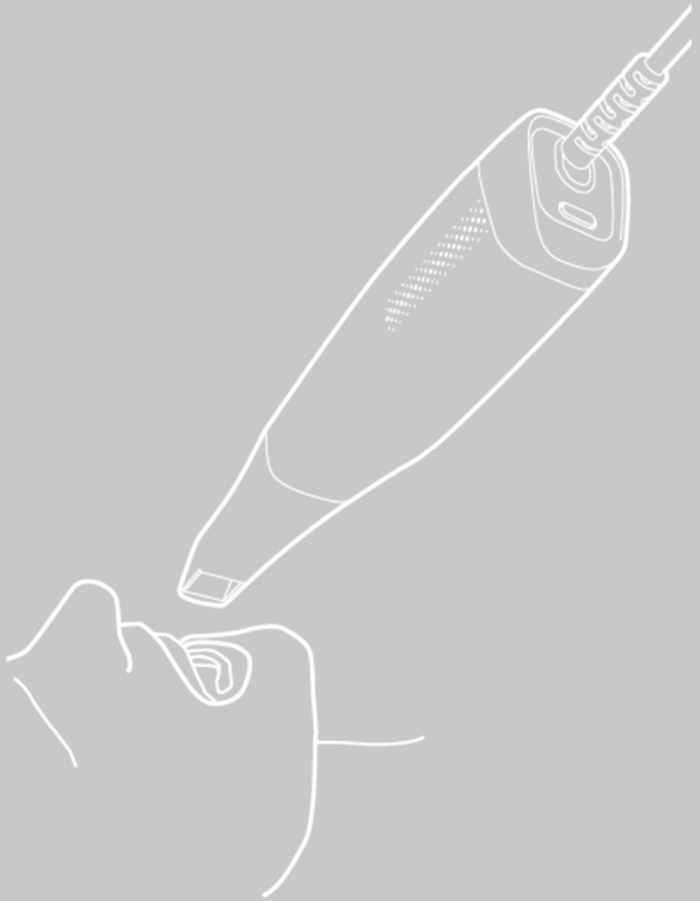
USER MANUAL

ENGLISH



This user manual provides the information needed to use a RAYiOS2 properly.
Please read this manual carefully before using the product.
Improper use or operation of this product may result in personal injury or damage to the product. The instructions and safety information described in this user manual must be observed.
This product is for professional use only. This product can only be used by trained dental professionals or licensed professionals.
This manual is subject to change without prior notice due to quality upgrades and specification changes.
This product is a “medical device”.

Caution (US only): This product must only be sold to dentists or oral health professionals as stated by federal law.

Software Version: D+ SCAN 1.1.4

The manual is subject to change without prior notice.
For further inquiries, contact your sales representative or customer service of manufacturer.

DDS Inc.
4F(Part), 265, Daeji-ro, Suji-gu, Yongin-si, Gyeonggi-do, 16882, Republic of Korea
Tel: +82-2-6121-4525 Fax: +82-2-6121-4545
HP: www.aegisdds.com

EC REP Emergo Europe B.V.
Westervoortsedijk 60, 6827 AT Amhem The Netherlands

1. General information

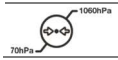
1.1. Use of symbols

1.1.1. Hazard identification

To avoid any personal injuries and damages to properties, follow the safety instructions specified in the document.

Symbol		Meaning
	WARNIG	Circumstances that may result in eriousinjury, death, or property damage
	CAUTION	Circumstances that may result in minor personal injury or product damage
	NOTICE	Circumstances that may damage the product or nearby objects

1.1.2. Packaging symbols

Symbol	Meaning
	Loading upwards as indicated
	Moisture protection
	Fragile, handling precautions
	Load limit
	Temperature limit
	Humidity limit
	Atmospheric pressure limit

1.1.3. Use of symbols

Symbol	Meaning
	Refer to the manual.
	Manufacturer
	Manufacture date
	EU representatitve
	Manufacturer's serial number
	Catalog number
	Medical device
	Protection against electric shock_TYPE BF APPLIED PART
	Non-metastatic electromagnetic radiation
	Prescription only, prescription device

~	AC
⎓	DC
	Directive on Waste Electrical and Electronic Equipment (WEEE)

1.2. Product label

Attached to the bottom of the Control HUB.

1.3. Certifications and applied standards

1.3.1. Certification

This product has been inspected and applied in accordance with the standards below.

CE certification
A certification that guarantees the safety of medical devices manufactured and distributed in the European market in accordance with the European Commission MDR (EU) 2017/745 regulations.

CSA certification
A certification that meets the safety standards of the product in accordance with the certification standards in the United States and Canada, approved by CSA, a NRTL (Nationally Recognized Testing Laboratory) designated by the OSHA (Occupational Safety & Health Administration), agency of the U.S. Department of Labor.

1.3.2. Standards

This product has been inspected and applied in accordance with the standards below.

- IEC 60601-1-2:2014/AMD1:2020
- IEC 60601-2-18:2015
- IEC 62304:2006/AMD:2015
- IEC 62366-1:2015
- EN 1041:2013
- ISO 15223-1:2016
- ISO10993, Part 5
- ISO10993, Part 10
- IEC 60601-1:2005/AMD1:2012/AMD2:2020
- IEC 60601-1-2
- IEC 61000-4-2
- IEC 61000-4-3
- IEC 61000-4-4
- IEC 61000-4-5
- IEC 61000-4-6
- IEC 61000-4-8
- IEC 61000-4-11
- ISO 20896-1

2. Safety instructions and precautions

2.1. Purpose of use

RAYiOS2(hereafter referred to as “PRODUCT”) is a device that captures 3D images of teeth and surrounding tissues in the oral cavity in real-time. The system is composed of a handpiece, a Control HUB, a reusable tip and software for 3D imaging. The 3D image captured using this system is saved on a PC or laptop connected by the operating software.

2.2. Safety information

Users need to check the safety precautions for safe and correct use. Improper use or handling of the product may result in product damage or failure, electric shock, fire, or personal injury. Users of the product must read and understand all precautions carefully and ensure that the product is well maintained.

2.3. Precautions for usage environment

Guidance and precautions for the right place to use the product

- PRODUCT is an intraoral scanner device for use indoors in dental or medical facilities.
- Use the product in a place where there are no flammable substances nearby.
- Restrict the use of the product in dusty or high humidity areas.
- The recommended operating environment temperature for this product is 15°C to 30°C. Restrict the use of the product in areas above or below the recommended temperature.
- Do not place the power cord in a place where it is difficult to separate it.

2.4. Precautions for safe use

Warning

Safety precautions for electrical safety, electric shock, and fire

- When connecting connected to power, check that the outlet and plug are not damaged. In case of damage, contact the manufacturer or dealer to exchange the outlet and plug.
- Check that the power socket and cables on the side of the Control HUB are not damaged. In case of damage, contact the manufacturer or dealer to exchange the socket and cable.
- Make sure that foreign materials do not get caught in outlets, plugs, and power sockets.
- Do not touch the power cord with wet hands.
- Do not spill liquids on the handpiece and Control HUB.
- Use a product with a grounding terminal for the power outlet.
- When disconnecting the power cable, be sure to turn off the power to the handpiece before disconnecting the power cable.
- When disconnecting the power cable, do not pull the cable. Be sure to hold the plug surface before disconnecting.
- Do not disassemble the handpiece or Control HUB product while the power is connected.
- Do not disassemble or assemble the Control HUB and handpiece

arbitrarily.

- Disassembling or assembling arbitrarily may cause electric shock or fire.
- For the power cable, use the cable provided when purchasing the product.
- Using a cable that does not conform to the specifications may cause damage to the product or a fire.

Safety precautions for use other than the intended use of the product

- RAYiOS2 is a product that scans the oral cavity and may not be used for any other purpose. Personal injury and product damage may occur when inserting or using the product in other parts of the body, such as photographing the face, photographing the airway inside the mouth, etc.
- Dentists and dental professionals cannot use the product on patients diagnosed with epilepsy or with symptoms. There may be a risk of injury from seizures.

Safety precautions for personal injury when using the product

- Do not shine the tip directly into the eyes while scanning. When the scanner is working, bright light emits from the tip. High levels of bright light may dazzle the eyes, and temporary vision loss and afterimages may remain.
- Do not use the tip if it falls to the floor and is impacted. A mirror is attached to the inside of the tip. The tip may be impacted and the mirror may be broken, and glass shards may fall into the oral cavity during scanning and cause injury. Dispose of tip impacted by falling in accordance with WEEE standards. (Refer to '6.3 Disposal').
- When using the scanner, make sure the tip does not have any sharp edges. Sharp edges may cause injury when scanning the patient's mouth. If there is a sharp edge, stop using it and replace it with a new tip before use.
- Use the tip after properly connecting the tip to the handpiece. The tip is attached to the handpiece and used together. When installing the tip, make sure it fits firmly into the handpiece connection area. If the mounting is loose or not connected correctly, the tip may fall off during scanning and injure the patient.
- Be careful not to let the cables touch the patient's body when scanning.

Precautions for interference with electronic devices

- Do not use the product on patients with pacemakers or implantable defibrillators.
- The electromagnetic wave characteristics of this product are designed to be suitable for use in hospitals (CISPR11 Class A). If the product is used in a residential environment (CISPR11 Class B), it may not provide adequate protection against electromagnetic

waves.

2.5. Precautions in case of malfunction

Precautions for product failure and damage

- Before using the product, visually inspect all appearances of the product, making note of any product damage and wear of parts. If any visible problems have been detected, discontinue use and contact the manufacturer or dealer.
- If noise, odor, or smoke occurs while using the product, immediately stop using the product, turn off the power, and contact the manufacturer or dealer to take action.
- Do not drop the handpiece on the floor or subject the body to impact.
- Be careful not to get liquids or foreign materials into the handpiece.
- Be careful not to block the air vent located on the side of the handpiece as it may overheat and damage the product.
- Be careful not to pull or bend the cable forcibly as it may cause product failure.
- Do not place the handpiece on an inclined surface or install the cradle on an inclined surface.
- Mount the product on a cradle holder or wall mount holder when not in use.
- Be careful not to let sharp or rough objects come into contact with the handpiece and tip. Sharp and rough objects may damage the product, especially if it touches the mirror inside the tip, which may cause scratches and affect product performance.

2.6. Precautions for storage

Precautions for storage to maintain the product integrity

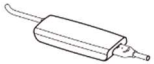
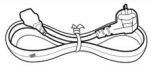
- If not in use for an extended period of time, turn off the power and separate the cable, handpiece, tip, and Control HUB, and store it in the original product packaging.
- Do not store in the presence of flammable substances, liquids, or chemicals.
- Do not store the product in direct sunlight.
- Do not store the product in high humidity or high temperature.
- Do not store the product in a place subject to vibration or shock.
- Do not store in a place where a fall may occur or a place where other objects may fall.

3. Product description

3.1. Product overview

This product name is RAYiOS2 that is a device that captures 3D images of teeth and surrounding tissues in the oral cavity in real-time. The system is composed of a handpiece, a Control HUB, and a reusable tip and software for 3D imaging. 3D images captured using this system are saved in a PC or laptop connected by the operating software.

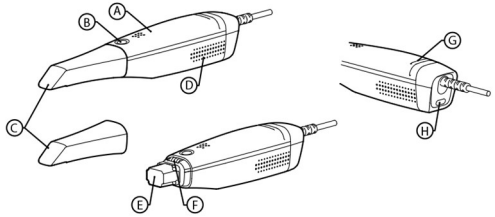
3.2. Product composition

No	Item	Qty	Image
1	Handpiece	1	
2	Control HUB	1	
3	Normal tip	3	
4	Small tip	1	
5	Cradle base	1	
6	Cradle holder	1	
7	Wall mount holder	1	
8	Calibration kit	1	
9	USB flash drive (w/ dedicated software)	1	
10	DC Adapter	1	
11	Power cord	1	
12	User manual	1	
13	Software dongle (optional)	1	

The small tip may use for hard-to-scan areas and patients with limited mouth opening. The accuracy of the small tip may be lower than the normal one.

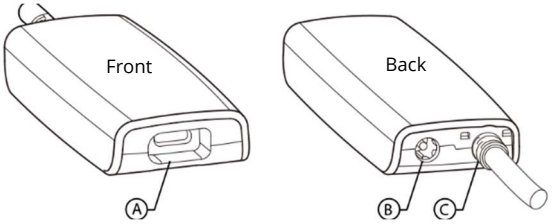
3.3. Component Functions

3.3.1. Handpiece



No	Item	Description
A	Handpiece	Intraoral scanner
B	Enter button	Start or pause a scan
C	Tip	Optical tube cover
D	Air vent hole	Ventilation opening
E	Cover glass	Lens protection glass
F	Hot-wire pin	Hot-wire contact
G	Status indicator LED	Display scanner status
H	Power button	Scanner power on/off

3.3.2. Control HUB

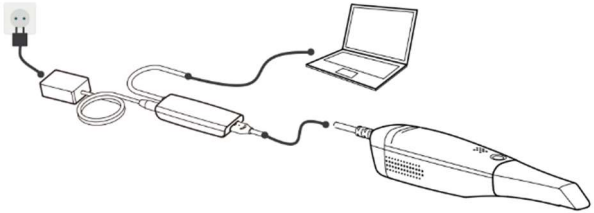


No	Item	Description
A	USB socket	Handpiece and connection socket
B	Power socket	DC power cord from adapter
C	USB Cable (PC)	USB 3.0 cable to PC

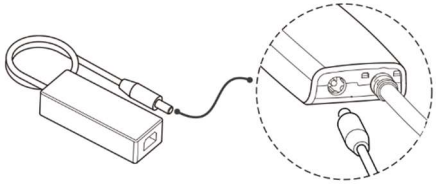
4. Product installation

Make sure to Install D+SCAN program first without connecting the product to your laptop. It may cause errors such as no connection, etc.

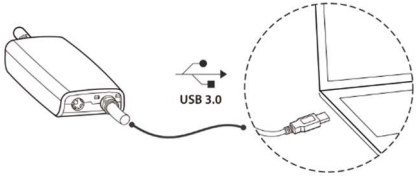
4.1. Basic settings



① Plug the power cord into the adapter on the side of the Control HUB and connect it to the outlet.



② Connect USB 3.0 cable to the USB 3.0 port on the laptop.

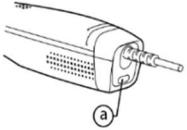


Using unauthorized Commercial USB Multi-Hub may cause no connection or an unstable connection. Connect the USB 3.0 cable to your laptop.

③ Connect the cable of the handpiece to the USB socket in side of the Control HUB (When connecting the cable check the direction of cable connector.)

Do not PULL the USB cable, it may cause disconnection or damage of the product.

④ Press the ⓐ power button on the back of the handpiece to turn on the handpiece.



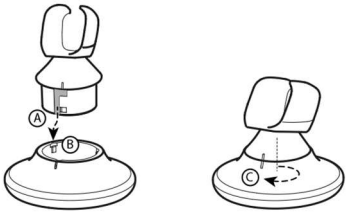
4.2. Status LED Handpiece

Turn on the power switch of the Control HUB and handpiece, and the intraoral scanner is ready for operation. The LED on the handpiece indicates the power and operation status of the intraoral scanner shown below.

No	Status	Description
A	Green light	The scanner is powered on and the scanner is not scanning.
B	Blue light	Scanner is scanning.
C	Green winker	A USB 3.0 connection error occurred. Check the USB connection between the PC and the Control HUB.

4.3. Desktop cradle holder

① Insert the groove of the cradle holder into the projection groove of the cradle base in the direction of the arrow.

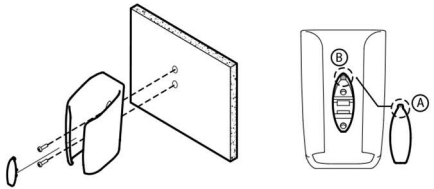


② Turn the cradle holder clockwise (C direction) to match the projection.

③ Check that it is firmly fixed before use.

4.4. Installation of wall-mount holder

① Select the area to install the wall mount. Insert the screw into the wall mount hole and screw it onto a hard surface to fix it.



② Attaching it, and then fit the cap projection (A) into the groove (B).

③ Check that it is firmly fixed before use.

5. D+SCAN program

5.1. Program overview

The D+SCAN program provided with RAYiOS2 is a software that captures 3D images of the surfaces of teeth and surrounding tissues in the oral cavity in real-time. Users can check the 3D image data on the monitor and save it to the computer using the functions provided in the program.

5.2. Program Installation

5.2.1. System requirements

• Minimum requirements

	Laptop	Desktop
CPU	Intel Core i7-11800H / i7-11850H	Intel Core i7-10700 / i7-11700
RAM	32GB	32GB
Graphic	RTX 3060 VRAM 6GB	RTX 3060 12GB
OS	windows 10 pro 64-bit	windows 10 pro 64-bit

INTEL CPU only guarantees the best accuracy and performance.

• Recommended requirements

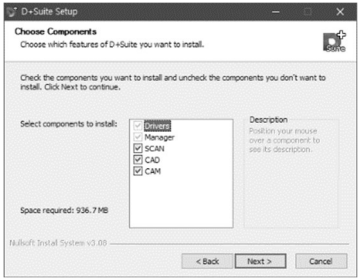
	Laptop	Desktop
CPU	Intel Core i9-11900H	Intel Core i9-10900 / i9-11900
RAM	32GB	32GB
Graphic	RTX 3070 VRAM 8GB	RTX 3070 8GB
OS	windows 10 pro 64-bit	windows 10 pro 64-bit

Use PC and monitor certified IEC 60950, IEC 55032, IEC 55024

5.2.2. Program installation guide

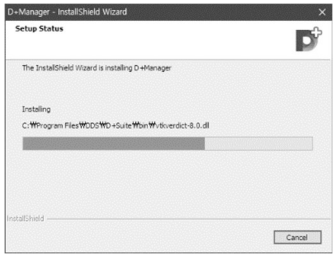
① If you run D+Suite_Installer_Vx.x.x.exe, Installation preparation screen appears. If you want to stop the installation, select Cancel. Click Next to move on to the next step.

② After selecting the program to use, click Next to move to the next installation step. Drivers and Manager programs are installed by default, and you can select SCAN for intraoral scanner.

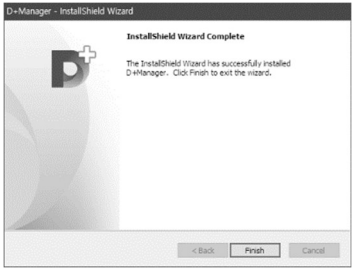


* SCAN: Select and install when using an intraoral scanner

③ The program installation automatically proceeds, and this process will take several minutes. Please do not turn off your PC until the installation is complete.



④ When the installation of the selected program is completed, click Finish to exit. If there are multiple programs to be selected, program installation will repeat ② ~ ④ to install the rest of the selected programs.



⑤ After the installation of all selected programs is complete, click Finish to end the installation. Restart your PC before using D+ Suite program.

5.3. D+SCAN

Scanning software that allows a user to scan teeth and edit scanned images by simply using a handpiece.

5.3.1. Lower and Upper Pre-op scan

Pre-op step is created when you select the Pre-op function on the case registration screen.

Display	Step / Function	Description
	Lower Pre-op scan	Lower Pre-op scanning
	Upper Pre-op scan	Upper Pre-op scanning
	Upper/lower swap	Replace lower and upper data

5.3.2. Lower and Upper scan

Display	Step / Function	Description
	Lower scan	Lower scanning
	Upper scan	Upper scanning
	Upper/lower swap	Replace lower and upper data

5.3.3. Scanbody scan

Display	Function	Description
	Lower scan body	Lower scan body scanning
	Upper scan body	Upper scan body scanning

5.3.4. Bite Scan

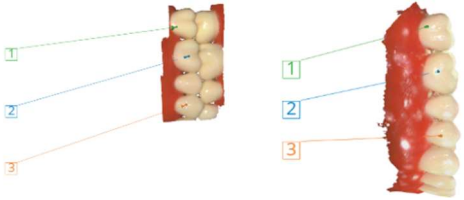
Display	Step / Function	Description
	Bite scan	Bite scanning
	Pre-op bite scan	Pre-op bite scanning
	Bite 1	Start scanning the Buccal Bite
	Bite 2	Photograph Bite 2 data.
	Registration	Manual alignment is possible if automatic alignment fails due to insufficient upper/lower and bite scan data
	Undo	Undo previous action
	Reset	Reset registration

• Manual Bite alignment (Registration)

Manual bite alignment function can be used when the unique shape of the upper/lower bite or buccal bite surfaces is insufficient, or when automatic alignment is difficult.

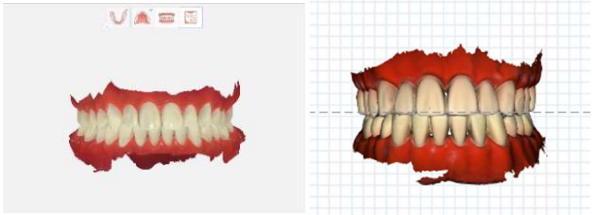
① Click the [Registration] button on the left tool menu.

② Specify the corresponding 3 point on the upper/lower teeth. The first point should start with the Upper or Lower.



③ Auto bite is set.

5.3.5. Scan completed and saved (Done)

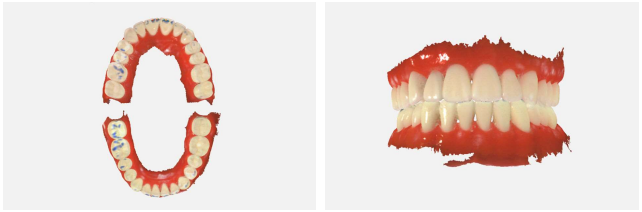


Display	Step / Function	Description
	Done	Scanning completed and saved
	Bite analysis	Analyze the bite condition and display the contact area as a colormap
	Undercut	Show undercut
	View occlusal data	Check occlusal data

• SAVE : Save scan data and end scan.

• Frontal Alignment : With the arch closed, fit the teeth face to face. Move the 3D data with the mouse and horizontally align the upper and lower teeth.

• Bite analysis



Display	Function	Description
	Open arch	Check the colormap with the arch open.
	Close arch	Check the colormap with the arch close.
	View colormap	View the colormap for current screen orientation.
	Adjust occlusal alignment On/Off button	Adjust occlusal alignment On/Off
	Adjust occlusal alignment	Move the slide bar to the right for strong occlusion, Move the slide bar to the left for loose occlusion

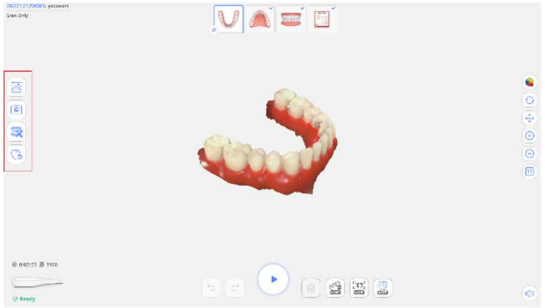
• **Undercut**

Display	Function	Description
	Upper	Upper selected
	Lower	Lower selected
	View Undercut	Analyzes undercut region based on insertion direction. Current viewing of direction is insertion direction.

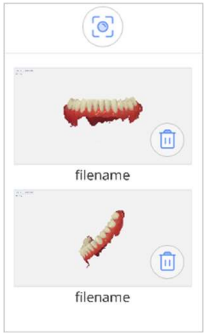
• **View occlusal data**

Display	Function	Description
	Target data for occlusion	Select the bite analysis target. (Show if there are 2 data)
	Upper scan occlusion data	Select occlusion target between preoperative upper scan data and postoperative upper scan data.
	Lower scan occlusion data	Select occlusion target between preoperative lower scan data and postoperative lower scan data.

5.3.6. Main Function panel



• **Screenshot**



Display	Function	Description
	Screenshot	Save current screen as a Screenshot. Screenshot images are stored in D+Manager. It can be used simultaneously with other functions.
	Take screenshot	Add screenshot
	Delete	Delete selected screenshot

• **Camera**

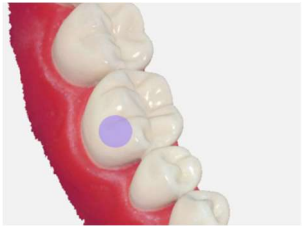
Display	Function	Description
	Camera	Acquire pictures of teeth in the oral cavity with scanner
	View larger image	View larger image
	View multiple images	View multiple images
	Delete	Delete selected image

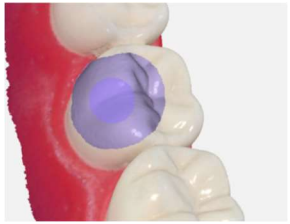
• **Trim**

Display	Function	Description
	Trim	Select and delete the scan data area. Select the area you want to delete among inside/outside of the specified area, the data will be deleted.
	Polygon	Select an area with single click and finish with double click

	Brush	Select an area with a brush
	Reset	Initialize the action state
	Brush size selection	Brush comes in 3 different sizes.

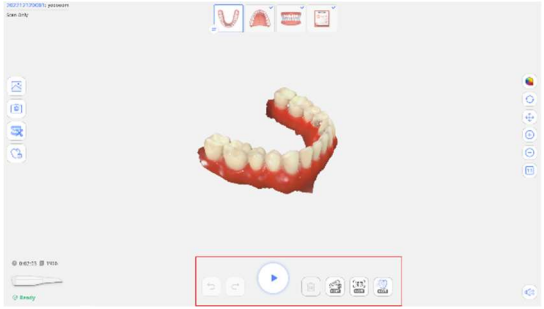
- **Lock surface**





Display	Function	Description
	Lock surface	The set area is not scanned.
	Brush size selection	Brush comes in 3 different sizes.
	Eraser mode	Works with selected brush eraser mode
	Reset	Initialize area selection

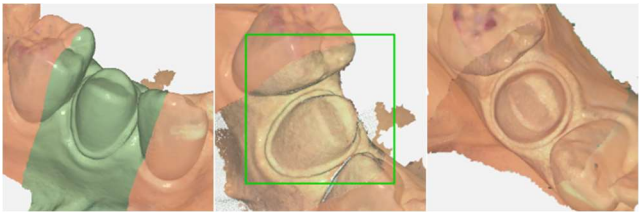
5.3.7. Bottom panel



Display	Function	Description
	Start scanning	Start scanning. It can be executed with the button on handpiece body.
	Stop scanning	Stop scanning. It can be executed with the button on handpiece body.
	Undo	Undo some of scanning actions
	Redo	Redo the undone action
	Delete	Delete scan data

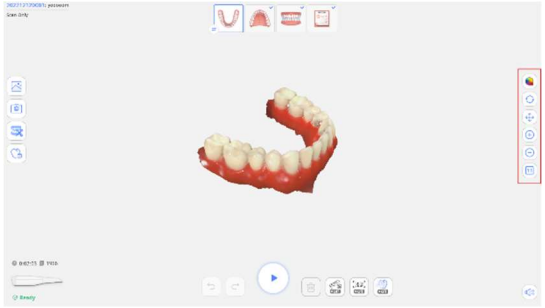
	Small tip	The small tip may use for hard-to-scan areas and patients with limited mouth opening. The accuracy of the small tip may be lower than the normal one.
	HD Scan	Select ana scan the area that requires precise data
	Smart filter	Automatically exclude and scan soft tissue.

• **HD Scan**



Display	Function	Description
	Brush size selection	Brush comes in 2 different sizes.
	Reset	Initialize area selection

5.3.8. View function panel



Display	Function	Description
	Photo mode	Represent scanned data similar to real color.
	Graphic mode	Check the curves and margin lines of the scan data in detail.
	Mono mode	Scanned data is represented in monotone.
	Rotate	Rotate data
	Move	Move data
	Zoom in	Zoom in data

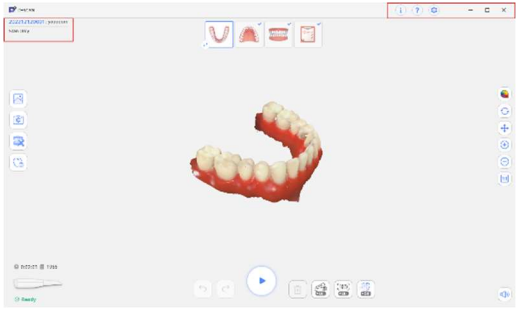
	Zoom out	Zoom out data
	Fit to screen	Center of the screen

- **Photo mode**

- **Graphic mode**

- **Mono mode**

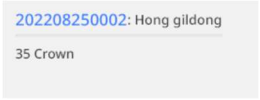
5.3.9. Interface



Display	Function
	Setting
	Help
	Information
–	Minimize
	Maximize
×	Close

• **Case information**

Case information is displayed in the top left corner of the screen.



- Patient ID / Patient name
- Tooth number / Prostheses type

• **Scanning steps**

Display	Function
	Lower pre-op scan
	Upper pre-op scan
	Lower scan
	Lower scanbody scan
	Upper scan
	Upper scanbody scan
	Pre-op bite scan
	Bite scan
	Create final scan result and end scan

• **Scan viewpoint**

Display	Function	Description
	Green corner	Scan data stabilization in progress
	Green Rectangle	Scanning and alignment is optimal
	Yellow Rectangle	Scan speed too fast. Away from the subject
	Red Rectangle	Alignment is lost

• **Displaying the status of the scan**

Display	Function
	Display the duration of scan
	Display a frame

• **Live** view

Display	Function	Description
	Reset	Initialize the position and size of the live view to default.

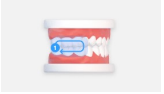
• **Handpiece status information**

Display	Function	Description
	Not connected	Handpiece is not connected. The handpiece's power or Control HUB is turned off.
	Ready	Scanning is ready.
	Scanning	Scanning is in progress.
	Need Calibration	Notifications at intervals specified in setting. Display only in standby mode.
	Overheating	The handpiece temperature is high. Stop working.
	Warm up	Handpiece is warming up. Warming up is recommended for best performance.
	Tip Heating	Tip is heating up. Tip heating is strongly recommended for intraoral scan. If the tip is not heated enough, fog may occur during scanning.
	Tip detached	The handpiece tip is detached. Please make sure the tip is properly connected to the handpiece.

• **Display sound status**

Display	Description
	Sound on
	Sound off

5.3.10. Information message

Display	Function	Description
	Pre-op Lower scan	This scanning step is the pre-treatment condition of the upper arch. Proceed with a scan from the occlusal surface of the posterior region to the anterior region.
	Pre-op Upper scan	This scanning step is the pre-treatment condition of the upper arch. Proceed with a scan from the occlusal surface of the posterior region to the anterior region.
	Lower scan	Proceed with scanning a lower arch. Start the scan on the occlusal surface of the posterior region, and then the lingual and buccal surfaces.
	Upper scan	Proceed with the Upper scan. Start the scan on the occlusal surface of the posterior region, and then the lingual and buccal surfaces.
	Bite scan	Proceed with scanning the first bite as Bite 1. Scan at least three teeth located in the central area of the posterior occlusion. For full arch scanning, select Bite 2 and scan on the last posterior tooth on the opposite side.
	Lower scanbody scan	Once the lower scan is complete, connect the scanbody and start the scan to overlay new data on the lower jaw data. Scan slowly to obtain enough scan data.
	Upper scanbody scan	Once the upper scan is complete, connect the scanbody and start the scan to overlay new data on the upper jaw data. Scan slowly to obtain enough scan data.

5.3.11. Manipulation

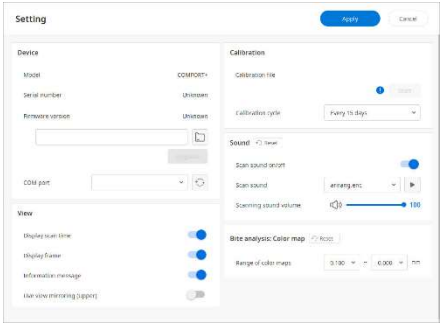
• **Scan 3D image**

Content	Manipulation
Move model	SHIFT + Right click + Drag Wheel + Drag
Zoom In/Out	Wheel scrolled
Rotate model	Right click + Drag Ctrl + Right click + Drag

• **Tool**

Content	Manipulation
Strength	CTRL + Wheel scrolled

5.3.12. Setting



• **Handpiece**

Menu	Description
Model	Connected scanner model name
Serial number	Serial number of connected scanner
F/W version	F/W version of the connected scanner
COM port	Select the port connected to the scanner

• **View**

Menu	Description
Display scan time	Display or turn off the scan time at the bottom left of the screen
Display frame	Display or turn off the scanned frame at the bottom left of the screen
Information message	Display or turn off the guide window at the bottom of the screen
Live view revers (Upper)	Live view left and right are reversed (Upper)

• **Calibration**

Menu	Description
Start	Start a calibration
Calibration cycle	The calibration interval can be set in 15-day or 30-day increments. When the set date is exceeded, a calibration notification pops up.

Calibration steps	Description
	Welcome to the calibration wizard. Please proceed with the calibration by following the instructions. Assemble the calibration kit and put the handpiece into the calibration kit. Please start the calibration after finishing the warm-up.
	Turn the kit to the market line. And then select the 'Shoot' button. The overall calibration will be done within 8 steps.
	Acquiring the calibration image.
	A new calibration file will be created.
	Failed to create a new calibration file. - You have to restart the calibration again from the beginning
	Calibration process is successfully completed. You can now remove the scanner from the calibration kit.

- **Sound**

Menu	Description
Scan sound on/off	Sound on or off while scanning
Scan sound effect	Select scan sound
Scanning sound volume	Adjust the sound volume

- **Bite analysis: Colormap**

Menu	Description
Range of color map	Change the range of the Color map

6. Maintenance

Caution

Disassembly / assembly for product repair may only be performed by DDS Inc. or a company or person certified by DDS Inc. Arbitrary disassembly/assembly may seriously affect product performance.

- Users must calibrate, clean, disinfect, and sterilize the product to maintain the product in an accurate and safe operating condition.
- RAYiOS2 scanner is designed to work with D+SCAN software. If there is a new version of the software, users may use it after upgrading to the latest version through the software upgrade menu.

6.1. Calibration

If foreign materials enter the calibration kit, it may affect the quality of the calibration. The cover of the calibration kit must be kept closed when not in use.

- If the cover is closed, there is no need to clean the inside of the calibration kit, but if foreign materials are visible, blow with clean air to keep the inside of the calibration kit clean.
- It is recommended to perform periodic calibration to keep the intraoral scanner working correctly. The recommended calibration cycle is 15 days and set the calibration cycle in the "Settings" menu of the program. Then calibration time will be notified.

Caution

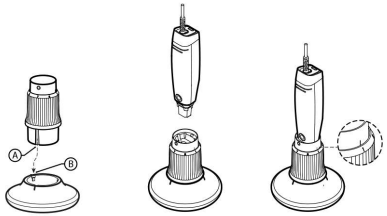
As it may reduce accuracy, do not lay down or tilt during the calibration

6.1.1. When calibration is required

① When the scan data acquisition is difficult, or the quality of the scan data is significantly deteriorated.
② When external conditions such as operating temperature are changed.
③ When the scan accuracy (Crown/Inlay/Full arch) is significantly reduced.

6.1.2. Calibration method

① Remove the cradle holder from the cradle base, mount the calibration kit to fit the protrusion groove of the cradle, and make sure it does not move. (Connect "A" and "B" in the circle.)



② Remove the tip of the handpiece and mount it in to the calibration kit. Make sure that the handpiece is firmly fixed to the calibration kit.
③ Power on the handpiece and run the program.
④ Turn on the power of the handpiece to start the program.

⑤ Select "Setting > 3D Calibration" from the program menu and press the "Start" button to run 3D calibration.

⑥ Follow the instructions on the software screen to perform calibration by turning the dial on the calibration kit. The dial consists of a total of 8 steps from 1 to 8.

6.2. Cleaning, disinfection, and sterilization

This manual includes cleaning, disinfection, and sterilization for the handpiece and tip, which are components of PRODUT. Since each part has a different procedure, follow the procedures in the user manual to ensure patient hygiene and safety.

6.2.1. Reusable Tip

Tips separated from handpieces require high-level disinfection or high-temperature steam sterilization. Tip can be reused and must be disinfected or sterilized after cleaning when reused.

Caution **A combination of high-level disinfection and high-temperature steam sterilization of the tip may reduce the number of times the tip can be reused.**

- After cleaning, disinfecting, and sterilizing the tip mirror, check the condition of the mirror surface before use.
- Any stains or scratches on the mirror surface have a significant impact on the product's performance.
- If it is difficult to use due to damage to the tip, see ‘6.3 Disposal’ to dispose of it.
- Do not hold the mirror when removing the tip from the handpiece. The mirror may be damaged.
- Do not sterilize the tips by chemical or ultrasonic sterilization.

Disposal of tips

- Since the tip is a consumable part, if performance degradation occurs, a new tip must be used. You need to contact the manufacturer or retailer to purchase it.
- Discard the tip if the scan quality has severely degraded or if there is contamination and has damaged the mirror part. (Refer to ‘6.3. Disposal’.)

Cleaning the tip

- Use a cleaning solution with a soft brush to remove contaminants from the mirror edge of the tip.
- After rinsing with clean running water, check if there are any stains on the mirror surface.
- If there are stains or contaminants on the mirror surface, repeat the process.
- After cleaning the tip, remove moisture from the mirror surface with a dry cloth that does not form lint and dry it.

Caution **Cleaning the mirror surface with a brush may damage the mirror surface.**

6.2.2. Disinfection and sterilization

• High-level disinfection of tips

① Keep the cleaned tip immersed in a high-level disinfectant solution of at least 2% glutaraldehyde. See the manufacturer's instruction manual for the temperature and soaking time of the disinfectant solution.

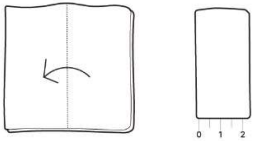
② After disinfection, rinse thoroughly with running water and remove the moisture from the mirror surface with a dry, sterile, lint-free cloth and dry it.

Caution **For details on the use of disinfectant solution, see the manufacturer's instruction manual for the glutaraldehyde-based disinfectant.**

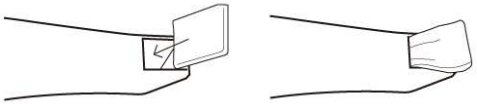
• High-pressure steam sterilization on the tip

① After cleaning the tip, use a soft cloth to remove dust and residual cleaning solution from the tip mirror.

② Please Fold 8 layered 5 x 5cm (2 x 2in) size of gauze as follow;
- Normal tip: Add 4 of each gauze and fold it in half
- Small tip: Add 2 of each gauze and fold it in half



③ Insert the gauze folded in half carefully so that it completely covers the tip mirror as shown below. Allow the tip of the gauze to protrude slightly outside the tip so that the gauze can be easily removed after sterilization is complete.



④ After putting the gauze on the tip glass area as above, seal the tip in a sterilization pouch and then place it in the autoclave. Select one of the conditions below to proceed with sterilization.

- Gravity Type: Sterilize at 121℃ for 30 min, dry for 15 min.
- Pre-Vacuum Type: Sterilize at 134℃ for 4 min, dry for 20 min.

⑤ Dry the packaged tip thoroughly before opening the autoclave.

⑥ After drying the tip, remove the gauze inside the tip. If the mirror has steam stains, use a soft cloth or gauze moisture with a small amount of alcohol to remove the stain.

Caution **Put only one used tip in the sterilization pouch and proceed with sterilization.**

- **High-pressure sterilization without using a sterile pouch or sealing the sterilization pouch may damage the mirror surface.**
- **When using autoclave steam sterilization, read the manufacturer's instruction manual before use.**

6.2.3. Handpiece

Handpieces require a moderate level of disinfection. Cleaning and disinfection shall follow the procedure as explained in this manual.

① Turn off the power by pressing the power button on the back of the handpiece.

② Disconnect the USB cable of the handpiece from the Control HUB.

③ Separate the handpiece and the tip.

④ Prior to disinfection, use the disinfecting tissue used by the dentist to remove contaminants from the patient.

⑤ Disinfect the surface of the handpiece using the disinfecting tissue used by the dentist.

⑥ When disinfection is complete, remove the disinfectant solution remaining on the surface of the handpiece with a dry, lint-free cloth.

The cover glass and heating wire pins on the front of the handpiece must not be disinfected. Since the handpiece is made of precision optical components, performance degradation or malfunction may occur.

When cleaning and disinfecting the handpiece, if the cleaning solution or disinfectant enters through the air vent holes on the left/right side of the handpiece, it may cause malfunction.

When cleaning or disinfecting the surface of the handpiece, do not spray or immerse the cleaning solution or disinfecting solution. Cleaning or disinfecting solution may flow inside and cause malfunction.

Never sterilize the handpiece in a high-pressure steam sterilizer as it may damage the product.

6.3. Disposal

PRODUCT is an electrical device containing electronic components and must be disposed of in accordance with national environmental laws. Follow the applicable disposal regulations for each country.

Professional handling (cleaning, disinfection, and sterilization) must be performed when disposing of the product.

Products and accessories marked with this symbol must be collected separately for disposal.

Do not dispose of this product in a household or household waste in accordance with the European Directive on Waste Electrical and Electronic Equipment (WEEE).

Please help promote sustainable resource recycling by recycling this product separately from other waste.

7. Actions required in case of failure

Failure	Action
The handpiece is not turned on.	Check that the DC power cable of the Adapter is plugged into a Control HUB.
	Check that the AC power cable of the Adapter is plugged into an outlet.
	that the USB 3.0 cable of the handpiece is connected to the Control HUB.
A calibration message has occurred.	The handpiece must be calibrated periodically to ensure accuracy. Proceed with calibration with the calibration kit included in the component.
Scan is not running.	Check that the handpiece is powered on.
	Check that the USB cable is connected.
	Check that COM Port is set to USB Port of the handpiece in the 'Settings' menu of the D+SCAN program. If the USB COM Port is not displayed, check if the USB is connected to the PC again.
Not connected.	Check that the PC you are using supports USB 3.0.
	Check that the USB cable of the handpiece is connected to the Control HUB.
	Check that the USB cable of your PC is properly connected to the Control HUB.
	Using an unauthorized Commercial USB Multi-Hub may cause no connection or an unstable connection. Please directly connect the USB 3.0 cable in Control HUB to the USB in your PC.
	Check that PC Device Manager → Universal Serial Bus Controller → FT601 USB 3.0 Bridge Device is displayed.
	If there is an error indication in the FTDI FT601 item, reset or update the FTDI driver.
A temperature notification occurred while using the handpiece.	Stop using the handpiece, and then use it after the temperature has returned to a safe level.

8. Product specification

Model name	COMFORT+	
Product license number	20-4622	
Packaging unit	1 Set	
Classification by protection type and degree of protection against electric shock	Class 1 device BF type mounting part 	
Interlocked software	D+SCAN	
Handpiece	Weight (w/ tip & cable)	350 g
	Size (w/ tip)	263.5 x 43 x 49.4 mm
	Input	12 V ⎓, 3.34 A

Control HUB	Weight	70 g
	Size	106.5 x 37.2 x 15.9 mm
DC Adapter GSM40A12-P1J	Input	100-240Vac / 50-60Hz 1.0~0.5A
	Output	12 V ⎓, 3.34 A
Terms of use	Temperature	15 ~ 30 ℃
	Humidity	20 ~ 60 %
	Atmospheric pressure	800 ~ 1060 hPa
Transport and storage conditions	Temperature	-10 ~ 60 ℃
	Humidity	10 ~ 90 %
	Atmospheric pressure	700 ~ 1060 hPa

9. Electromagnetic compatibility information

9.1. Electromagnetic emissions

The RAYiOS2 is intended for use in the electromagnetic environment specified below. The customer or user of the PRODUCT should assure that it is used in such an environment.

Emission measurement	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The PRODUCT uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The PRODUCT is suitable for use in all establishments including domestic establishments, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded.
Harmonic emissions IEC 61000-3-2	Class A	* Warning This PRODUCT is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the PRODUCT or shielding the location.
Voltage fluctuations /flicker emissions IEC 61000-3-3	Complies	

9.2. Electromagnetic immunity

The PRODUCT is intended for use in the electromagnetic environment specified below. The customer or user of the PRODUCT should assure that it is used in such an environment.

9.2.1. Electrostatic discharge (ESD) IEC 61000-4-2

Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, a relative humidity of at least 30% is recommended.

IEC 60601 test level	Compliance level
±8kV contact ±2kV, ±4kV, ±8kV ±15kV air	±8kV contact ±15kV air

9.2.2. Electrical fast transient/burst IEC 61000-4-4

Mains power quality should be that of a typical commercial or hospital environment.

IEC 60601 test level	Compliance level
±2kV 100 kHz repetition frequency	±2kV 100 kHz repetition frequency

9.2.3. Surge IEC 61000-4-5

Mains power quality should be that of a typical commercial or hospital environment.

IEC 60601 test level	Compliance level
±0.5kV, ±1kV, ±2kV	±0.5kV, ±1kV, ±2kV

9.2.4. Power frequency (50/60Hz) IEC 61000-4-8

Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. If image distortion occurs, it may be necessary to position the PRODUCT further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.

IEC 60601 test level	Compliance level
30 A/m	30 A/m

9.2.5. Voltage dips and interruptions IEC 61000-4-11

Mains power quality should be that of a typical commercial or hospital environment. If the user of the PRODUCT requires continued operation during power mains interruptions, it is recommended that the PRODUCT be powered from an uninterruptible power supply or a battery.

IEC 60601 test level	Compliance level
0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles single phase: at 0° 0% UT; 250/300 cycle	0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles single phase: at 0° 0% UT; 250/300 cycle

9.2.6. Conducted RF EN/IEC 61000-4-6

Portable and mobile RF communications equipment, including cables, should be used no closer to any part of the EUT than the recommended separation distance as calculated using the equation below, according to the frequency of the transmitter.

$d=[3.5/V1]\sqrt{P}$

$d=[3.5/V1]\sqrt{P}$ 80 MHz to 800 MHz

$d=[7/E1]\sqrt{P}$ 800 MHz to 2.5 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strengths1 from fixed RF transmitters, as determined by an electromagnetic site survey, should be less2 than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

IEC 60601 test level	Compliance level
3V, 150kHz – 80 MHz 6V in ISM bands between 150 kHz and 80 MHz 80% AM at 1 kHz sine-wave	3V, 150 kHz – 80 MHz 6V in ISM bands between 150 kHz and 80 MHz 80% AM at 1 kHz sine-wave

9.2.7. Radiated RF EM fields EN/IEC 61000-4-3

Portable and mobile RF communications equipment, including cables, should be used no closer to any part of the EUT than the recommended separation distance as calculated using the equation below, according to the frequency of the transmitter.

$d=[3.5/V1]\sqrt{P}$

$d=[3.5/V1]\sqrt{P}$ 80 MHz to 800 MHz

$d=[7/E1]\sqrt{P}$ 800 MHz to 2.5 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strengths[1] from fixed RF transmitters, as determined by an electromagnetic site survey, should be less[2] than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

IEC 60601 test level	Compliance level
3V/m 80 MHz ~ 2.7 GHz 80% AM at 1 kHz sine-wave	3V/m 80 MHz ~ 2.7 GHz 80% AM at 1 kHz sine-wave

[NOTE]

1. The ISM (industrial, scientific, and medical) band between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz ~ 27.283 MHz; 40.66 MHz ~ 40.70 MHz.
2. Higher frequency ranges are applied at 80 MHz and 800 MHz.

[1] Field strengths from fixed transmitters, such as base stations for radio(cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the RAYiOS2 is used exceeds the applicable RF compliance level above, the PRODUCT should be observed to verify normal operation. if abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PRODUCT.

[2] The electromagnetic field strength should be [V_1] V/m or less over a frequency range of 150 kHz to 80 MHz.