	
11502503	**Nose Cushion** Green opaque, á 10 pieces	
11502508	**Overhead Strap** For use with the facebow	

REF	Description	Picture
11502512	**Clip-on headband** For JMA-Optic USB-S	
11511140	**Connecting clamp** For JMA-Optic USB-S	
58310141	**Knurled Nut** For use with the facebow, á 2 pieces	
58310121	**Knurled Screw** For use with the facebow, á 2 pieces	
01960501	**Screw Set** Set consisting of 3 pieces each, in the lengths 30, 45 and 60 mm, for digital model transfer	
01960505	**Set of knurled nuts for positioning screws**	
01960510	**Positioning Foil Set** Set for mounting on the transfer table for digital model transfer, á 5 pieces	
58310147	**Knurled screw** black, for ZFT—zebris Fast Transfer	
79011105	**Hardware Instructions for Use** Availability within 7 days after receipt of order	
79011106	**Software Instructions for Use** Availability within 7 days after receipt of order	

5 Putting the system into operation

Commissioning the JMA-Optic system requires the USB adapter 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 facebow.

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

The batteries are fully charged after about 1.5 hours charging time.
A fully charged battery allows an average recording time of 30 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 IEC 62368-1 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, 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, see chapter *9.2.3 Multiple sockets, S.49.*



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

5.2. UK-sensor OJM-UK1



Before the UK-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.

The UK-sensor must be stored in the holder provided on the inductive charger/ table stand. This is the only way to prevent the battery from discharging prematurely and causing scratches on the top of the sensor.

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 date 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.



Only if a PC / laptop is included in the scope of delivery, the manufacturer for damage or malfunctions caused by incorrect software installation or unsuitable computer hardware.
If the operator installs additional hardware or third-party software, this is the sole responsibility of the operator and is not covered by the manufacturer‘s liability.



The computer needs to be CE-marked and satisfy the requirements of DIN EN IEC 62368-1 and / or DIN EN 60601-1.



Connecting the JMA-Optic 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 determine, 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 reliable 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. Set the transport switch on the facebow to the **OFF** position (0) and store the facebow in the transport case.
After 12 minutes of inactivity, the facebow switches off automatically to prevent the battery from discharging. The device reactivates itself when it is moved in standby mode.
Finally, remove the charger from the mains socket and store it in the transport case together with all other components of the JMA-Optic system.

7 Functional checks and 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 determined, 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. Periodic inspections and safety inspections

- 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.
  b) the cables or plug connectors show any damage.
  c) parts of the sensor technology are damaged.
  d) covers are damaged or have come off.
  e) a defect or fault is either suspected or determined.
- If the product label or other labeling (e.g. warning notices) on the system are damaged or unreadable, these are to be replaced.



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

7.2. Controlling 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 blows or if the facebow or UK-sensor has fallen to the floor, it is imperative that the manufacturer checks the measuring accuracy to ensure the high accuracy of ± 0.05 mm (x, y, z).

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 facebow and / or UK-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 LEDs on facebow and UK-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:

7.4. Checklist for the recording of error messages

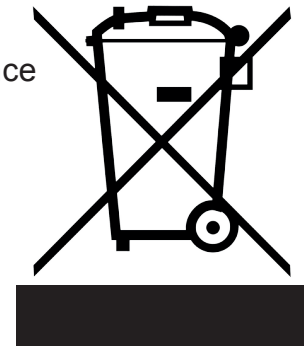
- Serial numbers of facebow and the UK-sensor.
  The serial numbers are on the type plates located on the bottom of facebow and UK-sensor.
- WINJAW+ software version.
  The version of the WINJAW+ software can be found in the ”Program Information” in the ”About” dialog (question mark button) of the software.
- 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.

7.5. Disposal

7.5.1. Packaging

All transport packaging delivered by zebris can be recycled within Germany via the local recycling depots. 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 electronics



The symbol on the right (a crossed-out wheelie bin) indicates that, in accordance with EU Directive 2012/19/EU on waste electrical and electronic equipment (WEEE) and its national implementations (in Germany: ElektroG), this product must not be disposed of with household waste but must be separated from unsorted municipal waste.

Return to the manufacturer

At the end of its service life, zebris Medical GmbH, as the manufacturer, will take back the measuring system free of charge as part of its product responsibility. The return must be arranged in advance with the following collection point:

zebris Medical GmbH Collection Point for Waste Electrical Equipment
Heinrich-Nicolaus-Str. 15, 87480 Weitnau
Contact: zebris Sales Team
Telephone: +49 7562 9726 0 | Email: sales@zebris.de

The end user is liable for the costs of delivery or postage to the collection point. The return of the device and its subsequent proper recycling by certified recycling companies are free of charge for the end user. No refund will be granted.

User responsibility for data erasure

Before returning the device, end users are personally responsible for erasing all personal data (in particular patient and measurement data) from the device. zebris Medical GmbH accepts no responsibility for data erasure on returned devices.

Background

The improper handling of end-of-life equipment can have negative effects on the environment and human health due to potentially hazardous substances frequently contained in electrical and electronic equipment. By disposing of this product properly, you are contributing to the effective use of natural resources.

7.5.3. Batteries and Rechargeable batteries

This product contains or may be powered by batteries. Rechargeable batteries and batteries must not be disposed of with household waste. The provisions of Regulation (EU) 2023/1542 (EU Battery Regulation) and the German Battery Act Implementation Act (BattDG) apply.

Return options

End users are legally obliged to dispose of used batteries via separate collection. Used portable batteries can be returned free of charge to:

- local collection points (recycling centers, mobile collection vehicles),
- retail collection points wherever batteries of this type are stocked,
- zebris Medical GmbH, provided the batteries originate from a zebris device (see chapter *7.5.2 Disposal of electronics, p. 39)* Return is free of charge for the end user.

Contributing to waste reduction

By using rechargeable and non-rechargeable batteries responsibly, we can conserve resources: opt for rechargeable batteries, avoid deep discharge, and store batteries in a cool, dry place when not in use.

Safety instructions

- Do not open, short-circuit, deform or throw batteries into a fire.
- Lithium-containing batteries pose a risk of fire and explosion if handled improperly.
- Do not touch damaged or leaking batteries with bare hands.
- Keep out of reach of children.

Meaning of the symbols

The crossed-out wheelie bin symbol on the battery indicates the requirement for separate collection. Chemical symbols (e.g. Pb for lead, Cd for cadmium, Hg for mercury) provide information about ingredients of particular environmental concern.
The improper disposal of used batteries can have negative effects on the environment and human health due to the heavy metals and other substances they contain.

8 Preparation



After each use of the JMA-Optic system, reprocessing according to DIN EN ISO 17664 is necessary.



All parts with semi-critical contact to the patient must be cleaned, disinfected and sterilized before each use, *see chapter 8.8. Overview table, p. 47.* This applies in particular to the first use after delivery, as these parts are delivered non-sterile.



Disposable products are intended for single use on one patient and must not be reprocessed after use, *see chapter 8.8. Overview table, p. 47*.

8.1. Manual pretreatment



Electronic components (such as the facebow and the UK-sensor) must not be pre-cleaned under any circumstances, *see chapter 8.8. Overview table, p.47*.



Pretreatment is obligatory for semicritical components after each application if they are intended for multiple use, *see chapter 8.8. Overview table, p.47*.
Remove coarse impurities immediately after use (within one hour at the most, avoid anti-drying).
Do not clean components with metal brushes or steel wool.

Work sequence manual pre-cleaning
(General hygiene safety regulations must be observed):

- Rinse the components for at least one minute under running water (drinking water quality, 30°C ± 5°C, flow rate 2 l / min). If applicable: Flush all cavities of the components five times using a disposable syringe (if necessary, syringe volume at least 5 ml) or water pressure gun. Remove all visible contamination with the aid of a suitable cleaning brush (or a clean, soft and lint-free cloth). which serves only this purpose. Openings brush out with a conical interdental brush.
- Rinse again under running water for at least one minute. If applicable: Flush all component cavities five times using a disposable syringe (if necessary, syringe volume at least 5 ml) or water pressure gun.

8.2. Manual cleaning and disinfection



The electronic components can be disinfected by wiping and must under no circumstances be immersed in a cleaning solution or cleaned with cleaning liquids or cleaning sprays containing solvents, *see chapter 8.8. Overview table, p. 47.*

Wipe disinfection is only permissible when the unit is switched off and the unplugged charging power pack.

Recommended wipe disinfectants:
Mikrozid Wipes, Mikrozid PAA (cleaning wipes soaked with Mikrozid) Schülke and Mayr or comparable.
Composition approx. 25% ethanol, 35% propanol.



If possible, a mechanical workflow (WD, washer-disinfector) should be used for cleaning and disinfection of semi critical components. Manual cleaning even when using an ultrasonic bath should only be used if a mechanical cleaning process is not available. In this case, the significantly lower effectiveness and reproducibility of a manual process must be taken into account.

The instructions of the detergent and disinfectant manufacturers with regard to concentration, temperature, immersion time and rinsing must be observed.

Please use only freshly prepared solutions, as well as exclusively sterile or low contaminated water (max. 10 germs / ml) as well as low endotoxin contaminated water (max. 0.25 endotoxin units / ml), e.g. purified / highly purified water and a soft, clean and lint-free cloth and / or filtered air for drying.

When selecting cleaning and disinfecting agents, the following points must be observed:

- Basic suitability for cleaning instruments made of metal or plastic.
  If an ultrasonic bath is used: suitability of the cleaning agent for ultrasonic cleaning (no foam formation).
- Use of a suitable disinfectant with tested effectiveness (for example: approval /registration by VAH / DGHM or FDA / EPA or CE marking), compatible with the cleaning agent used.
- Combined cleaning agents and disinfectants should not be used.
  Only in the case of exceptionally low contamination (no visible contamination) combined cleaning agents and disinfectants can be used.

Workflow

Manual cleaning

- Place the components in the cleaning solution for the duration of the specified immersion time, so that the components are sufficiently covered. Ensure that the components do not touch each other and that no air remains in cavities.

  Support the cleaning process by careful brushing with a soft brush and ultrasonic treatment (duration in addition to brushing at least as long as the required immersion time).
  If applicable: Clean all cavities of the components at the beginning and after the immersion time has elapsed, flush at least five times using a disposable syringe (minimum volume 5 ml).
  Brush out openings with a conical interdental brush.
- Remove the components from the cleaning solution and rinse them intensively at least three times (for at least one minute) rinse with water.
  If applicable: Rinse all cavities of the components at the beginning and at the end of the immersion time, flush at least five times using a disposable syringe (minimum volume 5 ml).
- Check components, see chapter *7 Functional checks and disposal, p. 36*.

Disinfection

- Immerse the components in the disinfectant solution for the specified immersion time so that the components are sufficiently covered. Ensure that the components do not touch each other and that no air remains in cavities.
  If applicable: All cavities of the components must be rinsed at least five times with a disposable disinfectant at the beginning and at the end of the immersion time, flush at least five times using a disposable syringe (minimum volume 5 ml).
- Remove the components from the cleaning solution and rinse intensively at least five times (for at least one minute) with water.
  If applicable: flush all cavities of the components at the beginning and at the end of the immersion time, flush at least five times using a disposable syringe (minimum volume 5 ml).
- Dry and pack the components immediately after removal, see chapter *8.5. Packaging, p.46*.

8.3. Mechanical cleaning and disinfection

When selecting the washer-disinfector (WD), the following points must be observed:

- The cleaning and disinfection device must have a fundamentally tested effectiveness (e.g., CE marking in accordance with DIN EN ISO 15883).
- Basic suitability of the program for instruments as well as sufficient rinsing steps in the program.
- Post-rinse exclusively with sterile or low-contaminated water (max. 10 germs / ml, max. 0.25 endotoxin units / ml, for example purified or highly purified water).
- Exclusive use of filtered air (oil-free, low contamination with microorganisms and particles) for drying.
- Regular maintenance and inspection / calibration of the WD.

Consider the following points when selecting the cleaning agent:

- Basic suitability for cleaning instruments made of metal or plastic.
- Additional application: if thermal disinfection is not used - of a suitable disinfectant with tested efficacy (e.g., approval / registration with / from VAH / DGHM or FDA / EPA or CE marking), compatible with the used cleaning agent.
- Compatibility of the cleaning agents used with the components. The instructions of the manufacturers of the cleaning agents regarding concentration, temperature, immersion time and rinsing must be observed.



Do not expose components to temperatures above 142°C.

Mechanical cleaning/disinfection (validated process)					
Phase	Step	T[˚C / ˚F]	t[min]	Waterquality	Comment
I	Pre-rinse	< 40 / 104(cold)	3	T-W	
	Emptying				
II	Cleaning	55 / 131	10	T-W	neodisher® MediClean Dental
	Emptying				
III	Rinse	< 40 / 104	2	T-W	
	Emptying				
IV	Rinse	< 30 / 86(cold)	1	VE-W	
	Emptying				
V	Thermo-disinfection	90 / 194	5	VE-W	
	Emptying				
VI	Drying	> 90 / 104	30		

T-W: Drinking water
VE-W: Fully demineralized water (demineralized, microbiologically at least drinking water quality)
Validated with: neodisher® MediClean Dental in a Miele PG 8535

Workflow:

- Carefully place the product in a suitable rinsing basket. Make sure that the product does not touch any other instruments / instrument parts (no rinsing shadow).

Start a tested program with the following characteristics:

- Sufficient cleaning effect.
- Final rinse with distilled or fully demineralized water.
- Thermal disinfection with deionized water: 5 minutes at 90° - 95° C , A0 >=3000.
- Sufficient product drying (no visible liquid residues).
- Check and pack the components immediately after removal, see chapter: *8.4. Inspection, p.45 and / 8.5. Packaging, p. 46*.

8.4. Inspection

All components must be checked for the following in each case after cleaning / disinfection:

- Damage to the product, e.g. cracks, chipping.
- Damage to the surface.
- Deformations on the product or parts of the product.

If the product still has visible contamination after the end of the program, repeat the pre-cleaning and machine cleaning / disinfection. Damaged components must not be used any further.

8.5. Packaging

Place the cleaned and disinfected components in sterile single-use packaging that comply with the following requirements:

- EN / ISO / ANSI AAMI ISO 11607 (for the USA: FDA approval).
- Suitable for steam sterilization (temperature resistance to at least 142°C, sufficiently penetrable by steam).
- Sufficient protection of the components as well as the sterile packaging against mechanical damage.

8.6. Sterilization

For sterilization, please use only the listed sterilization methods:

- Steam sterilization
- Fractionated vacuum process
- Autoclave according to EN 13060 / EN 285 or ANSI AAMI ST79 (for the USA: FDA approval)
- Validated according to EN ISO 17665 valid IQ / OQ [commissioning] and product-specific performance assessment [PQ])
- Sterilization time (exposure time at sterilization temperature)

Area	Method	Procedure	Temperature	Minimum holding time
USA	Steam sterilization	Vacuum method (3x fractionated pre-vacuum) Drying time minimum 20 min	132°C (270°F)	4 minutes
Other countries	Steam sterilization	Vacuum method (3x fractionated pre-vacuum) Drying time minimum 20 min	132°C / 134°C (270°F / 273°F)	5 minutes

The basic suitability of the products for effective steam sterilization has been verified by an independent accredited and recognized (§ 15 (5) MPG) testing laboratory using the Tuttnauer EHS 3870 steam sterilizer and both the fractionated vacuum method, taking into account typical conditions in clinics and medical practices and the procedure described above.

8.7. Reusability

Undamaged and clean components that come into contact with mucous membranes or diseased skin (semi-critical) can be reused if appropriate care is taken.
Excluded from this are single-use products, *see chapter 8.8. Overview table, p. 43*.
The user is responsible for any further use, as well as for the use of damaged and contaminated components (no liability in case of non-observance).

8.8. Overview table

REF	Product Designation	Pretreatment	Manual Cleaning / Disinfection	Mechanical Cleaning / Disinfect ion (validated)	Sterilization	Recommended Classification according to RKI / BfArM / Kriniko guideline	Multiple use
01170010	JMA-Optic Facebow	not permissible	Immersion not permissible Wipe disinfection	not permissible	not permissible	non-critical	permissible
01170011	JMA-Optic Facebow USB	not permissible	Immersion not permissible Wipe disinfection	not permissible	not permissible	non-critical	permissible
01170012	JMA-Optic Facebow USB-S	not permissible	Immersion not permissible Wipe disinfection	not permissible	not permissible	non-critical	permissible
01470000	UK-sensor OJM-UK1	not permissible	Immersion not permissible Wipe disinfection	not permissible	not permissible	non-critical	permissible
01570510	Induktive Charger JMA-Optic	not permissible	Immersion not permissible Wipe disinfection	not permissible	not permissible	no contact to the patient	permissible
01870011	Table Stand JMA-Optic	not permissible	Immersion not permissible Wipe disinfection	not permissible	not permissible	no contact to the patient	permissible
01860010	IR-Remote Control	not permissible	Immersion not permissible Wipe disinfection	not permissible	not permissible	no contact to the patient	permissible
01970212	C-Positioner	not permissible	Immersion not permissible Wipe disinfection	not permissible	Standard procedure	non-critical	permissible
01910025	Pointer Pin 80	permissible	not recommended	permissible	Standard procedure	semi-critical A	permissible
01960160	Porion Buttons	permissible	not recommended	permissible	Standard procedure	semi-critical A	permissible
01970120	Bracket Bipupillary Position	permissible	not recommended	permissible	Standard procedure	semi-critical A	permissible
01970110	T-Pointer	permissible	not recommended	permissible	Standard procedure	semi-critical A	permissible
01960250	Para-occlusal Attachment with Lip Arch	permissible	not recommended	permissible	Standard procedure	semi-critical B	permissible
01960255	Para-occlusal Attachment with Support Surface Size M	permissible	not recommended	permissible	Standard procedure	semi-critical B	permissible
01960254	Para-occlusal Attachment with Support Surface Size L	permissible	not recommended	permissible	Standard procedure	semi-critical B	permissible
01960280	Occlusal Attachment UN	permissible	not recommended	permissible	Standard procedure	semi-critical B	not permissible
01960360	Bite Fork UN	permissible	not recommended	permissible	Standard procedure	semi-critical B	3x permissible
01960341	Bite Fork PS1	permissible	not recommended	permissible	Standard procedure	semi-critical B	3x permissible
01960320	Bite Fork Adapter UN	permissible	permissible	permissible	Standard procedure	semi-critical A	permissible
01960430	Alignment Fork	permissible	not recommended	permissible	Standard procedure	semi-critical B	permissible
01960140	Retainer for Facebow	not permissible	permissible	not permissible	not permissible	non-critical	permissible
11502501	Bearing Cushion	not permissible	permissible	not permissible	not permissible	non-critical	permissible
11502503	Nose Cushion	not permissible	permissible	not permissible	not permissible	non-critical	permissible
11502508	Overhead Band	not permissible	permissible	not permissible	not permissible	non-critical	permissible
11502502	Clip-on headband	not permissible	permissible	not permissible	not permissible	non-critical	permissible
11511140	Connecting clamp	not permissible	permissible	not permissible	not permissible	non-critical	permissible

Non-critical products: Medical devices that come into contact with intact skin only.
Semi-critical devices: Medical devices that come into contact with mucous membrane or pathologically altered skin.

9 Safety standards and system classification

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

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

9.2. Safety of medical electrical devices

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

Classification according to DIN EN 60601-1:

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

9.2.1. Connecting the system to other electircal devices

(also refer to DIN EN 60601-1 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 IEC 62368-1 or DIN EN 60601-1, or the manufacturer has confirmed their compatibility.

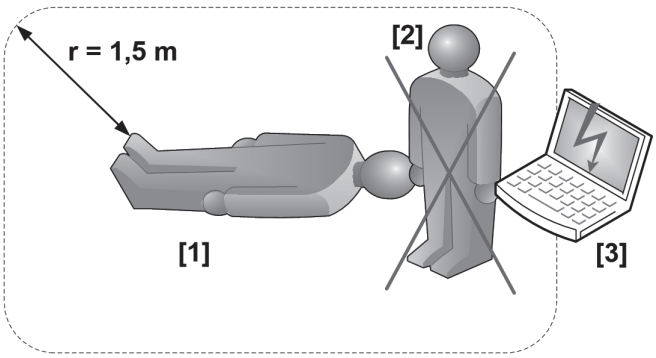
When coupling several devices to one measuring station, please note that no danger through summation of leakage currents can occur.

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, section 16.

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

9.2.2. 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 nonmedical 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 (facebow, UK-sensor, C-positioner)
- IR foot switch
- Accessories



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).

9.2.3. 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 facebow and PC / inductive charger the multiple socket and complete interconnection of the system must adhere to all the requirements of DIN EN 60601-1, 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 patient‘s vicinity.

9.3. Electromagnetic compatibility, guidelines

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 DIN EN 60601-1-2, 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 declaration - Electromagnetic emissions		
The JMA-Optic system is intended for operation in the electromagnetic environment specified below. The customer or the user of the JMA-Optic system should ensure that it is operated in such an environment.		
Interference emission Measurements	**Compliance**	**Electromagnetic environment - Guideline**
RF emissions according to CISPR **11**	Group 1	The JMA-Optic system uses RF energy exclusively for its internal function. Therefore, its RF emission is very low and is unlikely to interfere with nearby electronic equipment.
RF emissions according to CISPR 11 Harmonics according to IEC 61000-3-2	Class B Class B	The JMA-Optic system is suitable for use in all establishments, including domestic establishments and those directly connected to the public power supply network, which also supplies buildings used for domestic purposes.
Voltage oscillations /flicker according to IEC61000-3-33	Compliance	

Guidelines and manufacturer‘s declaration - Electromagnetic immunity			
The JMA-Optic is intended for operation in the electromagnetic environment specified below. The customer or the user of the JMA-Optic system should ensure that it is used in such an environment.			
Immunity tests	**IEC 60601-1-2 Test level**	**Compliance level**	**Electromagnetic environment - Guideline**
Discharge of static electricity (ESD) according to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be made of wood or ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Fast transient electrical disturbances / bursts according 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 that of a typical commercial or hospital environment.
Surge voltages (Surges) according to IEC 61000-4-5	± 1 kV Push-pull voltage ± 2 kV Common mode voltage	± 1 kV Push-pull voltage ± 2 kV Common mode voltage	The quality of the supply voltage should be that of a typical commercial or hospital environment.
Voltage dips, short-term inter-ruptions and fluctuations of the supply voltage according to IEC 61000-4-11	< 5% U_T (> 95% dip of U_T) for ½ period 40% U_T (60% dip of the U_T) for 5 periods 70% U_T (30% dip of the U_T) for 25 periods < 5% U_T (> 95% dip of U_T) for 5 s	< 5% U_T (> 95% dip of U_T) for ½ period 40% U_T (60% dip of the U_T) for 5 periods 70% U_T (30% dip of the U_T) for 25 periods < 5% U_T (> 95% dip of U_T) for 5 s	The quality of the supply voltage should be that of a typical commercial or hospital environment. If the user of the JMA-Optic system requires continued operation even in the presence of the power supply, it is recommended that the JMA-Optic system be powered from an uninterruptible power supply or a battery.
Magnetic field at supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at the power frequency should be similar to the typical values found in commercial and hospital environments.
NOTE: UT is the AC line voltage before the test levels are applied.			

Guidelines and manufacturer's declaration - Electromagnetic immunity

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

Immunity tests	**IEC 60601-1-2 Test level**	**Compliance level**	**Electromagnetic environment - Guideline**
			Portable and mobile radios should not be used at a distance from the JMA-Optic system, including lines, less than the recommended separation distance, which is calculated according to the equation applicable to the transmitting frequency.
			Recommended guard distance:
Conducted RF disturbances according to IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 V_{eff}	$d=1,2\sqrt{P}$
Radiated RF disturbances according 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
			Where P is the transmitter's rated power in watts (W) according to the transmitter manufacturer's specifications and the recom-mended separation distance in meters (m). The field strength of stationary radio transmitters at all frequencies according to an on-site investigation a is lower than the compliance level b. In the vicinity of equipment that bear the following symbol, interference is possible

NOTE 1 At 80 MHz and 800 MHz, the higher value applies.

NOTE 2 These guidelines may not be applicable in all cases. The propagation of electromagnetic quantities is affected by absorption and reflection from buildings, objects, and people.

a The field strength of stationary transmitters, such as base stations of radio telephones and land mobile radios, amateur radio stations, AM and FM radio and television transmitters, cannot theoretically be predicted. In order to determine the electromagnetic environment with respect to stationary transmitters a study of the electromagnetic phenomena of the site should be considered. If the determined field strength at the site of the JMA-Optic system exceeds the above compli-ance levels, the JMA-Optic system should be observed for field strength to verify that it is operating as intended. Demonstrate that it is functioning as intended. If unusual performance characteristics are observed additional measures may be required, such as changing the orientation or location of the JMA-Optic system different location of the JMA-Optic system.

b Over the frequency range from 150 kHz to 80 MHz, the field strength should be less than 3 V/m

Recommended protective distances between portable and mobile RF communications equipment and the JMA-Optic system

The JMA-Optic system is intended for operation in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the JMA-Optic system can help prevent electromagnetic interference by maintaining the minimum separation between portable and mobile RF communication devices (transmitters) and the JMA-Optic system, depending on the output power of the communication device.

Rated power of the transmitter (W)	**Protective distance, depending 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

For transmitters whose maximum power rating is not specified in the above table, the recommended guard distance d in meters (m) can be determined using the equation associated with the respective column, where P is the transmitter‘s rated power in watts (W) as specified by the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not be applicable in all cases.The propagation of electromagnetic quantities is affected by absorption and reflection from buildings, objects and people.