



USER MANUAL







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RAYPLICKER™ USER MANUAL

Version 1.3 DM - 2019 -

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PART 1 - GENERAL INFORMATIONS

1. Introduction

1.1. Dear customers

Congratulations on your purchase. The Rayplicker $^{\text{\tiny TM}}$ 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 ΔE =1. This self-calibrated device is intended for dentists and prosthetists.

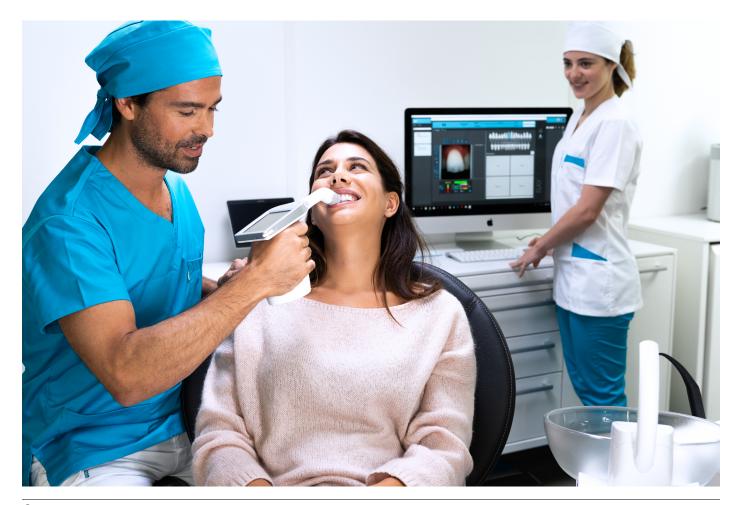
This French-made wireless electro-optical device is equipped with an on-board environment that makes it possible to determine exactly the shade of natural teeth and prostheses according to most shade guides used to determine teeth color.

Accurate and ergonomic, the Rayplicker ™ 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 easily contextual pictures to your file, 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 manual.

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

Borea Team.



1.2. Terms choices

Terms used in the user manual:

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. (Lipolymer battery 3.7V 2000 mAh). The use of an other battery is prohibited and may damage the battery or the unit. BOREA SAS will not be held responsible in this case.
- 2) Do not look in the light source direction.
- 3) Do not immerse the Rayplicker[™] device or charger in water or other liquid.
- 4) All repairs or maintenance must be performed by authorized persons. Failure to comply with this rule will cancel the warranty..
- 5) Please follow the instructions contained page 29 to clean and sterilize the Rayplicker™ and its calibration tip.
- 6) Please follow the instructions listed at the page 13 to place the sterilizable calibration tip and the protective sheath.
- 7) When using the Rayplicker[™] device, respect safety instructions for dental practices and dental laboratories.
- 8) Do not expose to temperatures above 40 °C (104°F) or below 0° C (32°F).
- 9) Protective sheaths designed against infection are single use.
- 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 (104°F) and 30 °C (86°F).





1.4. Symbols description

| CEM | Certification marking indicating that the product complies with the requirements of the «German Product Safety Act (ProdSG)». | SD Grinds |
|------------------|---|------------|
| | Certification C-UL-US means that representative product samples have been evaluated and indicates compliance with the United States requirements. (Regarding mechanics, fire and electrical shock risks) | C UL US |
| CE | The Rayplicker™ is a class 1 medical device. CE marking in accordance with the applicable standards: • Directive 93/42 EEC concerning Medical Devices. • IEC 60601-1: General requirements for basic safety and essential performance of medical electrical equipment. • IEC 60601-1-2 for the electromagnetic compatibility. • RoHS Directive 2011/65/CE According to standard EN-50581:2013 • RED Directive 2014/53/UE with justification EMF • DEEE Directive 2012/19/CE | CE |
| Elimination | This product and all accessories marked with this symbol must not be disposed of with unsorted household waste. Return of the old device to Borea SAS. | |
| Protection class | Equipment of protection class II. | |
| | Read instructions before use. | i |
| | Туре | MODEL |
| | Serial number | SN |
| | Catalog Number | REF |
| | Batch number | LOT |
| | Non-sterile | NON |
| | Do not reuse | (2) |
| | Place of manufacture | |
| | Temperature limits | 10°C 104°F |
| | Recyclable | |

2. Rayplicker™ solution description

The Rayplicker $^{\text{M}}$ is a device for the determination of the shade and translucency of the tooth. It's 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. Due 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 (focus is facilitated and it also reduces the impact of stray light).

These calibration tips play an important role because they incorporate a chromatic reference (pattern of gray) necessary for 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 map of hues and translucence of the analyzed tooth. It will also allow the user to specify the analyzed tooth, select the ceramic powder manufacturer, choose the resolution of the mapping (segmentation of the tooth by 3, 9, detailed mapping).

2.1. Information about Rayplicker™ device

The Rayplicker[™] 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 for the realization of a dental prosthesis :

- A polarized picture
- A complete and accurate mapping of the shade variations in all the tooth area thanks to a bi-dimensional sensor and a spectrophotometer.
- A translucency mapping.

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

2.2. Information about Rayplicker™ software

Rayplicker[™] software is intended to follow up customer files, to realize an order form and follow up the order process. It allows, depending on the selected option and thanks to the optional Service Pack Rayplicker[™] (Cloud), to exchange digital data between dentists (and dental technician) and offshore laboratory.





2.3. The different packs available



DENTIST









1 Dentist pack including:

1 Rayplicker™ device
1 Dentist software license (x4 users)
1 Mobile application
5 years of the Service Pack Rayplicker™ (Cloud)
6 Calibration tips (Autoclavable)
50 Protective sheaths
1 Quickstart guide

Ref: RP0001

LABORATORY







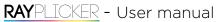


1 Laboratory pack including:

1 Rayplicker™ device
1 Laboratory software license (x4 users)
1 Mobile application
5 years of the Service Pack Rayplicker™ (Cloud)
6 Calibration tips (Autoclavable)
50 Protective sheaths
1 Quickstart guide

Ref: RP0002





3. Delivered set and charging

3.1. **Delivered set**

| Articles | | Quantity | RAYPLICKER™ Items |
|---|---|----------|-------------------|
| Hand-piece Rayplicker™ | 1 | 1 | - |
| Docking station | 2 | 1 | Ref : SF0010 |
| Stylus for touch screen | 3 | 1 | Ref : PA0011 |
| Calibration tips (autoclavable) | 4 | 6 | - |
| Protective sheaths | | 50 | Ref : SF0005 |
| USB 2 cable (A type to B mini) | 5 | 1 | Ref : CA0005 |
| AC-DC Power supply, universal input (Wall plug adapters 5V 1A) | 6 | 1 | Ref : CA0004 |
| Quick start | | 1 | - |
| Cleaning wipe | | 1 | - |
| Activation key for Rayplicker™ software | | 1 | - |
| Rayplicker™ box | | 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 tip (Autoclavable) | Ref : RA0008 |

| SPARE PARTS | | | | |
|---|-----------------|--------------|--|--|
| | Main plug 5V 1A | Ref : CA0004 | | |
| ٷۛؠٷ | USB cable | Ref : CA0005 | | |
| | Battery | Ref : EA0007 | | |
| | Stylus | Ref : PA0011 | | |
| \$\frac{1}{2}\frac{1}{ | Docking station | Ref : SF0010 | | |

PART 2 - RAYPLICKER™ DEVICE

4. First start

4.1. Installation of the protective sheath

Before each utilization on a patient, place a protective sheath over the measuring head of the Rayplicker™.

Be careful, the installation of the protective sheath must always be carried out before the installation of the calibration tip.

These sheaths must be disposed of according to regulations.

4.2. 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 (facilitated focusing and screen reducing the impact of stray light).

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

Before each use on a new patient :

- The measuring head of the device must be decontaminated / disinfected,
- The calibration tip must be decontaminated / disinfected and sterilized. (See: "8. Cleaning and sterilization", page 29)

4.3. 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.





4.4. Turning on/off Rayplicker™ device

| V_2016_017 | V_2019 ₋ |
|------------|---------------------|
| | 1 |

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

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).



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



The top banner gives you indications on battery charge and the available sheets.

The « » icon allows you to turn off the device.

The « » icon is used to access the basic settings of the device (see p.17).

The « » icon allows you to choose the user (see p.17).



The top banner gives you indications on battery charge and the available sheets.

The « » icon allows you to turn off the device.

The « » icon is used to make an acquisition (see p.21).

The « » icon allows the view of the files on the devices. (see p.26)

The « » icon is used to access the basic settings of the device (see p.17).

The « » icon allows you to choose the user (see p.17).



4.6. Battery status



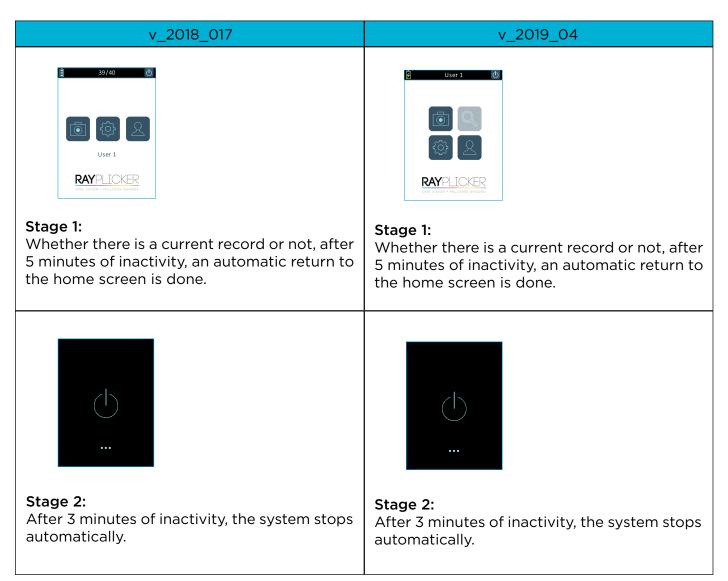
On the main screen of your device, the battery symbol will indicate its charging status.



4.5. Automatic switch-off

Charged

To ensure the maximum battery charge, there is a system shutdown in two stages.





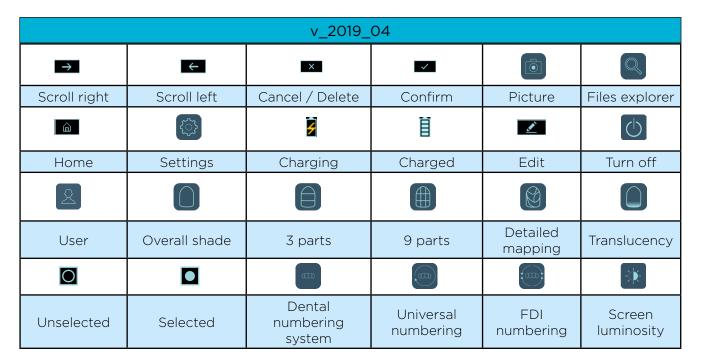
4.8. Device restarting



| v_2018_017 | v_2019_04 |
|--|---|
| Data recovery: If the device stops automatically while the file wasn't 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 | With the version v_2019_04, files are automatically saved on the device memory and they can be viewed with the file viewer. |
| shutdown. Click on the icon « » for a recovery, or on « » to delete this old acquisition. | |

4.7. Observations concerning the device illustrations

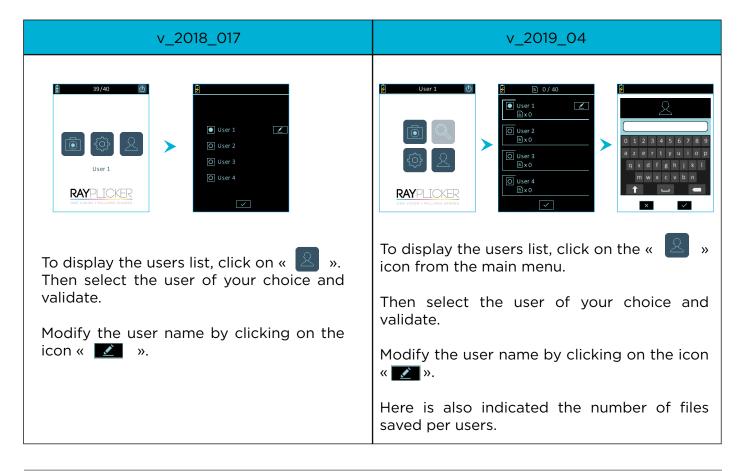
| v_2018_017 | | | | | |
|---------------|------------------------|-----------------|----------|---------------------|--------------------|
| \rightarrow | ← | × | ~ | | <u> </u> |
| Scroll right | Scroll left | Cancel / Delete | Confirm | Picture | Save |
| <u> </u> | $\widehat{\mathbb{Q}}$ | ¥ | Ē | <u> </u> | $\boxed{\bigcirc}$ |
| Home | Settings | Charging | Charged | Edit | Turn off |
| | | | | | |
| User | Overall shade | 3 parts | 9 parts | Detailed mapping | Translucency |
| O | | | | | |
| Unselected | Selected | | | | |



5. Settings for Rayplicker™ device

5.1. Basic settings

Users personalization and choice





v_2018_017 v_2019_04



By clicking on the icon « » you will access to the basic settings of the device.

- 1 Change Rayplicker™ 's name
- 2 Information concerning the device

Click on the icon « » to go back on the main screen.

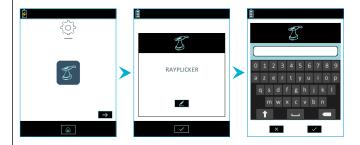


By clicking on the icon « » you will access to the basic settings of the device.

- 1 Change Rayplicker™'s name.
- 2 Information concerning the device.
- 3 Change the Dental Numbering System.
- 4 Adjust the screen luminosity.

Click on the icon « a » to go back on the main screen.

Change device's name



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

Change device's name



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



v_2018_017 v_2019_04

2 Information concerning the device



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

2 Information concerning the device



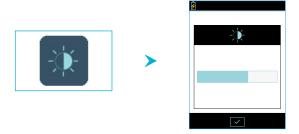
Find here information about your device's serial number and the software version.

3 Change the Dental Numbering System



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

- Universal Numbering system « ».
- 4 Personalize the screen luminosity



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.



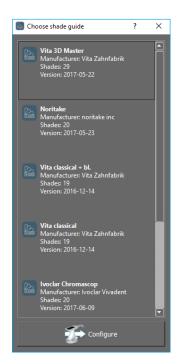
5.2. Rayplicker[™] device's referent shade guide configuration



To change the referent shade guide of your device, it has to be connected on your computer and turned on the main screen.

From your Rayplicker™ software, go to: Settings > Device > Change device shade guide

Click on «Change device shade guide», a window opens.



Select the shade guide you wish and click on « configure ». Your Rayplicker™ device will automatically turn off. Next restarting, this one will be configured with the new shade guide.

5.3. Device information

| Device serial number | See on the label of the device / Settings (page 19) | | |
|----------------------|---|--|--|
| Version | See on the label of the device / Settings (page 19) | | |

5.4. Automatic calibration

The Rayplicker[™] device performs an auto-calibration before each acquisition.

This is done through the sterilizable calibration tip that has a gray pattern. 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 $^{\text{\tiny TM}}$.



6. Realization of an acquisition

6.1. Introducing the right way to use the Rayplicker™ device

The specific design of the measuring head is the result of an ergonomic study that gives it access to all the teeth of the mouth, and an easy manipulation thanks to its wireless technology. In order to obtain consistent results, some good practices must be respected:







- Check that the tip is correctly positioned (The gray scale must be parallel to the edges of the screen).
- The gingiva and a black background should appear on the screen.
- The tip must be in contact with the gingiva and the teeth adjacent to the reference tooth.
- The positioning aid cross must be in the middle of the tooth.
- The tooth must be in the plan of the image, without inclination.
- The patient's mouth must be open (this one must breathe through the nose during the acquisition time).
- The acquisition lasts about 1 second, do not move the device during this period of time.





• The tip should be well parallel to the reference tooth, ensuring that it is in the center of the image. Also check the correct angle of the acquisition. (Be parallel to the surface of the tooth)





• The patient's mouth must be open correctly. The gingiva and a black background should appear in the image.





- The tip is too far from the tooth, it must be against the tooth and the lip must not appear on the image. Place the measuring head of the device in contact with the gingiva.
- The tongue must also not be visible on the screen.





 The tooth should be positioned in the center of the screen, with the cross in the middle. the tip should not press too hard on the patient's gums. (To avoid white coloring of the gum)





6.2. Shade taking interface presentation

v_2018_017

In order to take a shade, from the Rayplicker™ main menu:



Video display

The video display of the target area will allow the user to correctly position the head of the device on the tooth to be analyzed. The cross is also here to help you in having the tooth well 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 last about 1 second, the device should not move during this period of time. The device can then be removed from the patient's mouth.

Once the acquisition is complete, a photo of the tooth appears on the screen of your device.

In order to take a shade, from the Rayplicker™ main menu:

v 2019 04

- Click on the button in the center of the handle.



Video display

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



Acquisition

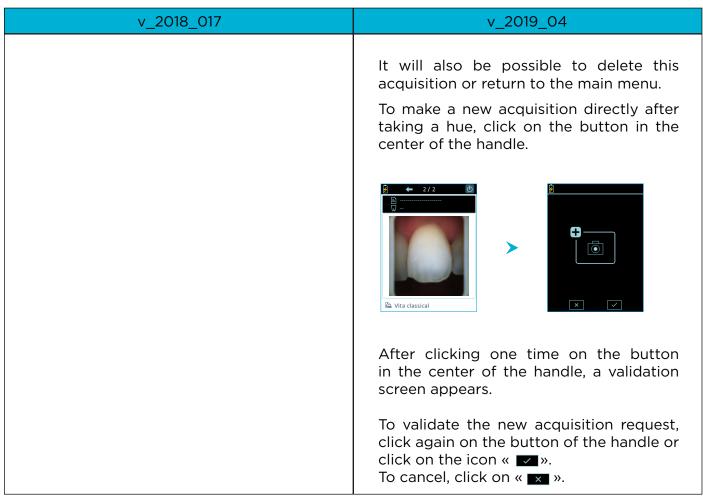
Once the device is correctly positioned on the reference tooth, press the button in the center of the handle.

The acquisition last about 1 second, the device should not move during this period of time. The device can then be removed from the patient's mouth.

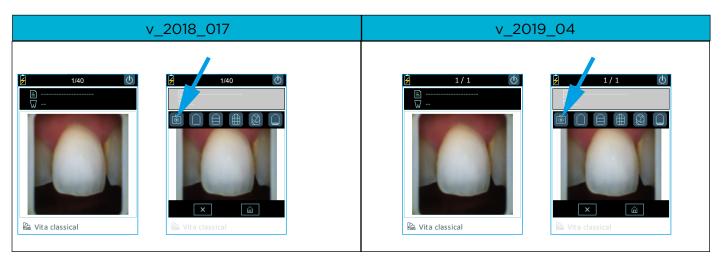
Once the acquisition is complete, a photo of the tooth appears on the screen of your device.

When the tooth is displayed on the screen after the acquisition, it is possible to view the different mappings available by clicking on the touch screen of the RayplickerTM device.





6.3. Introducing to the different mappings available



Color polarized picture:

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

WARNING

- V_2018_017: The number displayed on the top banner indicates the number of files availables over the 40 potential saving in the device memory.
- V_2019_04: The number displayed on the top banner indicates the number of files saved in the device memory per user. Use the arrows to naviguate and see saved files.
- All other icons remain the same in both versions.









General mapping:

This icon allows you to view the global tooth color.

The device automatically detects the contour of the reference tooth.





3 parts mapping:

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

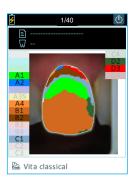
- Cervical
- Middle
- Incisal

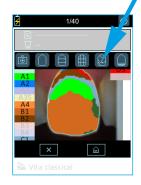




9 parts mapping:

This icon allows you to view a map into 9 areas of the tooth.





Detailed mapping:

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

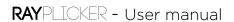




Translucency:

This icon allows you to view indicatively the translucency of the tooth according to the gray scale on the right edge of the screen. In this scale, the darker the area, the higher the translucency of the area.







6.4. Complementaries information

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





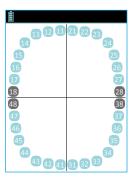


- *The patient's name
- *The referent tooth



Patient's name:

Use the stylus to click on the « **B** » field and access the numeric keypad. Enter a name and validate.



Number of the referent tooth:

Click on « ₩ ». representative diagram of the tooth numbers appears, point the number of the tooth.



Referent shade guide:

Indication of the referent shade guide installed on your device. It can be changed from the Rayplicker[™] software. (See «5.2.», page 20)

Observation:

The information related to the patient (tooth number and patient name) can be filled in / modified directly on a file from the Rayplicker™ software. Do not forget to save the file after that.

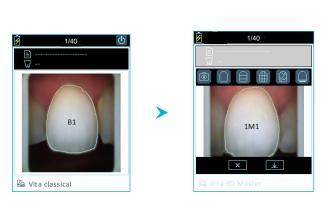




7. Storage of the acquisitions

7.1. Acquisition record





v 2019 04

After a shade taking, click on « w » to save the file.

It is possible to record up to 40 files on the internal memory of the device.

When recording, the device also records the date, time, file number, patient name and reference tooth number if those information have been specified. You will find this information when importing the file on the RayplickerTM software, they make it easier the patient identification.

After each shade taking, the acquisition will be displayed on the screen of the device. To access the different mappings, simply click on the screen of the device.

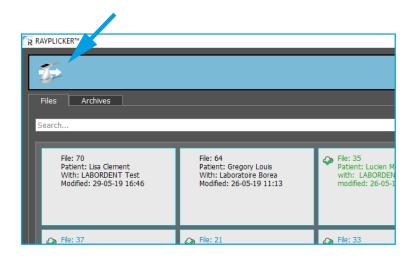
It is possible to record up to 40 files on the internal memory of the device. To view the files available on the device, click on the « » icon from the main menu.

To navigate between the files, click on the arrow « • » to see the first acquisition made or on the arrow « • » to see the latest acquisitions. The files are classified in order of anteriority.

The device records automatically the date, time, file number, patient name and reference tooth number if those information have been specified. You will find this information when importing the file on the Rayplicker™ software, they make it easier the patient identification.



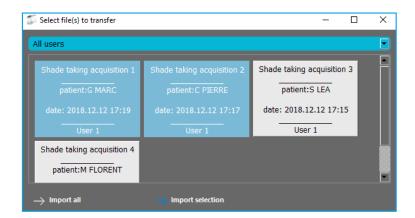
7.2. Acquisitions transfer



USB:

Put the device on its docking station. Connect the docking station to the computer with the USB cable.

In order to import the files, open the Rayplicker[™] software, then from the main page, click on the icon « » then « ».

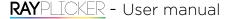


If you want to import only some of the files, click on the files that you want, they are highlighted. Import them by clicking on «import selection».

«Import All» allows you to import all the files.

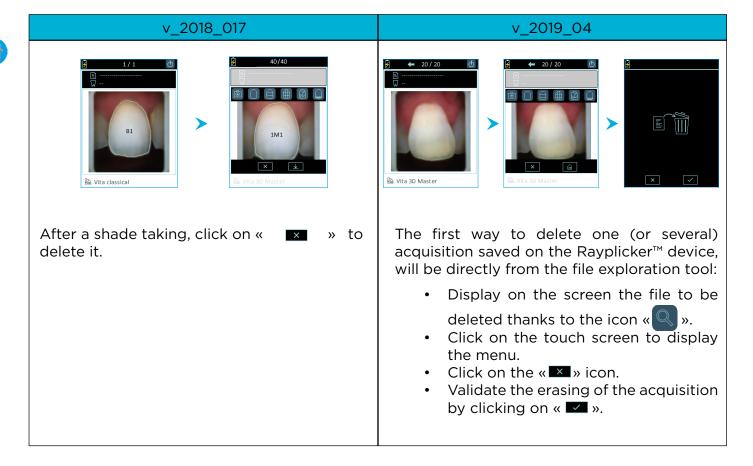
Imported files are transferred to the software on the main page. Follow the instructions from the page 36 to process the data and create a purchase order.

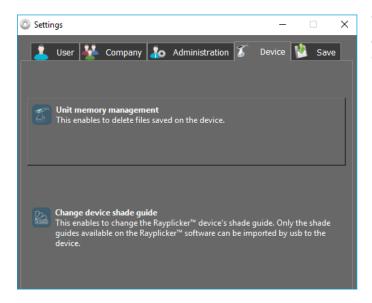
Observation: Once imported, the data are no longer available on your Rayplicker[™] device. The number of records available on your device is then updated automatically.





7.3. Delete recorded acquisitions





The second way to remove one (or several) acquisition that is present on the Rayplicker[™] device will be from the Rayplicker[™] software.

- Put the device on its base connected by USB to the computer.
- Turn on the device on the main menu.
- On the software, click on the «Settings» icon and then on the «Administration» tab.
- Click on the «device memory management» option.
- Select the file(s) to delete and validate the erasing.





8. Cleaning and sterilization

The Rayplicker[™] device:

To clean the Rayplicker[™] it is recommended to use cleaning and disinfection wipes for medical devices. Type Unisepta Plus Wipes / Unisepta Foam 2 Wipes.

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.

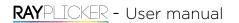
- For decontamination: it is recommended to use the product to be diluted «HEXANIOS G+R» or any other equivalent product. Attention, make sure to respect the manufacturer's specifications, especially the soaking time.
- For sterilization: autoclaving at 134 ° C for 20 min. (Prion cycle). Lifespan verified for 100 passes.

WARNING

- If the manufacturer's specifications for the use of the decontamination product before autoclaving, in particular the soaking time, 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.

Protective sheaths:

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





PART 3 - RAYPLICKER™ SOFTWARE

Download the Rayplicker™ software for free from the BOREA website:

https://borea.dental/Download



9. Install the Rayplicker™ software on a computer

In order to use the maximum capacity of the Rayplicker $^{\text{\tiny M}}$ solution, install the software allowing the analysis of your tooth shade, the follow-up of the patient's file and the realization of purchase orders.

9.1. System compatibility



Windows®

Windows® minimum configuration

Operating system: Windows Xp or superior Processor: Intel Core I3 or AMD equivalent

RAM: 2 GB Hard disc: 5 GB Ports: USB 2.0 x 1

Screen resolution: 720 p

Internet: High speed connection

Windows® recommended configuration

Operating system : Windows Xp or superior Processor : Intel Core I5 or AMD equivalent

RAM: 4 GB Hard disc: 5 GB Ports: USB 2.0 x 1

Screen resolution: 1080 p

Internet: High speed connection



Mac minimum configuration

Operating system: macOS 10.13 High Sierra

or ulterior RAM : 2 Go Hard disc: 5Go Ports : USB 2.0 x 1

Screen resolution : 720 p

Internet: High speed connection

Mac recommended configuration

Operating system: macOS 10.13 High Sierra

or ulterior RAM: 4 Go Hard disc: 5 Go Ports: USB 2.0 x 1

Screen resolution: 1080 p

Internet: High speed connection



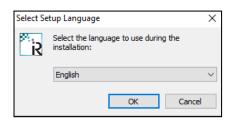
9.2. Drivers installation



Drivers will install automatically at the end of the Rayplicker[™] software installation.

偷

9.3. Install the Rayplicker™ software



Download for free the file « setup_rayplicker.exe » from the download tab on the website :

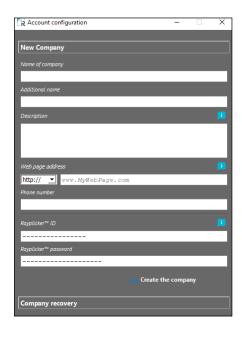
https://borea.dental/Download

Double click on the « setup_rayplicker.exe » file to start installing the software and select the installation language.



Follow directions of the different screens. Click on « finish » to complete the setup.

9.4. Rayplicker™ software account setup



Open the application from your desktop. First, you must create a company. To do so, fill the requested informations.

Indicate your Rayplicker[™] personal login in order to activate your Rayplicker[™] software.

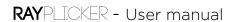
Click on « create a company » to confirm.

For data recovery, follow the instructions on the page 32.



Geolocation configuration:

Click on « add an address » or « ignore ». Complete your address in order to get the geolocation option and be able to send files by Cloud.







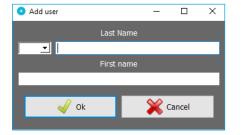
To complete your address, use the automatic fields or the free search. For each completed field, select the proposal that appears on the drop-down menu by clicking on it.





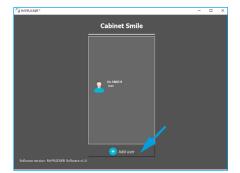
After completed your address, your company is geolocated on the map.

If the data are correct, click on « Validate address » otherwise you have to return to the previous stage.



Identification of the first user:

Fill the requested information then press confirm to create a new user.



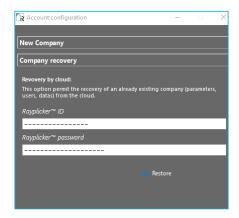
Home screen identification:

Once all the information has been completed, a welcome window will appear.

Click on your user to open the work session.

Click on «Add User» to create a new user.

9.5. Restore company's data from the Cloud



When setting up your account, you can perform a cloud restore. This option is available as part of a re-installation of the software on a new computer for example. To do this, please fill in your Rayplicker $^{\text{TM}}$ ID and password in the corresponding fields and click on «Restore».

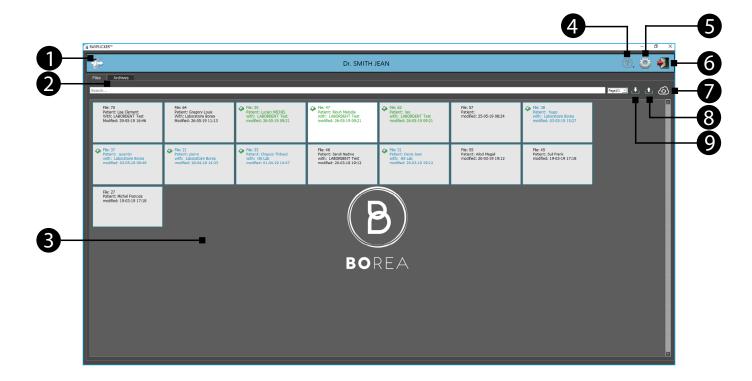
10. Using the Rayplicker[™] software with the dentist pack

The Rayplicker[™] Dentist Pack allows shade taking thanks to the Rayplicker[™] device, transfer these data and realize production files from the software. Then, these production files can be printed, sent by email or directly by Cloud as part of the Rayplicker[™] Service Pack.

1

The Rayplicker™ Service Pack option allows dentists to directly transfer production sheets in digital format to different prosthetists also equipped with the Rayplicker™ solution. The Cloud allows you to view the progress of your order in real time and also gives you access to a community of users.

10.1. Introduction to the main screen



- 1. Import acquisitions from the Rayplicker™ device
- 2. Main tabs: Files / Archives
- 3. Storage area for imported cards
- 4. Help
- 5. Settings
- 6. User menu
- 7. Refresh the page (update files in progress or received)
- 8. Export a file from the Rayplicker™ software
- 9. Import a file to the Rayplicker™ software



10.2. Software Illustration

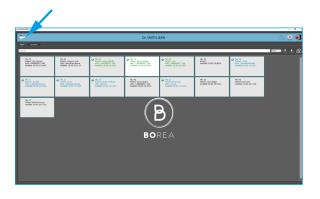


| • | • | 2 | • | \$ | 6 | |
|-----------------|-----------------------------------|-----------------------------|--------------------------------|----------------------------|----------------------------|-------------------------|
| Previous | Next | User | Add | Refresh Cloud | Files pending | Settings |
| | | | T | | | |
| Disconnect | Import from the Rayplicker™ | Import picture | Rayplicker usb connected | Polarised image | Overall shade | 3 parts |
| | | | | | | |
| 9 parts | Detailed mapping | Shade guides | Lock the tab | Tooth border editing | Translucency | B&W picture |
| | | | | 1 | • | > |
| Ruler | Δ E analysis | Colorimetric coordinates | Print | Export | Import | Send |
| | | | + | _ | \bigotimes | |
| Low | Standard | High | Add translucency | Reduce translucency | Delete translucency | No Colar |
| | | | | | | |
| 360° Collar | Lingual | Occlusal Metal | Pontic design case 1 | Pontic design case 2 | Pontic design case 3 | Pontic design case 4 |
| | 4 | ~ | % | | | √ |
| On the Cloud | Received by the laboratory | Accepted by the laboratory | Files timer | Add by Cloud | Manual add | Validate |
| * | | igg[oxtimesigg] | | A | * | <u>**</u> |
| Cancel | Information | Mail contact | Cloud contact | Error | Delete data | Company |
| 20 | | T | | | ? | |
| Administration | ID | Memory management | Save files | Save contacts | Help | |

10.3. Import shade taking



Open the Rayplicker™ software and select a user. To create a new user or recover files, please refer to the explanations described on page 32.



On this main page, it's possible to select several sheets imported form the Rayplicker[™] device. They are classified by date.

The icons and colors of the sheets give information on their states of progress. All the different states of progress are described on page 44.

» to import files from Click on this icon « your Rayplicker[™] device.



The software will show you the Rayplicker™ device available. To be able to connect your device to the software, make sure your device is light on the main screen and connected by USB to the computer. Click on the corresponding icon to import files.

Observation:

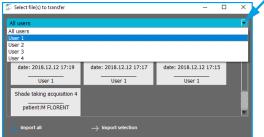
The process to connect your Rayplicker™ device to a computer is explained in details on page 27.



On this page, it's possible to select « the User », «Import all the files» or, select the files of your choice and « Import the selection ».







Click on the arrow to chose the user and sort the files.



Then, click on the files you want to import. They appear in blue.

Click on « Import the selection ».



On each file, you will have the following informations:

- Patient name (if it was defined on the Rayplicker[™] device after the acquisition).
- Date and time of the acquisition.
- User of the Rayplicker[™] device.

10.4. Open a file



After import files from your Rayplicker™ device, they are displayed on the software main page. The files you just imported appear in gray.

Click on a file to open it.

Observation:

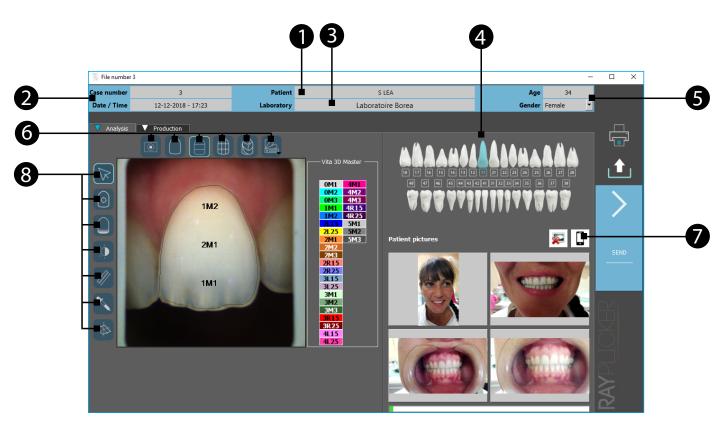
Files colors and progress are explained on page 44.





10.5. Shade taking tab

When a file is open, it will display the information of the «analysis» tab.



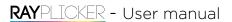
1 Fill the patient name



- 2 File number and date of the acquisition.
- 3 Add a recipient laboratory for the order form.

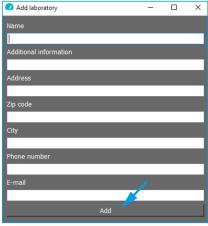
Two options are available to add a laboratory to my contact list:

«Manual add» or «Cloud add»









Manual add:

This option is destined to add a Laboratory who doesn't use the Rayplicker^{TM} solution with the Rayplicker^{TM} Service pack.

It is necessary to add the Laboratory email address in order to send an order form as PDF file but also to fill your own email address in :

Settings » User » Email address.

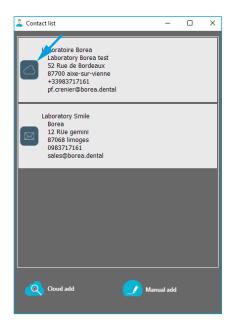
Fill the other information then click on « Add ».



Cloud add:

Use the map or do a research by address and then doubleclick on the selected Laboratory to add it to your contact list.

To have more explanation about the cloud add, go on the paragraph «10.6. Select a laboratory by Cloud.», p.40.



The created or added by Cloud contacts appear on the contact list.

If you want to remove a Laboratory, click right on its name then « delete ».

The laboratories registered in your contact list differ in the presence or not of the Cloud icon which shows if they are using the Rayplicker $^{\text{TM}}$ Service Pack.

If a laboratory has a «cloud», you can send him numerical order forms by Cloud.

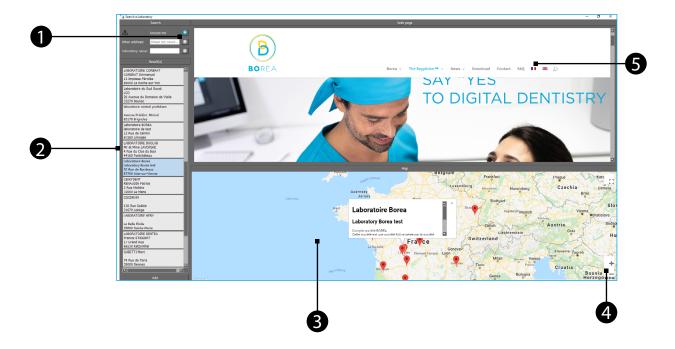
- 4 Choose the « referent » tooth
- Fill the patient « age » and « gender ».
- 6 Chose the mappings and change the referent shade guide
 - *Polarized picture
 - *Overall shade
 - *3 parts
 - *9 parts
 - *Detailed mapping
 - * Shade guides
- Click on the phone icon to import patient pictures taken with the mobile application «Rayplicker™ Pics App Solution». The process is explained on page 56.
- 8 Click on one of the following icons to show the image treatment tools:
 - *Block the toolbar
 - *Tooth border edition tool
 - *Tooth translucency analysis
 - *Black & White analysis tool
 - *Ruler
 - *Colorimetric analysis tool
 - *Colorimetric coordinates



10.6. Select a laboratory by Cloud.



Click on «Add Cloud» and follow the instructions just below.



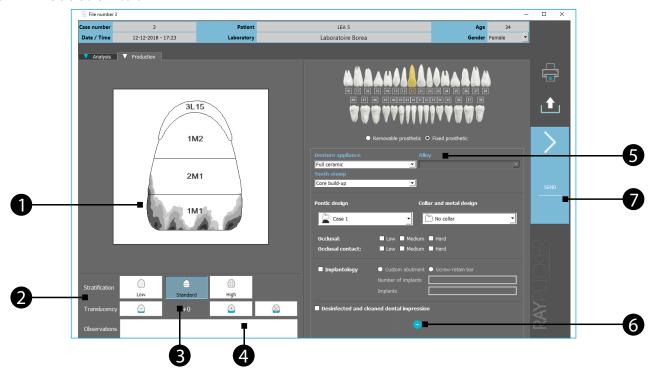
- Click on the blue arrow to search a laboratory around you. Search by address. Search by the laboratory name.
- Once founded on the map, the list of laboratories appears on the left.

If you select it by clicking, its description appears on the map and its website in the top window. (Only if this information has been entered by the laboratory).

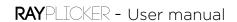
Double-click on the laboratory of your choice to add it to your contacts list. Or click on «Add» at the bottom left.

- 3 Use the map to visualize the different laboratories registered on the Cloud.
- 4 Use the mouse scroll wheel or the « + » and « » icons to modify the map view.
- After selecting a laboratory, you can see some of its informations on this window. (only available if the laboratory has already provided these information)

10.7. Production tab



- 1 Scheme of the production tooth.
- 2 Select the prosthesis stratification needed:
 - *Neck of the tooth and overall shade
 - *Neck of the tooth and 3 horizontal zones
 - *Neck of the tooth and 9 zones
- 3 Translucency adjustment. Click on:
 - *To add translucency
 - *To reduce translucency
 - *To delete translucency
- Leave notes about the order form to the laboratory in this banner. (Specific features for the prosthesis wished ...)
- Fill in here the information in link with the prosthesis realization.
 Use the drop down menu and select the elements.
 These information are compulsory before sending your order form.
- 6 Click on the arrow to select additional informations linked to the order form. These informations are optional but allow more informations in prosthetic realization by the laboratory.
- After filling your order form, click on «send», a new window opens.





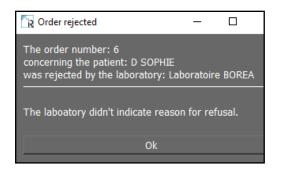
10.8. Validate the order form





Select the wished delivery date and the sending way.

Tick the privacy statements then validate the order to send it.



Once the order form has been sent and received, the laboratory can accept or refuse it.

This option is only valid with the Rayplicker[™] Service Pack because the order must be sent by the Cloud.

- An accepted command will result in a change of state of the form (see the different states on page 44)
- A rejected order will result in the receipt of a message indicating the rejection of the order and its reason (if informed by the laboratory).



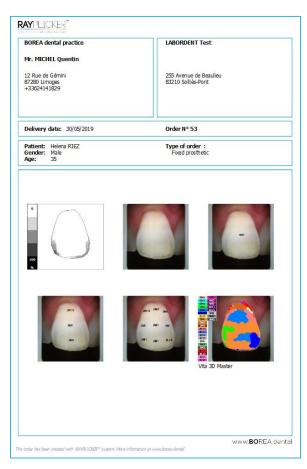
10.9. Order form example



Page 1: Production sheet



Page 3: Patient pictures



Page 2: Mappings



Page 4: Patient pictures



10.10. Sheet's colors meaning

Without using the Rayplicker™ Service Pack option :





File:1

Patient: M SOFIA

Avec : Borea Laboratory Modifiée : 28-07-17 12:22



File:1

Patient: M SOFIA

With: Borea Laboratory Modified: 28-07-17 12:22

Gray sheet:

The sheet is just imported from the Rayplicker[™] device. The order form has not been sent.

Green sheet:

The order form has been sent.

Using the Rayplicker™ Service Pack option :



File:1

Patient : M SOFIA With : Borea Laboratory Modified : 28-07-17 12:22



Grey blurred sheet:

The file is blurred when it is transferring on the cloud.



File:1

Patient : M SOFIA With : Borea Laboratory Modified : 28-07-17 12:22



Blue sheet:

The sheet has been sent. It is on the cloud.



File:1

Patient: M SOFIA With: Borea Laboratory Modified: 28-07-17 12:22



Blue sheet:

The order has been received by the laboratory.



File:1

Patient : M SOFIA With : Borea Laboratory Modified : 28-07-17 12:22



Blue sheet:

The order has been accepted by the laboratory.



File:1

Patient : M SOFIA With : Borea Laboratory Modified : 28-07-17 12:22



Green sheet:

The order has been sent by the laboratory.



Observation:

This icon indicates that sheets are waiting for update (Here there are 3 files waiting).



11. Using the software with the Rayplicker[™] laboratory pack

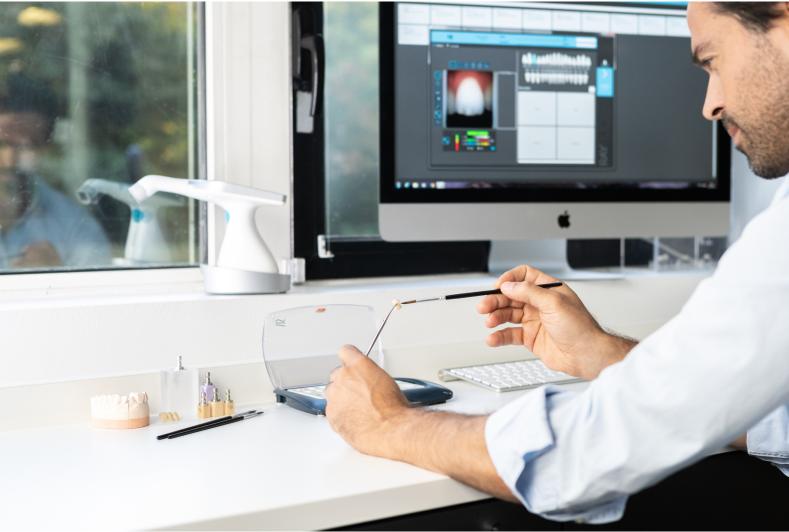
11.1. Similarities with the Rayplicker™ Dentist Pack



The Rayplicker[™] laboratory pack offers the same solutions than the Rayplicker[™] dentist pack (shade taking, viewing and follow up of patients' folders).

However, the use is somewhat different thanks to the possibility of order form received from dentist using the RayplickerTM solution.

Moreover, orders can be exported and sent to other laboratories in digital format as a «.borea» file if the recipient is also equipped with the Rayplicker $^{\text{TM}}$ software solution.





11.2. Receive and process an order





Orders are received on this main page.

Click on the icon « » to actualize the cloud, receive new orders and update existing files.

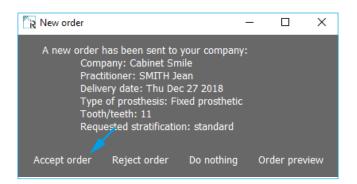
The cloud is automatically updated every 5 minutes.

Sheets are sorted by date.



The last received commands appear in gray at the top left.

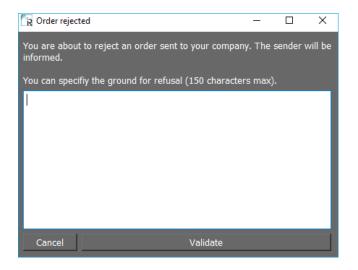
After receiving a file, click on it to see some information.



The origin, the wished delivery date, the type of prosthesis and the type of stratification are specified.

You can ignore it by clicking on «do nothing», in this case, the tab closes and the order doesn't open.

The order opens when you accept it.



It is possible to reject the order and specify the reason.

Validate to send the rejection to the practitioner.



11.3. Interpret an order

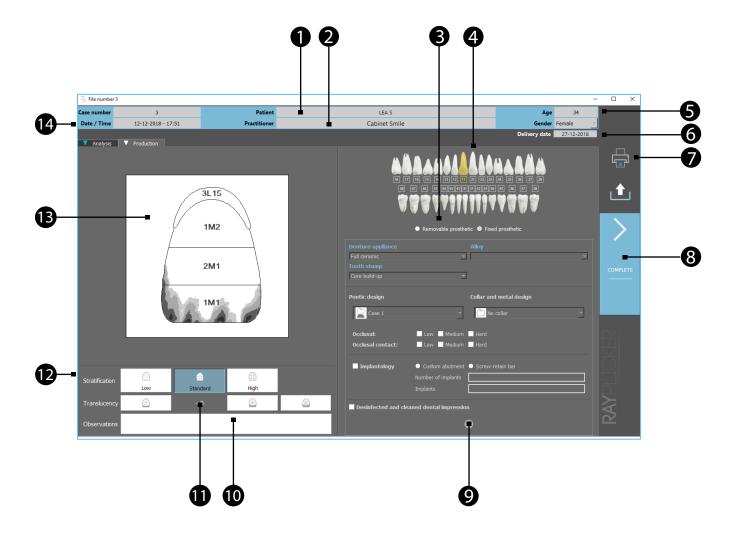
After clicking on an order sheet and accept it, it opens on the production tab.

Here are presented the different specifications of the ordered prosthesis.

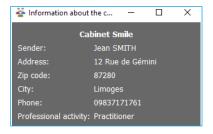
The upper banner indicates general informations about this order.

Important:

The information specified in the order form by the practitioner can't be modified. With the exception of the tooth contour for a command received by Cloud.



- Patient name.
- 2 Information concerning the practitioner who sent the order form.

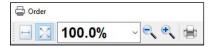


Click on the practitioner name to open a window with his contact details.



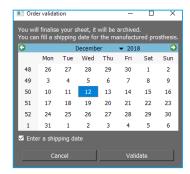
- 3 Type of prosthesis ordered (removable or fixed).
- 4 Number of the production tooth wished.
- **6** Patient age and gender.
- 6 Delivery date requested by the practitioner.
- Click on the icon to print the order form.

The order form opens, click on the icon printer to print it.



An example of order form is detailed on page 43

Click here to finish.



Select a shipping date to the practitioner. The file is then automatically saved. It can be consulted from the «Archives» tab on the main page.

- 9 Here are described order additional information.
- 10 Here are the notes about the order destined for the laboratory.
- Indication about translucency of the desired prosthesis.
- 12 Indication about stratification of the desired prosthesis.
- **B** Scheme of the production tooth.
- Information about the file number, date and hour of the shade taking.

The analysis tab is also accessible by clicking on it.

Here are presented details of shade taking registered by the practitioner.

Patient pictures can also be joined.

Important:

The information specified in the analysis tab can not be changed. With the exception of the tooth contour for a file received by Cloud.



- See the mappings and change the referent shade guide.
 - *Polarized picture
 - *Overall shade
 - 3 parts

- *9 parts
- *Detailed mapping
- *Shade guide
- 2 Click on one of the following icons to show the image treatment tools:
 - *Block the toolbar
 - *Tooth border edition tool
 - *Tooth translucency analysis
 - *Black & White analysis tool

- *Ruler
- *Colorimetric analysis tool
- *Colorimetric coordinates



- 3 Patient pictures. Click on it to enlarge.
- 4 Export the sheet as a «.borea» file.
- **5** Print the order form.
- Delivery date requested by the practitioner.

 In the upper banner, we find the same informations as those presented in the « production » tab. (See page 47)

11.5. Sheet's colors meaning



File:1

Patient : M SOFIA With : Borea Laborator

With: Borea Laboratory Modified: 28-07-17 12:22



Gray sheet:

An order came by cloud. It hasn't yet been opened or accepted.



File:1

Patient : M SOFIA With : Borea Laboratory

Modified : 28-07-17 12:22



Blue sheet:

The order has already been opened but hasn't been finished.

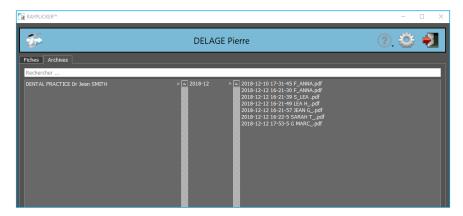


Observation:

This icon indicates that sheets are waiting for update (Here there are 3 files waiting).

Observation: Once processed and sent, the order is automatically saved in the «archives» tab on the main page.

11.6. Archived files



From the « archives » tab on the main page, you can access to the saved files. To open it, just double click on it.

12. Analysis tools

To access the analysis tools, hover the left edge of the image with your mouse. A menu appears with the different tools available. Click on the icon « 🔊 » to lock the menu.

*Tooth border edition tool

*Tooth translucency analysis

*Black & White analysis tool

*Ruler

*Colorimetric analysis tool

*Colorimetric coordinates

Tooth border edition tool



Click on «automatic contour» and then click on the tooth for an automatic border detection.

If the contour is compliant click on «Validate».

If the contour is not conform, you can do a manual contour.



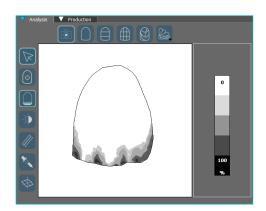


Click on «Manual contour» and then make the contour of the tooth point by point.

Finish the outline by clicking on the starting point.

Click on «Validate» to confirm the new contour.

Tooth translucency analysis



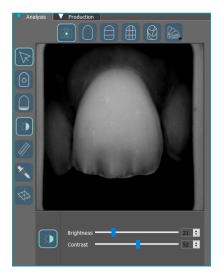
This tool allows you to visualize a map of the translucency of the tooth.

This is indicated by a gray scale indicating the presence of translucency on a scale from 0% to 100%.





Black & White analysis tool

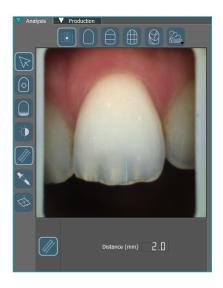


This Black & White analysis tool allows to converts the color polarized picture into a gray-scale image.

Use the sliders to change the brightness and contrast settings to highlight the distribution of dentin, enamel, or other notable features.



Ruler



This tool makes it easy to locate the location of translucent areas or other notable features.



Colorimetric analysis tool

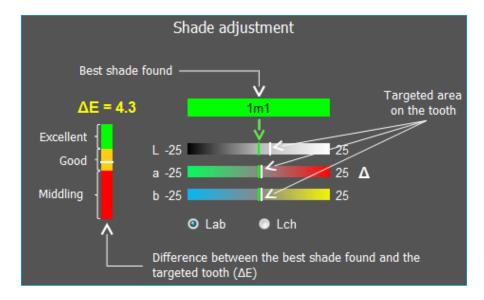


Calculate pixel by pixel the color difference «Delta E or Δ E» between the actual shade of the tooth and the closest shade according to the reference shade guide.

Visualize the differences according to the 3 dimensions of the color: brightness, saturation and hue.

This analysis can be performed under the Cie Lab or Lch references.

Interpretation of the data communicated by the tool:



Colorimetric coordinates



Determine, pixel by pixel, the colorimetric coordinates according to the Cie Lab or Lch references.

13. Rayplicker™ Software settings manager

13.1. User tab



In this user tab, you can edit your user's contact information.

Click on «Delete my account and my data» to delete your user.

Validate to save changes.

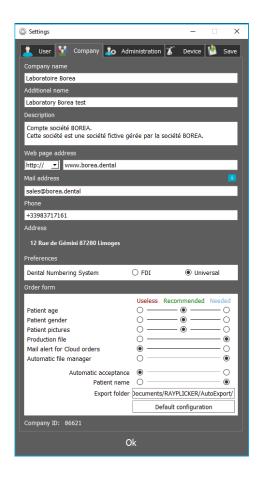
For «Dentist» accounts, it is possible to register an e-mail address by specifying your address and your password then click on «Test and save»

(Your server may also be necessary)



13.2. Company tab





Dentist and Prosthetist Accounts:

In this company tab, you can change the contact information of your company.

It is also possible to choose the Dental Numbering system:

- FDI Numbering System
- Universal Numbering System

Prosthetist Account only:

Specify a description that will be presented on the geolocation map.

Specify your website address, this information will also be displayed on the Cloud search page for dentists using the Rayplicker™ Service Pack option.

You can also configure your preferences in three categories (Useless / Recommended/ Needed).

The Automatic file manager option allows to directly export a new file after its acceptance (Automatic or Manual), to a chosen folder.

Validate to save the changes.

13.3. Save files on the computer



From this tab, you can save unsent files to the cloud.

Save the list of Laboratories contacts.

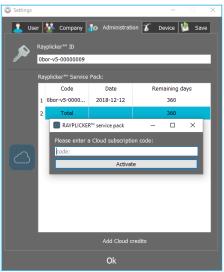


13.4. Administration



The «Administration» tab lets you access your Rayplicker™ ID and manage your Rayplicker™ Service Pack.

Here you can add credits to activate your Rayplicker[™] Service Pack.



Reloading the Rayplicker™ Service Pack:

Click on «Add Recharge». Enter your activation code in the «code» field to extend your subscription to the Rayplicker™ Service Pack.

13.5. Device



To manage a Rayplicker[™] device memory, it must be connected to the software. Click on « device memory management », this will open a new window where you can select files and delete some of them by clicking on « delete ».

To change the shade guide of your Rayplicker[™] device, it must be connected to the software and turned on the main screen. Click on «change shade guide», a new window will open. Select the wished shade guide and click on « configure ».



14. Mobile application «Rayplicker™ Pics App Solution»

To complete your order form, the mobile application «Rayplicker™ Pics App Solution» allows you to take patient pictures and transfer them by wifi.

Contextual pictures are an additional support to the order form for prosthetist.

Observation: Pictures are temporarily saved on the application until their transfer. If you log off the application without transferring the pictures, they will be lost.

14.1. Download and compatibility.

You can download freely the application Rayplicker[™] Pics App Solution for your mobile or tablet on the different online stores :



14.2. Take contextual pictures



There are four shooting views:

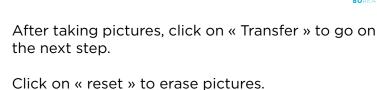
- *Face
- *Smile
- *Retractor 1 and 2

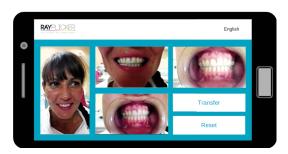


Take the pictures.

The bottom banner allows pictures improvement :











Fill the patient name.

Do a software research by clicking on the arrow «)».

Select the software that will receive the data then click on « send ».

Pictures will automatically be transferred to the Rayplicker[™] software by wifi.

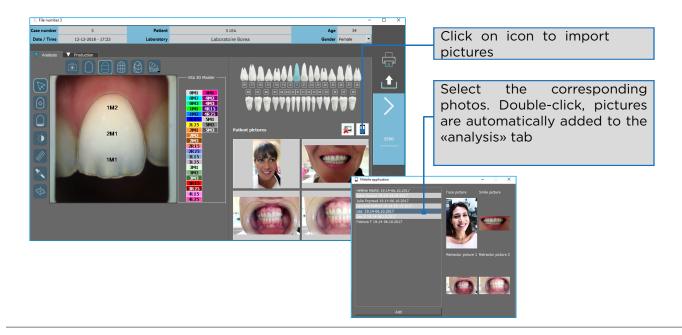
*Important: make sure both your devices (phone/tablet and computer) are connected on the same wifi network.

It will also be needed to have the Rayplicker[™] software launch on the computer.

14.3. Import contextual pictures

Files are classified by name and date.

Double-click on the file to add them to the order.



PART 4 - TECHNICAL DATA

15. Technical specifications

15.1. Identification

| Manufacturer | BOREA |
|----------------------------|------------|
| Name of the Medical device | Rayplicker |

15.2. AC Adapter

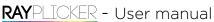
| Manufacturer | XP POWER | |
|------------------|---------------|--|
| Version | VER05US050-JA | |
| Supply voltage | 100-240 V AC | |
| Power frequency | 50/60 Hz | |
| Consumed current | 0.18 A | |
| Output voltage | 5 V DC | |
| Output current | 1 A | |

15.3. Handpiece

| Mass (g) | 450 | |
|--------------------------------------|------------------------------|--|
| 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) | 165 | |
| Docking station dimension (mm) | L. 133 x l. 101 x H. 43 | |
| USB | 1 output USB 2.0 | |

15.4. Battery

| Туре | Polymer Lithium |
|----------|------------------|
| Capacity | 2200 mAh / 3.7 V |



15.5. Environmental characteristics

| Operating temperature | +10°C à +40°C | |
|--------------------------------|----------------------------------|--|
| Relative humidity of operation | 30% à 75% | |
| Operating atmospheric pressure | 800 hPa à 1060 hPa | |
| Maximum operating altitude | < 2000m | |
| Storage temperature | 0°C à +50°C | |
| Relative humidity of storage | 10% à 95%, condensation included | |
| Atmospheric storage pressure | 500 hPa à 1060 hPa | |

15.6. Regulation and standardization

The Rayplicker[™] is a class 1 medical device. CE marking in accordance with the applicable standards:

- Directive 93/42 EEC concerning Medical Devices.
- IEC 60601-1: General requirements for basic safety and essential performance of medical electrical equipment.
- IEC 60601-1-2 for the electromagnetic compatibility.
- RoHS Directive 2011/65/CE According to standard EN-50581:2013
- RED Directive 2014/53/UE with justification EMF
- DEEE Directive 2012/19/CE

Refer to the technical file RP1 DOC Q RD200 ind 002

15.7. EMC

The use of the Rayplicker[™] device at the same time or close to another electronic device should be avoided as this may affect its proper operation.

If this use can't be avoided, check that both devices are working normally.

The use of accessories and cables other than those specified or provided by the Rayplicker™ manufacturer may result in increased electromagnetic emissions or decreased electromagnetic resistance and may result in improper operation.

Portable radio communication equipment, mobile phones, portable WiFi access points or similar systems should not be used within 30cm of the Rayplicker™ device, including manufacturer specified cables. If these conditions are not respected, the performance of the Rayplicker™ device may be degraded.

The user can therefore take preventive measures, such as changing the location of the device or orienting it differently.

Regarding electromagnetic compatibility, Rayplicker™ complies with IEC 60601-1-2.



16. Annex

16.1. Errors messages

Error messages of the Rayplicker™ device :



The battery level of the device is low.

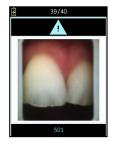
The device must be positioned on its docking station and connected by USB or directly to a power outlet.



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



The internal memory of the device is full. Please transfer the files via the Rayplicker[™] software (See : page 35).

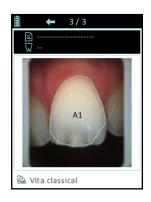


The device has detected movement during the analysis.

Please redo the acquisition without moving during one second (time of the acquisition).

See point «6.1. Introducing the right way to use the Rayplicker™ device», page 21.

| Error number | Reason | Solution |
|--|--|---|
| 101 & 102 | Error during the tooth border calculation. Misuse. | Redo the acquisition (See page 21) |
| 301, 302, 303, 304, 305, 306 401, 402, 403, 404, 405, 406 | Power measured during the acquisition is out of thresold. Misuse or calibration tip must be changed. | Redo the acquisition (See page 21) Change the calibration tip (See page 20) |
| 501 | movements detected during the acquisition. Misuse. | Redo the acquisition (See page 21) |
| 201 & 601 | Error during data treatment. Data | Redo the acquisition (See page 21) |

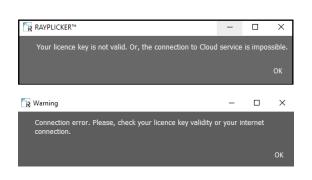


Following the acquisition, the automatic contour does not conform to the shape of the tooth.

Two possibilities:

- The acquisition does not respect the good practices presented on page 21. It is thus necessary to erase this acquisition and to start again by following the instructions given on page 21.
- The acquisition respects the good practices presented on page 21. You can adjust the contour from the software after importing the file page 51.

Error messages of the Rayplicker[™] software:



Check your username and license number.

IDs and passwords contain only zero «O» digits and no «O» letters.

Check the correct internet connection of your computer and check the ports. (See point 16.2 below)

If the problem persist contact Borea.

16.2. Port configuration

How to set up the Rayplicker[™] solution.

If you are behind a firewall or a network device, such as a router, you may have to modify the configuration to allow your Rayplicker $^{\text{\tiny{TM}}}$ device or your Rayplicker $^{\text{\tiny{TM}}}$ mobile application to communicates with the Rayplicker $^{\text{\tiny{TM}}}$ software on your computer.

This operation is sometimes called "port opening".

Rayplicker[™] software needs the following ports to be opened:

(Mandatory for using Rayplicker[™] software)

Port 3306 (TCP)

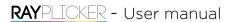
Rayplicker[™] mobile application «Rayplicker[™] Pics App Solution» needs the following ports to be opened:

- Port 7777 (UDP et TCP)
- Port 7778 (UDP et TCP)

Note:

Communications between the different elements of the RayplickerTM solution takes place on the local network. All the different elements of the RayplickerTM solution needs to be connected on the same local network.

If you encounter difficulties to configure your network, call your network administrator or your internet provider to open the ports above, used by the Rayplicker $^{\text{\tiny{M}}}$ solution.





16.3. 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.

16.4. Patents

Rayplicker™ is protected by the following patents:

France:

1556140; 1556141; 1651452

US:

14837,449

16.5. Warranty

The guarantees are specified in the terms of sale.

These can be found on the www.BOREA.dental (download tab)





NOTES:





BOREA SAS
12 rue Gemini
CIRE Bâtiment 3
87068 Limoges Cedex
+33 (0)9 83 71 71 61
contact@borea.dental