# pa–on

## Instructions for Use

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# 1. DEAR CUSTOMER

## 1.1. Prologue

The pa-on Parometer is state-of-the-art technology and has been produced in accordance with the strictest quality criteria. As we are constantly developing our products further, it is possible that the illustrations and drawings in this document may differ slightly form the product that you have purchased.

This instruction manual describes in detail the pa-on Parometer and its usage. If you have any additional questions or ideas, we would be pleased to help you by telephone or by email.

This manual accompanies the Parometer. Please keep them to hand. If you pass this product on to a third party, please give them this document too as it contains important information on commissioning and handling the product.

Please use these instructions to familiarize yourself with the product before you use it during treatment.

### 1.1.1. Copyrights and Trademarks

Microsoft®, Windows®, Windows XP® and Excel® are a registered trademark or a brand of Microsoft Corporation in the USA and/or other countries.

### 1.1.2. Responsibility of the Manufacturer

The pa-on Parometer and its equipment are manufactured in accordance with the state-of- the-art technology and the recognized safety-related rules and regulations.

orangedental GmbH & Co. KG [hereafter referred to as orangedental] only considers itself responsible for the effects on safety, reliability and performance of the device, if:

>> Assembly, add-ons, readjustments, alterations or repairs are only carried out by persons authorized by orangedental,

>> the device is used in accordance with the instructions for use.

### 1.1.3. Responsibility of the Operator

Among other things, the operator is responsible for:

>> adherence to the accident prevention regulations as well as the regulation concerning the installation, operation and use of active medical products (German regulation MPBetreibV);

>> the operation;

>> the maintenance;

>> the proper and safe condition of the product;

>> the storage of the instruction manual at the location of use;

>> following the safety instructions contained in these instructions (see chapter 1.3: Conventions, Symbols used).

### 1.1.4. Serious Incidents

A “serious incident” means any incident that directly or indirectly led, might have led or might lead to any of the following:

- the death of a patient, user or other person

- the temporary or permanent serious deterioration of a patient's, user's or other person's state of health

- a serious public health threat

All serious incidents should be reported to the manufacturer and the competent authority of the country. All communication methods are available for this purpose.

# 1.2. Contents

## 1.3. Conventions, Symbols used

In these instructions, the conventions set out below indicate important information:

**WARNING:** This symbol is used if deviating from the procedure described can lead to physical injury or death.

**CAUTION:** This symbol is used if deviating from the procedure described can lead to damage to the product or to loss of data.

**IMPORTANT:** The usage of the term **IMPORTANT**, formatted in bold capitals, provides instructions about the use of the device or a process.

**Note:** Notes are used to highlight important or unusual points.

The meaning of the symbols, which are used on this product, its packaging or in these instructions, is listed below:

**CHECK INSTRUCTIONS**

By labeling the product with this symbol, the manufacturer is pointing out that the instructions for use (i.e. this document) contain warnings and safety information which should be observed when the product is used.

**ATTENTION**

This term indicates that there are warnings or regulations concerning the product which are not specified on the label itself.

The device complies with ETSI EN 300 220 for so called SRD (short range device).

**APPLIED PART TYPE BF**

Level of safety against electric strike: Type BF.

**DO NOT REUSE**

It is a single-use product and cannot be reused.

**DO NOT RESTERILIZE**

The tips cannot be sterilized again.

**MANUFACTURER**

This symbol is used in order to display the name and address of the manufacturer of the medical product.

**DATE OF MANUFACTURING**

This symbol is used in order to display the date of manufacturing of the medical product.

**UDI-DI**

This symbol indicates the UDO-DI number and the GTIN.


**BATCH DESIGNATION**

This symbol indicates the batch designation.


**SUITABLE UNTIL**

Shows the date when the sterilization expires, given a storage as prescribed.

**SERIAL NUMBER**

This symbol is used to indicate the serial number.


**MEDICAL DEVICE**

This symbol is used to indicate that the product is a medical device.


**ALLOWABLE TEMPERATURE RANGE**

Only store the tips within the specified temperature range.

**DO NOT USE IF PACKAGING DAMAGED**

Do not use the content if the package shows damaging.

**CE MARKING**

This symbol, attached by the manufacturer, indicates that the medical product is in conformity with and fulfills all requirements of Directive 93/42/EEC 'Medical Devices Directive' and that the product has been certified by the Notified Body 2797.


The product utilises the transitional periods of Regulation 2017/745 MDR, Article 120 in accordance with Regulation EU 2023/607.

# 2. ABOUT THE PRODUCT

The Parometer is a tool to measure pocket depths and loss of attachment levels as well as all important values of peridontal findings.

## 2.1. Mode of Operation / Intended Usage

The pa-on Parometer in combination with the one time usable, sterilizable measurement tips is intended to measure the deep of pockets of teeth and attachment losses as well as the recording of other diagnostic findings during a periodontal examination by dental healthcare professionals (dentists, dental assistants).

Measured values can be read and documented manually or being transmitted wireless to a particular software. The byzzParo software is one of the possible software products indented for the recording, storage, archiving, visualization and documentation of such periodontal data.

The pa-on Parometer and the byzzParo software can be used in combination or as individual products.

There are no known contraindications for the use of the pa-on Parometer. There are no restrictions regarding the intended patient group.

### 2.1.1. Overview of the pa-on Parometer

With the pa-on Parometer measured values are read and written down manually or transferred to a specific software. byzzParo is one of the possible software solutions to gather, save, archive, visualize and manage periodontal findings.

It is also possible to use the pa-on Parometer with pa-on Transfer and a special interface to an accounting software.

The measurement tips are intended to use inside the patient's oral cavity and the measurement wire inside the gingival pockets. The probe's neck is intended to contact only uninjured mucosa.

**WARNING:** The measurement tips contain coated stainless steel wires. These contain nickel and could trigger an allergic reaction. Please ask your patients about a nickel allergy.

## 2.1.2. Equipment

>> pa-on Parometer
>> Docking Station with USB cable
>> set of sterilizable tips, single-use
>> Reference Scale
>> Instructions for use
>> Discharging magnet
>> pa-on Transfer CD

pa-on reference scale

Figure: pa-on in its docking station

## 2.1.3. Spare parts and Accessories

| | |
|---|---|
| zubpaon 0491040 | Hygienic Pouches for pa-on probe |
| zubpaon 0492000 | 10x pa-on sterilizable measurement tips |

# 3. INSTALLATION

## 3.1. Connecting the Parometer

You need a PC with correctly installed USB 2.0 interface and driver. If you are not sure, please read the PC manual.

Plug the docking station to your computer, using the supplied USB cable. Your PC will inform you by a message box that it installed a HID interface. Further input is not required. The docking station does not need a power supply; the second port is not used.


Put the probe into the docking station and leave it there until it is fully charged (green control lamp). If the probe needs recharging the lamp switches to red.

## 3.2. Installation of Software

If you use the byzz nxt software, please initially start the installation program of byzz nxt to install the enclosed software package. Otherwise continue with section 4: pa-on with your Accounting Software: pa-on Transfer

### 3.2.1. Requirements

Please note that byzzParo requires at least Windows 7 with SP1.

Requirement for pa-on transfer is at least Windows XP with SP3.

### 3.2.2. Installation of byzzParo

Please install the byzzParo software according to the enclosed installation instructions. After the installation of the .NET files, which may last more than 30 minutes, installation of the actual software will follow. You could accept the recommended directories or, if desired, adapt them to your directories.

To license the byzzParo software, please call the orangedental hotline (+49 (0) 7351 474 99 20).

### 3.2.3. Installation of pa-on Transfer

If necessary, install pa-on transfer. Please follow the enclosed pa-on installing instructions.

### 3.2.4. Configuration of Parometer Interface in Accounting Software

If you want to use pa-on Transfer, you have to activate the Parometer interface in your accounting software initially. Please follow the enclosed connection instructions.

# 4. PA-ON WITH YOUR ACCOUNTING SOFTWARE: PA-ON TRANSFER

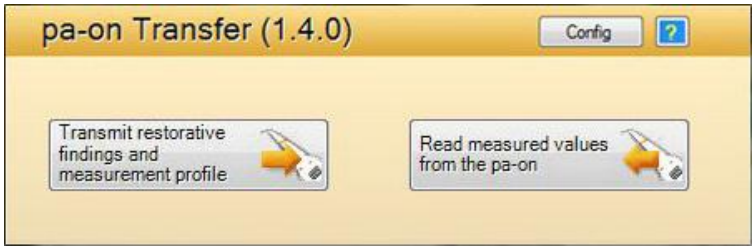
If your accounting software has an interface to the Parometer implemented, you can use the Parometer also without the byzz nxt or byzzParo software. Measurements will start directly out of the accounting software. Measurement process will be the same in both cases.

## 4.1.1. Installation of Parometer Interface in Accounting Software

If you want to use pa-on Transfer, you have to activate the interface in your accounting software. Please follow the enclosed instructions.

## 4.1.2. Using pa-on Transfer

Start your accounting program. Select a patient and start pa-on Transfer in your software.




Before you can begin the measurement, you have to define where and what to measure. Therefore click on the button "Config" and choose a measuring profile. For details read the chapter "Configuration".

Click the button to transfer the patient's data to the probe. Now the probe has a copy of the set of teeth and can skip missing ones.


Pull the probe out of the docking station and start the measurement. For more information on how to use the Parometer and its programs see chapter 6.3: Measurement Programs.

After completion of measurements, plug the probe into the docking station. Click on this button to transfer the data from the probe to your accounting software. Now you can work with the findings in your software.

# 5. MEASURING WITH THE PAROMETER

You can start measuring immediately after the installation.

## 5.1. Four Steps to Follow

Follow the next steps to measure with the Parometer in combination with byzzParo:

>> Select the patient and start byzzParo

>> Choose a profile and transfer the data to the Parometer

>> Use the probe to measure

>> Transfer the results to byzzParo

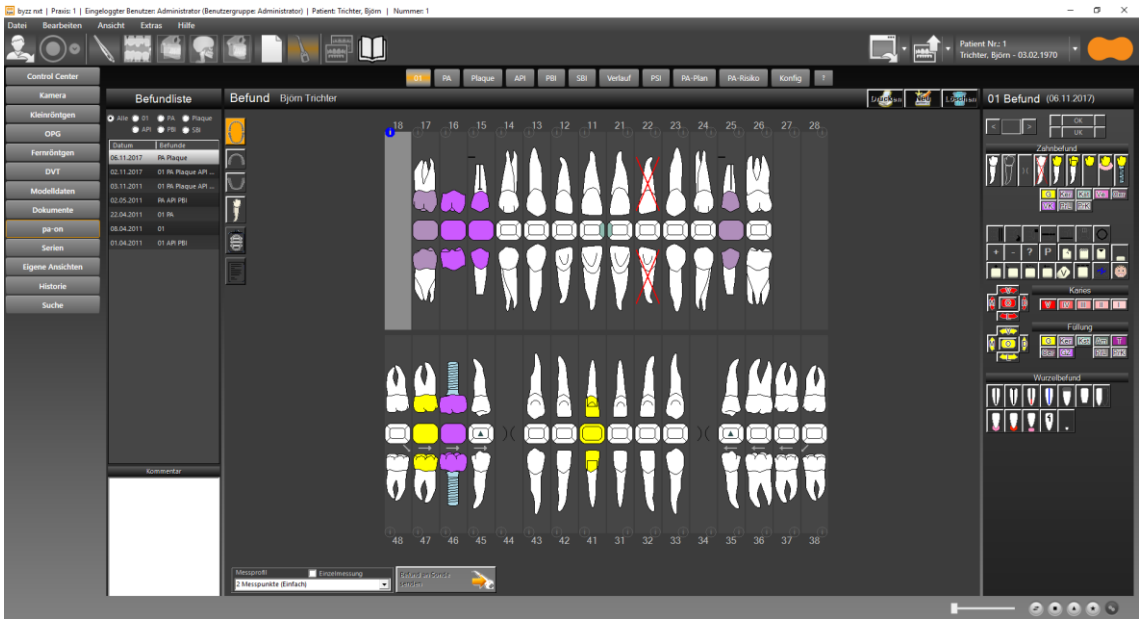
The paragraphs below show the four steps in detail.

### 5.1.1. Select a Patient and Start byzzParo

If your accounting program has an interface to the byzzParo module, select the patient for whom you want to record the periodontal findings. Then start byzz nxt.

If your accounting program does not offer an interface, just select the patient in byzz nxt.

Click the Parometer icon in byzz nxt to transfer the patient data to byzzParo.




Some dental accounting programs transfer both the patients' data and the dental examination. In this case, you do not need to add a new result and you can start measuring immediately. Otherwise, you should at least add simple findings.

**Add Restorative Findings**


Open the category "New" to add new initial examination results for your patient. To use the findings with the Parometer you only need a rudimentary result, just to let the probe know which teeth are missing. Click „New“ to enter the findings. If you want to add more detailed findings, select a tooth and add caries or fillings in different materials. You may even add a crown, a bridge or an implant. You find all details of how to work with byzzParo in the section 7: Usage of byzzParo.


Save the entry by clicking the corresponding button. The examination is inserted into the list of all findings of the current patient.

## 5.1.2. Choose a Profile and Transfer the Data to the Parometer

Before you start the measurement, you must define how to measure. The profile defines what to measure and the order. Choose a measuring profile from the pop-up menu below the notation. The default is the last chosen profile.

When you move the cursor over the selected profile, you see the settings of the current measuring profile.


If you have not defined any profiles yet, you can measure with the program's pre-setting. Or specify a new profile in the configuration category. To read how to add a new profile or alter an existing one, see chapter 7.9: Configuration.


Now transfer the examination results to the Parometer. This ensures that the probe only considers existing teeth for all inputs and measurements.

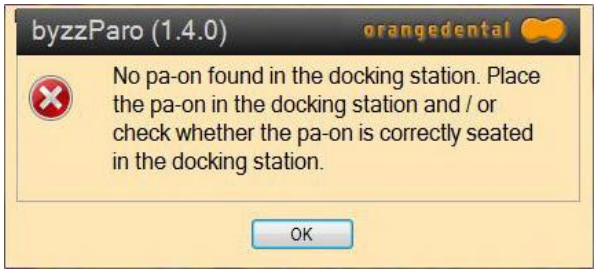
If the probe is properly connected, a message box shows a successful data transfer.

The transfer button turns green. If you do not want to see the pop-up message every transfer, deactivate the checkbox "Show every time".


When byzzParo switches to category "PA", you may start the measurement.

**Note**: If there are any problems with the connection, you get an alert box and the probe button changes to red.


Take the Parometer out of the docking station and plug it in again. Click „OK“ and then start the transfer by clicking on the transfer button.




## 5.1.3. Use the Probe to Measure

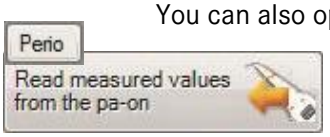
Now you may start the measurement. For more information on how to use the Parometer and its programs see chapter 6: Usage of the Parometer.

Afterwards, do not forget to plug the probe into its docking station.

## 5.1.4. Transfer the Results to byzzParo

Once you transfer the patient's data and the dental exam to the probe, byzzParo changes automatically to the category "Perio".

You can also open the Periodontal Category by clicking on the "Perio" button.




Click the button below the dental notation to read data from the Parometer.

>> A message box shows the successful transfer.

**Note**: If you do not want to see the message every transfer, deactivate the checkbox "Show every time".



After data recording, you can have a look at it in the respective categories of byzzParo.

You will find the explanation of each category and byzzParo in chapter 7: Usage of byzzParo.

## 5.1.5. Export Findings

**Note**: You can manage the findings in byzzParo. If your dental accounting program offers an interface to handle the data, byzzParo can make the data available to it.

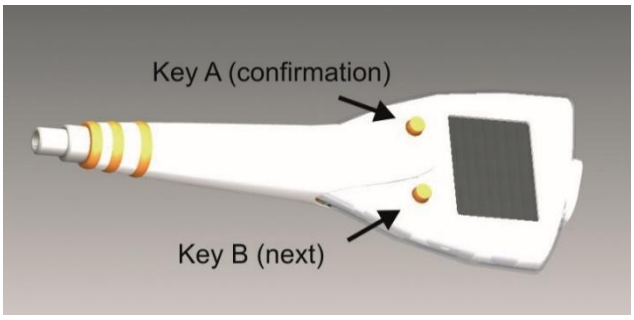

To transfer the data to your accounting program click the "Export" button. byzzParo writes the recorded measurement results into an export file. You can select an export format in „Config“. Your program then reads the file and you can work with the data.

# 6. USAGE OF THE PAROMETER

Switch on the probe by plugging it into a connected docking station. Transfer the findings and select the measurement profile to start probing. The measurement works pressure controlled and does not need a button to start.

## 6.1. The two Buttons

Probing is operated by two buttons:




**Note**: The buttons trigger different functions dependent on the program sequence, but are the same in the basic function.

**Button A:** Button A works like the return key, hence you confirm a selection or set the results.

Turn off the probe by pressing button A for 10 seconds and then releasing it.

**Button B:** Button B moves to the next selection or tooth or diagnostic point.

**In the main menu:**

**Button A:** starts the currently selected program

**Button B:** swaps to the next menu item

## 6.2. How to Measure

### 6.2.1. Data Transfer to the Parometer

Before you start measuring, you have to transfer the examination results to the Parometer (cf. chapter 5: Measuring with the Parometer). This way the probe knows which teeth are missing and can adjust for it.

Otherwise, the probe asks you to skip missing teeth by pressing button B. To avoid this, just create a simple rudimentary dental exam by removing missing teeth from the dental notation in byzzParo (cf. section 7.2.1: Input and Modification of Dental Exam Findings).


Click this button to transfer the data. You can repeat the transfer as often as you like. The probe deletes the previous dental exams.

## 6.3. Measurement Programs

Use the probe menu to select the measurement you want wo perform, for example pocket depths, loss of attachment, sulcus bleeding, plaque or tooth mobility.

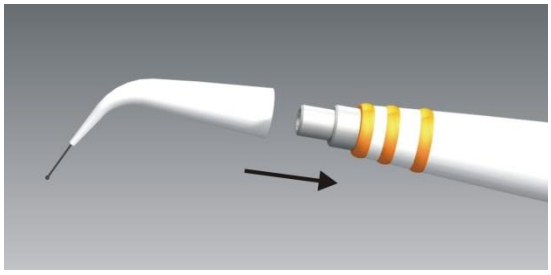
Button A starts the measurement and button B switches to the next measuring program. The program symbols are shown on the display.

### 6.3.1. Pocket Depth

Select this program to measure the pocket depths, and if chosen, the loss of attachment and the BOP Index. Confirm with button A.

Now you will be instructed to calibrate the probe. Attach the plastic sheath by pushing it as far as possible onto the probe. The plastic should reach the orange rings.

**WARNING:** Do not touch the sterilized, sterile tip.



Calibrating the zero position: Gently push the thin metal probing needle into the plastic sheath until it stops. Be careful not to bend or twist the needle. This might happen on very smooth surfaces.

Wait a moment until a beep signals that the calibration is completed.

Now you can let the needle slip slowly back out of the plastic sheath.

The first measuring position is shown and announced. The default measuring starts with the upper arch at tooth 18 buccal and continues up to tooth 28. After that palatal 28 to18, then 38 to 48 buccal and finally 48 to 38 lingual. You can alter the order of the measurement (see 7.9: Configuration in byzzParo).

The measuring point is shown as a purple point.
This is the upper jaw, tooth 28 (US 16) mesial palatal

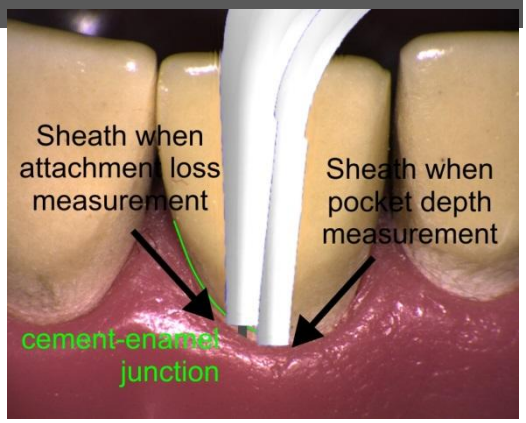
This is the lower jaw, tooth 38 (US 17) mesial lingual

Slide the metal probing needle into the pocket and press the rim of the plastic sheath gently to the gum. Wait a moment quietly until the probe beeps (or tells you the value). The probe will continue to show the result until you pull it out of the pocket.

The probing needle must slide smoothly into the plastic sheath. If you have to press with more than 20 to 30 grams, you should control the correct function of the probe outside of the pocket. If necessary, replace the needle or put the Parometer out of service.

### 6.3.2. Attachment Loss

You may measure the loss of attachment, if you chose “Attachment Loss” and ticked the check box “Attachment loss measured”. Do not fully remove the measuring needle after the pocket depth measurement, but only pull out the sleeve slightly (2-3 mm). The Parometer shows a green measuring point on the display. Adjust the plastic sheath until it is at the CEJ (Cemento-Enamal Junction). Wait a moment until the current measured value is stored automatically and then pull out the needle. The program jumps to the next measuring point.



If you chose “Recession” and “Recession measured directly” in the configuration category, the recession is calculated with the measured attachment values.

### 6.3.3. Bleeding on Probing

After pocket depths have been recorded, you can start to enter the bleeding. If you selected BOP to be measured, all measuring points are shown again on the probe as a red circle.

If there is any bleeding, press button A and then button B to get the next measurement point. If there is no bleeding, you skip the tooth via button B.

If you want to repeat a measurement, press button A for about 0.5 to 1 second.

**Button A short push:** set/remove bleeding

**Button A long push:** one tooth back

**Button B:** forward to next measuring point

### 6.3.4. Papillary Bleeding Index

Measure the papillary bleeding

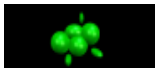
To measure papillary bleeding, press button A to advance the index by one position. Index zero shows no bleeding, grade 1 displays a red point, grade 2 a red line, grade 3 a filled triangle and grade 4 a big drop of blood. Button B jumps to the next tooth.

**Button A short push:** bleeding incremented by one, then back to zero

**Button A long push:** one tooth back

**Button B:** forward to next tooth

### 6.3.5. Plaque Index



With this program you can measure the Plaque Index.

If you chose API (Approximal Plaque Index) in the configuration category, for each tooth you may set the plaque as Yes/No. If you chose PCR (Plaque-Control-Record), the probe asks for plaque on distal, buccal, mesial and lingual surfaces. Button A sets or removes plaque, button B goes further on to the next tooth or next surface.

**Button A short push:** set/remove plaque

**Button A long push:** one tooth back

**Button B:** forward to next tooth or next surface

### 6.3.6. Mobility and Furcation

Here you measure mobility from 0 to IV and furcation degrees from 0 to 3.

Press button A to advance the mobility degree by one position. The value is shown by roman numerals I-IV (excluding zero). Grade I means perceptible mobility, grade II is visible up to 0.5 mm, grade III is up to 1 mm and grade IV means very loose.

If the tooth has several rooths, the furcation is measured afterwards. Press button A to advance the furcation by one position (1 to 3). Press button B to jump to the next tooth. Furcation grade F1 is a furcation up to 3 mm, F2 more than 3 mm and F3 means the probe passes completely through the furcation.

**Button A short push:** increment mobility degree from I to IV, then back to zero

**Button A long push:** one tooth back

**Button B:** forward to next tooth

## 6.4. Transfer Results to byzzParo

To transfer the measured data to byzzParo plug the probe into its docking station. If you did not choose a patient before, do it now in byzz nxt.

Select category “Perio” if necessary and then click on the button to transfer the data. After transfer, the probe deletes the findings in the probe. The findings are shown in the dental notation.


## 6.5. Turning off the Parometer

You can turn off the probe by pressing button A for ten seconds and releasing it.

The probe turns off automatically when left in the docking station without power or when it has not been used for more than 30 minutes. When the docking station gets power again, the probe turns on.

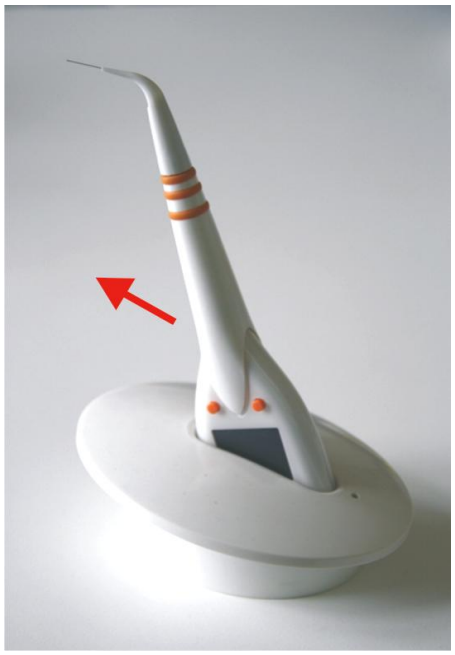
If there is any data left in the probe, it remains on unless the battery is empty, so that no measurement gets lost. Please do not leave findings in the probe, always transfer the last measurement data to byzzParo. Otherwise, the next day you will have an empty battery and will have to recharge the probe.

## 6.6. Charging the Parometer

When the Parometer is not in use, please always plug the probe into the docking station. The station controls the battery and recharges it. This only works if the station is connected to a powered on PC.

Please plug the Parometer into the docking station only as shown, facing away from the small lamp. Otherwise the station does not recognize the probe and the Parometer cannot be recharged.

A tiny icon on the display shows the charging state. The recharging of an empty probe takes about 1.5 to 3 hours. If one day the recharging does not work anymore, send the probe back to the manufacturer. It is not possible to change the battery by yourself.

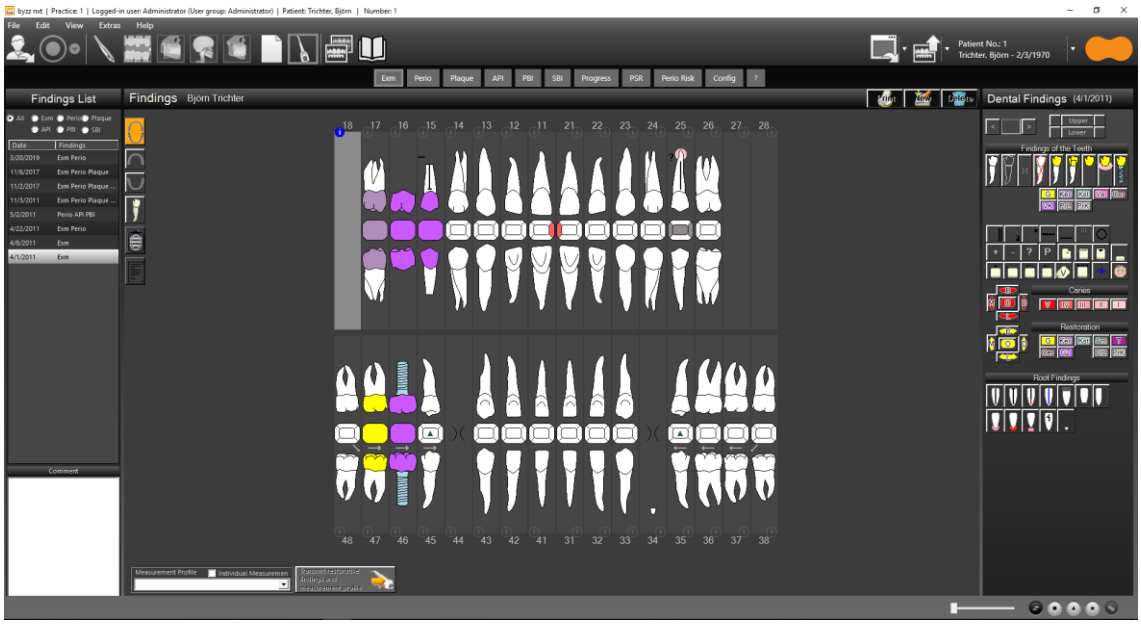


## 6.7. Storing the Parometer

If you do not use the probe for a long time (longer than 3 to 4 weeks), you should store the Parometer in its original package. There the Parometer is disconnected by the embedded magnet. Otherwise, there can be total discharge because the Parometer would stay on standby and requires minimal energy.

# 7. USAGE OF BYZZPARO

byzzParo can be used as a tool to manage and analyze the data you get from the Parometer. byzzParo is divided into categories. Category "Patient" manages the patient's data. "Exm" displays the restorative findings. "Perio" to "SBI" show the results of the indexes and pocket measurements. "Progress" and "Perio Risk" show analyses of the findings. In "Config" you can customize the program to your daily routine.





In general, these buttons have the same function in every category.

Please note that not always all control buttons are visible. For example, it is not possible to export dental examinations.


If your dental accounting program has an interface to byzzParo you can export the findings easily via this button. All data is written in an export file and your software reads the file so that you can manage the findings just as you are used to. You can select an export format in „Config“.

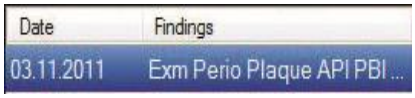

Click on this button to print out the current findings and the notes.


To create a new finding click on this button. Then enter the dental findings.


Click "Save" to save the new entries or the modifications you made.

The new input will be added to any other finding of today.

If you have just added a new dental examination, the newly entered periodontal data is saved along with it: "...Exm Perio". If you afterwards determine API, the entry in the list would read "...Exm Perio API".




If you changed the finding inadvertently you can return to the former finding by clicking on “Don't save“ in the message box.


You can delete findings. Be aware that it is not possible to restore any deleted findings. If you are sure you want to remove the data then confirm the deletion in the alert panel. Here you decide what data shall be removed: only the currently open finding, for example perio, or all connected findings, like the dental examination.

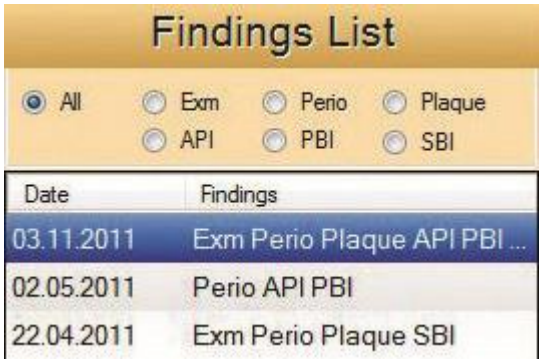
**Note:** Please note that not always all control buttons are visible. You only can "Save" findings if there are modifications or "Delete" findings after saving them.

### Findings List

Click on check box “All” to see a list of all findings of the current patient. The list is sorted by date and shows all conducted measurements per date.

In this example list, you see on November, 3, an entire examination with the dental exam, the periodontal exam and several plaque findings. In May, there was a periodontal examination and an API and a PBI session.

Tick one or more of the check boxes to choose which findings should be shown in the list, for example only entries which include periodontal findings. The list arranges the results according to their date.




The list remains visible even if you switch to another category. Beneath the list you can add some notes. These notes are valid for all findings, independent of the date and category. The printouts of the findings always include these notes.

## 7.1. Choosing a Patient

Before you can start working with byzzParo you must choose a patient in byzz nxt or in your dental accounting program. The measurement and the management of the findings are linked to the patient. The heading shows the patient's name and date of birth.


To switch to another patient just click on the "Open patient" button and choose a patient in byzz nxt or your accounting software. Then, reopen byzzParo by clicking on the probe symbol.


Via this button, you return to byzz nxt.

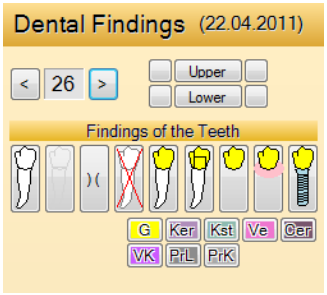
## 7.2. Dental Examination


In this category you see the comprehensive dental exam with charting of the current patient. The heading shows the patient's name.

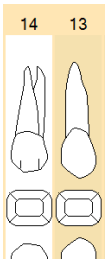
Besides the patient data, many dental accounting programs offer the possibility to export the examination result of the patient to byzzParo. If you use the Parometer without or independent of an accounting program, you may edit the findings of your dental examination in this window. Please note that it is not possible to export the restorative findings to your accounting program.

### 7.2.1. Input and Modification of Dental Exam Findings


You add new examination results plus the current date to the list of findings with "New".




Then you can insert the findings using the buttons on the right.




Choose a tooth in the dental notation by clicking it. The tooth will be highlighted.


*Tip:* You can also select a tooth by using the arrow keys or the space bar.


A click on the corresponding button highlights the upper or lower jaw or selects one of the quadrants. For example, click on the upper left box to highlight the first quadrant.

## 7.2.2. Examination Results


If one or several teeth are selected, you can enter the findings by clicking on the respective symbols or keying in the shortcuts. When you move your mouse over a symbol, you get more information. To undo any entry, click on the symbol on the left.

The symbols (with shortcuts):

| | |
|---|---|
| NAD | (ESC) |
| missing tooth | (x) |
| missing tooth closure | (8 or 9) |
| extraction | (⇧ x) |
| crown | (c) |
| telescope crown | (t) |
| bridge | (b) |
| prosthesis | (p) |
| implant | (i) |

## 7.2.3. Material

You can choose the material before or after the examination. It is possible to change a golden crown to a ceramic crown and vice versa. Using the keyboard, you key in "c" and then "g" to get a golden crown. Some materials must be set by mouse-click.

Use the following shortcuts:

| | |
|---|---|
| Gold | (g) |
| Ceramic | (e) |
| Plastic | (s) |
| Veneer | |

Cerec
Full Ceramic
Long-term Provisional
Short-term Provisional

The materials can be configured or new materials can be added; see Section 7.9.11: Configuration Crown material.

### 7.2.4. Further Findings

Additionally, there are several more findings you can add to your dental notation, for example attachment, ligament, root rotation or tooth contact. When moving the mouse over a symbol you see the explanation.

Enter attachment, brackets and blocking by clicking on the respective buttons. After the first click, the symbol is inserted on the left of the tooth. Click again to move the symbol to the right. A third click adds the symbol on both sides. Finally, click again to remove the symbol.

Example: 

By means of these buttons, you add a ligament or a splint. A second click removes the symbol.

Click on this button to add an orthodontic band. A second click removes the symbol.

Example: 

You may add braces by clicking this button: first click – front part of tooth, second click – lingual part, third click – both, fourth click – no braces at all.

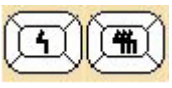
Example: 


To add a symbol for vitality just click the buttons "+" or "-", or in case of indeterminate vitality click "?". The symbols are shown to the left of the root in the dental notation. In case of percussion click on "P" to insert "P" to the right side of the root. A second click removes the entry.

Shortcuts vitality:

| | |
|---|---|
| vitality + ... | (+) |
| vitality - ... | (-) |
| vitality ? ... | (?) |

If there is a tooth fracture, you can add the symbol via this button. A repeated click sets the degree of the fracture (1 to 3). A fourth click removes the symbol.

Example: Fractures degree 1 and 3 

Add an abrasion or a defect by clicking the respective button. A further click removes the symbol.

Example: 

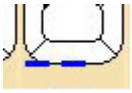
Add the cutting of a tooth by clicking this button. A repeated click sets the degree of the cutting (1 to 3). A further click removes the symbol.

If you want to indicate a high or low position of a tooth or a tooth angulation you can add an arrow. The first click displays the arrow in grey, meaning a slight dislocation, a second click displays it in black for a severe dislocation. The next click reverses the direction. Click again to remove the arrow.

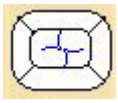
Example: 

If there is a shifted tooth, you can add this information by clicking this button. The tooth will be marked with a V and displayed grey. A further click removes the symbol.

To visualize a contact, click this button. Click repeatedly to insert the symbol (seven possibilities): first click indicates contact on the left, then center, then right then left+middle, then left+right, then center+right and finally left+center+right.

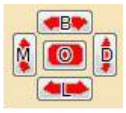
Example: 

A complete fissure sealant is shown by a black symbol. If it is defective click the button again to change the color to blue or red. A fourth click removes the symbol.

Example: 

You may change permanent teeth to deciduous teeth. Highlight a tooth and click this button. A second click changes to permanent tooth.

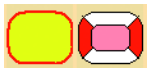
## 7.2.5. Caries




Highlight the tooth and then choose the caries class (I to V) which is shown in different shades of red: the more caries the darker red. Now click the position of the cavity in the icon. To remove the entry just click once again.

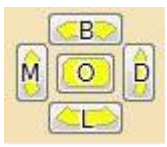
Shortcuts:

Key the caries classification (1 to 5) and then the shortcut for the position. For example enter "3" and "⇧ d" to get distal caries class 3. Alternatively, you can enter “⇧ c” to mark the whole tooth as decayed. A further enter of “⇧ c” deletes the decay.

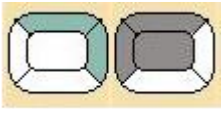


To add marginal caries, click in the center of the tooth “⇧ o”. A further click removes it. Marginal caries with restorations are set for each position. Marginal caries is shown as red circle – independent from caries class.

## 7.2.6. Restoration




To enter fillings, highlight the tooth, select the material and then click the position of the filling in the icon. Click once again to remove the filling.

Example: 

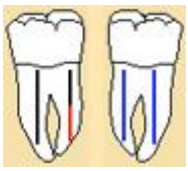
When using the keys you type in the material and then the position: for example a buccal plastic filling is added by keying in "s" and then "⇧ l".

The materials can be configured or new materials can be added; see Section 7.9.12: Configuration Fillling Material.

## 7.2.7. Root Treatment

There are several symbols to add root findings. Highlight the tooth and then click on the respective button. The findings for multi-root teeth are inserted by clicking the respective button repeatedly: The first click selects all parts of the root, the second click only one part etc.

To add a root filling or an endodontic post, select the tooth and click on the button. If the root filling is insufficient, you first add a root filling and then click the button to show the tip in red. The next button inserts a temporary root filling in blue.

Example: 

The symbol for a root cap and a root resection are set by clicking on the respective button. A second click removes the symbol. Repeated clicks on the symbol for hemi-section remove root by root.

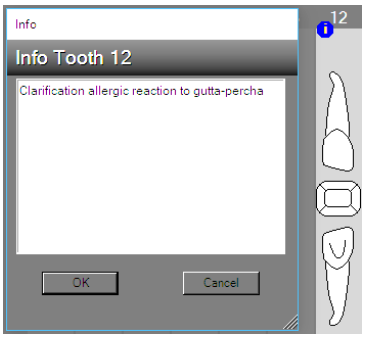
Example: 

You can add an apical lesion or a cyst with these buttons. A second click removes the apical lesion or cyst. In this cases and for fractures of multi-rooted teeth click to move to the next root. A further click removes the symbol.

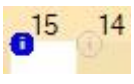
Example: 

## 7.2.8. Tooth Info


You can add information to each tooth. To do this, click on the small "i" next to the tooth number.




Now type in the desired text and click on "OK".




Now you can always access the text by clicking on the blue "i", even in the periodontal or plaque tooth scheme.

### 7.2.9. Display upper / lower Jaw

By clicking on this button, the upper and lower jaw are displayed. This is the basic setting.

By clicking on this button, only the upper jaw is shown. The display is enlarged and therefore the legibility is improved.

By clicking on this button, only the lower jaw is displayed.

### 7.2.10. Clipboard

You can copy the findings to the clipboard as an image. Click this button to save the current findings to the clipboard.

### 7.2.11. Patient letter

Clicking this button opens a window for selecting a text template or text modules. Depending on the template, the corresponding data and images are inserted directly into the letter. For further information, please refer to the byzzParo online help for text templates and text modules.

### 7.2.12. Window Size

Since the findings in the periodontal area are very extensive, you can hide the navigation bar on the left for better readability. To do this, click this button at the bottom right. Click the button again to display the navigation bar again.

### 7.2.13. Measuring Profile

The number of measuring points and the way to measure are defined in the measuring profiles. Choose one of the profiles from the pop-up menu.

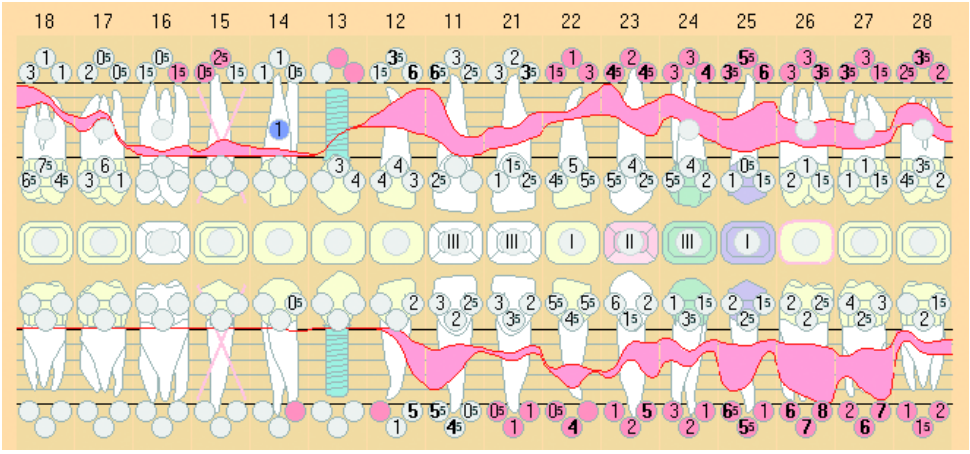

See chapter 7.9: Configuration on how to add new profiles or alter existing ones. You can create as many profiles as you need and then choose one out of the pop up menu before measuring.

### 7.2.14. Transfer Data


You can use the Parometer without any predefinitions. But if there are any missing teeth it is easier to transfer the dental findings to the probe before measuring. Thus, you do not have to skip missing teeth during measurement. Missing teeth are removed from the dental notation as described above.

## 7.3. Periodontal Findings

After the successful transfer the dental notation shows all periodontal findings. Pocket depths and recession are displayed graphically. The pocket depth values are shown in the measuring points and likewise graphically as "pockets" in the dental notation. Bleeding points are displayed as red-coloured pocket depths points. The values for mobility degree are shown in the center of the teeth as roman numerals. The dental notation displays the furcation as a purple circle in the upper root area (tooth 14 in the picture below).

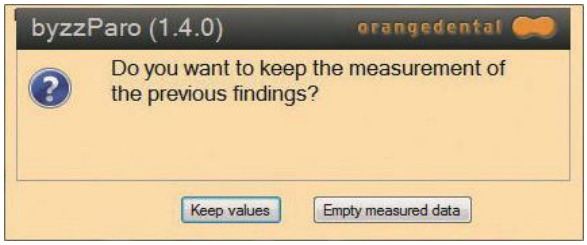



### 7.3.1. Entering Periodontal Findings Manually


By using the Parometer, you do not need to enter the periodontal findings manually. But it is still possible to add some or change the findings, if you wish to. The plaque index SBI has to be entered manually.


Click the "New" button to add new periodontal findings. If you have already generated a dental examination today then the new periodontal findings are added to it, for example "Exm Perio Plaque ...". Otherwise a new line will be added to the list of findings.

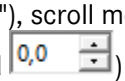
If you want to add or alter only some of the values, you can use the values of the previous finding. Otherwise you can start with a blank dental notation. Click on the respective button in the message box.





If you have not used the Parometer to record measurements, you have to select a measurement profile now to define the number of measuring points in the dental notation.


Select the tooth in the dental notation or via the buttons on the right.

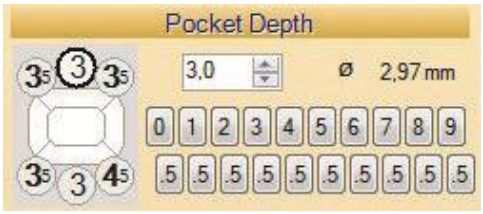
Enter the values by keys (and "Return"), scroll mouse wheel in 0.5 steps (hold the mouse pointer directly over the respective input field 

) or click on the appropriate button. Via keys you can even add values in 0.1 mm increments. The findings, besides zero, are shown in the measuring points near the teeth.

The teeth are selected according to the settings in the preferences (see chapter 7.9: Configuration). With "Return" you skip the next tooth.

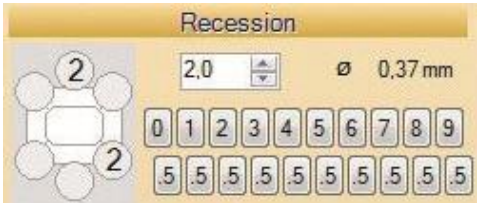
### 7.3.2. Pocket Depth

You may add pocket depth values directly. Select a tooth and then click on the measuring point in the notation or in the icon on the right. Depending on the number of measuring points enter two to six values per tooth. The findings are additionally shown graphically in the dental notation as red "pockets" depending on the recession.




### 7.3.3. Recession

Recession values are entered the same way as the pocket depth values. Please note that the values for recession are only displayed when you click the corresponding check box in the configuration category ("Config").




### 7.3.4. Attachment Loss

If defined in "Config", you can switch between recession and attachment by clicking on the title "Recession". The dental notation then shows the loss of the attachment level. Please note that the measurement values are only displayed when you click the corresponding check box in the configuration category ("Config").


### 7.3.5. Bleeding on Probing

BOP values are entered with keys ("+" or "-"), by scroll wheel, by clicking on the symbols or by right-clicking on the point. Bleeding points are displayed as red-coloured pocket depths points.

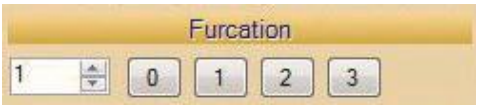
Pus or bleeding with pus can also be entered using the corresponding buttons. This is indicated by a green or green-red circle.


### 7.3.6. Mobility Degree

Enter the mobility degree by mouse or keys. The values are shown in the centre of the teeth as roman numerals.


### 7.3.7. Furcation

To add furcation just select the tooth and enter the values 0 to 3. The dental notation displays the furcation as a purple circle in the upper root area.



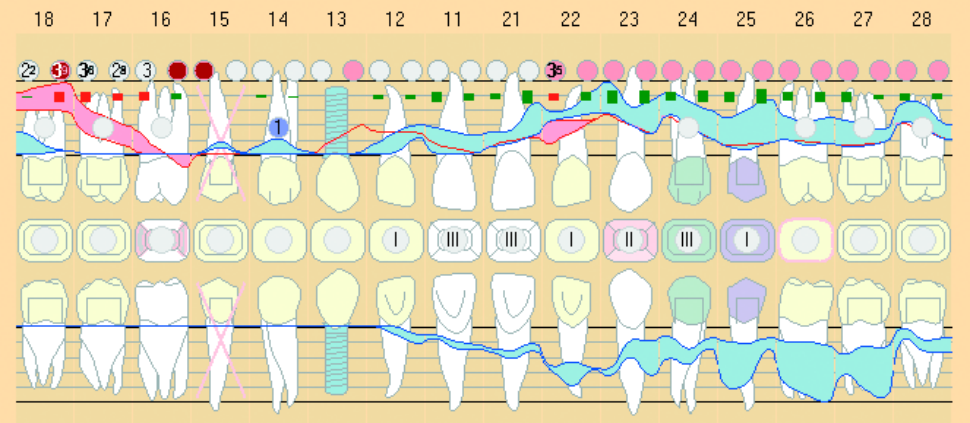
### 7.3.8. Comparison

You will find a list of all previous findings on the right. The list shows the degree of pocket depths, the recessions, the attachment losses and the BOPs as percentage.

Comparison

| Date | PD | RC | AT | BOP |
|---|---|---|---|---|
| 03.11.2011 | 2,97 | 0,37 | 3,34 | 4% |
| 02.05.2011 | 3,15 | 0,38 | 3,54 | 13% |
| 22.04.2011 | 3,44 | 0,39 | 3,83 | 22% |

Click on one of the previous findings to see the changes compared to the current results shown in the notation.




**The changes are displayed as follows:**

**Perio** (graphically)

| | |
|---|---|
| blue: | previous findings |
| red: | current results |
| red bar: | worsening |
| green bar: | improvement |

**BOP** (points)

| | | |
|---|---|---|
| | white: | still not bleeding |
| 6 | light blue: | no longer bleeding or no longer pus |
| | light red: | still bleeding |
| 4 | dark red: | new bleeding |
| 3 | green: | still pus |
| 3 | dark green: | new pus |

## 7.4. Plaque

Plaque

You may add or alter the plaque index manually for each tooth.

New

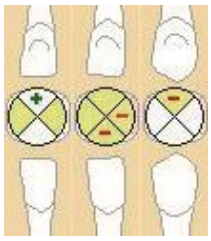
Click on the "New" button to add a plaque index. The index will be attached to today's findings, if there are any. Otherwise, a new entry will be added to the list.

### 7.4.1. Modifying Plaque Findings

Select a tooth in the dental notation or start with the first quadrant. Use keys ("+", "-" or "1", "0"), the scroll wheel or the mouse to add plaque. Tip: Alternatively, you can insert plaque via the right mouse button. Measurement starts in the first quadrant and asks for values in four measure points. The display shows the plaque values and the average plaque index of all teeth.


### 7.4.2. Comparing Findings

When saving findings, the results are included into the list of comparison findings. If you click on one of the previous findings, you see the changes between now and then.



green +: improvement, less plaque
red - : worsening, more plaque

## 7.5. API, PBI, SBI


Just as the periodontal results, the API and PBI findings are imported after probing with the Parometer. If needed, you can add and modify the findings directly.


Click the "New" button. If there is already a dental exam today, this new finding will be attached to it. Otherwise, a new entry is added to the list.

### 7.5.1. Modifying API, PBI, or SBI Findings

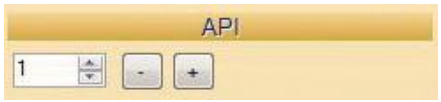
Select a interdental space or a tooth (for SBI) in the dental notation. You can use the arrow keys left/right or the spacebar to move to the next tooth in the arch. To move to the other arch press the up/down keys. Missing teeth are displayed as a little dot in the table.

All values are entered per session.

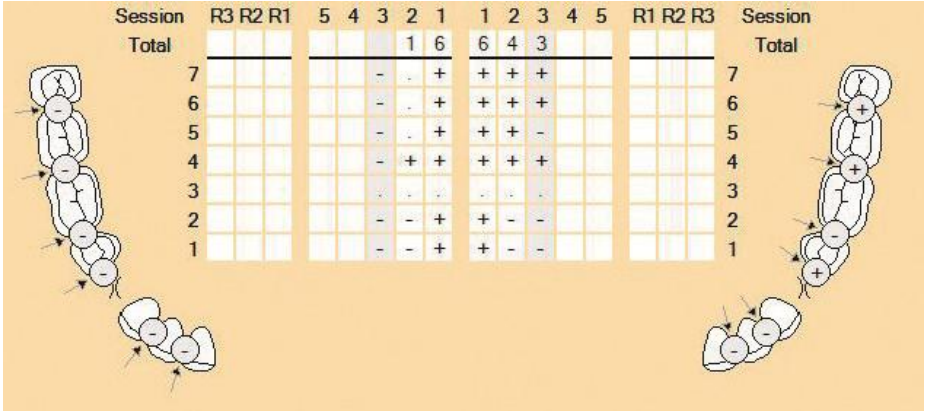
#### API


Enter the values by using either a keyboard ("+", "-" or "1", "0") or mouse-click on the respective buttons (“+”, “-“).

By using the scroll wheel, click on the next point after entered the value or accept the value by clicking next to the measuring point.




Each column in the table represents one session. The current session is coloured in grey. Plaque is marked with “+”, if there is no plaque a “-“ is displayed.

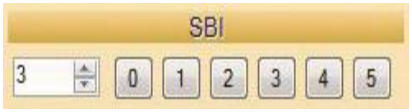


### PBI


Click on the interdental tooth space in the graphics or the table. Now you can insert by mouse, keyboard, or the scroll wheel (confirming with "Return" or clicking the next gap) the occurring bleeding with numbers 0 to 4.

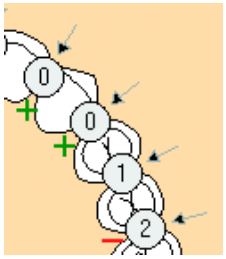

### SBI


Similar to the PBI, you set the values 0 to 5 for the SBI. Please note, that the SBI is not measured with the Parometer.




## 7.5.2. Comparing Findings

By clicking a result in the list, you can see how the current result differs from former findings. A red minus points out a worse result, a green plus means improvement. The size of "+" and "-" shows the degree of worsening/improvement.




| | |
|---|---|
| green +: | improvement |
| red- : | worsening |

# 7.6. Progress

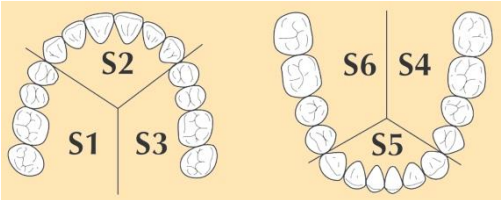

Under this category, you can see the progress your patient has made up till now. You can compare different findings. The charts show progress during a given time, from the first measurement up till today. Each chart shows one kind of finding.


Choose the measurement by ticking one of the upper check boxes. You can print the progress charts together with the notes you added to the findings.

# 7.7. Periodontal Screening and Recording (PSR)


The PSR uses codes 0 to 4 to indicate how far periodontitis has progressed and whether there is a need for action. The findings are collected with the periodontal probe and then read in to visualize the PSR.

The PSR divides the teeth into sextants S1 to S6. For each of the sextants there is a measurement value from the probe. The highest measured value of the teeth assigned to the respective sextant is taken over as PSR.




## 7.7.1. New PSR Finding with Probe


To determine the current PSR, first transmit the dental exam to the probe. This ensures that the probe only measures existing teeth.

Now you can perform the measurement.

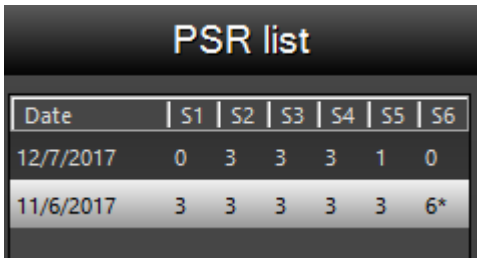

Finally, read out the measured values from the probe.

| S1 | S2 | S3 |
|---|---|---|
| * | 3 | * |
| S6 | S5 | S4 |
| * | 3 | * |

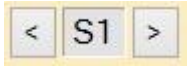
The new findings are entered in the list of PSR findings.

## 7.7.2. New PSR Finding without Probe

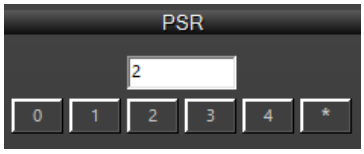

Click on the "New" button to determine the PSR from the last finding. The PSR result will be added to the list on the left. In this list you will find all PSR, sorted chronologically.



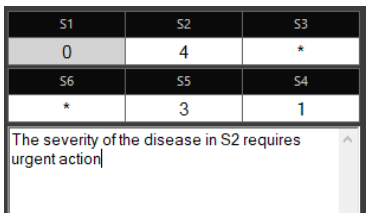

## 7.7.3. Manual Input




If you want to change a value directly, click with the mouse on the corresponding sextant in the table and type in the new value. You can also use the arrow keys to move forward and backward in the table.



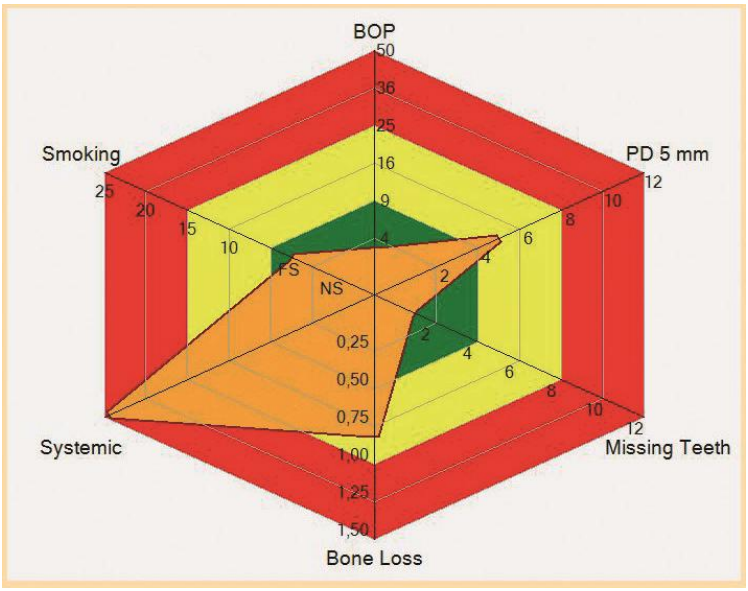

You can also click the input buttons to select a sextant and enter a value. The possible input values are explained in detail on the right side.




In addition to the values, you can also add a findings text, which is also printed out.

## 7.8. Perio Risk


Here you can see in bright colors the more or less strong risk areas. The orange color shows the personal risk of the current patient determined upon the detected findings.





Below the graphics you will find the risk rating. Here you may add notes.

### 7.8.1. Risk Factors

The first four risk factors are determined by the recorded measurements. When you record a new measurement you must generate a new risk report by clicking on "New". Add more factors by ticking the check boxes.

For smokers, add the number of cigarettes they smoke daily. The default values are the ones of former risk factor evaluations.



### Comparison

When you evaluate the risk, the data is written into the list for comparison. To compare one of the entries with the current risk just click on the entry.


You can print the graphical risk report by clicking on this button.

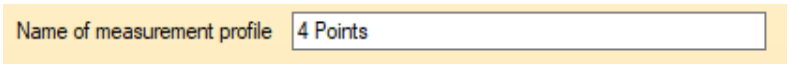
## 7.9. Configuration

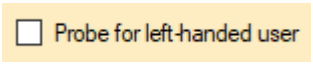
### 7.9.1. Measuring Profiles


In this category you customize byzzParo. Here you define the measurement profiles. Each profile sets the position and the number of measuring points. You can choose six, four or two measuring points.

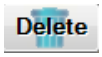
#### Creation of a new profile


To create a new profile, click the "New" button and then enter a title.



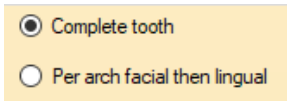

Click this button to adapt the probe to a left-handed user and reverse the buttons.



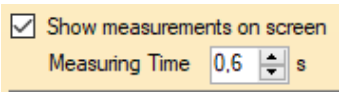

Click this button, if you want to delete the selected measuring profile


If you made any changes in a new profile, the button “New” switches to “Clear”. Click this button if you want to clear all settings. Now you can enter the new profile.

#### Measuring of Pocket Depth




Define how to measure each tooth: completely at one time or per arch starting with each tooth facial then lingual.

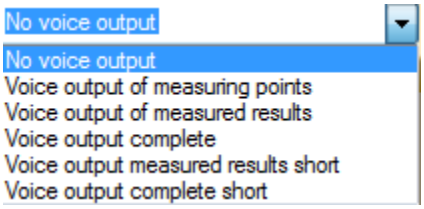



If you want to have byzzParo display the measured values during measuring (see picture below), click this button. You can also set measurement duration.

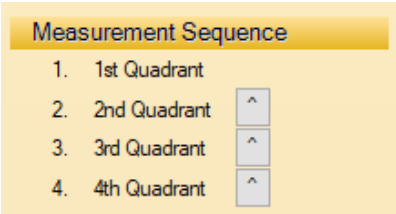
**Note**: The measuring time is determined by how much time you wait until the measure value will be recorded. If the value changes within this period of time, then this value will not be recorded.


#### Voice Output

byzzParo offers the possibility to hear the results of your measurement. byzzParo may tell either the position of the tooth, only the value measured or both. The “... short” voice output omits the decimals.



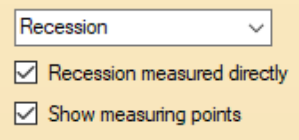
### Measurement Sequence




You may choose the order of measuring the quadrants. The default is starting with quadrant I to IV.

Click on the buttons to swap the order of one quadrant with its neighbour above.

### Recession or Loss of Attachment

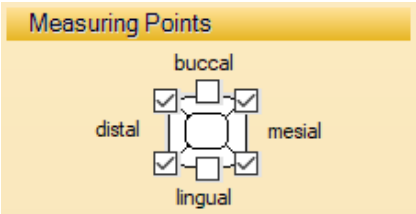



Decide if you want to record values for recession or for attachment loss. Choose the desired entry from the pop-up menu. If this measurement is to take place directly after the pocket depth measurement, check the box "Measure recession (or attachment loss) directly". If recession is chosen, it will be calculated with the measured attachment loss and pocket depth.

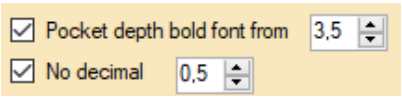
You can also tick the checkbox if you would like measuring points to be visible in the dental notation.

**Note:** In pa-on Transfer there is no configuration “Show measuring points”.

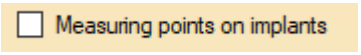
### Measuring Points




Set the number and position of measurement points. You can choose up to six points. Tick the respective check boxes for what points you would like to measure.

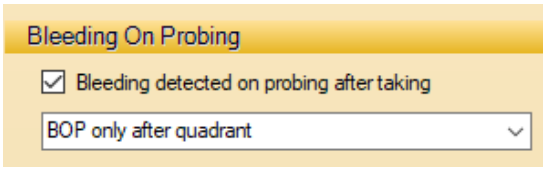



Here you decide if you want to print the pocket depths in bold, if the values should have decimals and when the values should be rounded up.




To measure values also on implants just tick the check box.

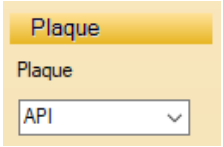
### Bleeding



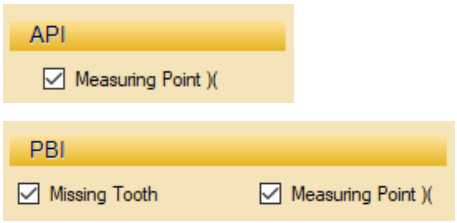

If the check mark is set, you can enter the bleeding values directly after the measurement of the pocket depths. Here you define when you want to record bleeding. You may enter the values for each measuring point either

- directly after measuring the pocket depths per surface
- after measuring a whole quadrant
- or just entering "Yes/No" after measuring the tooth, independent of the surface.

### Measurement of Plaque




Decide what you want to measure: API between teeth, or PCR on surfaces.




Tick the check boxes if you want to measure all surfaces, also around missing tooth closures ")(" or at the papilla to a missing tooth.

### Saving the measurement profile


Save the new or altered profile by clicking on the Save button. Now you can choose this profile in the pop-up menu.


If you want to discard your entry and return to the last saved data click on "Back". You can return your last saved settings by clicking „Save“ and then clicking on „Discard“ in the message box.

## 7.9.2. Probe Status

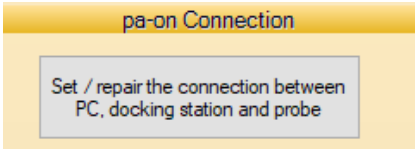

On the right panel, you get information about the probe status and docking station.

The example shows that probe named "Probe Blue“ with serial number 0210 is in its connected docking station. It is ready to begin the measurement.

You may define this profile as your default setting. This profile will be used when working without having transferred patient findings.

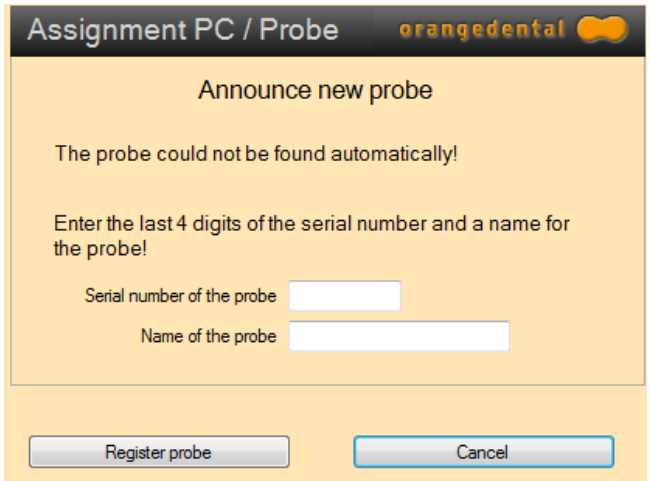
## 7.9.3. Connecting Probe and PC

If you are using several probes, you must tell the computer which one to use. To add a new probe, you have to connect the probe to the computer, too.




Click on the button to connect the probe. byzzParo starts to look for the docking station. If the probe has been detected, you have to click “Use new probe” in the message box.

**Note**: If there is a new probe in the docking station, the following message box opens:




Please enter the serial number and a name and then click on "Register probe". Now you can use the new probe.

**Possible problem message boxes**

“Docking station has not been detected“ or “The docking station contains no probe”. Please follow the instructions of the message boxes and then click on “Repeat”.

## 7.9.4. Renaming the Probe

If you want to rename a probe, the docking station must be plugged into the computer and the Parometer must be in the station.


Click on this button to connect the probe and click on "Rename probe" in the opening window. In the next message box, you can enter the new name and finally click on “Rename probe”.

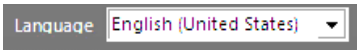
## 7.9.5. Export

After measurements are taken, the data is transferred to byzzParo. If you want to use the data with your accounting software, you must export the findings whereby byzzParo creates a file that can be read by your software.


There are the following export file formats to choose from:

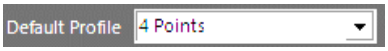
- CSV orangedental
- XML orangedental
- CSV FP
- INI
- Excel

## 7.9.6. Language



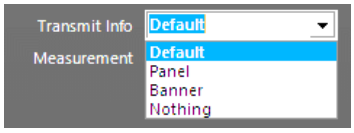

Here you can select a language. Select "Default" if you want to use the default language of byzz nxt or select a different language.

## 7.9.7. Default Profile




Here you can select the profile which is transferred to the pa-on Parometer as default for the findings transfer (tab Exm).

## 7.9.8. Transmit Info




When you send data to or receive data from the probe, the successful transmission is confirmed by a message window. With this selection menu you decide whether the message window must be confirmed explicitly by mouse click or return key or not.

You have the following options:

*Default:* The window will appear and expect confirmation unless you have checked the "Show again" box at the bottom of the message window. In this case, no message window appears.

*Panel:* The window appears and expects confirmation. A default is not possible.

*Banner:* The message window only appears briefly and does not need to be confirmed.

*Nothing:* No message window.

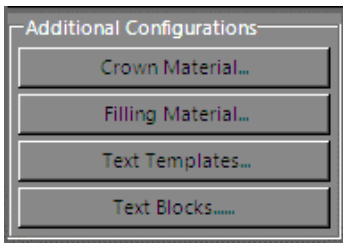
In each of these cases, the transmission button turns green if the transmission was successful, and red if the transmission was not successful.

## 7.9.9. Configuration Measurement


If you select this option, the probe data will be read automatically when inserted into the docking station. You do not have to click on the read button first.

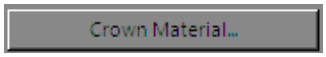
(In pa-on transfer, you can use the "Quick measurement" switch to transfer the exam finding immediately and automatically to the Parometer when it is transferred from the practice management software.)

## 7.9.10. Additional Configurations




Click on one of the buttons here to create crown materials or text templates, for example. You can return to the original configuration page by clicking the "Measurement profiles" button.

## 7.9.11. Configuration Crown material

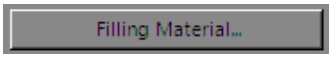



With this button you can define up to 15 crown materials in byzzParo. After clicking this button, the configuration window Crown material opens.

(Since pa-on Transfer does not display a tooth scheme, this configuration is not available in pa-on Transfer.)

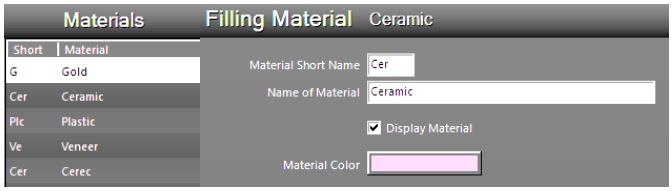

To create and edit crown materials, read the chapter "Configuration of materials" in the online help.

## 7.9.12. Configuration Fillling Material




With this button you can define up to 15 filling materials in byzzParo. After clicking this button, the Filling material configuration window opens.

(Since pa-on Transfer does not display a tooth scheme, this configuration is not available in pa-on Transfer.)



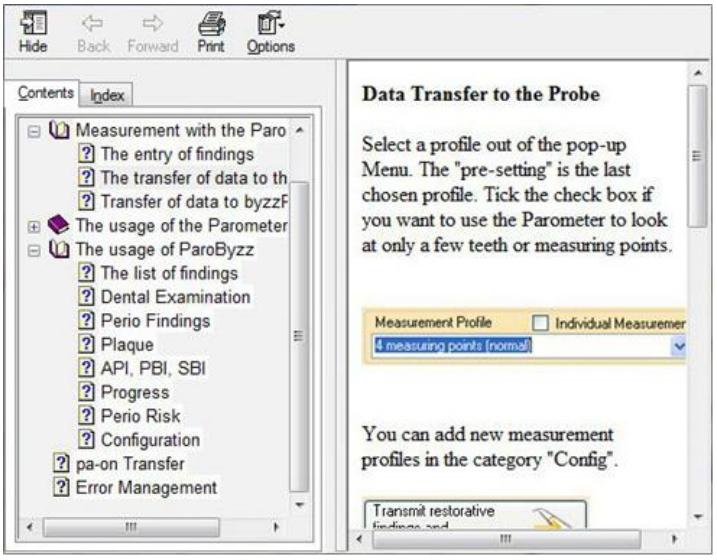
For information on creating and editing filling materials, refer to the chapter "Configuration of materials" in the online help.

## 7.10. Online Help

byzzParo comes with an extended online help. Click on the button with the question mark to open the helping text for the currently active category.

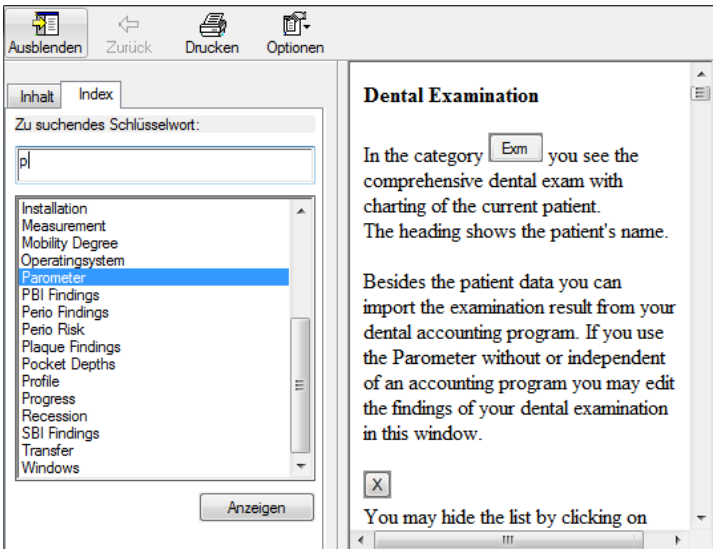
The help consists of “**Contents**” and “**Index**”.

You can find a specific text by clicking on "**Contents**" and opening the sub-items with "+".




Or you start a keyword search in the "**Index**". Enter the word into the input field. Often one or two letters are sufficient to find the respective help text. A list in alphabetical order shows all possible key words.

Click one word to get a list of texts containing this word. Click „Display“ to read the help text.



# 8. SAFETY, HANDLING AND MAINTENANCE

Read the instruction manual thoroughly, before launching and using the pa-on Parometer.

## 8.1. General

Use the Parometer only with its original equipment.

**WARNING:** Do not conduct any modifications on the Parometer or the equipment. Those can impair your safety and will void any warranty claim against the manufacturer.

**WARNING:** Do not use the Parometer within explosion-prone areas. Be especially aware of flammable gases, vapors, solvents or anaesthetics.

**WARNING:** Make sure to plug the docking station only into the USB port of computers, monitors or additional equipment (like printers) if they comply with DIN EN or IEC 60950-1. Those devices as well as the docking station have to be positioned out of reach of the patient.

**CAUTION:** Do not plug in the docking station after it has been carried out of a colder room into a warmer one. The water condensation can destroy the device. Wait until it has room temperature.

**WARNING:** Place the docking station and the Parometer so that they are protected from moisture and water.

**WARNING:** The wire of the disposable needles contains coated stainless steel with nickel. Before using the Parometer with a patient, please ask for a nickel allergy.

**WARNING:** The disposable tips of the parometer are not sterile. They must be sterilised before use.

## 8.2. Hygiene

**WARNING:** For each patient you must use a new tip.

Be careful and avoid contamination when preparing the tip and attaching it to the Parometer.

### 8.2.1. Cleaning and Disinfecting the Parometer

**WARNING:** The measuring tips are sterilizable and disposable for single use.

**CAUTION:** Do not autoclave the Parometer and its docking station. The heat will destroy the plastics and the electronics.

**Note:** The Parometer is sealed for cleaning / disinfection with humid wipes.

You should clean the Parometer straight after use to prevent that blood or protein residues coagulate.

#### Cleaning

1. Remove the used measuring tip.

   **Note:** Used measuring tips are contaminated und have to be disposed in a suitable manner.

2. Remove potential residues by wiping with mild detergent.
3. Remove potential residues of the detergent with humid, lint-free disposable wipes.

### Disinfection

The subsequent disinfection of the probe is carried out as wipe disinfection.

4. For this purpose please use a humid (not wet) disinfection wipe.

   **Note**: The following table lists the products tested for approval on the probe. Not tested products might destroy the surface of the probe.

5. Please wipe from the body in direction of the neck of the probe for several times and clean the neck and metal cape very intensively.
6. Let the disinfectant work according to the manufacturer's instructions.
7. Remove potential residues of the disinfectant with a sterile, lint-free, disposable wipe. Let it dry completely afterwards.

   **CAUTION**: Be careful that the detergent and disinfectants do not get into the speakers or the measuring tube.

8. Please prevent the Parometer from contamination until next use by suitable storage.
9. Only use soft cloth and no sharp-edged or scratchy tools.

### Disinfectants to use with the Parometer

The following products have been tested and approved with the probe:

Innocid DW-i 20 Disinfection wipes

PRISMAN Pharma International AG; Am Stalden 16; CH-4622 Egerkingen

Omnizid spray und wipe disinfection

OMNIDENT Dental-Handelsgesellschaft mbH; Gutenbergring 7-9; D-63110 Rodgau

## 8.2.2. Hygienic Pouch

**Note**: To improve the protection of patient and clinician use disposable hygienic pouches. The pouches may be used only one time per patient and must afterwards be disposed of as contaminated waste.

1. Before fitting on the sterilized, sterile tip, please slip the pouch in such a way over the probe as to spare the metal sleeve.
2. Now slip a new, sterile tip.

You can purchase the pouches from orangedental.

# 8.3. Servicing and Maintenance

Have the Parometer repaired in a service center accredited by orangedental.

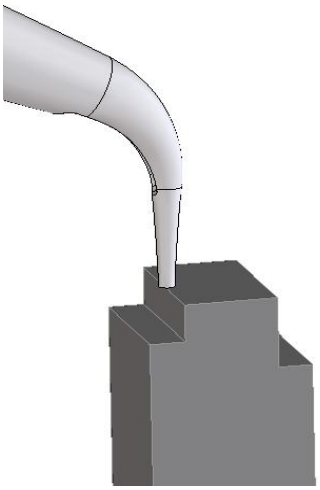
**WARNING**: You have to check the measurement accuracy using the reference scale, which controls the values 3 and 5mm, each month and document it.

**WARNING**: Put the Parometer immediately out of service, if there is apparent damage or malfunction. Call the orangedental service department.

### 8.3.1. Check with Reference Scale

To check the measurement accuracy, you have to slip a measurement tip on the probe. Be sure that the plastic should reach the orange rings. Then calibrate the zero position on one surface of the reference scale (see chapter 6.3.1: Pocket Depth). Be sure that the metal probing needle is pushed into the plastic sheath until it stops.

After successful zero position calibration, the measurement accuracy is checked with help of the 3 mm and 5 mm reference scale. Hold the measurement tip close to the reference scale so that the plastic rests on the top of the reference scale and the metal probing needle slides parallel to the vertical, stepped surface. Document the measurement result of the probe.



Please dispose the used measurement tips afterwards.

## 8.4. Error Management

**It is not possible to transfer the findings to the probe.**

>> Make sure that the probe is plugged into the docking station.

**The Parometer does not work - the battery is always empty.**

After taking measurements the Parometer awaits the transfer of its data to byzzParo. Unless the transfer has been completed the probe remains turned on, until the batteries are empty. Thus, it may be possible that the probe is empty the next day and has to be recharged.

>> Recharge the probe in the docking station.

**Penetration of moisture**

If moisture penetrated, please allow the pa-on Parometer to dry out before the next use. If you open the measuring tube by twisting off the cap, please take care that the inner spring does not jump out.

## 8.5. Proper Disposal

The pa-on Parometer and the equipment contain a rechargeable lithium polymer battery. The battery as well as several components must not be disposed of in the regular bin. To return the device contact your dental supplier or enretec GmbH (www.enretec.de). For further information feel free to contact orangedental.

# 9. SPECIFICATIONS, CONFORMITY

orangedental GmbH & Co. KG
Aspachstrasse 11 | 88400 Biberach

CE 2797

## 9.1. Environmental Conditions

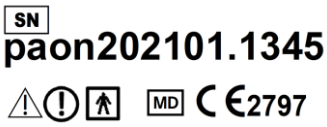
IMPORTANT: pa-on Parometer must be operated only by competent and trained users.

Keep the Parometer away from direct sun.

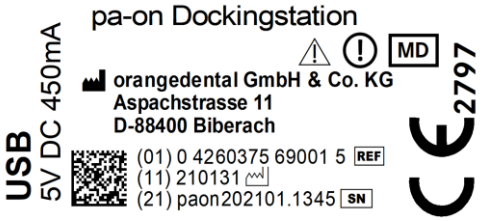
WARNING: The docking station has to be positioned out of reach of the patient.

## 9.2. Product Labeling

### 9.2.1. pa-on Probe Labeling




### 9.2.2. Docking Station Labeling




## 9.3. Technical Data

### 9.3.1. Physical Dimension

| | Data | Unit |
|---|---|---|
| Length of Case Parometer | 159 | mm |
| max. Width | 56 | mm |
| max. Height | 21 | mm |
| Weight | 65 | g |

### 9.3.2. Measurement

| | Data | Unit |
|---|---|---|
| Pocket Depth Range | >10 | mm |
| Accuracy | +/- 0.5 | mm |
| Pressure on Needle | <0.25 | N |

### 9.3.3. Electrical Properties

| | Data | Unit |
|---|---|---|
| Supply Voltage Docking Station | 5 | V DC |
| max. Power Input | 500 | mA |
| Supply Voltage Parometer | 3.2 – 4.2 | V |
| Battery LiPo | 1.3 | Wh |

### 9.3.4. Radio Properties

| | Data | Unit |
|---|---|---|
| Transmission Frequency | 868.3 | MHz |
| Transmission Power | <10 | mW |
| Used Wave Band | <1% | |

### 9.3.5. Service Life

| | Data | Unit |
|---|---|---|
| Life utility | 5 | Years |

### 9.3.6. Conformity with standards

| | Data |
|---|---|
| Protection Class | IP20 |
| Classification according to regulation (EU) 2017/745 and Directive 93/42/EEC | Im |
| Electrical Security, conform to norm | EN 60601-1 |
| Frequency regulations | ETSI EN 300 220 |

### 9.3.7. EMC Classification

| | Data |
|---|---|
| EN 60601-1-2 Group 1 | uses RF energy only for internal functions |
| EN 60601-1-2 Class B | suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |

### 9.3.8. Ambient conditions

**Operation:**

Temperature: +10°C to +40°C
rel. humidity: 25 to 75%
Air pressure: 800 hPa to 1060 hPa

**Storage and transport**

*Transport conditions*
Temperature: -20°C to +60°C
rel. humidity: 10 to 90%
Air pressure: 500 hPa to 1060 hPa

*Storage conditions*

| | |
|---|---|
| Temperature: | 5°C to +45°C |
| rel. humidity: | 10 to 75% |
| Air pressure: | 700 hPa to 1060 hPa |

## 9.3.9. Electromagnetic Compatibility

| Guidance and Manufacturer's Declaration – Electromagnetic Emissions | | |
|---|---|---|
| The pa-on is suitable for use in the specified electromagnetic environment. The customer and/or the user of the pa-on should assure that it is used in an electromagnetic environment as described below: | | |
| **Emissions Test** | **Compliance** | **Electromagnetic Environment – Guidance** |
| RF emissions according to CISPR 11 | Group 1 | pa-on Parometer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions according to CISPR 11 | Class B | pa-on Parometer is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Not Applicable | |
| Voltage fluctuations/flicker emissions IEC 61000-3-3 | Not Applicable | |

| Guidance and Manufacturer's Declaration – Electromagnetic Immunity IEC 60601-1-2 | | | |
|---|---|---|---|
| pa-on Parometer is suitable for use in the specified electromagnetic environment. The customer and/or the user of pa-on should assure that it is used in an electromagnetic environment as described below: | | | |
| **Immunity Test** | **IEC 60601 Test Level** | **Compliance Level** | **Electromagnetic Environment – Guidance** |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 6 kV contact discharge method<br>± 8 kV air discharge method | ± 6 kV contact<br>± 8 kV air | Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Electrical fast transient/burst according to IEC 61000-4-4 | ± 2 kV for power supply lines<br>± 1 kV for input/output lines | Not applicable | Mains power quality should be that of a typical commercial and/or hospital environment |
| Surge according to IEC 61000-4-5 | ± 1 kV differential mode<br>± 2 kV common mode | Not applicable | Mains power quality should be that of a typical commercial and/or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | < 5 % UT (>95 % dip in UT ) for ½ cycle<br>40 % UT (60 % dip in UT ) for 5 cycles<br>70 % UT (30 % dip in UT ) for 25 cycles<br>< 5 % UT (>95 % dip in UT ) for 5 seconds | Not applicable | Mains power quality should be that of a typical commercial and/or hospital environment. If the user of pa-on requires continued operation during power mains interruptions, it is recommended that the pa-on be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Mains power quality should be that of a typical commercial and/or hospital environment. |
| NOTE UT is the a.c. mains voltage prior to application of the test level. | | | |

| Guidance and Manufacturer's Declaration – Electromagnetic Immunity IEC 60601-1-2 | | | |
|---|---|---|---|
| The pa-on is suitable for use in the specified electromagnetic environment. The customer and/or the user of the pa-on should assure that it is used in an electromagnetic environment as described below: | | | |
| **Immunity Test** | **IEC 60601 Test Level** | **Compliance Level** | **Electromagnetic Environment Guidance** |
| Conducted RF IEC 61000-4-6<br><br>Radiated RF IEC 61000-4-3 | 3 Vrms 150 kHz to 80 MHz<br><br>3 V/m<br>80 MHz to 2,5 GHz | 3 Veff<br><br>3 V/m | Portable and mobile RF communications equipment should be used no closer to any part of the pa-on, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.<br>**Recommended Separation Distance:**<br>d = 1,17 √P<br><br>d= 1,17 √P 80 MHz to 800 MHz<br>d = 2,3 √P 800 MHz to 2,5 GHz<br>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manu-facturer and d is the recommended separation distance in metres (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |
| NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.<br><br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. | | | |
| a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the pa-on is used exceeds the applicable RF compliance level above, the pa-on should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the pa-on.<br><br>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. | | | |

**Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the pa-on Parometer IEC 60601-2**

The pa-on Parometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the pa-on Parometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the pa-on Parometer as recommended below, according to the maximum output power of the communications equipment.

| **Rated maximum output power of transmitter W** | **Separation distance according to frequency of transmitter m** | | |
|---|---|---|---|
| | **150 kHz to 80 MHz in ISM bands** $d = 1,17 \sqrt{P}$ | **80 MHz bis 800 MHz** $d= 1,17 \sqrt{P}$ | **800 MHz bis 2,5 GHz** $d= 2,3 \sqrt{P}$ |
| 0,01 | 0,12 | 0,12 | 0,23 |
| 0,1 | 0,38 | 0,38 | 0,73 |
| 1 | 1,2 | 1,2 | 2,3 |
| 10 | 3,8 | 3,8 | 7,3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the separation distance can be estimated using the equation in the corresponding column, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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