MODJAW
Live in motion

TWIM™ SET OF ACCESSORIES

THE 4TH DIMENSION LIVE AT THE CHAIR

USER MANUAL EN

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Medical Device
CE

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1 General product information

1.1 Copyright

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1.3 Patents and models

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MODJAW SAS 798 221 859 RCS Lyon.

1.4 Warranty

If the user installs additional hardware or third-party software, this will be the sole responsibility of the operator and the manufacturer's warranty will no longer apply.
MODJAW is not responsible for damage or operating errors caused by misuse of the software or use of inappropriate hardware.
The warranty for the device is 1 year from the date of delivery. It includes the parts contained in the patient kit.

1.5 Manufacturer information

MODJAW™
11-13 Avenue Albert Einstein
69100 Villeurbanne
France
Telephone: +33 (0)482771111
Email: support@modjaw.com
Website: www.modjaw.com

Australian sponsor name
Freyr Australia Pty Ltd

Australian sponsor address
46 Dora Street, Blacktown
NSW, 2148
Australia

United Kingdom (UK) sponsor name
APOTECH Consulting

United Kingdom (UK) sponsor address
71-75 Shelton Street Covent Garden
London WC2H 9JQ

CE Marking
TWIM™ set of accessories is a Class I accessory intended for use with the TWIM™ medical device software in accordance with Medical Device Regulation (EU) 2017/745 and CE marked by self-certification.

According to Therapeutic Goods Act 1989, device is “Approved for Australia” and the IFU is included in the Australian Register of Therapeutic Goods.

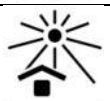
1.6 Structure of the user manual

This manual is intended for users of TWIM™ set of accessories. It contains instructions for installation, testing, pre-use, operation and storage of the device.
It also contains technical data as well as safety, health and maintenance instructions.
This document must be read by all persons interacting with the medical device.
Extensions, application of new parameters, modifications or repairs are carried out by MODJAW™, authorised technicians, or any authorised personnel.

Please read the instructions in this user manual carefully before using the medical device.

1.7 Use of labelling symbols

RM-074

Symbol	Description
	CE logo which indicates that the medical device meets the requirements of Medical Device Regulation (EU) 2017/745
	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	Indicates the medical device manufacturer
	To identify the country of manufacture of products
	Indicates the manufacturer's catalogue number so that the medical device can be identified
	Indicates the manufacturer's serial number so that a specific medical device can be identified
	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Electrical and Electronic equipment. Return waste to a collection system or treatment and recycling facilities. Applicable in the EU. Follow decontamination instructions before returning waste
	Indicates the date after which the medical device is not to be used
	Indicates a medical device that is intended for one single use only
	Indicates a medical device that needs protection from light sources
	Indicates the temperature limits to which the medical device can be safely exposed
	Indicates the range of humidity to which the medical device can be safely exposed
	Indicates the range of atmospheric pressure to which the medical device can be safely exposed
	Indicates a carrier that contains unique device identifier information : (01) Device Identifier (10) Batch number (11) Manufacturing date (17) Expiration date (21) Serial Number

MD	Indicates the item is a medical device
	Indicates the need for the user to consult the instructions for use
	Indicates the need to refer to instructions for use.

2 Usage environment and security

2.1 Intented purpose

TWIM™ set of accessories is a medical device accessory designed to be used with TWin In Motion Software to record mandibular kinematics.

2.2 Indication

TWIM™ set of accessories is indicated for edentulous or dentate patients at an age allowing understanding and cooperation during the recording protocol.
There is no gender restriction.

2.3 Contraindication

The patient must have a morphology compatible with the instruments in the Patient KIT.
The TWIM™ set of accessories should not be used in patients with:

- With pathologies that are incompatible with the proper acquisition of dental models;
- Unable to follow the instructions necessary to perform an examination;
- Unable to maintain proper posture during the examination.

RM-070

2.4 Clinical benefits and performances

- Correct acquisition of jaw motion directly on the patient.

2.5 Environmental conditions

The user agrees to install and use the device in a location that meets the environmental conditions specified below. The TWIM™ set of accessories is designed for use in dental offices only. The system is suitable for use in a dry indoor room, such as hospitals and medical offices.

RM-073

The optimal environmental conditions for using this device are as follows:

- Temperature: 15°C to 25°C;
- Atmospheric pressure: 80 kPa to 106 kPa;
- Humidity level: 30% to 75%;
- Altitude under 2000 m.

RM-003

The device is not intended to be used:

- In areas where there is a risk of explosion or in a flammable atmosphere (enriched with oxygen);
- Near high frequency surgical equipment;
- Near a strong source of heat or light at the risk of corrupting the proper functioning of the device (total cessation of use or malfunction leading to distorted data);
- Near magnetic fields (distorted data or data generation impossible);
- In a dirty environment (risk of contamination of the device).

2.6 Obligations of the user

The use of the device is restricted to qualified and trained dentists, or under their supervision (dental students) or dental technicians.
The device must not be used by unqualified and untrained persons.

RM-175 / RM-202

The user must ensure that all operating instructions provided on the system are accessible to all users at all times and kept close to the device.

The user must ensure that all operating instructions provided on the system are accessible to all users at all times and that they are kept near the device.

Do not use the device for any other purpose:

- Do not attempt to service the device in any way other than that described in this manual;
- Do not modify the device. If the device is modified without MODJAW's permission, the device's warranty will no longer be valid;
- Do not attempt to insert any inappropriate object into the device that is not part of the device;
- Do not connect devices not supplied by MODJAW.

The components of the device are not designed to be used with any system other than that supplied by MODJAW.

RM-105

2.7 Incident reporting

If the user/patient had a serious incident, please report it to MODJAW™ support (for contact details, see section 8), and the competent authority of the Member State in which the user/patient is established.

3 Product description

3.1 List of components

TWIM™ set of accessories consists of the following elements :

Name of the components	Picture
Operational Cart	
Pen tracker	
Frontal tracker	
Rear band	
Reflective markers (x36)	
Fork (x20)	
Mandibular Tracker	

3.2 Labelling

The following components of the system have their own individual labelling:

- The operating cart;
- The patient kit includes the frontal tracker, the rear band, the stylet, the mandibular tracker, the fork, the reflective markers.

3.3 TWIM™ set of accessories description

3.3.1 Operational cart

The operational cart consists of several components:

- A bracket that carries the Panel PC;
- An articulated arm that carries the camera. It can be blocked at 90° on the right or left side;
- A base on which 4 wheels with locks are attached, allowing it to be moved;
- A power cable.

The operating cart must not be disassembled, and no electrical components must be removed and/or replaced.
The cart is mounted on wheels, the user must ensure that the wheels are locked before each use.

Below are the electrical characteristics of the operational cart:

Specifications	Data
Input voltage	220 - 240 V~
Frequency	50/60 Hz
Power consumption	80 VA

3.3.1.1 Camera

RM-034

The camera is an optical tracking system specifically designed to detect and track reflective markers in real time. The following sections detail the features of the equipment.

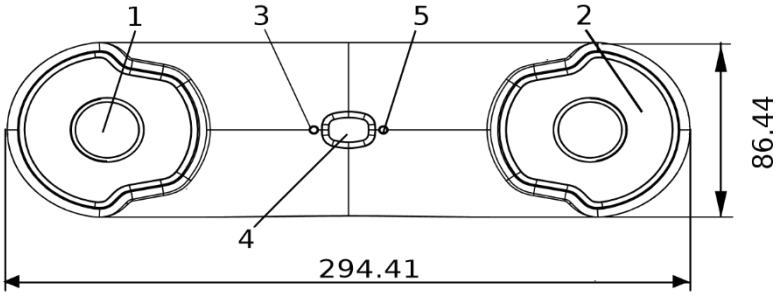
<u>Specifications of the camera</u>

The camera specifications are shown in the table below:

Characteristics	Data
Dimensions (L × W × H)	294mm × 86mm × 99mm
Weight	1.28kg
Infrared	~ 850nm
Power requirements	Power over Ethernet (*PoE*+ IEEE 802.3at-2009) 48V 0.6A

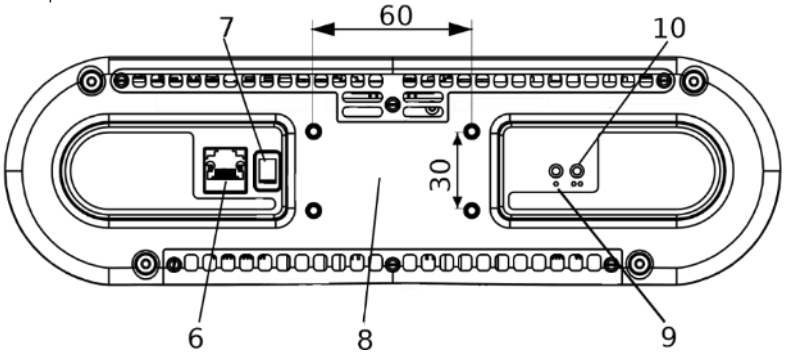
Description of the camera

1. The figure below shows the front view of the camera. It should be noted that “Left” and “Right” always refer to the vision of the camera.



Front view of the camera, showing: (1) camera sensor; (2) IR LEDs ring; (3) User status LED; (4) IR receiver; (5) Device status LED.

2. The rear plane of the camera is shown in the following figure. The Ethernet interface provides both communication and power. The device is switched on / off using the power switch. Finally, both LEDs indicate the status and speed of Ethernet communication.



Description of the rear plane of the camera, showing: (6) the RJ-45 connector, provides power and data transmission between the camera and the computer; (7) Power switch, turn on or off the unit; (8) Permissible surface for mounting on 4 × M4 screws; (9) LED Ethernet RX (10) LED Ethernet TX.

The LEDs on the front of the camera can have multiple states indicating normal operation or not of the camera. The different states are described in the table below.

Description of indications provided by the LEDs on the front of the camera.

LED indicating the status of the camera	green	Intermittent	The camera is heating, initialization course
	green	Continuous	The camera is ready to use
	red	Intermittent	Critical error, please contact Modjaw

The camera should not be used covered: this would change the operating temperature of the camera and could change the optical path, resulting in a change in the calibration parameters, leading to degradation of the camera.

RM-177

Be careful not to block the air ventilation paths of the camera and panel PC.

RM-178

The camera should be powered up at least once a month for at least 2 hours. In any case, the camera must be recharged for 24 hours, if the camera has not been used for 6 months.

RM-052

3.3.1.2 Panel PC

The Panel PC already fixes the system, the user does not have to change the installed connections. The fixing allows the Panel PC to be orientated to adjust the screen to the user's position.

However, the panel PC must be handled with care to avoid damage.

When delivered or in storage position, the panel PC can be rotated and placed in a vertical position (see photo below of the cart storage position) to minimise the size of the device.

The user must ensure that the cables that connect the computer to the cart are kept free at all times to avoid premature wear and tear

Illustration of the two possible storage positions of the PC Panel

The PC panel mounted on the device is an all-in-one computer. To enable optimal operation, the PC panel must have the minimum configuration as shown below:

Components	Characteristics
Operating system	Microsoft Windows 10 or Windows 11
Processor	Intel Core i7 or equivalent
RAM	32 GB
Hard disk	500 GB SSD
Screen Resolution	1920 x 1080 pixels

RM-032/RM-157

The user must check the PC panel at commissioning.

RM-053

3.3.2 Patient kit

The frontal and mandibular trackers, placed on the patient's head, allow the capture of mandibular movements during calibration and the acquisition of characteristic points previously located on the 3D models using the stylet provided for this purpose. The reflective markers on the stylet, the frontal and mandibular trackers communicate with the camera.

4 LIVE AND RECORD

4.1 Setting up the operational cart

1. Unfold the articulated arm of the cart so that it is at a 90° angle to the arm;

The user must not manipulate the arm while passing through the top.

RM-111

The camera should be placed horizontally. An orientation other than horizontal (e.g., vertical) may damage the camera due to temperature gradients within the camera.

RM-180

2. Place the cart along the dental chair between the patient's knees and pelvis;
3. Engage the locks on each wheel of the cart;
4. Connect the power cable to the mains outlet that contains a ground connection;

Block the cartwheels before each use.

RM-007

Do not make any unintended connections (network connection, keyboard with non-waterproof cable, mouse with cable...).
Do not remove the plugging accessories placed at the back of the computer.

The cart is not waterproof.
Do not use liquids near the cart.
In case of fluid ingress :

- Switch off the device immediately;
- Stop any operation in progress;
- Notify MODJAW technical support.

5. Turn on the camera and let it warm up for about 20 minutes;

Note: the camera is only operational after a warm-up time. Do not attempt to use it until the end of the warm-up period.

The camera should not be used if a hot air outlet is present between the camera and the markers. This could affect the camera acquisition.

RM-181

6. Ensure that the camera is turned on correctly (LED on);
7. Turn on the Panel PC. The operating system starts automatically.

RM-033

The user must check that the equipment is in good general condition (good connection cables, power supply, sockets, etc.) to ensure the protection of his patients, third parties, other operators and assistants.

The user must not use defective products (stripped, worn cables ...). In the event that the hardware condition is incorrect, any use of the device must be stopped.

The user must not disconnect the cables from the system during operation as it may damage the system and make it non-functional.

RM-113

4.2 Recommendations before clinical use

Before use, the instruments in the patient kit should be cleaned following the procedures described in section of this document.

The stylet is not delivered sterile. The user must sterilise the stylet before the first use and before each new use by following the protocol described in chapter 5.

RM-026

The tip of the stylet must be calibrated before each use.

RM-091

Any drop of an instrument before or during use may cause damage to the system. If the instrument is dropped between calibration and acquisition, it is recommended that the stylet is recalibrated, or the stylet is changed, and the calibration is repeated.

RM-080

The user should indicate the necessary precautions to be taken by dental technicians regarding the limitations of the data exported by MODJAWTM for the creation of dental equipment.

RM-193

Clean instrumentation should be unpacked on a clean surface to prevent contamination.

The user should check the condition of the instruments before use. Instruments should not be deformed or damaged as this may alter the information provided by the system or cause injury to the patient.

Check before each use that the instruments positioned on the patient are secure.

RM-025

4.3 The assembly of reflective markers

The reflector markers are for single use only. They are contained in a bag in the patient kit box. In preparation for each examination, the reflective markers should be assembled on the cleaned instruments.

The reflective side of the reflector marker should be positioned towards the front of the trackers (stylus, frontal and mandibular trackers). The reflective marker can be clipped on with a simple push of the finger.

Illustration of the positioning of reflective marker in the housings provided on the frontal tracker.

For more details about the installation of the reflective markers, refer to annex 1.

The user should check that the instruments are equipped with clean, new reflector markers before starting the installation of the instruments. Any poorly clipped reflector marker, or the use of deteriorated or deformed reflector markers, may impact on the components supplied by the system.

RM-025

The user should wear gloves when assembling the reflector markers to avoid contaminating clean parts.

Once the instruments are ready, the user can continue with the calibration of the tip of the stylet.

The user must be careful not to bend the tip of the stylet with excessive pressure. If bent, the information provided by the system may be altered, and the patient may be injured.

RM-083

The user must be careful not to injure the patient with the tip of the stylet, especially when operating close to the eyes.

RM-077

The user must ensure that the camera is never placed within 20 cm of the patient's skin or eyes.

RM-150

4.4 Setting up the instruments on the patient

4.4.1 Placing the mandibular tracers

In order to prepare the patient for the examination, the user must position the mandibular tracker. This mandibular tracker is held in front of the patient's mandible by a fork. The fork is a single-use part included in the patient kit box.

The fork is delivered clean. They should be handled with medical gloves.

The positioning of the mandibular tracker is therefore done in two steps:

- Fixing the fork in the mouth;
- Clipping the mandibular tracker on the bracket.

These two steps are described below:

Step 1: Fixing the fork in the mouth:

Before insertion, the fork can be adjusted in length if necessary. For this, just break the ends.

The user should be careful not to injure the patient with the ends of the mandibular marker holder, especially after adjustment. Check before introduction into the mouth that no roughness remains, likely to injure the patient.

RM-093

It is recommended to use a self-hardening resin model among those recommended by MODJAW (Structure types, VOCO company). The user must follow the application protocol specified by the resin manufacturer.

RM-055

After the setting time indicated by the manufacturer of the resin, the user verifies the proper fixation of the fork on the teeth of the patient. The fork must be positioned in such a way it should not disturb the patient mastication, the movements of the jaw must be possible and natural.

Step 2: Clip mandibular tracker

The mandibular tracker, equipped with reflective markers is then added to the fork. For this, place the male part located on the mandibular marker in the female part located on the outer part of the fork. The patient must close the mouth during this operation to facilitate posing the marker and avoid any pain. The addition of mandibular tracker should not interfere with the patient when moving the lower jaw.

Illustration of the fork clip on the mandibular marker

The user must visually check the consistency between the virtual movements and the actual movements displayed. If the movements are inconsistent, abandon the use of the system, or redo the acquisitions.

RM-082

4.4.2 Placing of frontal markers

The frontal tracker should then be positioned on the patient's head. The positioning is correct if the red rubbers located on the posterior face of the front piece are placed on the forehead and the top of the patient's nose.

The rear band is positioned high above the ears and is positioned above the patient's neck. Finally, the tightening is adjusted using the knobs on each side.

The frontal tracker must be fixed and move as little as possible to minimize inaccuracies during the acquisition.

Illustration of the position of the frontal tracker on the patient.

4.5 End of Acquisition

The frontal tracker is removed from the patient's head, the mandibular tracker is removed from the fork still in the mouth. The fork can then be removed from the patient's mouth. Be careful not to injure the patient by removing the fork.
All instruments must be cleaned according to the protocol indicated in this user manual between 2 uses.

The Panel PC and camera are switched off and the operational cart is put in storage position until the next use (see section 8 of this manual).

5 Hygiene and Cleanliness

5.1 Cleaning of the cart

Once the cart has been cleaned, the articulated arm must be placed along the stem. The cart should be cleaned with Anios Dentaspet SH wipes.

Do not spray cleaner on the cart to clean it, liquid could come into contact with the protected components, damage them or create an electrical hazard.

RM-017

5.2 Cleaning the camera

The camera can be disinfected with hospital disinfectant detergent type Anios Dentaspet SH wipes. Optical parts should be cleaned only with lens cleaning solutions. Eyeglass wipes should not be used as they may scratch the lens. Other surfaces should be dried with a clean, dry cloth.

RM-017/RM-107

The device must be switched off and unplugged before cleaning. Disinfectant detergent must not be spilled directly on the device or any of its components.

Spraying cleaning agent directly on the equipment is prohibited. It must be ensured that no fluid enters the camera. This can damage electrical components by causing short circuits and corroding the material.

Only non-corrosive and non-acidic detergents, whose interactions with materials are known, can be used.

Consequences of multiple clean up

The optics of the camera may be scratched, or the transparency of the window may be changed, resulting in poor image quality and therefore poor tracking precision.

5.3 Cleaning the instruments of patient kit

All reusable instruments (frontal and mandibular tracker) must be disinfected and cleaned before re-use in accordance with the described process.

RM-051/RM-107

5.3.1 Cleaning procedure for patient kit instruments

Remove the reflective marker from the instruments and clean the instruments by soaking with any Anyos Dentaspet enzymatic detergent following the protocol recommended by the manufacturer.

As an indication, the washing steps are as follows (refer to the manufacturer's instructions before starting cleaning):

1. Dilute the detergent to 1% (for example, 20mL for 2L of water)
2. Immerse the instruments completely in the solution, cover and soak for a recommended contact time of 15 minutes to achieve microbiological efficacy.
3. Remove the instruments from the solution and check for visible debris. If necessary, brush them.
4. Rinse under running water or by immersion.
5. Dry the instruments.

Particular case of the stylet: After each use of the stylus, since the latter comes into contact with the patient's oral mucosa, it must be cleaned according to the procedure indicated above and then sterilized before being used on a new patient.

The stylet is not delivered sterile. The user must sterilize the stylus before first use and before each new use by following the protocol described in this chapter. Sterilization must take place immediately after cleaning and must be carried out in accordance with good practice.

RM-092 /RM-106

The recommended sterilization cycle for the stylet is 134 ° C for 18 min with a dry time of 20 minutes.

The stylet is designed to resist at least 25 autoclave cycles according to the protocol indicated above. Beyond this number of cycles, the use of the stylet is not guaranteed by MODJAW™.

5.3.2 Single use devices

Fork and reflective markers are single use devices and are discarded at the end of the exam.

The user should discard the fork and reflector markers after each use and never reuse them for another patient.

RM-043

6 Transportation and storage

In order not to compromise the performance of the device, it is essential that the various components of the device are protected from falls, shocks, vibrations, inappropriate environmental conditions and possible contamination.

The storage and transport conditions to respect in order not to risk damaging the device are as follows:

- Temperature: -25 ° C to 50 ° C;
- Atmospheric pressure: 80kPa to 106kPa;
- Humidity level: 30% to 75%.

As indicated on the packaging and protections, it is necessary to take the following precautions to not compromise the performance of the device:

- The device should be used sheltered from the sun' ray;
- The device must be protected from hot or cold temperatures;
- The device must be protected from fluids.

Between two acquisitions, the device must be in storage position, the articulated arm of the carriage folded in storage mode along the stem.

7 Device malfunctions

RM-176/RM-094

In case of malfunction:

- Stop using the device immediately;
- Try to identify or eliminate the cause of the malfunction by referring to this document;
- If it is not possible to identify or eliminate the cause with this document, turn off the power and call Modjaw customer service (see the manufacturer section at the beginning of the document for detailed contact information).

In the event that the user is obliged to contact Modjaw customer service, please provide the following information to the customer service:

- Serial number of the device (it is on a cart);
- The software version of the device;
- The operating system version of the Panel PC;
- Screenshot of the bug or problem;
- Log exports, available with button “Export to support” in the “i” button of the Modjaw banner;
- Export the consultation on which the problem occurred;
- A description as accurate as possible of the process that led to the error message.

In the event of malfunctions of the device and / or defects suspected and / or noted, several actions must be taken:

- The user must remove the device from use;
- The device must be labelled as "Out of Service";
- The device must be secure and isolated to prevent its use.

The user may only use the device again after the repair or replacement of the defective parts.

The user must warn Modjaw of malfunctions so that the latter can carry out an inspection.

Immediate maintenance actions should be taken in the following cases:

- Penetration of liquids into the device;
- Damaged covers and cases;
- Damaged power cables;
- Malfunction of the cartwheels;
- Erased or detached labels;
- Other defect(s) suspected or verified.

8 After-sales service and monitoring

Contact:

MODJAW
11-13 Avenue Albert Einstein
69100 Villeurbanne
France
Telephone: +33 (0)482771111
Email: support@modjaw.com
Website: www.modjaw.com

In case of a malfunction or difficulties using the device, contact the MODJAW™ team.

RM-176

9 Guidance and Manufacturer's Declaration: Electromagnetic Emissions

Special precautions should be taken with electromedical devices regarding electromagnetic compatibility, their installation and commissioning must be carried out in accordance with the electromagnetic compatibility information provided in this document.
This statement currently applies to the TWIM™ set of accessories. This device complies with the requirements of EN 60601-1-2 which describes the conditions of electromagnetic compatibility (EMC) for medical devices. TWIM™ set of accessories requires precautions against EMC. MODJAW TECH IN MOTION™ must be installed and commissioned in accordance with the recommendations of this manual. Conformity of the EMC standards does not mean that a device is entirely immune from interferences. TWIM™ set of accessories can be affected by portable or mobile RF communication equipment. TWIM™ set of accessories should not be used next to other devices or stacked with them. If it is not possible to do otherwise, TWIM™ set of accessories should be monitored to check the normal operating conditions in the configuration in which it will be used.

Interference Hazards: The use of accessories, sensors and cables other than those specified, except sensors and cables sold by the manufacturer as spare or replacement parts could induce an increase in emission levels or a decrease in TWIM™ set of accessories immunity levels.

10 Recycling

The cart, the camera and the PC panel must be recycled according to the WEEE directive or national regulations. These components should not be thrown away with household waste but via suitable sorting channels.
Single-use items are discarded as healthcare waste.

11 Other versions

The instructions for use are available in different languages on the MODJAW™ website: https://modjaw.com/fr/usermanuals
Users can get a paper version of the instructions for use at no extra cost and in less than 7 days following receipt of their request.

RM-209/ RM-231/RM-234/RM-236/RM-239

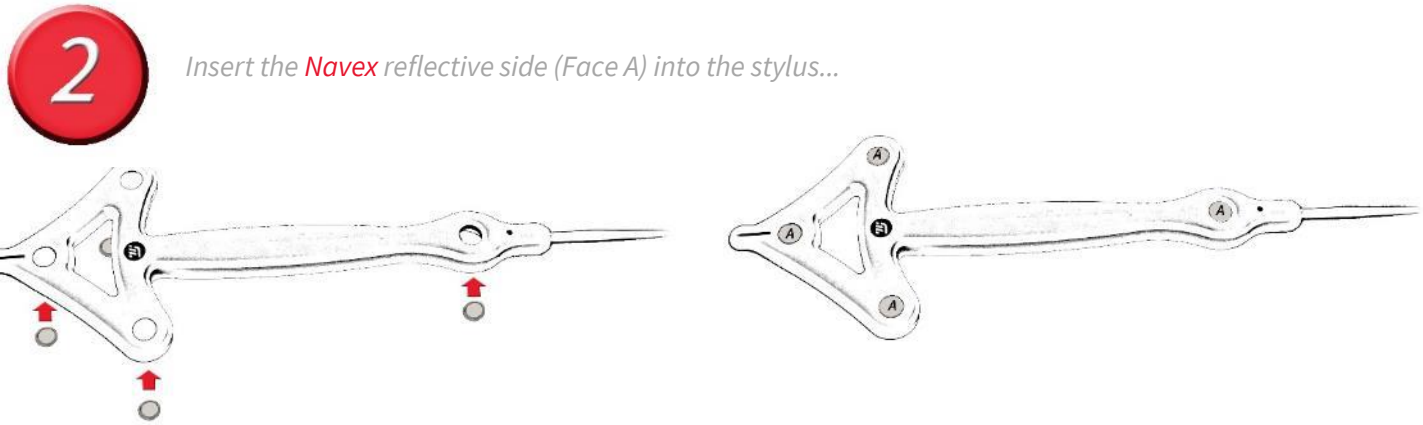
MODJAW™ will notify the user when new version of this document is released.

12 Acronyms

IR: Infrared
TWIM: Twin In Motion

13 Annex 1 : patient kit assembly

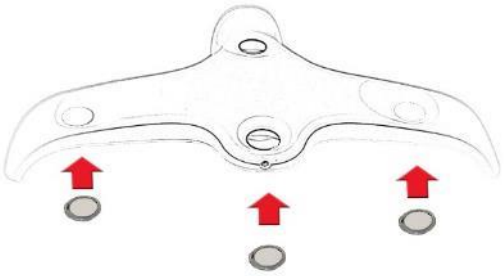
Navex reflective side A, non-reflective side B

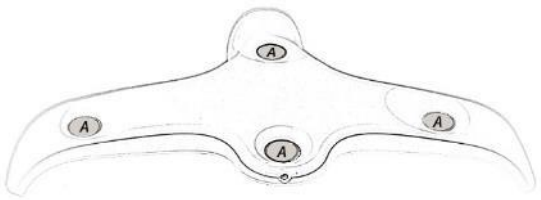


Insert the Navex reflective side (Face A) into the stylus…

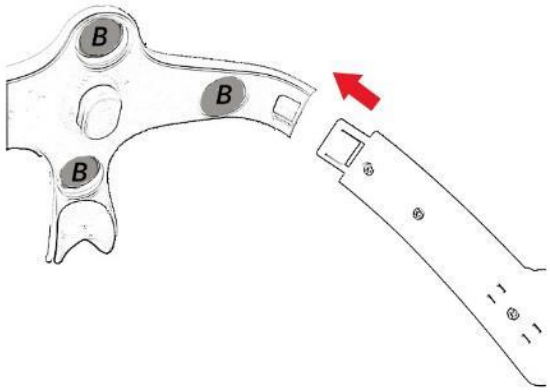
In the SMIL'IT…

And on the TIARA Helmet

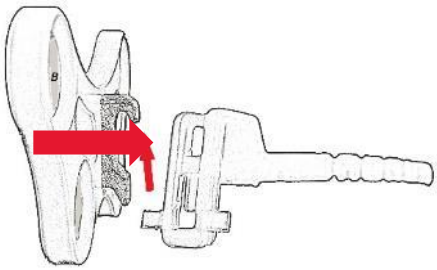


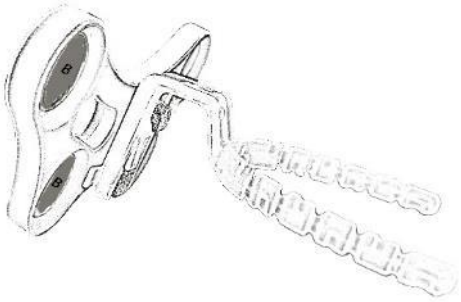


5 *Clip the back of the headband*



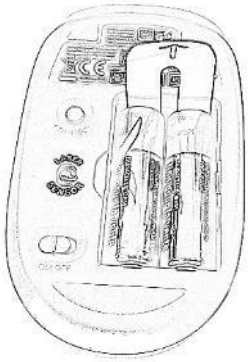
6 *Insert the fork on the SMIL'IT*



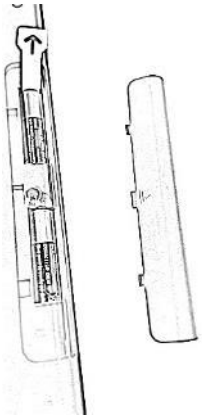


14 Annex 2: setting the mouse / keyboard

1 *Remove the mouse tab before use*



2 *Remove the keyboard tab before use*



3 *Insert the dongle on the back of the computer*