





Rayplicker Handy

Version 1.0 - 06.2022 Ref. UG.RPH.EN.1.0



RAYPLICKER HANDY USER GUIDE

Document version 1.0 Ref. UG.RPH.EN.1.0 / Date 06.2022 Compatible with the Rayplicker Handy spectrophotometer

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The most recent version is always available on: www.borea-dental.com

1.	ABOUT THIS USER'S GUIDE	5
1.1. 1.2. 1.3. 1.4.	Dear customers Terms choices Safety instructions Symbols description	5 6 7
2.	RAYPLICKER SOLUTION DESCRIPTION	8
2.1.	Information about Rayplicker Handy device	8
3.	DELIVERED SET	9
3.1. 3.2.	Delivered set Spare parts and accessories	9 10
4.	FIRST START	11
4.1. 4.2. 4.3. 4.4. 4.5. 4.6. 4.7.	Installation of the calibration tip Charging the device Turning on/off Rayplicker Handy device Battery status Automatic switch-off Device restarting after an automatic switch-off Observation concerning the device illustrations	11 11 12 12 13 13
5.	RAYPLICKER HANDY CONFIGURATION	14
5.1. 5.2. 5.3.	Basic configuration Device information Automatic calibration	14 16 17
6.	GOOD PRACTICES FOR USING THE RAYPLICKER	17
6.1. 6.2. 6.3. 6.4.	Protocol of use of the Rayplicker Handy Shade taking interface presentation Introducting the different mappings available Additional information	17 18 19 20
7.	ACQUISITIONS PROCESSING	21
7.1 7.2 7.3	Acquisition record Acquisition transfer Delete recorded acquisitions	21 22 22
8.	CLEANING AND STERILIZATION	23

25

9. TECHNICAL SPECIFICATIONS

9.1	Identification	25
9.2	Power adapter	25
9.3	Handpiece	25
9.4	Battery	25
9.5	Environmental characteristics	26
9.6	Regulation and standardization	26
9.7	EMC	26
10.	ANNEX	27
10.1	Notifications and error messages	27
10.2	Glossary	29
10.3	Patents	29
10.4	Warranty	29

1. ABOUT THIS USER'S GUIDE

1.1. Dear customers

Congratulations on your purchase. The Rayplicker Handy is a dental shade and translucency taking device according to the reference standards known in the dental art with a precision of the order of a $\Delta E=1$. This self-calibrated device is intended for dentists and prosthetists.

This French-made wireless electro-optical device is equipped with an on-board environment that makes it possible to determine exactly the shade of natural teeth and prostheses according to most shade guides used to determine teeth color.

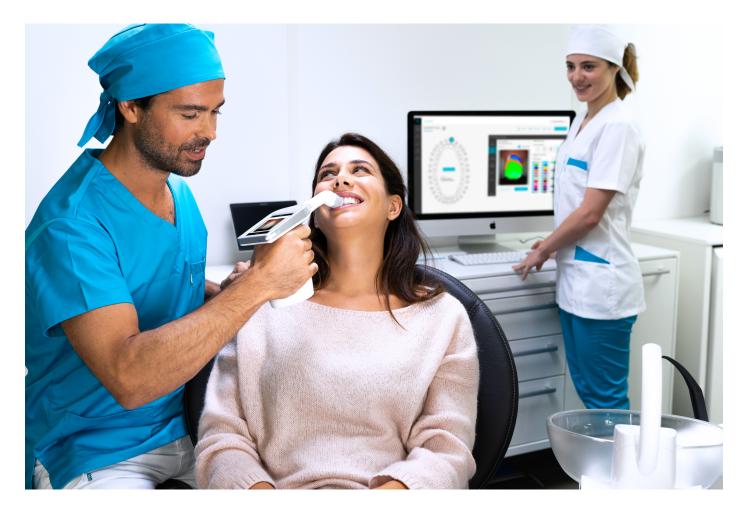
Accurate and ergonomic, the Rayplicker Handy solution is also equipped with a software allowing the data processing and recording as well as the creation of a purchase order with ease. The smartphone application « Rayplicker Pics App Solution » will give you the possibility to add patient pictures to your file easily, an essential element for the realization of a prosthesis by the dental technician.

In order to realize perfect shade taking, please read carefully this user guide.

We also invite you to refer to the user guide of the software mentioned in this document.

Forget about approximative measurements and be more efficient with the Rayplicker Handy.

Borea Team



1.2. Terms choice

The terms used in this manual are as follows:

Dentist, dental surgeon = Practitioner

Dental technician, dental prosthesis manufacturing laboratory, Prosthetist = Laboratory

Dentist and Dental technician = Users

1.3. Safety instructions

Warnings

- 1) Please ensure that you only use rechargeable battery supplied with the device. (Li-polymer battery 3.7V 2200 mAh). The use of another battery is prohibited and may damage the battery or the unit. BOREA SAS will not be held responsible in this case.
- 2) Please only use the mains charger supplied with the device by Borea (5V, 1A). Using a different charger may damage your device
- 3) Do not look into the light source direction
- 4) Do not immerse the Rayplicker Handy or charger in water or other liquid.
- 5) All repairs or maintenance must be performed by authorized persons. More specifically, the access and the replacement of the power source and the replacement of an electronic card must be realized by BOREA. Except as authorized in writing by Borea, failure to comply with this rule will cancel the warranty.
- 6) Please follow the cleaning, disinfection and sterilization instructions in this manual.
- 7) Please follow the instructions given in the RAYPLICKER user manual for the placement of the sterilizable calibration tip as well as the optional use of single-use protective sheaths.
- 8) When using the Rayplicker Handy, respect safety instructions for dental practices and dental laboratories.
- 9) Do not expose the device to temperatures below 0°C (32°F) or above 40°C (104°F).
- 10) Protect the device from direct sunlight. The device must be stored in a dry place.
- 11) Do not drop the device (there is a risk of equipment damage and electrical shock).
- 12) The temperature range for shade taking should be between 10 °C (50°F) and 40 °C (104°F).

1.4. Symbols description

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– <mark>40°C</mark> 104°F
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2. RAYPLICKER SOLUTION DESCRIPTION

The Rayplicker Handy is a device for the determination of the shade and translucency of the tooth. It is a device working with a multi-spectral measurements built around spectrophotometer based on a two-dimensional optical sensor. This enables acquisition of spectral data at all points on the tooth and the automatic realization of a complete and accurate mapping of color variations of the tooth. The analysis is performed on specific relevant spectral bands for recognition of hues. Thanks to its geometry, this wireless device allows access to all the teeth in the mouth.

It has a sterilizable calibration tip which comes in contact with the patient's teeth ensuring precise positioning of the device.

These calibration tips play an important role because they incorporate a chromatic reference (pattern of gray) necessary to the proper functioning of the device through a self-calibration step not perceived by the user.

A LCD screen is integrated in the device and displays real-time analyzed area, facilitating the positioning of the measuring head on the tooth. Finally, an interface and algorithms for data processing are embedded within the device and thus allow the user to interact and directly view shade mapping and translucency mapping of the analyzed tooth. It will also allow the user to specify the analyzed tooth, the patient name and choose the resolution of the mapping (segmentation of the tooth by one, three, nine, detailed mapping).

2.1. INFORMATION ABOUT RAYPLICKER HANDY DEVICE

The Rayplicker Handy works with most shade guides used to determine the dental color (VITA Classical A1-D4®, VITA 3D-MASTER®, Ivoclar Chromascop, ...)

A single acquisition automatically provides all the necessary information to the realization of a dental prosthesis :

- A polarized picture
- A complete and accurate mapping of the shade variations in all the tooth area.
- A translucency mapping.

When charging, the base of the device lights up in blue. It will turn off automatically when it is fully charged.

3. DELIVERED SET

3.1. Delivered set

Articles		Quantity	Rayplicker Items number
Hand-piece Rayplicker Handy	1	1	-
Docking station	2	1	Ref : SF0010
Stylus for touch screen	3	1	Ref : PA0011
Calibration tips (autoclavable)	4	6	Ref : RA009
USB 2 cable (A type to B mini)	5	1	Ref : CA0005
5V 1A charger, adapters	6	1	Ref : CA0004
Quick start		1	-
Cleaning wipe		1	-
Disinfection and sterilization procedures		1	_







3.2. Spare parts and accessories

The following spare parts and accessories are available from Borea SAS or your distributor.

	ACCESSORIES	
	50 Protective sheaths	Ref : SF0005
	6 Calibration tips (Autoclavable)	Ref : RA0009
	SPARE PARTS	
	Main plug 5V 1A	Ref : CA0004
(the second sec	USB Cable	Ref : CA0005
	Battery	Ref : EA0007
	Stylus	Ref : PAOO11
(Ċţ	Docking station	Ref : SF0010



4. FIRST START

4.1. Installation of the calibration tip



The calibration tip is positioned (clipping) at the end of the measuring head. Thanks to its specific design, it allows to take support on the patient's teeth, thus ensuring a precise positioning of the device.

It incorporates a chromatic reference (gray scale) necessary to the proper functioning of the device through a self-calibration step, not perceived by the user.

4.2. Charging the device



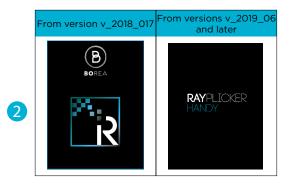
Before first use, the device must be charged. The charge can last up to 4 hours. For this, the device must be placed on its base and connected through the cable to a power outlet or USB.

When the device is charging, the base lights up in blue. Once charged, the base turns off.

4.3. Turning on/off Rayplicker Handy device



Turn on the device by pressing the measurement button in the center of the device handle.

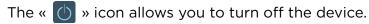


The main screen lights on (2) then the main menu appears (3).

User guide



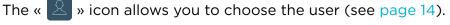
The top banner gives you indications on battery charge and the selected user.

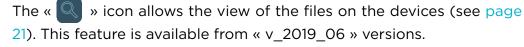


The « 💿 » icon is used to make an acquisition (see page 18).

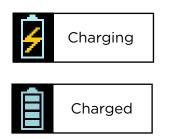
The « 💮 » icon is used to access the basic settings of the device (see page 14).







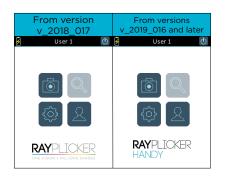
4.4. Battery status



On the main screen of your device, the battery symbol will indicate its charging status.

4.5. Automatic switch-off

To ensure optimal autonomy, a two-stage automatic shutdown system has been implemented.



Step 1:

Whether there is a current record or not, after five minutes of inactivity, an automatic return to the home screen is done.



Step 2: After three minutes of inactivity, the system stops automatically.

4.6. Device restarting after an automatic switch-off

From version v_2019_06, files are automatically saved on the device memory just after the acquisition. After an automatic shutdown, files can be viewed with the file viewer.

With the version v_2018_07 , if the device stops automatically before the file was saved,, recovery of this file will be possible when the device is restarted.



This display indicates that there was an unsaved acquisition before the automatic shutdown.

Click on the icon « 🔽 » for a recovery, or on « 💌 » to delete this old acquisition.

4.7. Observation concerning the device illustrations

		Version v_20	018_017		
\rightarrow	~	×	\checkmark		<u>*</u>
Scroll right	Scroll left	Cancel / Delete	Confirm	Picture	Save
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Home	Settings	Charging	Charged	Edit	Turn off
2					
User	Overall shade	3 parts	9 parts	Detailed mapping	Translucency
Unselected	Selected				

		Versions v_201	9_06 and later		
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Scroll right	Scroll left	Cancel / Delete	Confirm	Picture	Files explorer
â		4			Ċ
Home	Settings	Charging	Charged	Edit	Turn off
2					
User	Overall shade	3 parts	9 parts	Detailed mapping	Translucency
		مته	R		
Unselected	Selected	Dental numbering system	Universal numbering	FDI numbering	Screen Iuminosity

5. RAYPLICKER HANDY CONFIGURATION

5.1. Basic configuration

Users personalization and choice

Version v_2018_017	Version v_2019_016 and later			
🛃 User 1 🔥	🛃 User 1 🕚	B 0 / 40		2
同 Q		● User 1 ∠ □ □ □ □ User 2 □ □ □ User 3 □ × 0	>	Q 0 1 2 3 4 5 6 7 8 a z e r t y u i o q s d f g h j k l m w x c v b n
RAYPLICKER	RAY PLICKER HANDY	O User 4 □ x 0		↑ ⊔ =

To display the users list, click on the «2» icon from the main menu.

Then select the user of your choice and validate.

Modify the user name by clicking on the icon «

From version «v_2019_06», the number of saved files per users is also indicated.

Setting menu



By clicking on the icon « 🛞 », you will acess to the basic settings of the device.

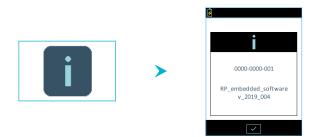
- 1 Change Rayplicker's name
- 2 Information concerning the device
- 3 Change the Dental Numbering System (from version v_2019_06)
- 4 Adjust the screen luminosity. (from version v_2019_06)

Change device name



Enter or change the name of the device, for this, click on the icon « Markov », use the keypad and validate.

2 Information concerning the device



Find here information about your device serial number and the software version.

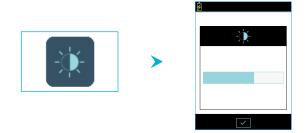
<u>3 Change the Dental Numbering System (from version v_2019_06)</u>



On this menu, it is possible to modify the dental numbering system :

- Universal Numbering system «».

4 Personalize the screen luminosity (from version v_2019_06)



To change the brightness of the screen, click on the « 🕦 » icon.

Then select the desired intensity by dragging the stylus on the gauge and then confirm.

5 <u>Referent shade guide configuration of the Rayplicker Handy</u>

To change the referent shade guide of your device, it has to be connected to your computer and turned on the main screen. We invite you to refer to the user manuals of the UG.RPL.EN.1.0 software for version 1.201 or UG.RPV.BC.EN.1.0 for the Rayplicker Vision and Borea Connect version.

5.2. Device information

Device serial number	See on the label of the device / Settings (page 15)
Version	See on the label of the device / Settings (page 15)

5.3. Automatic calibration

The Rayplicker Handy device performs an auto-calibration before each acquisition.

This is done through the sterilizable calibration tip that inside integrates a grey reference card. It is necessary to ensure the good condition and cleanliness of this calibration tip. It will also be needed to protect it from the sun or any other form of external aggression.

The tip condition ensures the quality of the calibration and guarantees the quality of the data collected by the Rayplicker Handy.

We invite you to check the condition of your tips, for this, please refer to the protocol of use of the Rayplicker Handy present on page 8.

6. GOOD PRACTICES FOR USING THE RAYPLICKER

6.1. Protocol of use of the Rayplicker Handy

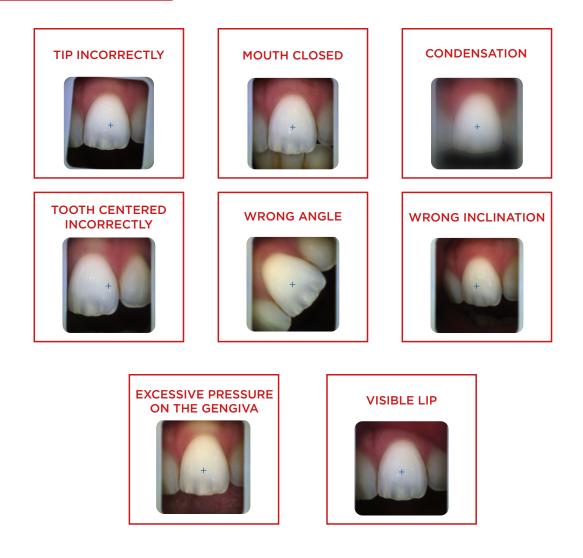
The specific design of the measuring head is the result of an ergonomic study that makes it accessible to all the teeth of the mouth, as well as easy to handle thanks to its wireless technology. To ensure proper results, a few good practices must be followed:

BEST PRACTICES FOR USING RAYPLICKER HANDY



- J GREY EDGES PARALLEL TO SCREEN EDGES
- ✓ MOUTH OPENED AND BREATHING THROUGH THE NOSE
- J SALIVA LIMITATION
- \checkmark Centering the tooth, without angle NOR inclination
- ✓ TIP UNDER THE LIP
- ✓ TIP IN CONTACT WITH ADJACENT TEETH
- TIP IN CONTACT WITH THE GINGIVA
- ✓ DON'T MOVE DURING THE ACQUISITION (1s)

INCORRECT PRACTICES



6.2. Shade taking interface presentation



To take a shade, launch the video mode from the Rayplicker home screen by clicking on the « 💿 » icon.

From version V_2019_06, you can also launch the video mode by pressing the button in the center of the handle.



Video display:

The video display of the target area will allow the user to position the head of the device correctly on the tooth to be analyzed. The cross is also here to help you in having the tooth right in the middle of the screen.



Acquisition :

- Once the device is correctly positioned on the reference tooth, press the button in the center of the handle.
- The acquisition lasts about one second, the device should not move during this period of time. The device can then be removed from the patient's mouth.
- When the acquisition process is finished, a picture of the tooth appears on the screen of your device. Click on the image to display a menu offering the possibility to display the shade analysis under different mappings as well as the translucency mapping.

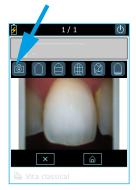
1/40

Version v_2018_017: The number displayed on the upper banner indicates the number of free files out of the 40 potentially saved files on the device memory.

剜 ← 2/2 → 🕚

From version v_2019_06 : The number displayed on the upper banner indicates the number of files saved in the device memory for each user. Use the arrows to navigate and see the saved files.

6.3. Introducing the different mappings available



🗟 Vita classical

Color polarized picture :

This icon allows you to view a color-polarized picture of the scanned tooth.





General mapping :

This icon allows you to view the global tooth color.

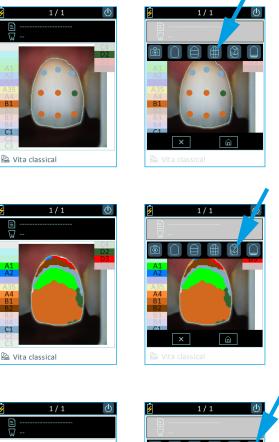
The device automatically detects the contour of the reference tooth.



Three parts mapping :

This icon allows you to view a three-thirds color analysis of the tooth:

- Cervical
- Middle
- Incisal



Nine parts mapping :

This icon allows you to view a map into nine areas of the tooth.

Detailed mapping :

This icon allows you to view the complete mapping of the tooth. The referent shade guide is specified under the picture and the references of this shade guide appear on the screen edges.

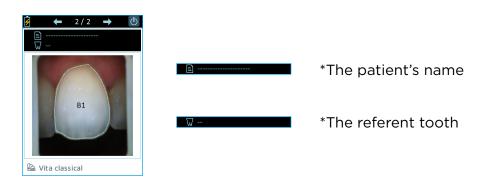


Translucency :

This icon allows you to view indicatively the translucency of the tooth according to the gray scale on the right edge of the screen. On this scale, the darker is the area, the more significant is the translucency.

6.4. Additional information

After taking a shade, you can complete this acquisition with additional information :

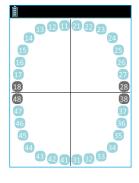


User guide

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Patient's name :

Use the stylus to click on the file icon « **D** », or the field and access to the numeric keypad. Enter a name and validate.



Reference tooth number :

🚵 Vita classical

Referent shade guide :

Indication of the reference shade guide installed on your device. You can change it from the software. Please refer to the software user manuals, UG.RPL. EN.1.0 for the 1.201 software and UG.RPV.BC.EN.1.0 for the Rayplicker Vision and the Borea Connect.

7. ACQUISITIONS PROCESSING

7.1 Acquisition record

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🗟 Vil	ta classical	



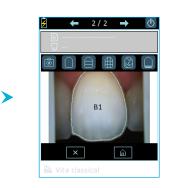
After having taken a shade, you can :

- Either cancel it by clicking on « 💌 » and come back directly to the video mode.
- Either save the file by clicking on « save and come back directly to the device main screen.

Versions v_2019_06 and later

>





After each shade acquisition, the file is saved automatically.

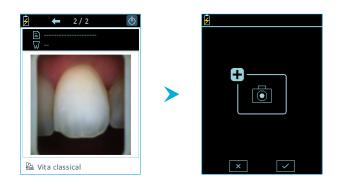
To navigate between the files, click on the arrow « **(**) » to see the previous acquisition or on the arrow « **(**) » to see the following one. Files are classified in order of anteriority.

To see the files availables in the device, click on the icon « \bigcirc » from the device main screen.

It is also possible to delete this acquisition or return to the main menu.

To make a new acquisition directly after taking a shade, click on the button in the center of the handle.

Version v_2018_017



After clicking once on the button in the center of the handle, a validation window appears.

To confirm the request for a new acquisition, click again on the button in the center of the handle again or click on the « 🔽 » icon. To cancel, click on « 💌 ».

Up to 40 records can be saved to the device's memory.

When recording, the device also records the date, time as well as the patient's name and the reference tooth number if this information has been specified. You will find this information when importing the file into the software Rayplicker Vision. These information make it easier to identify the patient concerned.

7.2 Acquisition transfer

The transfer of the acquisitions is done on the computer by connecting the device via USB to its docking station. The latter must be switched on on its home screen. To see the complete procedure, please refer to the software user manuals, UG.RPL.EN.1.0 for the 1.201 software and UG.RPV.BC.EN.1.0 for the Rayplicker Vision and the Borea Connect.

7.3 Delete recorded acquisitions

Compatible from version v_2019_06.



A way to delete one (or more) acquisition(s) saved on the Rayplicker Handy is to make it directly from the file explorer:

- Display the file you wish to delete on the screen using the « 🔍 » icon.
- Click on the touch screen to bring up the menu.
- Click on the « 💌 » icon.
- Confirm the deletion of the acquisition by clicking on « w ...

8. CLEANING AND STERILIZATION

The Rayplicker Handy :

To clean the Rayplicker Handy, it is recommended to use cleaning and disinfection wipes for medical devices, type FD 350 from Durr Dental.

Calibration tips:

The calibration tips (clipped onto the measuring head) are delivered by batches of 6. These must be decontaminated / disinfected and sterilized before use.

- For decontamination/disinfection: it is recommended to use disinfectant wipes for noninvasive medical device surfaces with bactericidal, fungicidal, virucidal and tuberculocidal properties (type FD 350 from Durr Dental) on the inner and outer parts of the tip. Please follow the manufacturer's instructions (contact time required).
- For rinsing: make an active rinse with water for at least 5 seconds then dry the tip.
- For sterilization: autoclave at 134°C for 20 minutes (Prion cycle).

Refer to page 24 for disinfection and sterilization procedures in pictures.

WARNING

- If the manufacturer specifications for the use of the decontamination product before autoclaving are not respected, degradation of the calibration tip may be noted. It is then necessary to change it.
- The sterilizable tip has a life-time validated for 100 autoclave sterilization cycles. Beyond this recommended sterilization quota, the calibration tip may be damaged and discoloration of the gray pattern may occur. It is then necessary to change the tip.





NEW CALIBRATION TIP Internal and external appearance grey and matt

Protective sheaths (optionals):

Protective sheaths are for single use only and must be disposed of in accordance with the regulations in force.

DISINFECTION AND STERILIZATION PROCEDURES

STEPS	CALIBRATION TIPS	RAYPLICKER DEVICE
- 1 - DISINFECTION	AUTHORIZED	WIPES (A)
- 2 - RINSING	RINSE THOROUGHLY WITH WATER	
- 3 - STERILIZATION	AUTOCLAVE STERILIZATION	

Lisinfectant wipes for surfaces of non-invasive medical devices with *bactericidal, fungicidal, virucidal and tuberculocidal* properties. Please follow the manufacturer's instructions. (contact time required). See below for details of sensitive areas.

(i) This device disinfection protocol, required after each use to avoid cross-contamination, also applies to the optional use of single-use protective sheaths.

RISKY AREAS IN CASE OF EXCESSIVE USE OF DISINFECTANT CHEMICALS

DOCKING STATION	MEASURING HEAD
DOCKING STATION	MEASORING HEAD
	DOCKING STATION

NON-COMPLIANT PRODUCTS AND PROCESSES

HEAVILY SOAKED WIPES	SPRAYABLE SOLUTION	DECONTAMINATION BATH	ULTRASONIC BANK
			(((((((()))))))))))))))))))))))))))))

9. TECHNICAL SPECIFICATIONS

9.1 Identification

Manufacturer	BOREA
Name of the Medical device	Rayplicker Handy

9.2 Power adapter

Manufacturer	XP POWER	
Version	VER05US050-JA	
Supply voltage	100-240 V AC	
Power frequency	50/60 Hz	
Consumed current	0.18 A	
Output voltage	5 V DC	
Output current	1 A	

9.3 Handpiece

Mass (g)	390
Dimension (mm)	L. 210 x l. 75 x H. 155
Sensor	CMOS 400 x 400 px
Spectrophotometer	Measuring range : 400-700 nm
Dimension of the measuring head (mm)	L. 76 x Ø. 25
Screen	TFT LCD Color screen
Resolution	320 x 240 NTSC
Internal storage	40 shade taking files
Docking station mass (g)	340
Docking station dimension (mm)	L. 133 x l. 101 x H. 43
USB	1 output USB 2.0

9.4 Battery

Туре	Polymer Lithium
Capacity	2200 mAh / 3.7 V
Lifespan	5 years

9.5 Environmental characteristics

Operating temperature	+10°C (+ 50°F) to +40°C (+ 104°F)
Relative humidity of operation	30% to 75%
Operating atmospheric pressure	800 hPa to 1060 hPa
Maximum operating altitude	< 2000m
Storage temperature	0°C (32°F) to +40°C (104°F)
Relative humidity of storage	10% to 95%, condensation included
Atmospheric storage pressure	500 hPa to 1060 hPa

9.6 Regulation and standardization

The Rayplicker Handy device is a class I medical device. It bears the CE mark in accordance with the European Regulation (EU) 2017/745 on medical devices. Date of first CE marking: 2017.

The unique identifier FR022935_05DXTJ attesting to the registration in the register of producers of the EEE sector, pursuant to Article L.541-10-13 of the Environmental Code has been assigned by ADEME to the company BOREA (SIRET: 79353699600036). This identifier attests to its compliance with its obligation to register with the register of producers of Electrical and Electronic Equipment and the realization of its declarations of marketing to ecosystem.

9.7 EMC

Use of the Rayplicker Handy at the same time or in close proximity to another electronic device should be avoided as it may affect its proper operation.

If such use cannot be avoided, check that both devices are functioning normally.

The use of accessories and cables other than those specified or supplied by the manufacturer of the Rayplicker Handy may result in increased electromagnetic emissions or decreased electromagnetic resistance, which may cause the Rayplicker Handy to malfunction.

Portable radio communication equipment, cell phones, portable wireless access points or similar systems should not be used within 30cm of the Rayplicker Handy, including the cables specified by the manufacturer. If these conditions are not met, the performance of the Rayplicker Handy may be degraded.

Therefore, the user may wish to take preventive measures, such as relocating the device or orienting it differently.

Regarding electromagnetic compatibility, Rayplicker Handy is in compliance with IEC60601-1-2.

10. ANNEX

10.1 Notifications and error messages



The battery level of the device is low. The device must be positioned on its docking station and connected by USB or directly to a power outlet.



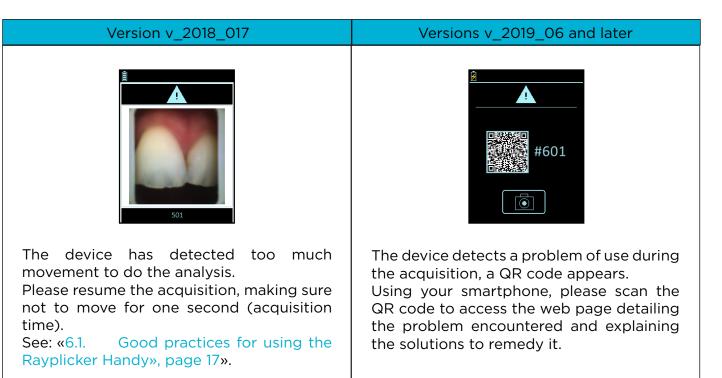
The device's battery is empty. It must be recharged to be used. Place it on its base connected by USB or directly on a power outlet.



The USB connection failed. Check that the cable is well connected and then re-connect.



The internal memory of the device is full. Transfer the files via the software (See the user manuals of the UG.RPL.EN.1.0 software for version 1.201 or UG.RPV.BC.EN.1.0 software for the Rayplicker Vision and Borea Connect versions).



ERROR CODE	WHY ?	SOLUTION
101 102	Problem detected during tooth contour calculation and/or Misuse	Redo the acquisition
301 to 306 401 to 406	Use problem and/or Failure of a led and/or Calibration tip damaged	 Redo the acquisition Redo the acquisition Check the correct operation of the leds Check the calibration tip if it is damaged
501	Movement detected during the shade taking process	Redo the acquisition without moving
201 601 to 609	Problem detected while processing data	Redo the acquisition



Following the acquisition, the automatic contour does not conform to the shape of the tooth.

Two possibilities :

- The acquisition does not respect the good practices presented on page 17. It is thus necessary to erase this acquisition and to start again by following the instructions given on page 17.
- The shade is taken in accordance with the good practices presented on page 17. You will be able to adjust the contour from the software after importing the sheet (see the user manuals of the UG.RPL.EN.1.0 software for version 1.201 or UG.RPV.BC.EN.1.0 for the Rayplicker Vision and Borea Connect version).

User guide



If the screen device freezes when you are using it, turn it over in order to put the screen face down.

When your device is upside down, take an object with a fine nib and hold down during two seconds the point which is in the center of the device.

When it is done, turn over your device and turn it on.

10.2 Glossary

Spectrophotometer :

Device for acquiring spectral data on all points of the tooth. These wavelengths are analyzed and compared to a data basis to deduct the color of a tooth.

Color :

It characterizes the dominant wavelength of light reflected by a tooth. It is the hue that gives this sensation of color (red, yellow, green or blue ...).

Translucency :

Characteristic of a material allowing the light rays undergoing diffusion to pass. We can see through a translucent material but we can not distinguish the shapes.

10.3 Patents

Rayplicker Handy is protected by the following patents:

France:

1556140; 1556141; 1651452

US: 14837,449

10.4 Warranty

The guarantees are specified in the terms of sale. These can be found on the website www.borea-dental.com on the dowload tab.

Rayplicker Handy User manual. Version 1.0 06-2022 Ref. UG.RPH.EN.1.0

BOREA SAS, 6 Allée Duke Ellington, 87100 Limoges Cedex, FRANCE +33 (0)9 83 71 71 61 - contact@borea-dental.com - www.borea-dental.com