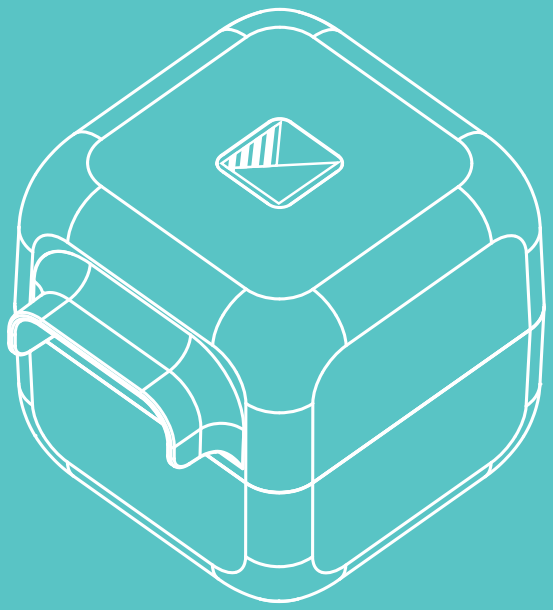
MIMETRIK

Cubit360

Operating Manual

HC-000035-TC_V5_12MAR26



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Important instructions and safety warnings appear in the Cubit360™ Quick Start Guide and Operating Manual. Please read both documents completely before use.

Keep these instructions in a safe place for future reference.

Contents

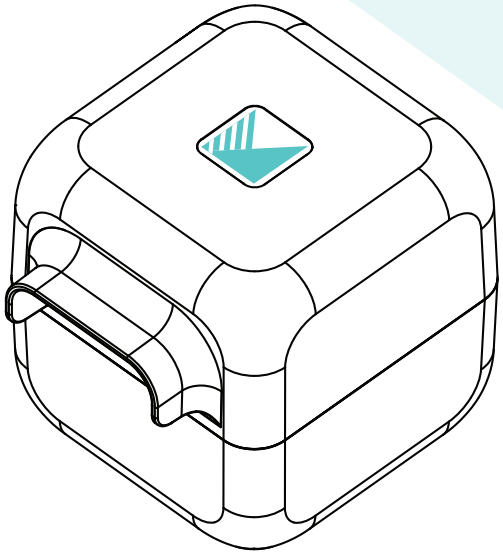
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For software updates and Operating Manual, go to:
https://cubitupdates.mimetrik.tech/Downloads/

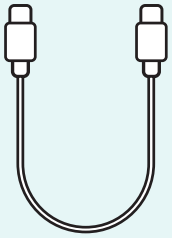
A free of charge paper copy of the Quick Start Guide and/ or Operating Manual can be requested by writing to support@mimetrik.tech

For further device and training information, go to:
www.mimetrik.tech/cubit360

Package Contents



Cubit360 Scanning Unit



USB-C Cable

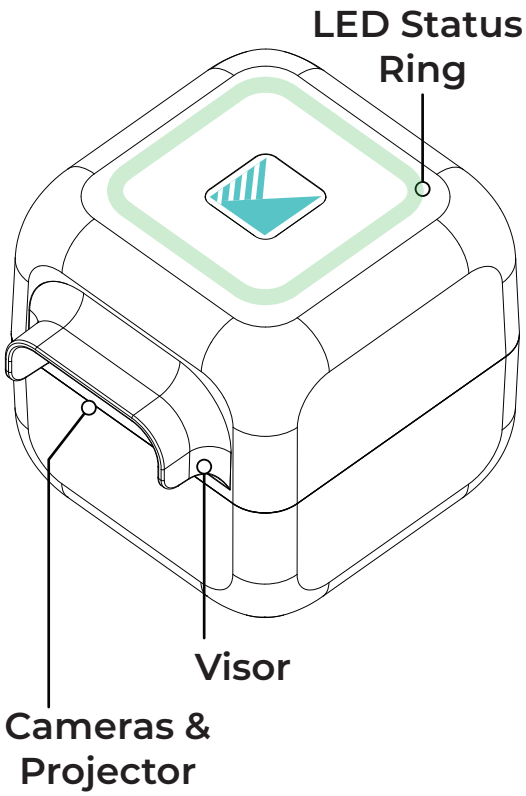


Quick Start Guide

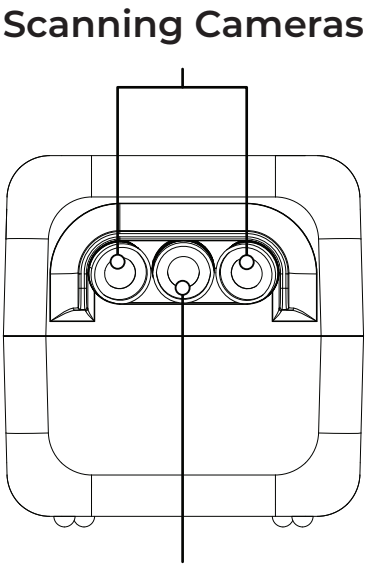
Components

Cubit360 is an optical acquisition unit consisting of two visible light cameras and a static dot pattern projector mounted in a cubic outer enclosure with an LED Status indicator.

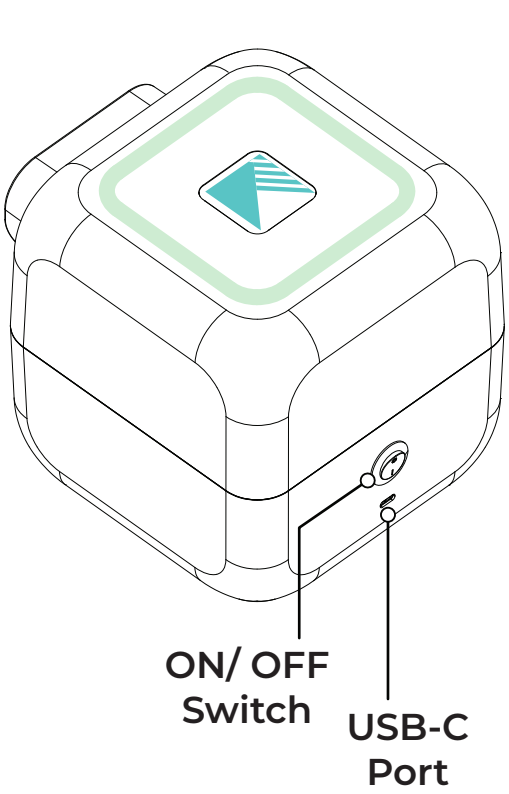
Front Quarter View



Front



Rear Quarter View



Operating System Requirements

Cubit360 software is required to use the system.
Host computer must meet the minimum specifications below:

Component	Minimum Requirement
Hardware	Desktop Windows computer with monitor, keyboard and mouse
Supported OS	Windows 11 (24H2 or more recent) Windows on Mac via Bootcamp is not recommended as lack of graphics card compatibility severely impacts performance.
Processor (CPU)	IntelCore i9 Gen12 or newer
Memory (RAM)	64 GB or greater
Storage	500GB storage is required
Graphics	NVIDIA RTX 4080 desktop or 50xx series with at least 16GB VRAM Latest NVIDIA device driver Display resolution: 2560x1440
USB Ports	USB 3.2 Gen 2x2 Type-C
USB Cable	1x USB Type-C Male; Speed: 10+ Gbps; Voltage: >= 5V Use only the supplied USB cable, alternatives may seriously impede performance.
Other	Use a PC and monitor certified to IEC 60950/ IEC 62368-1, IEC 55032, IEC 55024. Ensure only IEC-approved power supply used. Internet connection is required for software updates. Administrator privileges required for installation. The Cubit360 is not compatible with virtualisation environments. Minimum 1 x USB 3.2 Gen 2x2 Type-C maximum 3A.

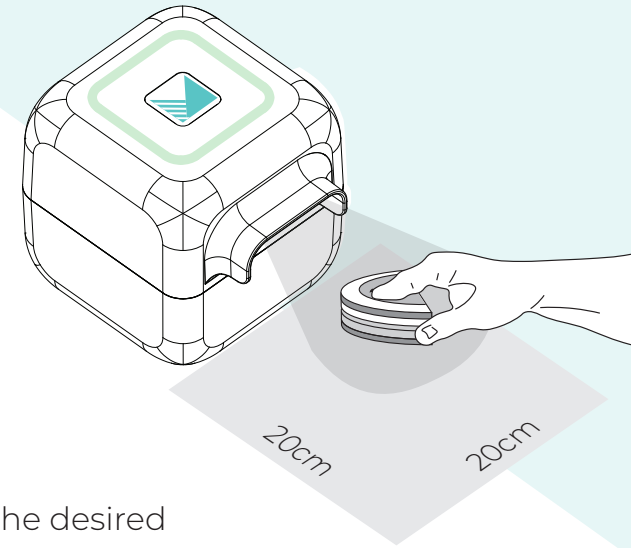
Cubit360 Specifications

Item	Specification
Dimensions (Scanner)	170 x 170 x 200 mm (Cube shaped, Visor protrudes 30 mm)
Weight	1.4 kg
Protection Class	Class I
Protection	Ordinary equipment (no protection against ingress of water) Closed unit, minimises ingress of dust but not water
Duration of Operation	Intended for continuous operation in normal laboratory use
Type of System	Desktop. Intended for use in a fixed dedicated area Not intended for portable use.
Port	1 x USB 3.2 Gen 2x2 Type-C.
Voltage	5V
Area of Use	For indoor use only. Working area must be stable, clean and dry. Avoid exposure to extremely bright light during use.
Operating Ranges (Environment)	Temperature: 18-27°C Humidity: 30-75% (non-condensing) Altitude: Up to 2000m

Installation

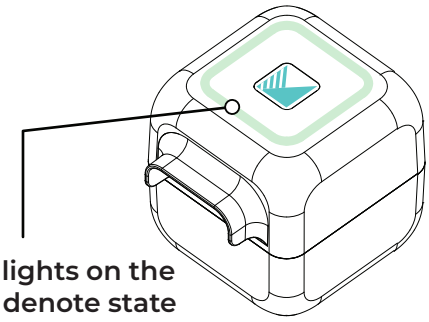
Installation Environment

- For indoor desktop use
- There are no special requirements for ventilation
- Operator must be able to manipulate items for scanning freely in front of the Cubit360 during use
- Allow a working footprint of at least 20 x 20 cm
- Working surface must be dry, clean, level and stable
- Area should be well lit by diffused ambient light (standard ceiling lights are ideal).
- Direct bright light onto the Cubit360 will adversely affect scanning. Avoid bright sunlight or lamps shone directly onto the unit or the item being scanned.



Installation Steps

1. Set the Cubit360 on working surface, and move to the desired position avoiding direct light
2. The computer should be connected to the Internet during software installation and updates.
3. Connect the USB cable from the Cubit360 to a high-speed USB 3.2 port on the computer. *Note: using an incorrectly specified USB port may prevent the system from operating correctly.*
4. Ensure the Cubit360 remains *switched off* during installation by ensuring the ON/ OFF switch on the back of the device *is in the Off position*.
5. Double click on the installer icon to start the installer, and follow the prompts.
6. Restart the computer to complete installation.
7. The Cubit360 can now be switched on using the ON/ OFF switch.
8. The Cubit360 software can now be started using the shortcut on the desktop.



Indicator lights on the Cubit360 denote state

Indicator lights

State	LED Lights
Plugged in but software not launched	Slow pulsing white
Initializing software and hardware	Spinning white
Software and hardware ready and waiting	Solid green
Scanning	Solid green
Relocation (trying to pick up scan if tracking is lost)	Pulsing green
Scanning paused (if user has stopped scanning for 30+ secs)	Slow pulsing green
Post-processing	Spinning green
Hardware error	Solid orange

Intended Use

Cubit360™ is a non-invasive optical scanning system intended for the digitization of dental impressions, dental models and dental prostheses for use in CAD/CAM workflows for the design and manufacture of dental restorations.

The Cubit360 3D scanning system is connected to and operated using a computer and proprietary Mimetrik software. Neither the scanning unit nor the operating software can be used in isolation.

The system is intended for use by trained dental professionals in dental laboratory or dental practice environments. Cubit360 is not intended for direct patient scanning, intraoral use, diagnosis, or treatment planning.

General Cautions

- The device should only be used by trained professionals.
- The device is not intended to scan teeth in situ, people or animals.
- Do not submerge or expose the device to liquids.
- Do not place objects or liquid on top of the device.
- The device is not intended to be portable.
- Use only the USB-C cables that are supplied with the device. Do not connect to other leads or voltages above the rating stated in Specifications. Do not connect the device to a USB port capable of delivering more than 3A.

LED Caution

This device contains an LED projector, classified as Risk Group 0. This is considered safe. Nevertheless, continual exposure to bright light can be harmful to eyes. The following precautions are recommended.

System

- Desktop systems used with this device should have the latest security updates installed.
- Use a PC and monitor certified to IEC 60950 / IEC 62368-1, IEC 55032, IEC 55024. The power supply serves as the means of isolation from the mains. Disconnect the power supply from the mains to fully isolate the device. Ensure only IEC-approved power supply used.

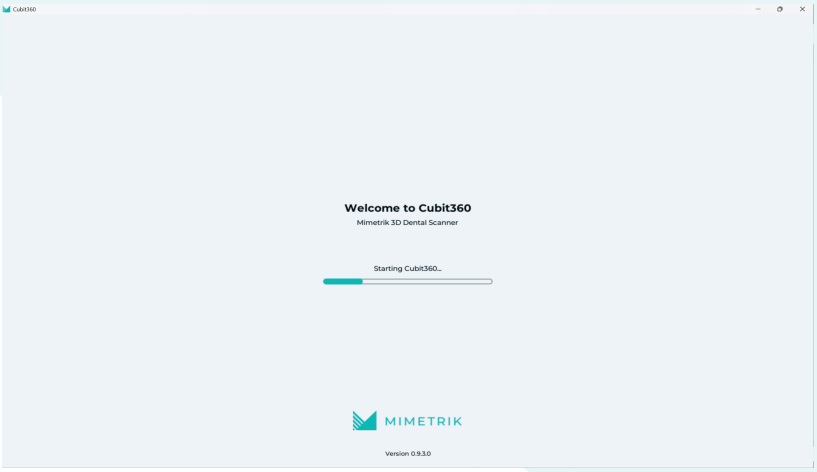
Storage & Transport

- Please store in a safe place to avoid breakage or damage.
- Exercise caution when moving the device.
- Temperature: 0°C to 40°C.
- Humidity 20-80% (non-condensing).

Scanning

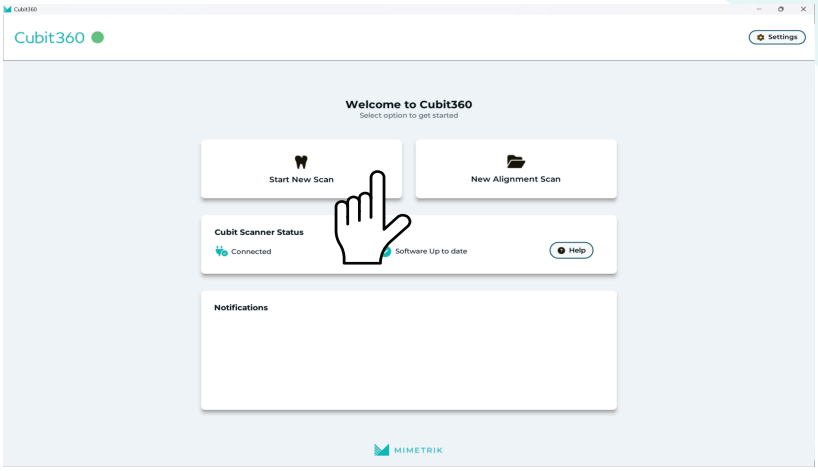
1. Turn on and initialise

- Ensure the Cubit360 scanner is switched on using the power switch on the back of the device
- Start the ‘Cubit360’ software using the shortcut on the desktop
- The Cubit360 initialises



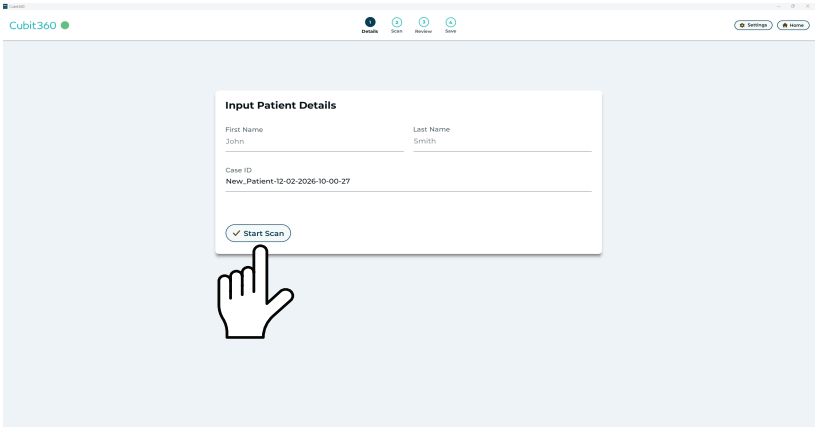
2. Start new scan

- Once initialised, the home screen loads
- Click on ‘Start New Scan’



3. Enter patient details

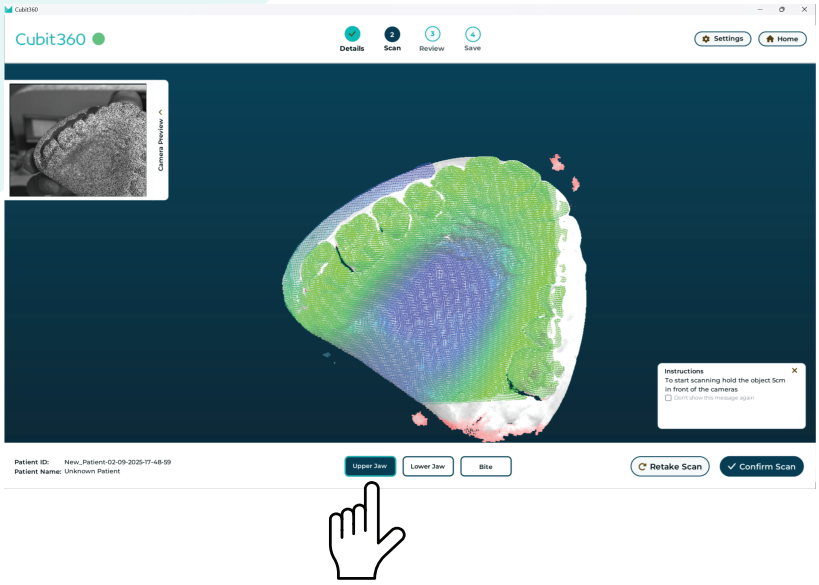
- Enter the patient details in the next screen. The patient name field is optional.
- Click ‘Start Scan’
- The scanning window opens, ready for a scan



Scanning
continued

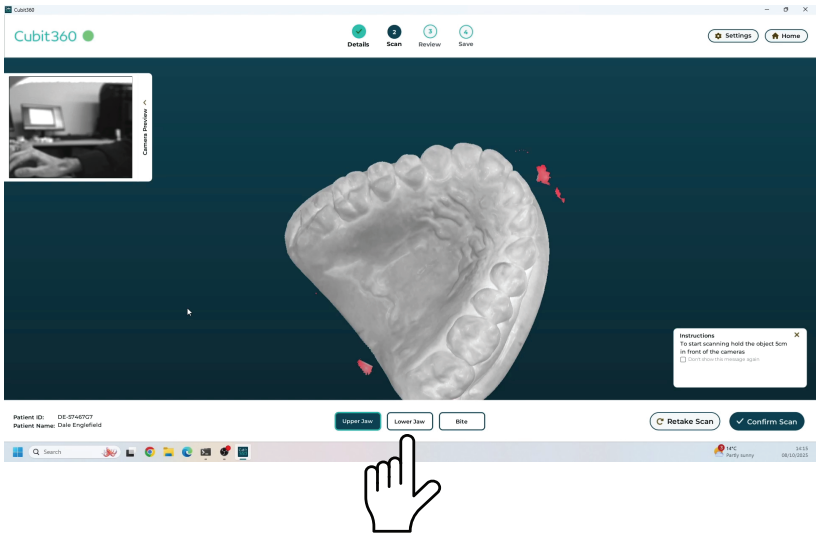
4. Scanning Models, Impressions & Dentures

- Indicate whether you are scanning the upper or lower jaw. The software assumes the upper jaw is being scanned first
- **Hold and move the dental object approximately 5cm in front of the Cubit360's cameras**
- Colours denote whether the scanned item is at the optimum distance, allowing the user to adjust for the best results.
  - Red indicates close proximity to the scanner, green indicates ideal position, and blue indicates the most remote region of the active scanning area.
  - Keep the area you wish to scan in the green region for optimal results.
- When not actively scanning, red indicates an under-scanned area. Ensure all areas of clinical interest are sufficiently scanned (not red) before processing.



Inspect the scan:

- Hold left mouse button, drag to rotate.
- Hold right mouse button, drag to pan.
- Double-click anywhere to set rotation point. (Double-click outside the model to recentre).
- Use mouse wheel to zoom in and out.
- If unhappy, click 'Retake Scan'.

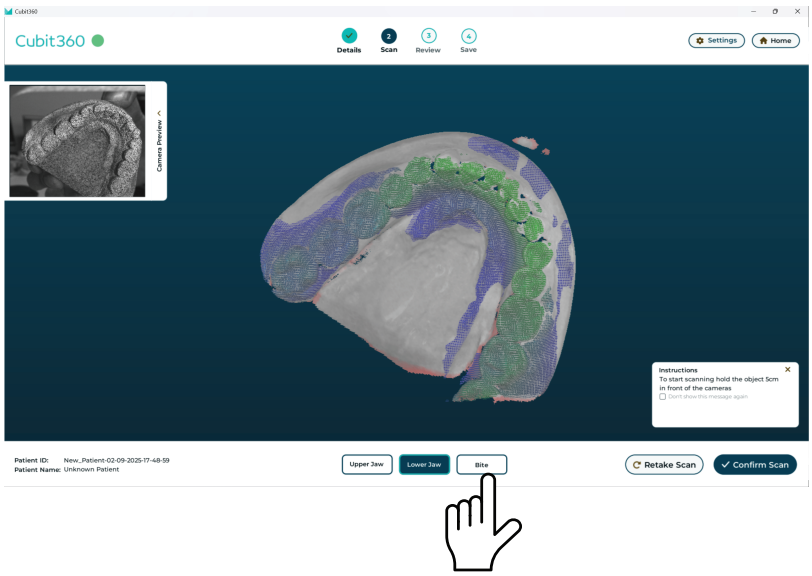


If satisfied with the scan, toggle to the upper/lower jaw to scan the opposing model.

The button on the previous scan greys out with a spinning border to denote that the model is processing in the background (only if using a sufficiently specified desktop computer).

5. Scan Opposing Model

- Repeat the process as above.
- Proceed to '**Bite**' (button on bottom bar) if you wish to articulate the models.
- If not, click '**Confirm Scan**'.



Scanning

continued

6. Bite Scan

Articulating Models

- Scan the models held in occlusion in one continuous scan
- Capturing the entire arch is more likely to produce a successful articulation than a smaller segment scan.

Articulating Impressions

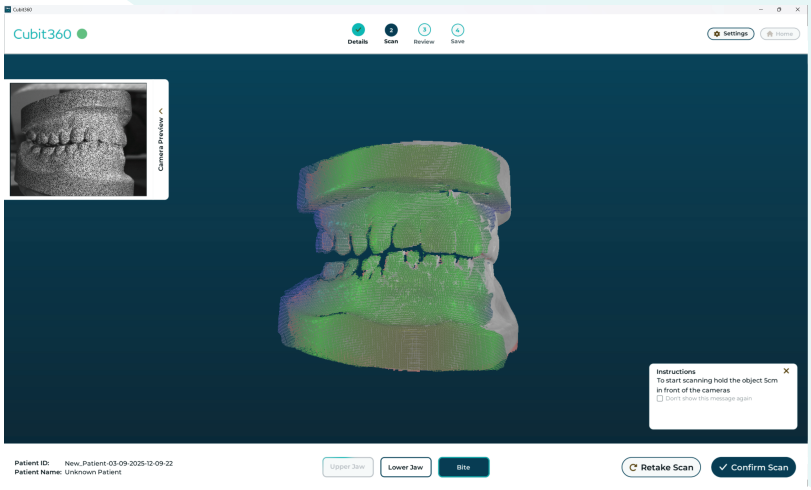
- **Clinical Workflow:** take two buccal bite registration records spanning molar to canine, up to, and beyond, the gingival margins, with sufficient thickness to remain rigid.
- **Digital Workflow:** once you have scanned these two impressions, scan the dental side of the first bite registration.
- Click on the '**+**' to add the second bite scan. These do not need to be labeled or in any specific order. Click on '**Confirm Scan**'.
- Alternatively, for certain clinical scenarios, 3D print the scanned impressions as models and physically articulate the original impressions scans against these, using the alignment scan tool.

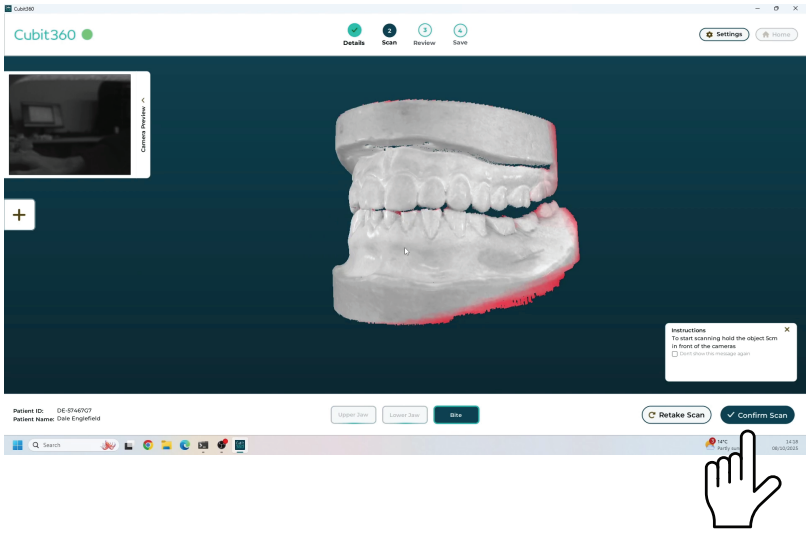
Articulating Dentures

- Proceed as suggested for model bite scanning, but using the provided wax rims.
- For copy denture techniques, if a bite registration has not been provided, stabilise the denture bite with wax prior to scanning. Proceed as suggested for model bite scanning.

- If you struggle to scan a particular dental model even after using '**Retake Scan**', try applying powder and '**Retake Scan**' again
- Once satisfied with the scan, click on '**Confirm Scan**'

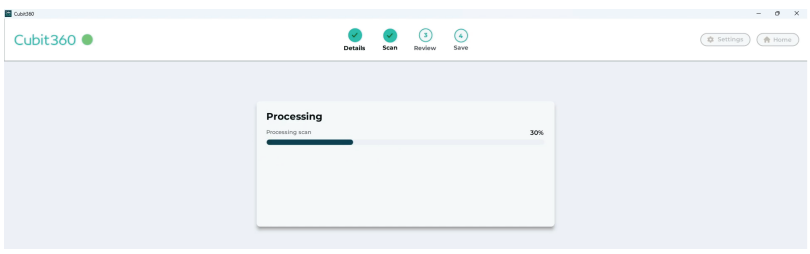
Example shown: Articulating Models





7. Processing

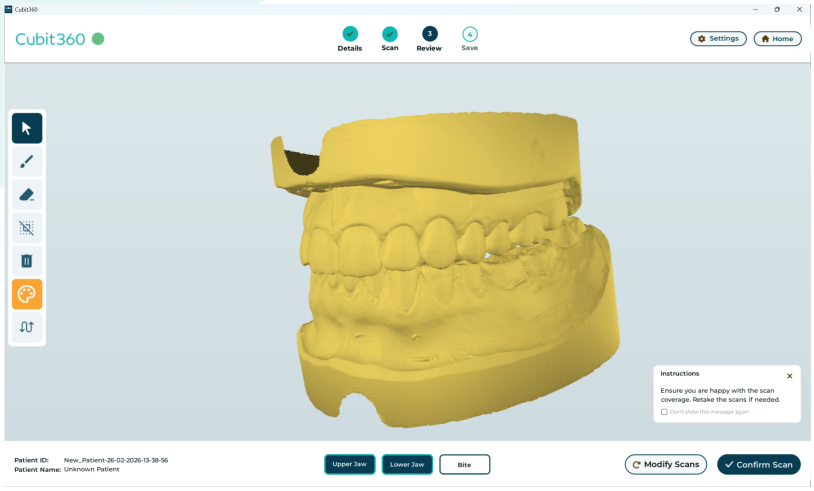
- The Processing screen appears
- The software will now process all data captured
- Please wait



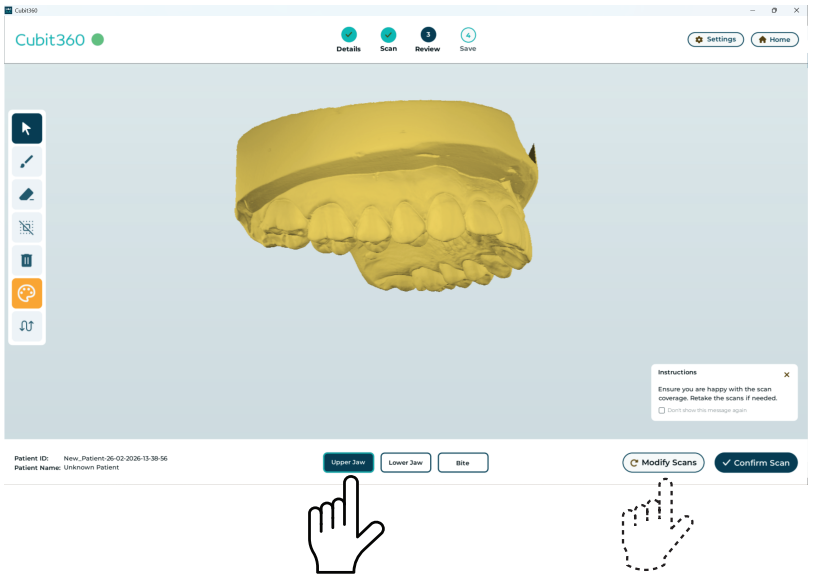
Scanning
continued

8. Review

- Once processing is complete, the final scans will be displayed



- Toggle visibility of the scans by selecting '**Upper Jaw**' or '**Lower Jaw**' buttons
- 3D navigation:
  - Left click and drag to rotate
  - Double click to recentre on point
  - Double click outside the scan data to recentre the scans
- Clicking on '**Modify Scans**' reverts back to the scanning screen, where you can choose to append or redo any of the scans
- Return to the review screen by clicking '**Confirm Scan**'



The toolbar on the left hand side of the Review screen can be used for the following fuinctions:

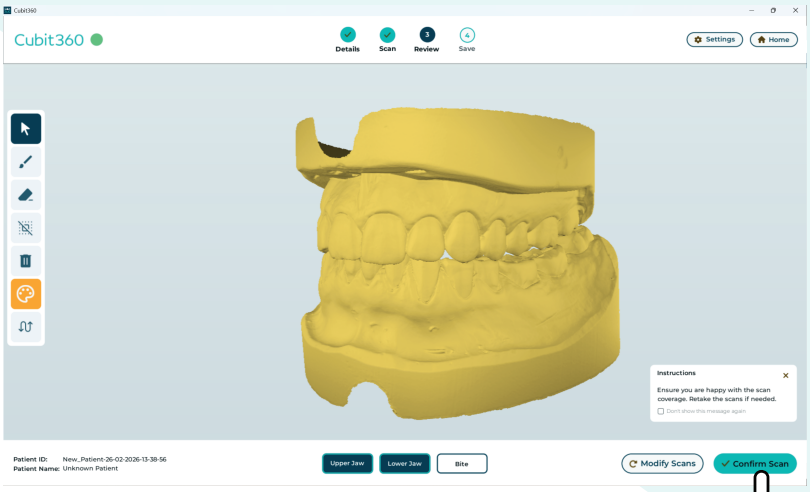
Tool	Keyboard Shortcut	Function
1. Cursor tool	q	Rotation, navigation. Double click to re-centre.
2. Select tool	p	Select parts of scan.
3. Deselect tool	d	Deselect parts of previous selection.
4. Clear selection	a	Clear the selection.
5. Delete selection	delete	Delete selected regions.
6. Run hole fill	h	Fill holes in scans.
7. Toggle colour mode	c	Change display colour of scan.*
8. Invert scan	i	Flip the face orientation of the scan. This will, for instance, turn an impression scan into a digital 'model'.

* This does not affect the exported scan.

Scanning
continued

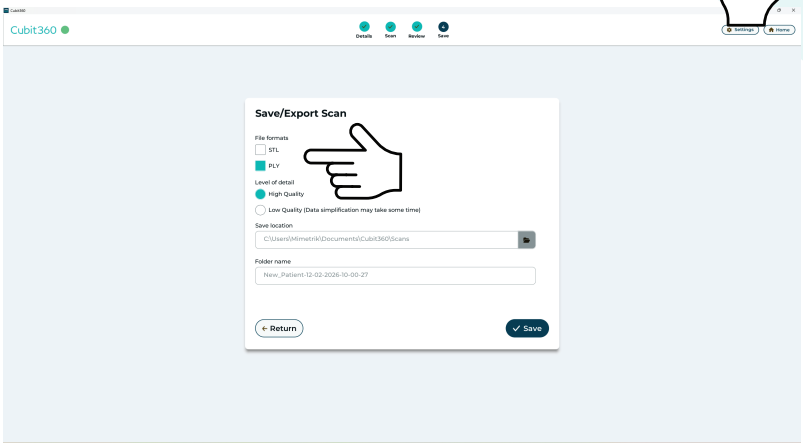
8. Review
continued

- Once satisfied with the scans, click on '**Confirm Scan**' to export the scan data.



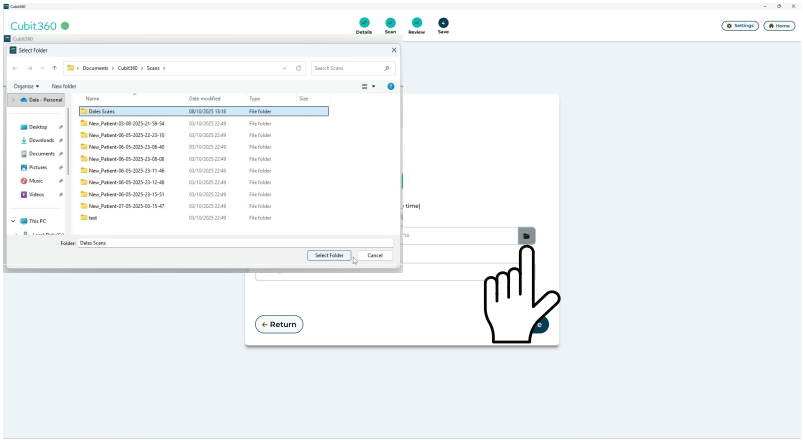
9. Save processed scan

- Select the required file format.
- Please note: PLY files retain colour information, whereas STL files do not.



- Click on the folder icon to select the file saving location
- By default, the Case ID is used as the folder name. This can be modified by entering a different Folder name

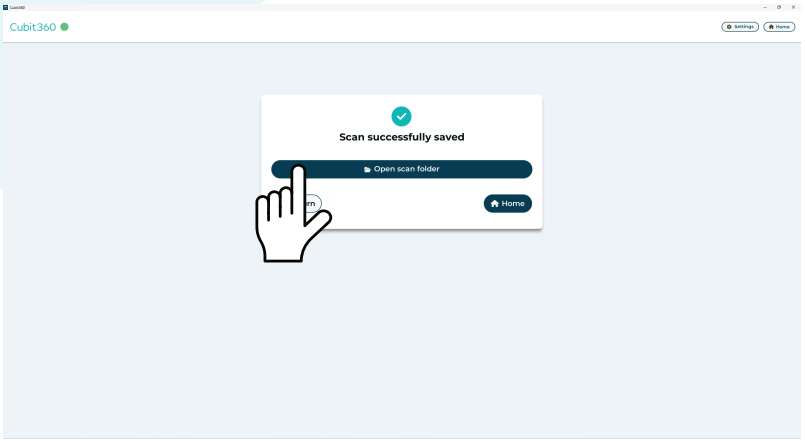
- Click on '**Save**'



Scanning
continued

9. Save processed scan
continued

- A confirmation screen appears confirming whether the scan data was successfully saved
- Select '**Open Scan Folder**' to inspect the saved files, or select '**Start New Scan**', '**Return to Home**' (or close the programme), as required



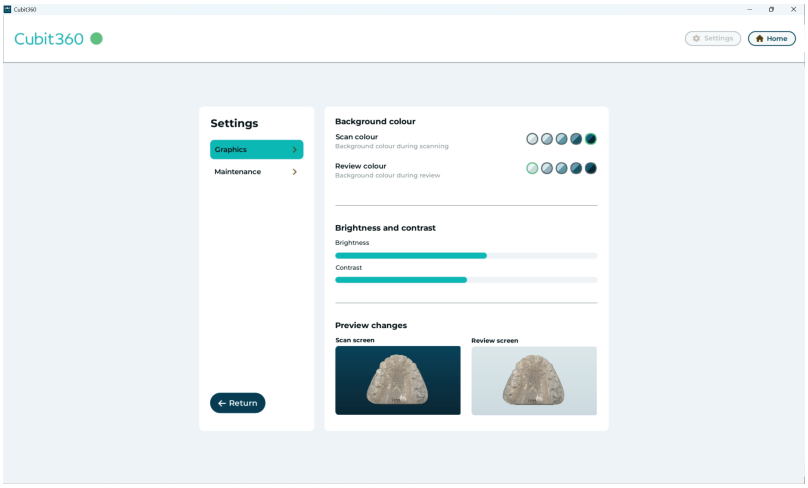
Settings

Access settings using the '**Settings**' button on the Home Screen (top right). Return to the Home Screen using the '**Home**' button (appears top right).

S1. Graphics Settings

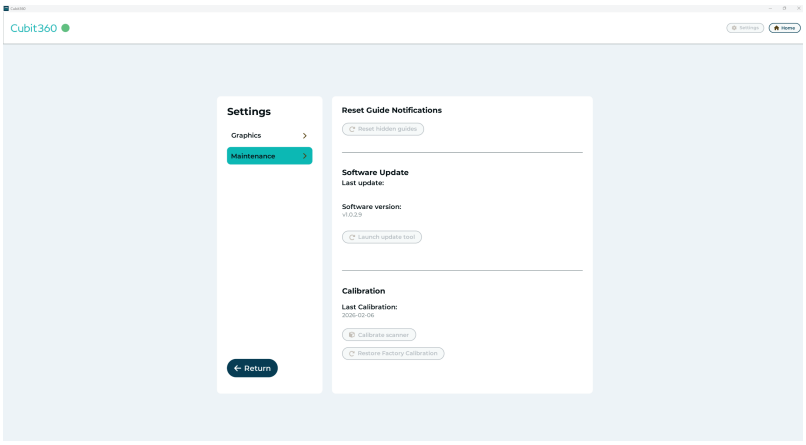
- **Scan Colour**: Select the background colour during scanning. Does not affect the colour of the saved scan.
- **Review Colour:** Select the background colour during review. Does not affect the colour of the saved scan.
- **Brightness and Contrast:** Changes the appearance of the screen. Has no effect on scans.

Settings are saved upon selection.



S2. Maintenance Settings

- **Software Update:** Click 'Launch Update Tool' to check for updates and to install the latest software. (A notification also appears on the Home Screen if an update is available).
- **Calibration:** Calibration is conducted at the factory before shipping. Cubit360 will also periodically auto-calibrate. ***If you believe recalibration is required, please contact Mimetrik.***



Maintenance

To ensure optimal performance of the Cubit360 and general hygiene, please clean the external surfaces of the device as needed - per conditions in your working environment and frequency of use.

Housing

Avoid contact with optical lenses!

- **Prepare a cleaning cloth** - Use a soft, lint-free, dry microfibre cloth. Check the cloth before use to ensure there is no grit or dirt that might damage the Cubit360.
- **Gently wipe the housing** - Gently wipe all exposed surfaces of the Cubit360 housing to remove dust, smudges, or other particles.
- **To remove stubborn dirt** - If residues are more difficult to remove, slightly dampen the cloth with water or a mild non-abrasive detergent suitable for computer equipment. Take care not to oversaturate the cloth.
- ***Do not spray cleaning solutions directly onto the scanner. Always apply the solution to the cloth first.***
- Clean the working environment and surfaces under and around the Cubit360 regularly, to avoid the buildup of dust and dirt around the unit.

Lens Cleaning

Avoid contact with optical lenses! Lenses are very sensitive and do not normally require cleaning if due caution is exercised.

- The 3D camera system is a very sensitive optical device and must be handled with utmost care. It is NOT normally necessary to clean the optical surfaces as these are located inside the device.
- Clean optical surfaces with extreme caution ONLY if cleaning is required as an exception, and as follows:
  - Attempt to blow away the dust. Use a photographic air blower for this.
  - If further cleaning is required, clean optical surfaces using fresh lint-free wipes intended for lens/optical cleaning.
  - Use very light up and down passes of the cloth over the lens - Do NOT use a swirling or circular action.
  - Do not use general purpose wipes to clean the lenses.
  - Do not put excessive pressure on the lenses as this could affect device performance.

Safety & Precautions

Incidents

- The dental professional remains responsible for determining if the 3D model created by the device is suitable for further use.
- If a serious incident has occurred in relation to the device it should be reported to Mimetrik using the contact details provided in these instructions and to the national competent authority where the user is established.

Safety & Precautions

- Switch off the device if the device is to be left unattended or not used for a long time.
- Do not disconnect the device during use.
- Do not disconnect the device during software updates.
- Do not disassemble, modify or attempt to open the device. Opening the device could damage the device and possibly result in electric shock or injury.
- All repairs must be performed by Mimetrik or a Mimetrik approved repair centre. If you suspect that there is an issue with the device, stop using the device and contact your country representative.
- Continuous or repeated transportation of the device may result in calibration drift.
- Avoid applying scan powder to objects near the device. If scan powder is deposited on the lens, follow the instructions for cleaning provided in the maintenance section.
- If you notice the device becomes excessively hot, begins to smoke or produces fumes, immediately stop using the device and notify Mimetrik. (The device will get moderately warm during normal use).
- The device is not suitable for use in the presence of flammable anaesthetic mixtures with air, oxygen, or nitrous oxide.

Safety and Electromagnetic Compatibility (EMC)

- This device has been tested and verified to meet all applicable safety and performance standards for medical electrical equipment, including IEC 60601 series requirements. It is safe for its intended use when operated according to these instructions.
- The device also complies with electromagnetic compatibility requirements of IEC 60601-1-2. To ensure proper operation:
  - Do not use the device near strong electromagnetic sources (e.g., mobile phones, RF transmitters).
  - Install and operate the device as described in these instructions.
  - If interference is suspected, increase the distance between the device and the source or switch off the source.
  - This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
  - Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Warranty



Mimetrik **guarantees and warrants** the Covered Product to be free of all defects in material and workmanship for 12 months starting from the date of documented initial device installation.

The Standard Warranty extends to the original buyer within the initial standard warranty period. Within the period of this warranty, Mimetrik will repair or replace, free of charge; any part proving defective in material, conformity or workmanship provided that:

- Mimetrik is promptly notified of the problem using support@mimetrik.tech.
- The Product has not been altered in any way or subjected to damage, misuse, abuse, repair or alteration by a person other than a person authorised by Mimetrik.
- The Covered Product is returned to Mimetrik.
- Mimetrik is given the right – at our discretion – to remove the Covered Product from the customer's premises and test at our manufacturing site before confirming a full warrantied replacement is applicable.

All warranty repairs and service must be performed by an authorised Mimetrik technician, or at an authorised Mimetrik service facility. The decision to repair or replace any part is solely at the discretion of Mimetrik.

Standard Warranty Exclusions

Warranties are non-transferable and are valid from the first installation of a new device by Mimetrik or a Mimetrik authorised distributor.

This warranty does NOT apply to the following or any costs, repairs, or services thereof:

- Service calls to correct the installation of the Covered Product, or to explain usage of the Product to the buyer or end-user.
- Damage caused due to installation by a person other than a person authorised by Mimetrik.
- Repairs necessitated by the buyer or end-user using the Covered Product in any way other than as intended and/or using the Product in any way that is expressly prohibited in Mimetrik product manuals and/or literature and/or in safety warnings and instructions.
- Improper use of the Covered Product not following Mimetrik manuals and literature or damage reasonably considered to be through the negligence of the user or due to modification of the Covered Product by the user or due to not following the cleaning and other maintenance instructions given by Mimetrik.
- Defects due to the use of spare parts or accessories that are not original Mimetrik products or products expressly specified by Mimetrik to be compatible or that have been tampered with, modified, or repaired by the client, user or any other person who has not been previously authorised by the manufacturer.
- Damage resulting from misuse, abuse, accidents, alterations, or improper installation.
- Acts of nature and/or events and circumstances beyond Mimetrik's control.
- Normal wear and tear, including, but not limited to, minor discoloration and scratches.
- Damage and loss during transport of the Covered Product to and from the buyer or end-user. Transport must be separately covered by insurance at the customer's cost, if necessary.
- Consumables, including, but not limited to, lens caps and USB cables.
- Injury to a person.

In addition to the above grounds for limitation of liability, the manufacturer shall not be held responsible for any consequences derived from use of the product in violation of health and safety regulations or any other regulations, and:

- The warranty is voided if damages are the result of improper use, such as using the Covered Product outside of the conditions stated in these instructions, or as a result of accidental damage, such as dropping the Product.
- The user/health professional is solely responsible for the application and the intended use of the Product and for the use of scans and 3D models created by the device.
- Mimetrik will not accept any responsibility for any consequences arising from the use of the scans and 3D models created by the device.
- Any attempt to open the device or service it by the buyer or end user may cause damage to the device or lead to personal injury and will void the warranty with immediate effect.

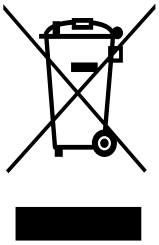
Certifications & Disposal

Mimetrik declares that the device, Cubit360 bearing the UKCA marking, complies with:

- UK Medical Device Regulation Regulations (SI 2002 No. 618), as amended.
- Electrical and Electronic Equipment Regulations 2013 (SI 2013 No. 3113), as amended.
- Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 (S.I. 2012/3032), as amended.
- UK Registration, Evaluation, Authorisation and Restriction of Chemicals (UK REACH) Regulation.

Mimetrik declares that the device, Cubit360 bearing the CE marking, complies with the following European Regulation and Directives with amendments and their relevant transposition into national laws of the member states into which we place the device:

- 2017/745/EU Medical Device Regulation.
- 2011/65/EU Restriction of Hazardous Substances (RoHS) Directive.
- 1907/2006/EC Registration, Evaluation, Authorization and Restriction of Chemicals (REA CH) Regulation.
- 2012/19/EU Waste Electrical and Electronic Equipment (WEEE) Directive.



This device is subject to the European Directive 2012/19/EU (WEEE) and the laws applicable in your country for environmentally responsible recycling / disposal.

Do not dispose of the device in household or general waste.

To prevent potential harm to the environment and human health from uncontrolled waste disposal, this device must be collected separately and disposed of at designated collection points for the recycling of electrical and electronic equipment (EEE). This product contains components that include substances of very high concern (SVHC) as defined under the EU REACH Regulation (EC) No. 1907/2006. These substances are securely enclosed within the device components and are not released during normal use. Contact your local waste management authority or the manufacturer for further guidance on proper disposal..

Disclaimer

The information in all Mimetrik literature and manuals is provided "as is" without any warranties, expressed or implied, including but not limited to the implied warranties of merchantability and fitness for a particular purpose.

The manufacturer, distributor, and sellers shall not be liable for any indirect, special, incidental, or consequential damages resulting from the use of this product.

It is impossible to cover every aspect of devices, safety, scanning, 3D modelling or applications in product manuals. The literature provided is not comprehensive and Mimetrik accepts no responsibility for errors or omissions or for any consequences arising.

Users are responsible for their own methods of use, risk assessments and safety.

For further information and advice on the use of your machine, please see our website at **www.mimetrik.tech** or contact Mimetrik.

Symbols & Regulatory Marks Glossary

Symbol	Title	Meaning	Reference
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1:2021, 5.1.1
	Catalogue number	Indicates the manufacturer's catalogue number so that medical device can be identified	ISO 15223-1:2021, 5.1.6
	Eurpoean Community Authorized Representative	Indicates the authorized representative in the European Community / European Union	ISO 15223-1:2021, 5.1.2
	Serial number	Indicates the manufacturers serial number so that specific medical device can be identified	ISO 15223-1:2021, 5.1.7
	Date of manufacture	Indicates the date when the medical device was manufactured	ISO 15223-1:2021, 5.1.3
	Consult instructions for use	Indicates the need for the user to consult the physical or electronic instructions for use	ISO 15223-1:2021, 5.4.3
	Caution	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 action in order to avoid undesirable consequences.	ISO 15223-1:2021, 5.4.4
	Unique Device Identifier	Indicates a carrier that contains unique device identifier information	ISO 15223-1:2021, 5.7.10
	Medical Device	Medical Device	ISO 15223-1:2021, 5.7.7
	For indoor use only	For indoor use only	IEC 60417- 5957
	Direct Current	DC voltage sign	IEC 60417 - 5031
	UK Conformity Assessed mark	The UKCA Mark indicates the product complies with applicable UK safety, health, and environmental regulations for sale in Great Britain.	
	Conformité Européenne (CE Mark)	The CE mark, which stands for "Conformité Européenne" (European Conformity) indicates that a product conforms to health, safety, and environmental protection standards within the European Economic Area (EEA).	
	WEEE Symbol	The crossed-out wheeled bin symbol indicates that the product must be disposed of separately from household waste. This equipment is subject to the European WEEE directive 2012/19/EU.	

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EC REP

Advena Ltd
Tower Business Centre
2nd Flr. Tower Street
Swatar
BKR 4013 Malta

Device Information

Model/ Product	Cubit360
Reference	FD1001
Basic UDI	506106348Cubit360SD
UDI-DI	05061063480005
Manufacturer	Mimetrik Solutions Ltd

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