OccluSense®
by Bausch

Instructions for Use

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OccluSense®
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Symbols

In compliance with relevant EU directives

In compliance with relevant UK directives
UK RP: OBELIS UK LTD, Sandford Gate, Oxford, OX4 6LB, UK

CH REP ALBO-Healthcare GmbH
Alte Steinhauserstrasse 19 | CH-6330 Cham

Follow Instructions for Use!

Do not reuse!

Medical Device Manufacturer

REF Order Number

UDI Unique Device Identifier

SN Serial Number

LOT LOT Number

IP IP Protection Class

Class II

Expiry date [yyyy-mm-dd]

Production date [yyyy-mm-dd]

Waste electrical and electronic equipment (WEEE) must be disposed of separately. These must not be disposed of with normal household waste.

Applied part of TYPE B, IEC 60601-1

Do not use if package is broken!

0°C 40°C Do not expose to heat!

Some chapters describe usage procedures. In order to see which action of the OccluSense®-System is required, the following symbols are used:

User interaction with the handheld

User interaction with the iPad

Interaction with the patient

WEEE-Reg-No.: DE 11349707

Terminology

Recorded raw data:

Recorded data by the handheld device.

OccluSense®-iPad-App:

The software that manages, stores and visualizes the raw data recorded by the OccluSense® handheld (Available for free in the Apple AppStore).

Recording:

Raw data converted by the OccluSense®-iPad-App.

OccluSense®-System:

Entire treatment unit according to chapter 4 "Device description".

Handheld:

The central electronic device of the OccluSense®-System, which executes the collection of raw data as well as its intermediate storage and transmission to the iPad (chapter 4.1).

Hardware requirements iPad

(not included)

Regarding the status of these operating instructions, an evaluation unit is an Apple iPad on which the app "OccluSense®" from the Apple App Store must be installed. In order to use the app, you first have to register the system within the app.

The OccluSense®-iPad-App has been developed for the following iPad models:

www.occlusense.com/ipad

Installation on an iPad mini is not recommended. In order to use the app in full functionality, the system must be registered first within the app. The instructions for the installation and registration can be found in chapter 10.

CAUTION

- Using the application on a not supported device is possible but at the user's own risk.
- It is possible to run the app on an unsupported iOS version at the user's own risk.

NOTE

- A particular notification will pop up when the app is running on a not supported iOS or hardware.
- The usage out of the application's technical scope will be logged for safety reasons.

GENERAL INFORMATION

1 Medical device manufacturer

Dr. Jean Bausch GmbH & Co. KG
Oskar-Schindler-Str. 4
D-50769 Köln - Germany
Phone: +49-221-70936-0
Fax: ++49-221-70936-66
E-Mail: info@bauschdental.de
Web: www.occlusense.com

2 Medical device distributors

(U.S. Initial importer)
Bausch Articulating Papers, Inc.
12 Murphy Drive
Nashua, NH 03062 - United States of America
Tel: (603) 883-2155 | Tel: 1-888-6-BAUSCH | Fax: (603) 883-0606
E-Mail: info@bauschdental.com | Web: www.bauschdental.com

Bausch Articulating Papers (Australasia) Pty. Ltd
G.P.O. Box 3733, Sydney NSW 2001, Australia
Tel: +61-2-9345-1945 | Fax: +61-2-9345-1955
E-Mail: info@bauschdental.com.au | Web: www.bauschdental.com.au

Bausch Articulating Papers Japan K. K.
5F, 1-1-31, Nishimidorigaoka
Toyonakashi, Osaka Japan 560-0005
Tel:+81 6-6845-0020 | Fax:+81 6-6845-0024
E-Mail: info@bauschdental.jp | Web: www.bauschdental.jp

Bausch Importaão de Materiais Odontológicos Ltda.
Rua Paulo Eduardo Xavier de Toledo, 379 salas 8 e 9
13304-240 Itu-SP, Brasil
Tel: +55 11 3020-9263
E-Mail: vendas@bauschbrasil.com.br | Web: www.bauschbrasil.com.br

Bausch Articulating Papers Co., Ltd.
#1004, The O Ville B/D, 344, Jong-Ro, Jongno-Gu, Seoul 03114, Korea
info@bauschdental.kr | www.bauschdental.kr

3 Intended Use

Analog and digital representation of antagonistic tooth contacts (occlusion) in the average adult dentition on the patient's entire dental arch (for transient use). The application is intended exclusively for dentists and physicians/physiotherapists with specialized further training (CMD, craniomandibular dysfunction).

4 Device description (components, etc.)

The OccluSense®-System consists of the following components:

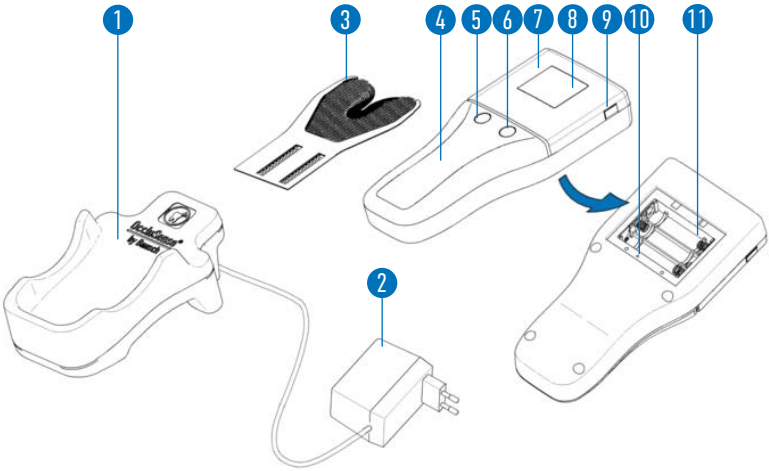
- Handheld	BK 5001
- Charging station incl. Power supply	BK 5002
- iPad App available in the Apple AppStore	BK 5100
(requires an Apple iPad [no medical device], not included)	
- 1 test sensor	BK 5011
- 25 OccluSense®-Sensors	BK 5025
- Manual	BK 5051
- 3 NiMH rechargable batteries	BK 5013
- 1 Screwdriver IP 6	BK 5012
- 25 OccluSense®-Sensors XL	BK 5035 (not included)

The medical device components do not contain any of the following substances:
- Pharmaceuticals
- Tissues or cells of human origin or their derivatives
- Tissues or cells of animal origin or their derivatives within the meaning of EU Regulation 722/2012

The touchable surfaces of medical device components consist of physiologically harmless plastics and colorants.

Environmental conditions:	
Temperature range	0° ... +35°
Relative humidity	20% ... 90%. noncondensing
Atmospheric pressure	650hPa ... 1060hPa
max. height a.s.l.	3000m
International Protection Rating:	IP 40
Class:	Class II

4.1 Operating and functional elements of the OccluSense®-System



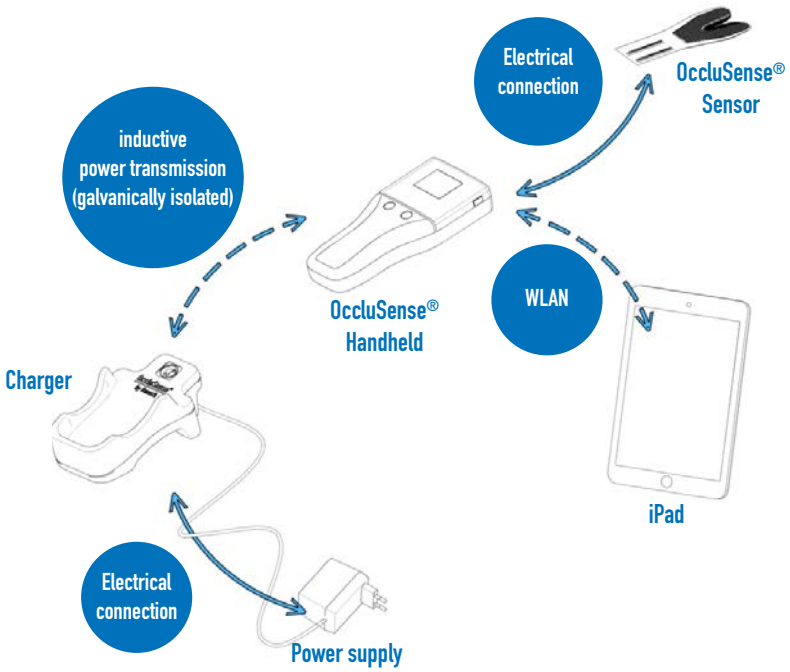
1 – Charging station incl. power supply 2
3 – Sensor (Applied Part type B)
4 – Handheld (ME-Device)
5 – Control button 1 (pink)
6 – Control button 2 (green)
7 – Sensor lid
8 – Display
9 – Unlock button
10 – Control button 3 (Reset)
11 – Battery compartment
12 – Test sensor (not shown)
13 – Screwdriver (not shown)
14 – 3 pieces AAA NiMH rechargeble batteries (not shown)

4.2 System features

The OccluSense® system is used to record and display occlusal contacts and the masticatory force. It does not provide direct diagnoses or therapy recommendations. Furthermore, the system does not control treatment/therapy and there is no monitoring of or intervention in vital functions.

The digital recording (and analog representation of the occlusion) is performed by the OccluSense® sensor, when connected with the handheld. The recorded raw data, captured during the occlusion test, are buffered in the handheld. Subsequently the handheld transmits this data via the wireless interface to the OccluSense®-iPad-App.

The OccluSense®-iPad-App saves the recorded raw data and displays it 1:1 (i.e. without interpretation or highlighting) graphically on the iPad screen.



5 Contraindications

The OccluSense®-System is for professional use only (see chapter 3) and is not suitable for:

- Patients with edentulous jaw
- Patients with incomplete full-grown jaw

6 Expected clinical benefit

The OccluSense® system allows the examination of the patient's antagonistic tooth contacts (occlusion) by means of the OccluSense® sensor.

Compared to conventional occlusion test materials (papers, foils), the system displays the occlusal contacts not only as a (final) state on the occlusal surfaces of the teeth, but also the temporal progression from the initial contact to the final intercuspal position as a graphical representation on the iPad.

This allows to illustrate the masticatory force distribution on the entire dental arch. The dentist has the option to compare several recordings with one another, e.g. before and after dental treatment (not an automatic function of the OS-iPad-App) and to save these on the iPad for documentation purposes (forensics).

The deduction of therapeutic measures must not be based solely on the information provided by the OccluSense® system. Additional information must be obtained in order to make a comprehensive diagnosis. The graphical representation of the occlusal contacts must not be used to draw conclusions from the actually exerted bite forces (absolute values). These are relative value representations.

7 Precautions/ Safety Instructions

OccluSense® is a medical device meant for professional use only (see chapter 3).

The OccluSense®-System must be used with the supplied or prescribed accessories only.

It is not allowed to connect any part of the OccluSense®-System to an external DC power source. The power supply of the system has to be carried out exclusively with the supplied charging accessory.

Before using the OccluSense®-System, components have to be checked for external damages (visual inspection). Damaged components must not be used.

The OccluSense®-System must not be altered without the manufacturer's permission. The sensor must not be modified (e.g. cut to size).

The handheld is designed for battery operation only. Mains operation is not intended and may result in serious injury of the patient or the practitioner.

The use of non-rechargeable batteries is not permitted and may result in serious injury of the practitioner or destruction of the handheld when attempting to recharge it.

The handheld must be disconnected from the charging station during use.

The charging station has to be located outside the patient´s vicinity.

The charging station must be positioned in such a way that the plug-in power supply unit is in easy reach and the separation from the mains can be accomplished without difficulty.

The charging station can be disconnected from the mains by pulling the plug-in power supply out of the socket.

All parts of the OccluSense®-System are not thermo-disinfectable or autoclavable and are not delivered sterile.

Only cleaning agents and disinfectants as described in chapter 21 „Cleaning and disinfection“ are allowed.

The charger is maintenance-free.

The treatment light should not be directed towards the handheld during treatment to ensure good readability of the display.

The OccluSense®-System is not intended to serve as the sole basis for diagnosis / therapy decisions.

PREPARATION

8 Installation of the OccluSense®-iPad-App

Before using the OccluSense®-System for the first time, install the OccluSense®-iPad-App on the iPad (www.occlusense.com/install).

Before initial operation of the OccluSense®-System or after reset to factory default, a network configuration of the handheld and the associated pairing with an iPad is required. The procedure is described below.

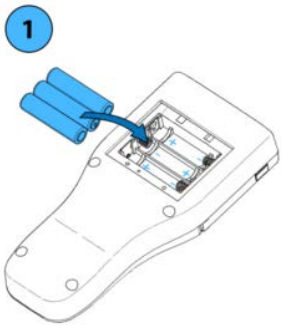
NOTE

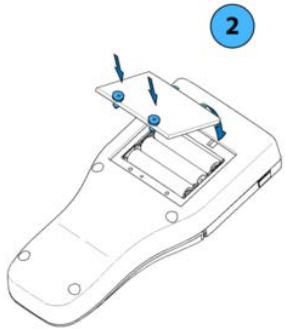
- The handheld comes with uncharged batteries. The rechargeble batteries must be charged before first use (see chapter 8.1).
- The OccluSense® handheld is designed for use with three AAA NiMH batteries only (included). The handheld can also be used with other AAA NiMH batteries than those supplied. These AAA NiMH batteries must have a minimum capacity of 1000mAh.
- Perform a visual inspection for external damages.
- Only use the handheld unit and charging station if there are no external damages.

8.1 Battery Charging

1. Loosen the screws of the battery compartment lid with the screwdriver supplied, remove the battery compartment cover and insert the supplied NiMH batteries into the battery compartment.

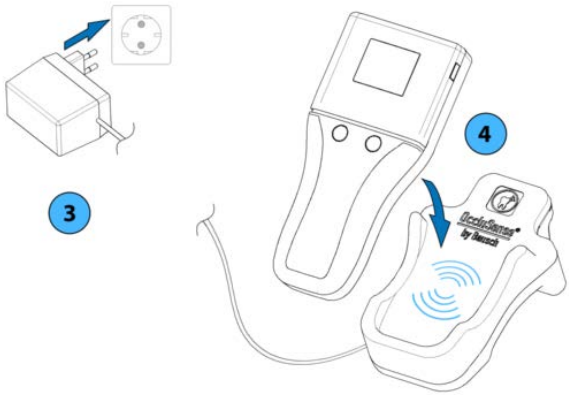
2. Insert the battery compartment cover and tighten the screws.





3. Connect the plug-in power supply unit to the supply voltage. (Rated Voltage: 100-240V, Rated Current: 160-80mA)

4. Insert the handheld into the charging station as shown.



CAUTION

- Batteries inserted inversely can reach high temperatures and damage the device.

5. The charging process is indicated by a permanently lit LED located between the two operating buttons. All OccluSense devices with a serial number A000500 - A002499 have a red LED, devices from serial number B002500 have a blue LED.

S/N A000500 - A002499

from S/N B002500

NOTE

- Both the permanently lit red or blue LED in the handheld unit and the flashing red or blue LED in the charger only indicate the battery charging process and **do not represent a warning!**
- With empty NiMH batteries, the handheld can be charged for a short time using a charging time of at least 15 minutes.
- If the handheld is left in storage for longer periods with batteries inserted, the batteries may discharge. If a prolonged storage without use is foreseeable, it is recommended to remove the batteries from the handheld. After a storage period of the handheld with inserted rechargeable batteries of more than 3 months, it is recommended to fully recharge the rechargeable batteries before reuse.
- If the batteries have discharged after a full charge and a too low battery voltage is displayed, the batteries have become unusable. In that case, replace the batteries.
- During the charging process, elevated temperatures may occur in the handle area of the handheld and in the charging station, which, however, decay immediately after the charging process has been completed and do not pose any risk to the user or patient.

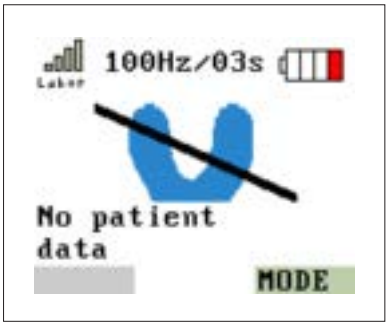


Figure 1: Empty Battery

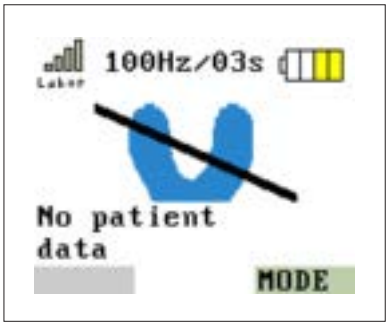


Figure 2: Low Battery

The rechargeable batteries must be charged at the latest when the battery icon shows only one bar in red (Figure 1). However, it is recommended to recharge them when two yellow bars of the battery symbol occur (Figure 2). The batteries can also be charged earlier if you want to ensure that they are ready for use.

CAUTION

- To charge the rechargeable batteries, only use the supplied charging station incl. the permanently connected power supply in order to prevent damage to the handheld unit and the rechargeable batteries.
- The use of the charging station is not permitted in the direct patient environment (directly at the treatment chair).
- Do not use a multiple socket to operate the AC adapter.
- The plug-in power supply must be connected directly to a mains socket.

The handheld can be charged both when it is switched on and when it is switched off. As soon as the handheld is placed in the charging station, the handheld switches to a charging state in which the operation is disabled and a battery charging icon (Figure 3) is displayed. Charging of the batteries is indicated by a permanently lit LED (No warning notice!) (Figure 4). After a full charge cycle, the LED turns off.

The charging process takes about 3-4 hours with 1000mAh batteries. The charging time may vary depending on the type of battery used and its capacity.
With one battery charge, at least 100 recordings in 150Hz and 10 seconds mode recording time (or 30 minutes of live mode) can be made.

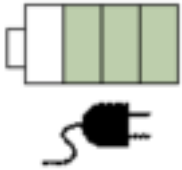


Figure 3: Initiating the charging process.

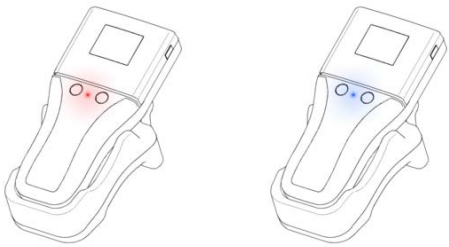


Figure 4: The charging of the batteries is indicated by a permanently lit red or blue LED (This is not a warning notice!).

9 Overview

9.1 Intended use of the OccluSense®-iPad-App

The OccluSense®-iPad-App allows to record and manage data from the OccluSense®-Handheld-Device.

During a recording, all occlusion data is transferred to the app, which enables to display the data two-dimensionally, three-dimensionally or in a combined view. The recorded data can be viewed and filtered. Furthermore the app allows zooming, tilting and rotating within the visualization.

Recorded data is automatically assigned to the respective patient and can be commented and compared with each other which makes an easy analysis of occlusion data possible.

9.2 Overview of the OccluSense®-iPad-App

The app consists of five main menu items (Figure 5) presented on the navigation bar on top of the screen. The currently active menu item is highlighted in blue. The structure and the functionality of each single menu item will be described in detail in the following chapters.

Figure 5: Main menu of the app

9.3 User manual

The user manual can be accessed via the integrated PDF viewer (Figure 6).

Figure 6: User manual

If you tap "MANUAL", the corresponding chapter in the PDF manual will automatically open according to the current action.
(Example: You are in the patient management, tap on "MANUAL" and the PDF manual opens chapter 13.)

At the bottom of the screen is the status bar (Figure 7). If the app is not connected to a handheld, the status bar is empty. If it is connected to a handheld, the firmware version of the handheld is displayed on the left and the status of the handheld is displayed on the right.

Figure 7: Status bar at the bottom of the app

Symbol of the handheld:	Handheld is connected to the app
Colored dot:	Quality of the WLAN connection
- Green:	good connection quality
- Yellow:	moderate connection quality
- Red:	poor connection quality
Battery symbol:	Battery condition of the handheld.

INSTALLATION

10 First use

10.1 Demo Mode

After installation the app starts in demo mode, indicated by "UNREGISTERED" in the top left corner (Figure 8).

Figure 8: "UNREGISTERED" label in the top left corner of the app.

In the demo mode predefined patients and recordings are available to give a first impression of the app. It is not possible to create new patients and recordings. Please refer to chapter 13 for further information about the patient management.

The functionality of the settings menu is restricted to the registration menu. For activating the full functionality of the app you have to leave the demo mode and connect the handheld device with the app (chapter 10). Please refer to chapter 10.2.4 for further information about the registration.

10.2 Initial Setup

At delivery, the handheld is not preconfigured for an existing WLAN. In the course of the initial setup your iPad will first connect to the OccluSense® handheld. Subsequently, it is possible to integrate the handheld into your existing WLAN.

Check if your iPad is connected to your WLAN network. Have your WLAN password ready.

NOTE

- **TECHNICAL REQUIREMENTS FOR THE WIRELESS LOCAL AREA NETWORK (WLAN)**
  - 2.4 GHz WLAN-Standard IEEE802.11 b/g/n (5 GHz is NOT supported)
  - No MAC filter activated (MAC = Medium Access Control)
  - DHCP server with two free IP addresses available
- OccluSense® is a network device - If you have any problems connecting the OccluSense® to your network, please ask your system administrator.

10.2.1 Switch on the handheld

To switch on the handheld, press button 1 (pink button, see chapter 4.1). The WLAN network name and password (WEP) are shown on the handheld display (Figure 9).

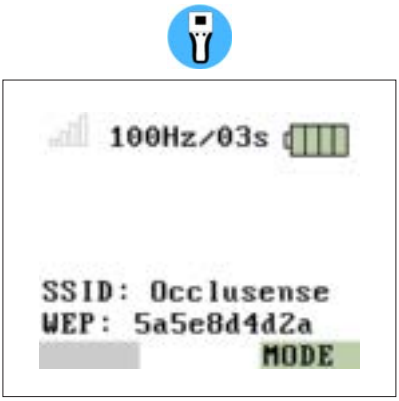


Figure 9: WLAN-SSID and password (WEP) provided

10.2.2 Starting the initial setup

Select "Initial setup" in the settings and tap "Start".

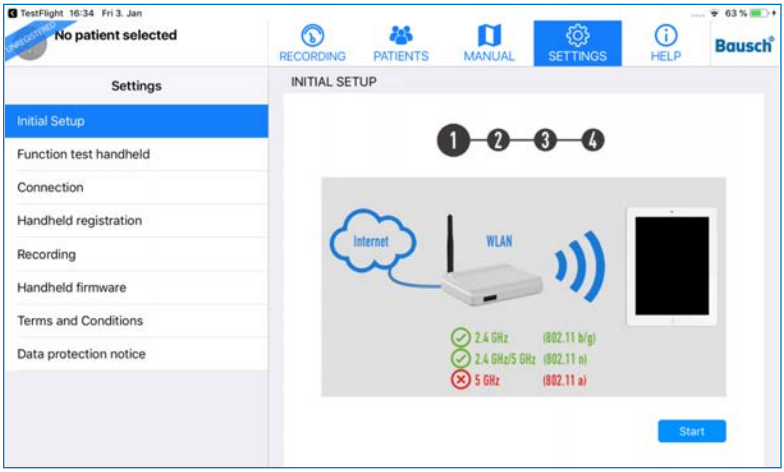


Figure 10: Initial setup

Now enter the WEP password in the field (Figure 11) which is shown on the display of your OccluSense® handheld device (Figure 9).

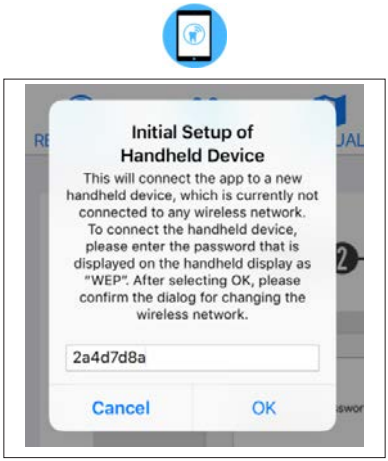


Figure 11: Input field for the WEP password

Allow access to the WLAN "Occlusense" by tapping on "Join".

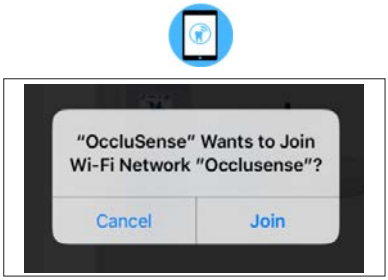


Figure 12: Connection to the integrated WLAN of the OccluSense® handheld

When the handheld has been successfully connected, the display shows Figure 13. This symbolizes "successful connection with the OccluSense® iPad app", "no sensor inserted" and "no patient data available".

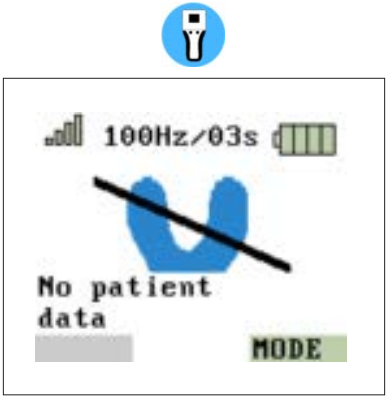


Figure 13: Handheld is connected

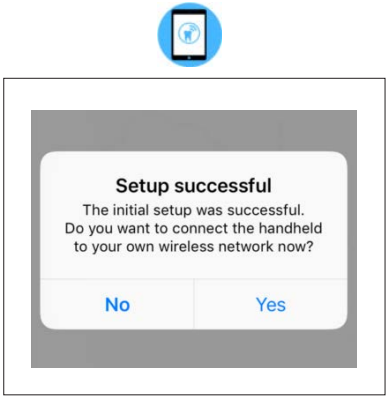


Figure 14: Successful setup

NOTE

- If the horseshoe shaped symbol appears in yellow, a function test is required (Chapter 12).

10.2.3 Integration into your own WLAN network

In the next step, you will see the dialog message from figure 14. Confirm the dialog with "Yes".

The OccluSense®-iPad-App now changes to the "Connection" settings.

Tap on "Next" (Figure 15). In the following screen please enter the WLAN credentials of your network (Figure 16).

The last WLAN network, the iPad has been connected to, will be suggested as the network SSID. Enter the password of your WLAN network and allow the OccluSense®-iPad-App to access the network in order to write the data to the handheld.

Figure 15: Instructions for the external WLAN-Setup

Figure 16: Enter WLAN name and password

A successful connection between the handheld and the WLAN is indicated by the green bars and the first 6 characters of the WLAN in the upper left corner of the handheld screen.

If the connection between the handheld and the WLAN has failed, the connection status is indicated on the handheld screen by transparent status bars.

10.2.4 Registration of the System

After the initial pairing, please restart the app. To do this, press the home button twice (iPad without home button: swipe up from the bottom of the screen) and swipe up the preview of the app to close it. Now the full functionality of the app is available.
In case you have not yet registered the app you have access to all functions for 14 days. After this period the demo mode will be reactivated and you have to register the app for further use (Figure 17).

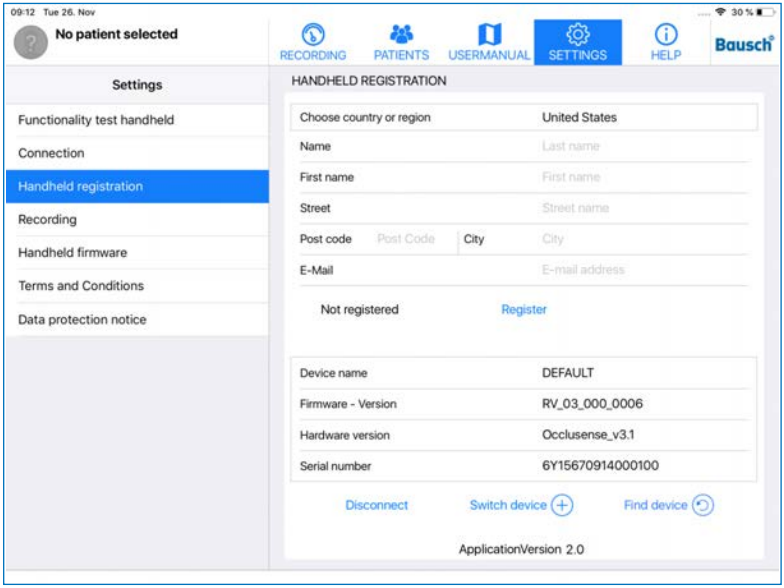


Figure 17: The handheld registration form is located in the "Settings" menu

NOTE

- The registration is mandatory for full functionality of the app in combination with the handheld device.
- For the registration an Internet connection is required.

Step 1: connect your handheld device to the app and to fill the registration form with your name, address and e-mail address.

Step 2: tap the "Register" button to send your registration data. You will receive a confirmation e-mail.

NOTE

- If you have not received a confirmation e-mail, check your junk mail folder or check the e-mail address you have entered.

Step 3: press the "Confirm" button in the e-mail and switch back to the app. The app still needs Internet access to receive the confirmation of your registration data. If your registration was successful a green checkmark is being displayed:

After the registration process, the OccluSense®-iPad-App has to be restarted to exit the DEMO mode. To do this, press the home button twice (iPad without home button: swipe up from the bottom of the screen) and swipe up the preview of the app to close it. Then reopen the OccluSense®-iPad-App.

NOTE

- When reactivating the demo mode none of your data will be deleted by the app although it is no more visible. After successful registration your data is available again.

10.3 Administration of OccluSense® handheld devices

Beside the initial setup, the OccluSense®-iPad-App provides other functions for the administration of handheld devices.

10.3.1 Rename handheld

If you intend to use several handhelds with one app, you should immediately assign a name to the handheld to make identification of each individual handheld easier. You can assign a name to a handheld within the registration settings section (Figure 18). Tap on the field "Device name" to change the text.

Figure 18: Screen for renaming the device, “Disconnect, “Switch device” and “Find device”.

10.3.2 Disconnect handheld

In order to use another handheld, the connection of the current handheld with the OccluSense®-iPad-App must be disconnected.

This process requires the handheld to be turned on and connected to the iPad-App.

Then tap on „Disconnect“.

The WLAN data and the name of the handheld remain stored in the device so that it can be reconnected at any time (see chapter 10.3.3).

10.3.3 Pairing the handheld with the OccluSense®-iPad-App

The app shows unpaired handhelds in the "Devices" list (OccluSense®-iPad-App -> Settings -> Handheld Registration -> Switch device) (Figure 18).

To pair, select the handheld from the "Devices" list (Figure 19)
(default name is "DEFAULT").

Once the pairing has been completed successfully, the OccluSense®-iPad-App will from now on connect automatically to this handheld.

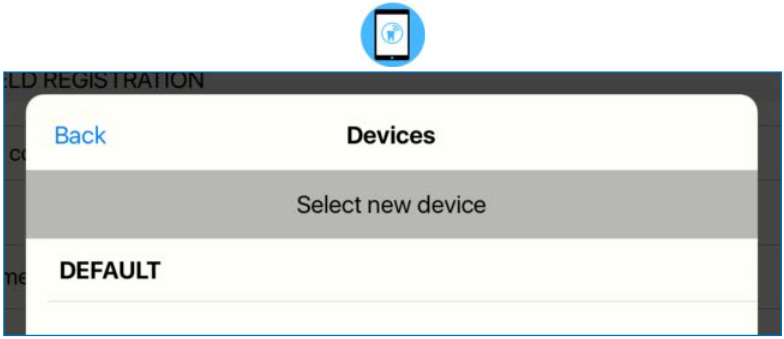


Figure 19: List of available devices after "switch device" button has been selected.

NOTE

- Only previously disconnected handheld devices can be reconnected (Chapter 10.3.2).
- If your device is not shown in the list of available devices, please close the list, press "**Find device**" on the previous screen, and try again.

NOTE

- The purpose of integrating the handheld and the evaluation unit into the IT-network is to enable the live mode. Minimum IT network requirements are the following:

  - WPA/WPA2 WLAN encryption
  - DHCP server in the IT network with at least two free IP addresses
  - WLAN standards IEEE802.11 b/g/n (2.4 GHz)

  If these requirements of the IT network can not be met, there is a risk that the handheld can either not be used at all or in full functionality. If the entered WLAN data is incorrect, communication between the iPad and the handheld is not possible. In this case, a factory reset is required (Chapter 19.2).

- If no WLAN network is available in the dental office, the WLAN network provided by the handheld device can be used to a limited extent. However, an independent WLAN network is recommended in the dental office!

CAUTION

- Integrating the handheld into an IT-network that includes other devices can result in risks for patients, operators or third parties that the manufacturer can not evaluate.
- For this reason, practitioners must identify, analyze, assess and control these risks.
- Changes in IT networks can lead to new risks and therefore require additional analysis.

SAFETY

11 Safety check

The function test described below ensures that the OccluSense®-System works properly and that the masticatory pressure distribution is displayed correctly. It is therefore necessary that the function test is performed once a day.

First of all, a visual inspection for external damages of the device must be made. If damages of the handheld, charging station or test sensor are detected, e.g. broken parts of the sensor lid, the device must not be used.

In this case, see chapter 19 "Troubleshooting".

12 Function test

To initiate the sensor test of the handheld, the handheld has to be connected to the app first. Then tap "Next" and follow the instructions on the screen (Figure 20-23).

The function test is performed with the supplied test sensor, following these five steps:

1. Place the test sensor in the correct position and close the sensor lid

2. Switch on the handheld and establish a connection with the iPad

3. Follow the instructions in the OccluSense®-iPad-App. The function test is performed automatically

NOTE

- A sensor test notification will pop up every day. However, you can proceed without conducting the sensor test. If a test has not been performed for the last 5 days the app will disable any live mode or recording functionality until the sensor test has been performed successfully (Figure 20-23).

Figure 20: First step of the sensor test, insert the test sensor into the handheld

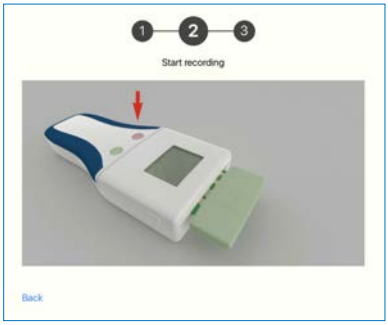


Figure 21: Second step, press the left (pink) button to start

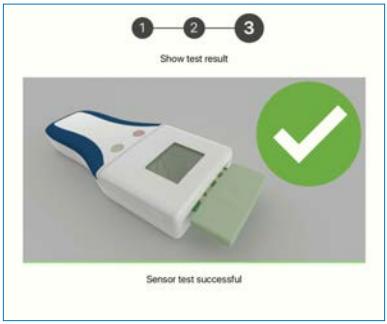


Figure 22: The sensor test was successful

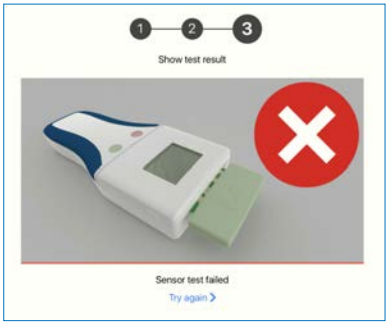


Figure 23: The sensor test failed

4. The result of the function test is displayed in the app. If this is repeatedly negative, the device must not be used. In this case, see chapter 19.5 "Troubleshooting".

5. Remove the test sensor from the handheld and place it in the storage box.

NOTE

- If the sensor test fails permanently (Figure 23), please visit our support website: help.occlusense.com

PATIENT MANAGEMENT

13 Manage patient data

13.1 Overview

In the „Patients" section you can manage patients and their recordings (Figure 24). It is possible to create, edit, delete and export patient data as well as viewing and deleting old recordings of occlusion data and editing the attached notes. In this view you are also able to switch the active patient.

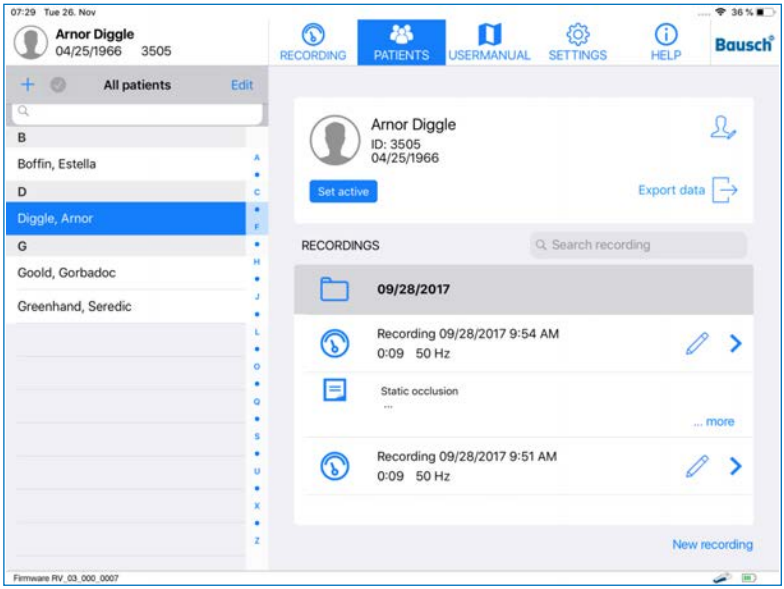


Figure 24: Patient management of the app

The view is split into two sections. On the left side, a list of all patients is located. At the top of this list, you find the tools to search the list, create a new patient and to switch into edit mode, where patients can be deleted or exported.

NOTE

- The search mechanism takes the ID and the last name of the patient into consideration.

13.2 Create patient

Tap the "Plus"-symbol at the top left of the screen to create a new patient. After that you will be asked to enter the patient data (Figure 25). All fields are mandatory and have to be filled in. As soon as you have entered all the data, confirm by tapping on "Done". If you do not want to create a new patient, tap on "Cancel".

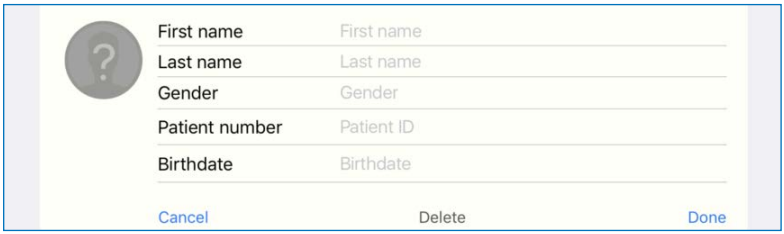


Figure 25: Detailed view when creating a new patient in the patient management

If you enter for instance asian, arabic or cyrillic characters in the first or last name field, new fields for the first and last name will appear. The new name fields only accept ASCII characters and the names entered in these fields are used for the handheld device to display the active patient. ASCII characters are the latin alphabet. The patient number field accepts only ASCII characters (Figure 26).

Figure 26: Detailed view with additional name fields

13.3 Edit patient data

In order to edit a patient's data, the patient's name has to be selected first. Then tap on the "Edit Patient"-symbol at the top right of the screen. After that the data can be edited. The patient number can not be changed. If you want to save your changes, tap the "Done" button. If you want to discard your changes, tap the "Cancel" button.

13.4 Delete a patient's data Delete

To delete a patient's data, the patient has to be selected first. Then tap on the "Edit Patient"-symbol at the top right of the screen. Finally tap on "Delete".

To delete several patients at once, tap on "Edit" at the top of the patient list. Now you can select the patients you want to delete. Then tap on "Delete" at the bottom of the list.

RECORDINGS

14 Start a recording

14.1 General

Before starting the recording, the following preparations have to be made:
- Create / select patient
- Insert the sensor into the handheld
- Select capture mode

An upright sitting position of the patient is recommended.

NOTE

- If this has not yet been performed, the initial setup has to be made first (see chapter 10).
- The recording will be started and stopped by the control buttons of the OccluSense® handheld only.
- For recording, a permanent, wireless connection between the handheld and OccluSense®-iPad-App is required.

CAUTION

- The handheld may only be used with closed access covers (battery compartment and sensor lid) AND inserted sensor in the patient environment.
- Replacing the sensors or batteries which require to open the respective access covers must be done outside the patient environment.
- The practitioner must not touch the patient when the access covers are open.

14.1.1 Switch off handheld

The handheld must be switched off to prevent unwanted operation. If the unit has been turned on after removing it from the charging station, press and hold button 1 (pink) for more than 2 seconds. The handheld then turns off (display off).

14.1.2 Insert sensor

The OccluSense®-Sensor is a horseshoe shaped pressure sensor. The sensor consists of a printed electronic circuit inside featuring a sensibility of 256 pressure levels.

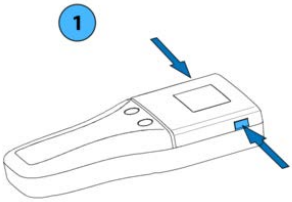
The red color coating on the outside enables the dentist to control the occlusion just like with regular occlusion test materials. The total thickness of the sensor is only 60 microns which allows testing the dynamic occlusion as well.

The OccluSense®-Sensor is a single-use product, limited to one patient in the same treatment only.

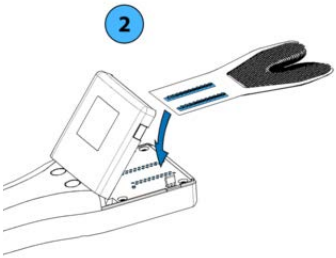
CAUTION

- Only use sensors from undamaged original packagings!
- Observe expiry date!

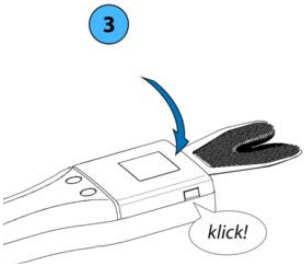
To insert the sensor:



1) Unlock the sensor lid of the handhed by simultaneously pressing the side release buttons. Open the sensor lid.



2) Remove the sensor from its packaging and insert it into the contact area.
The insertion direction and position are determined by the marking on the sensor as well as by positioning pins, over which the sensor must be inserted.



3) Close: To do this, press the sensor lid downwards until the snap-in lugs of the release buttons snap in on both sides.

14.1.3 Switch on the handheld

Figure 27: Display after switching on the handheld

To switch on the handheld, briefly press operating button 1 (pink). During initialization, the device displays the product logo including the version number of the firmware. (Figure 27).

14.1.4 Check WLAN connection

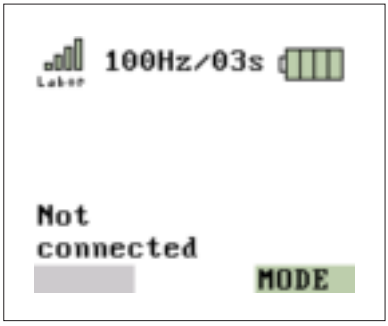


Figure 28: successful WLAN connection

When the handheld is switched on, it automatically connects to the last configured WLAN network. The connection is indicated by the colored bar diagram in the top left of the display. If no network has been configured before, see chapter 10.3. The connection is to be checked after switching the handheld (Figure 28).

14.1.5 Check if sensor is ready for recording

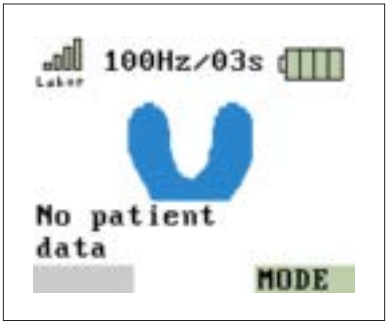


Figure 29: Sensor inserted properly

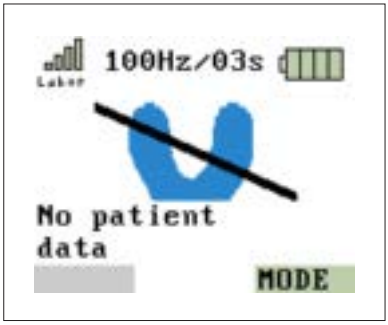


Figure 30: Sensor inserted improperly

The graphic on the left (Figure 29) shows that the OccluSense®-iPad-App is connected to the handheld and the sensor is inserted properly.

If the sensor is defective or inserted improperly, the graphic on the right appears on the display (Figure 30). The sensor or its position must be checked (chapter 14.1.2).

14.2 Set a patient active

In order to start a recording, the patient must be activated first. When you select a patient from the patient list, a message field is being displayed in order to activate this patient (Figure 31).

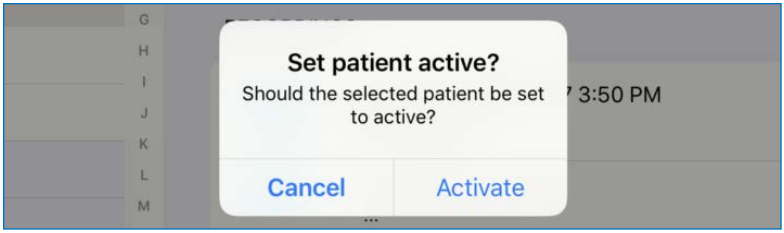


Figure 31: Set patient active

14.2.1 Patient data

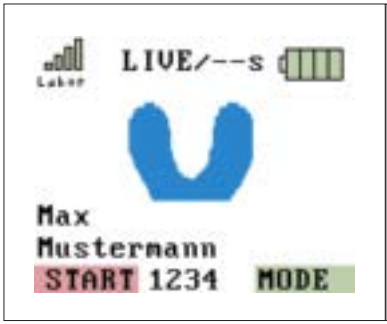


Figure 32: Patient set active (handheld)

Figure 33: Patient set active (iPad)

Create a new patient (chapter 13.2) and/or activate a patient (chapter 14.2). The patient's name is transferred to the handheld (Figure 32). Check if the patient's data is correct. The currently active patient is always displayed in the upper left corner of the iPad screen (Figure 33). If no name is displayed, no patient is activated.

The occlusion test can now be performed.

NOTE

- The patient data is used to assign a recording to a patient and is stored together with the recorded data. Only after activating a patient, the handheld is ready to start a recording.

14.3 Recording modes

A recording can be performed in different modes:

Live mode

The handheld records raw recording data at a frequency of 20Hz (= 20 frames per second) and transmits it without intermediate storage to the OccluSense®-iPad-App. The OccluSense®-iPad-App displays this data graphically in realtime. The duration of the live mode is not limited.

Recording mode

The handheld records raw recording data at an adjustable frequency (50Hz, 100Hz, 150Hz, Hz = frames per second) over a recording time which has to be previously set. The data is buffered in the handheld. Only after a complete recording the data is being transferred to the OccluSense®-iPad-App.

Live + Recording mode

The live mode is started first (e.g. for setup). Pressing the button 1 (pink) terminates the live mode and starts a recording just like in recording mode, saves it and transmits it to the OccluSense®-iPad-App.

The currently selected recording mode and recording time are shown on the handheld display and in the OccluSense®-iPad-App.

NOTE

- The "Live mode" as well as the "Live + Recording" mode are only available if the OccluSense has been integrated in your WLAN network (Chapter 10.3) to ensure the best performance.

14.3.1 Recording and Live-Mode

To start a recording, a handheld with an inserted sensor has to be connected to the app (Chapter 14.1.2) and a patient has to be activated (Chapter 13). The currently active patient is always shown at the top left of the screen (Figure 34). By tapping on the top left patient information, the app will switch to the patient management screen, described in chapter 13.

Figure 34: Active patient, including the full name, the birthdate, a gender icon and the patient ID

To be able to start a recording, the handheld has to receive information about the operation mode and the duration of the recording (Figure 35). These values can be set in the recording view and are transmitted automatically to the handheld. Default values for the recording are set in the settings and are applied when a new patient is selected and activated or when the "New recording" button in the patient management is pressed.

Figure 35: Recording settings in the recording view

For the duration of the recording, a value between 1 and 99 seconds can be chosen. For the operation mode, one of the following options can be selected (Figure 36):

Live	Realtime mode (no recording)
Recording 50Hz	Recording 50 pictures/sec. (no live view)
Recording 100Hz	Recording 100 pictures/sec. (no live view)
Recording 150Hz	Recording 150 pictures/sec. (no live view)
Live + Recording 50Hz	Recording 50 pictures/sec. (with live preview)
Live + Recording 100Hz	Recording 100 pictures/sec. (with live preview)
Live + Recording 150Hz	Recording 150 pictures/sec. (with live preview)

Figure 36: Recording mode and duration

The live mode can only be selected if the handheld is connected to the app via your local area network.
After choosing both values for recording mode and duration, the recording can be started by pressing the left (pink) button of the handheld. If the recording view is not currently active, the app will automatically switch to this view.

NOTE

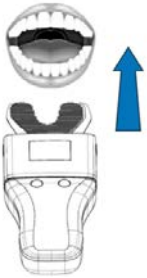
- In live mode the data is only displayed but not recorded. However, it is possible to save a snapshot of the live data. A snapshot is like a recording with only one image. To save a snapshot, press the right, green button of the handheld. When the live mode is active, it is indicated by red dot and the text "LIVE MODE" at the bottom of the screen (Figure 37).

Figure 37: Live mode icon in the recording view

14.4 Recording of the masticatory pressure distribution

The practitioner must perform the following steps in order to record the masticatory pressure distribution of a patient:

14.4.1 Insert the sensor into the patient's mouth



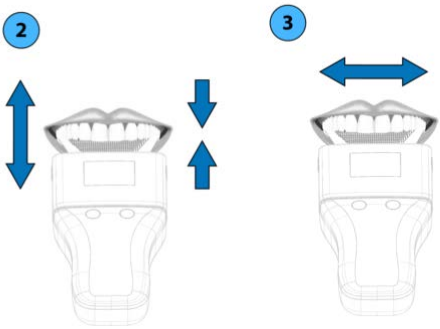
NOTE

- Slightly squeezing the cardboard frame makes it easier to insert the sensor into the patient's mouth.
- The printed red triangle on the sensor marks the centerline.
- Only touch the sensor on the cardboard frame.

CAUTION

- Do not insert the sensor too deep into the mouth!
- Do not bend the sensor!

14.4.2 Recording



- Start the recording on the handheld by pressing button 1 (pink).

- The patient opens and closes the mouth according to the instructions of the practitioner. In recording mode, the recording does not begin until a minimum force is exceeded or by pressing button 1 (pink). The handheld indicates the start and end of the recording through an acoustic signal.

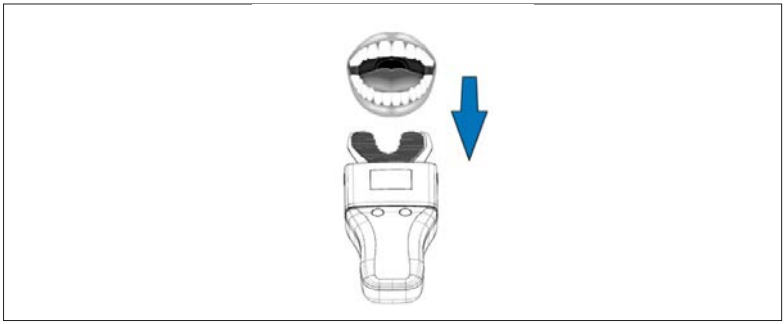
- Stopping the recording depends on the selected mode:
  Live mode: In live mode, the start/end is not being indicated by an acoustic signal. The recording is ended by pressing button 1 (pink).

- Recording Mode / Combined Mode: The recording ends automatically after the specified recording time has elapsed.

NOTE

- Static and dynamic occlusion recordings are possible.

14.4.3 Finish recording



- Remove the sensor from the patient's mouth.
- The evaluation of the recorded raw data as well as the visualization of the masticatory pressure conditions are processed by the OccluSense®-iPad-App.
- Remove the sensor from the handheld and dispose of it properly after the desired recordings have been made.
- Perform the cleaning and disinfection procedure as described in chapter 20.

NOTE

- Occlusal contact points are also marked on the occlusal surfaces of the patient's teeth.

CAUTION

- The OccluSense®-Sensors are medical devices for single use and must be disposed of immediately after use (chapter 24).

NOTE

The interpretation in the OccluSense®-iPad-App and storage of the data depends on the selected recording mode:

- Live mode: the interpretation is shown in realtime. Live recordings are not being saved. However, it is possible to save individual snapshots by pressing button 2 (green).
- Recording mode / combined mode: After recording, the raw data is being stored in the patient's file of the OccluSense®-iPad-App and displayed automatically after the recording has been finished.

EVALUATION OF RECORDINGS

15 Viewing recordings

15.1 Overview

In the section "Recording", you can start a recording or the live mode (Figure 38). A graphical representation of the data is arranged in the center of the screen. The recorded or live data can either be displayed two-dimensionally, three-dimensionally or in a combined view. The following chapters describe, how it is possible to record data using this menu item and which features are available for data analysis and processing.

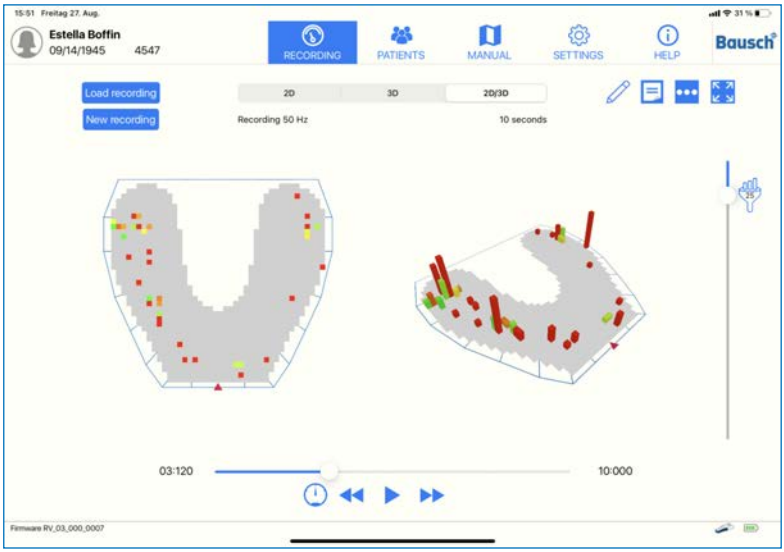


Figure 38: Recording view of the app

NOTE

- The color distribution and bar height of the images are always individually dependent on the patient's teeth shape and occlusal behavior. Therefore, recordings are not comparable with the recordings of other patients.

2D View

The recorded data can be displayed in three ways. The first view is called "2D" which shows the recorded data of the masticatory pressure by two dimensionally colored squares (Figure 39).

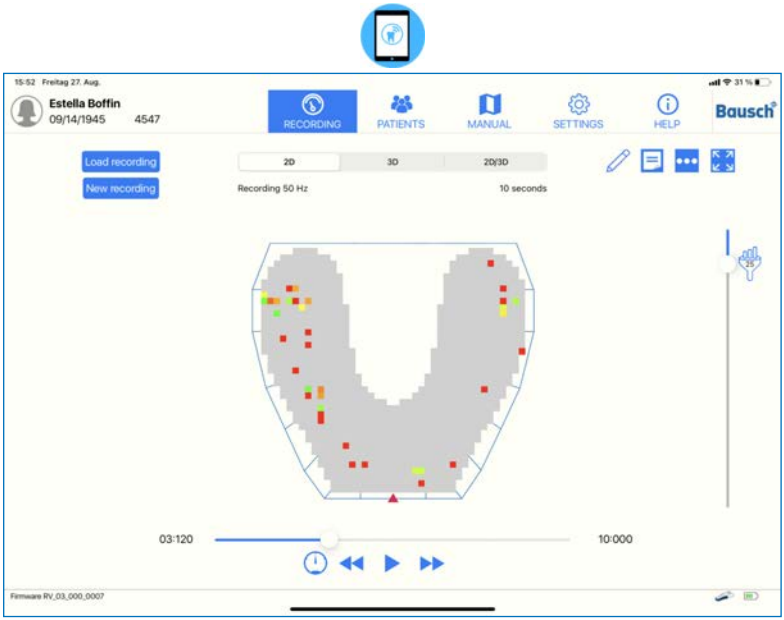


Figure 39: 2D view of the occlusal pressure distribution

3D View

The second option is the three dimensional view, called "3D" (Figure 40) which shows the data by using a bar diagram. The bars have different heights which represent the occlusal pressure - the higher the bar the higher the pressure of the occlusal contact.

When calculating the masticatory pressure distribution, the ratio of individual contact points with the surrounding areas as well as with all contact points of the entire dental arch is taken into consideration. This includes the number of contact points as well as the bite force.

The bars show a color gradient from green to yellow to red and imply the masticatory pressure distribution in a certain area. A pin-point pressure is being displayed from red to orange while a pressure on a larger surface area is being displayed from yellow to green.

The relative pressure difference between these pressure points and surfaces is illustrated by the height of the bars in the 3D view.

The bars show a color gradient from green to yellow to red and represent the relative difference of a contact point to its adjacent contacts. A green color implies a small relative difference between the adjacent contacts. The color gradient will turn from yellow to red if the difference between the adjacent contacts will become higher.

In addition to the markings on the occlusal surfaces, like with conventional occlusion test materials, OccluSense® is able to record the temporal sequence of intercuspidation. During this dynamic process, the pressure points and surfaces change in their appearance.

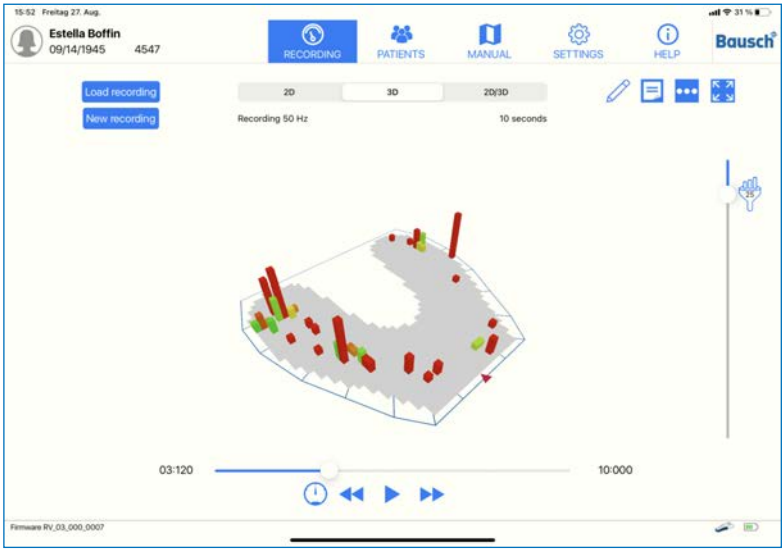


Figure 40: 3D view of the occlusal pressure distribution

2D/3D View

The third option is to combine the previous two views, called "2D/3D" (Figure 41) in order to view both on one screen.

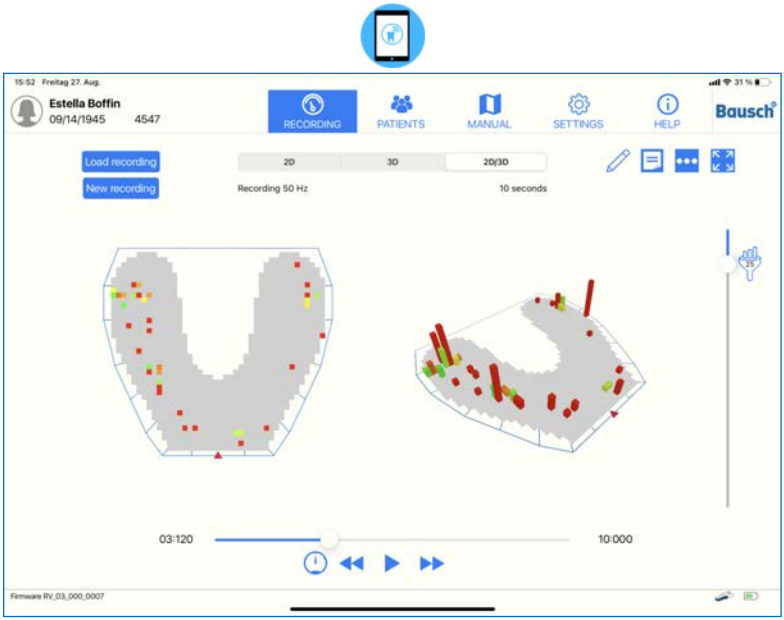


Figure 41: Combined 2D/3D view

15.2 Resizing, turning and tilting the view

The three dimensional view can be resized by a pinch gesture with two fingers. The view can also be rotated by swiping horizontally across the diagram and tilted by swiping vertically across the diagram.
The position and direction of the two dimensional view can not be changed.

15.3 Playing recordings

If the recording is not a snapshot, it is possible to view all occlusion pressure changes over time, just like a video.
The operative elements for this purpose can be found on the bottom of the screen (Figure 42).

Figure 42: Controls of a recording (while the recording is paused)

To play back the recording, press the "Play" button which is depicted as a simple arrow pointing to the right. If the recording is already running, the "Play" button is replaced with the "Pause" button, which is depicted as two vertical parallel bars (Figure 43).

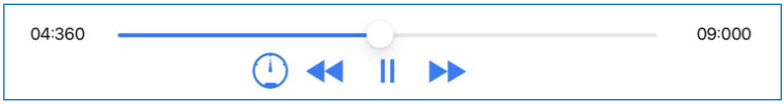


Figure 43: Controls of a recording (while the recording is playing)

On the left and right of these buttons are two double-headed arrows which are pointing to the left or right. These buttons move the recording back or forward by one frame, allowing to find the exact moment of the recording which is relevant for you.
Above the described buttons, you will see a blue line with a white point. This line symbolizes the total length of the recording, while the point shows where the current frame is located in relation to the total length. Both of these time units are shown in seconds and milliseconds (current time: left, total time: right).

The button can be used to set the playback speed in three modes. It should be noted, that the selected frame rate of 50 Hz, 100 Hz, or 150 Hz during the recording has an influence on the playback speed (see table on page 57). This feature enables a detailed temporal evaluation of the occlusal contacts.

Recording 50 Hz Example: 10 sec. Recording =	1/4 Speed 40 sec. Playback	1/2 Speed 20 sec. Playback	1/1 Speed (Realtime) 10 sec. Playback
Recording 100 Hz Example: 10 sec. Recording =	1/8 Speed 80 sec. Playback	1/4 Speed 40 sec. Playback	1/2 Speed 20 sec. Playback
Recording 150 Hz Example: 10 sec. Recording =	1/12 Speed 120 sec. Playback	1/6 Speed 60 sec. Playback	1/3 Speed 30 sec. Playback

15.4 Filtering

At the right edge of the screen you can find a vertical line with a white dot (slider). The slider enables you to manually set the threshold of the graphical representation between "0" (= upper end of the slider) and "256" (= lower end of the slider) to highlight relevant pressure points and areas. With the setting of the threshold you determine the type of representation, so that changes in color and height of the columns in the diagram may result (Figure 44). The set value is displayed in the filter icon. The preset filter value is set to "30" to omit electrical noise of the sensor.

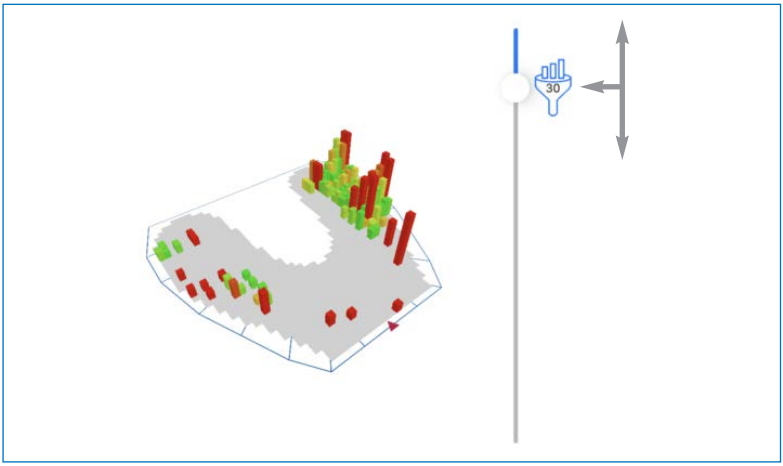


Figure 44: Slider to adjust the threshold

15.5 Viewing recorded data

The recorded data is available in the section "Recordings". It is also possible to load and view older recordings and snapshots. Tap on the "Load recording" button in the top left and select the recording that shall be viewed (Figure 45).

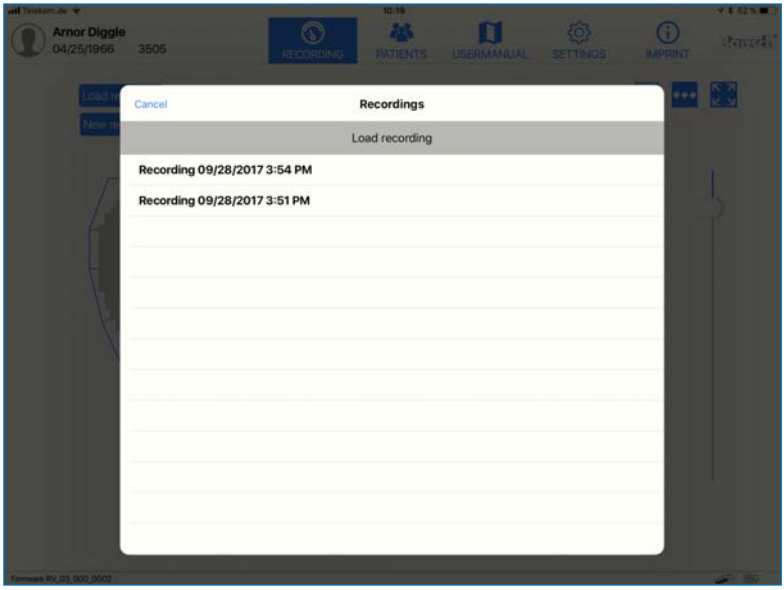


Figure 45: List of available recordings of the activated patient

15.6 Additional visualization options

At the top right edge of the screen are three buttons. A tap on the button in the middle, with the three dots opens a small menu with the options to activate or deactivate the visualization of the occlusal force distribution (Figure 46). It represents the occlusal pressure distribution by the sensor zones. If one or both menu options are activated, the visualization is only displayed in the 2D view.

The "Show Force Distribution in Percent" option shows twelve percentage numbers for the twelve zones of the sensor. These zones are indicated by the blue lines around the sensor.
The "Show quartered Force Distribution" option shows a circle with four quarters in the background of the sensor diagram (Figure 46). The color of each quarter is a gradient ranging from green to yellow to red and shows the difference of the pressure between the quarters. The pressure of a quarter is calculated with the bar values of the quarter. Depending on the height of the difference, the quadrant color changes from green to yellow to red.

Figure 46: Occlusal pressure with both options for the occlusal force distribution enabled

15.7 Renaming recordings and adding notes

Renaming recordings

By using this button, you can edit the name of a recording. This option is available in the section "Recording" as well as in the "Patients" section. The search field in the list of recordings can be used to find a recording by the name.

Notes

By using this button you can add a note to a recording or edit an existing one. At the top of the note view are two buttons:

- the trash bin to delete the open note
- the button to save and close the note

The note is attached to the recording and is also shown within the patient management below the recording. The length of the note is not limited (Figure 47).

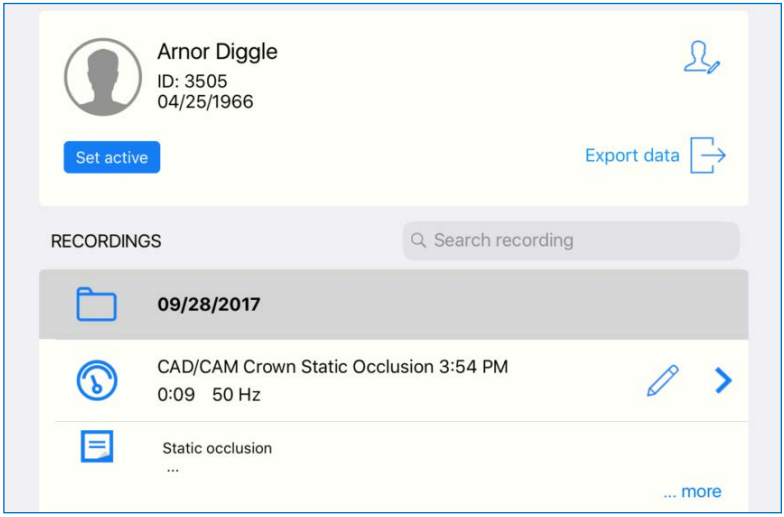


Figure 47: Renamed recording including a note

15.8 Fullscreen

At the top right, the fullscreen-button is located. By using this you can maximize the diagram view and all controls, not necessary to interact with the diagram, are hidden.

The fullscreen view also permits the export of recordings as pictures, PDF or video (chapter 16).
To leave the full screen view, tap on the button again (Figure 48).

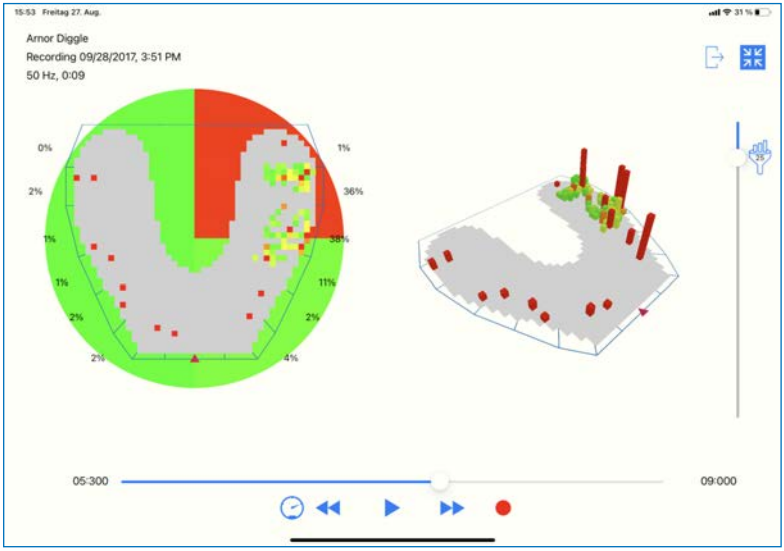


Figure 48: Fullscreen view of a recording

16 Manage and export recordings

You can manage your recordings from within the patient's folder (Figure 49). When a patient has been selected from the patients list, all recordings of this specific patient appear. Recordings will be collected in folders sorted by date. Renamed recordings (chapter 15.7) can easily be found by using the search field.

The note of a recording, if existent, is displayed below the recording entry and adapted to the first two lines if the text is too long. To see the note in full length, tap on the "... more" button and the full text will appear.

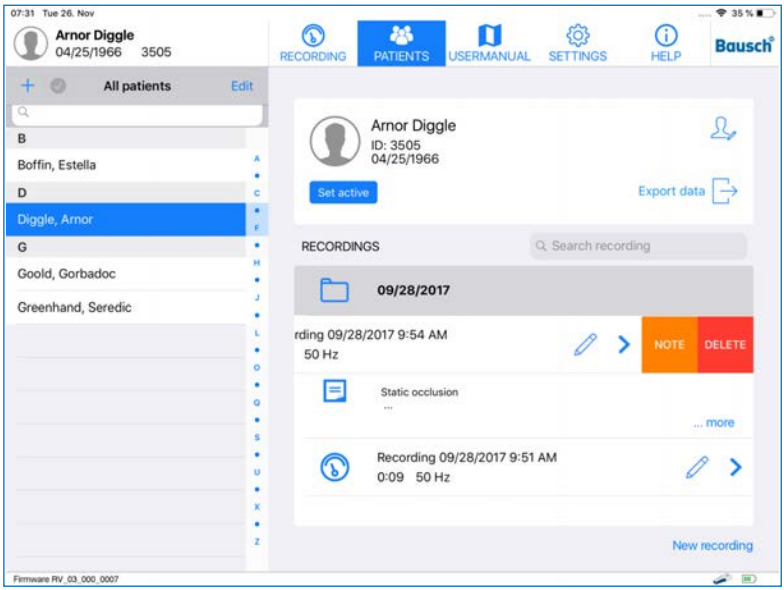


Figure 49: Recordings of a patient

If you want to delete a recording, swipe to the left to open the submenu "NOTE/DELETE" and tap on "DELETE". The menu item "NOTE" enables editing of the note (chapter 15.7). To start a new recording for the selected patient, tap the "New Recording" button at the bottom right corner of the screen. The patient will be set active and the view will be switched to "RECORDING".

16.1 Play back recordings

To play back a recording a patient has to be selected from the patient´s list. After selection, a list of recordings related to this patient will appear. Tapping on recording, all occlusion data will be displayed in a new diagram view, as described in chapter 13.3. When displaying a recording, you can easily switch between all recordings of the same patient using the list on the left.

16.2 Compare recordings

The "Compare Recordings" button in the playback view enables you to select two recordings of a patient and display them next to each other (Figure 50).
To change the recordings to be compared, use the "Load Recording" button at the top right of the respective segment.

The comparative view does not offer the functionality of the occlusal force distribution (Chapter 16.2), full screen (Chapter 15.8) or the combined 2D / 3D view (Chapter 15). To return to the playback view, tap the "Back" button located at the top left of the screen.

Figure 50: Comparison view of two recordings

NOTE

- This functionality only allows the comparison of recordings of the same patient. Hence, at least two recordings or snapshots need to be available.

16.3 Export recordings and snapshots

Recordings can be exported as images in .png format, or as pdf files including the notes of the recording, or as videos. This export functionality is only available in the full screen mode of a recording, described in chapter 15.8. There is an export button at the top right corner, which opens a message box with the option to choose the format (Figure 51).

- PDF: A preview including the respective notes opens and subsequently can be exported or printed .

- PNG: The export will take a screenshot of the current scene and save it in the "Photos" App on the iPad.

Additionally, the images or PDFs are being copied to a shared folder of the app, accessible via iTunes on your PC or Mac (chapter 16.5).

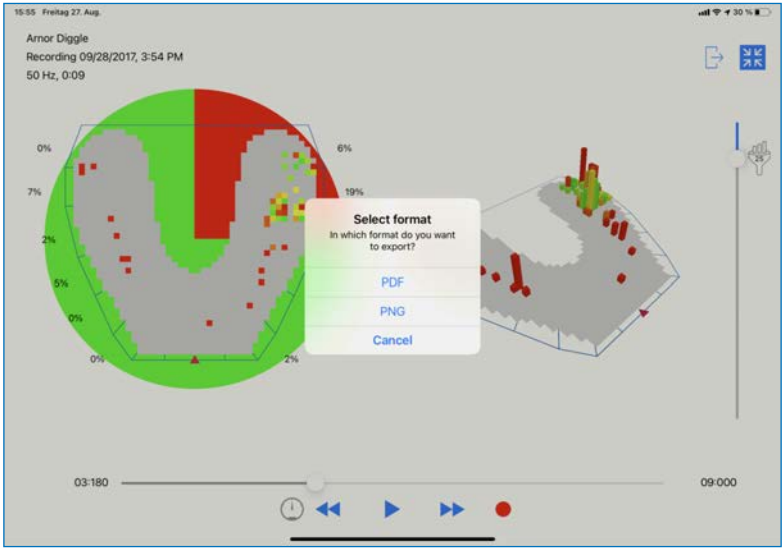


Figure 51: Exporting a screenshot is possible as either PDF or as PNG

16.4 Export recordings as videos

Recordings can also be exported as MP4 videos by recording the playback. The videos include your interactions with the recording like the rotation, tilting, zooming, adapting the threshold or using the default controls to display the desired frame. Exporting a recording as video is also only available in the full screen mode.

Use the timeline slider to select the frame you want to start the video export. Then tap the red recording button. Accept the capture of the screen to start the recording. Now tap on the play button to start the playback and interact with the recording in the way you want it to be seen in the video. When finished, tap on the grey "Stop" symbol. Now a preview of the recorded video will be shown (Figure 52). The video can be trimmed via the controls at the bottom. After trimming the video, this has to be confirmed by tapping the "Done" Button at the top right corner. Then use the "Save" button in the same position to save the video to the iOS "Photos" app.

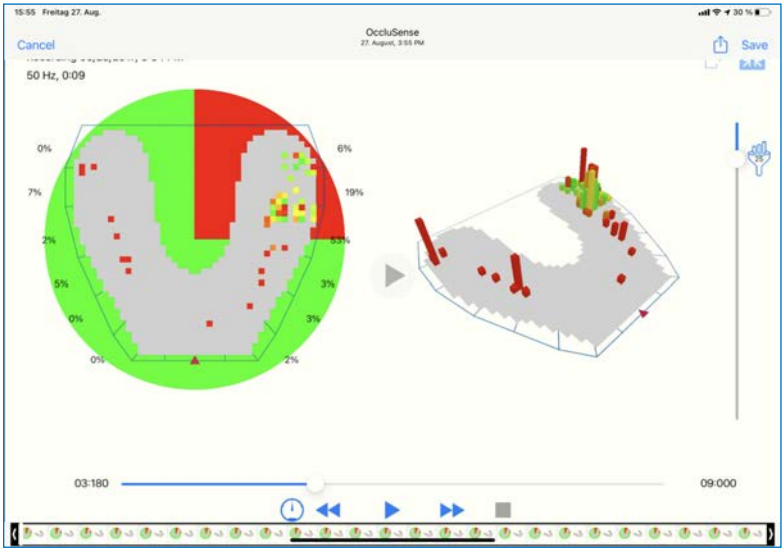


Figure 52: The preview of the video recording mode.

CAUTION

- iOS offers the storage of photos/videos in the iCloud photo library. We recommend to disable this feature in the iCloud settings. We expressly point out that the storage of personal data in cloud services is under the sole responsibility of the user.

16.5 Export data via iTunes PC/Mac software

To export data to a PC or Mac, you have to connect the iPad to the PC/Mac. The cable is included with the iPad. The software "iTunes" has to be installed on the PC/Mac. (www.apple.com/itunes/download/).

The data of a selected patient can be exported by tapping on the "Export" button at the right side, below the "Edit Patient" button. In the context menu, select "iTunes" and the export will be confirmed.
To export one or more patient's data, tap on "Edit" at the top of the patient list. Now you can select any number of patients. The button selects all patient records at once. As soon as all patients are selected, tap on "Export" at the bottom of the list. In the context menu, select "iTunes" and the export will be confirmed.

Exported recordings are saved as raw binary data. You can access and copy the exported data via iTunes to any PC or Mac by navigating to the specific application folder (Figure 53). This is necessary for a data backup.
Exported images and PDFs as well as video recordings of a patient can be transmitted to a PC or Mac in the same way.

NOTE: as of macOS Catalina (10.15), the file manager is located in the Finder.

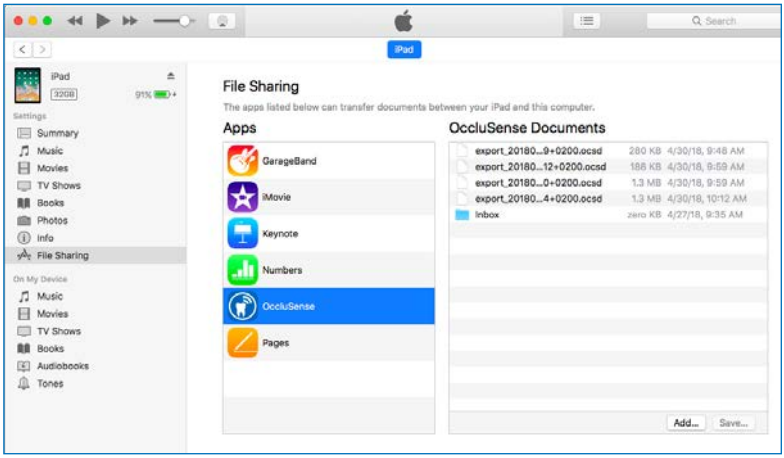


Figure 53: Location in iTunes to access exported files from the app

16.6 Export patient's data via AirDrop

The data of a selected patient can be exported to another iPad or Mac by tapping the "Export Data" button on the right side below the "Edit Patient" button. In the context menu, select the other device in the section "AirDrop".
To export several patient data simultaneously, tap "Edit"at the top of the patient list. Select all patient's recordings that you want to export. The button selects all patient records at once. In the context menu, select the other device in the section "AirDrop".
The data received on a Mac is used for data backup. If data is sent to another iPad with an installed OccluSense®-iPad-App, it can be imported and used there.

CAUTION
In addition to the AirDrop and iTunes export functions, iOS may also offer cloud-based services. We do NOT recommend the use of these services and expressly point out that the storage of personal data in cloud services is under the sole responsibility of the user.

16.7 Import

To import previously exported data to another iPad running the OccluSense®-iPad-App, connect the iPad to a PC or Mac, open the iTunes software and navigate to the specific application folder (Figure 53) as described in chapter 16.5.
Click the "Add" button in iTunes to add the previously exported data (Figure 53). Start the OccluSense®-iPad-App and go to the patient management screen. Tap the "Edit" button on top of the patients list and use the "Import" button to start the import process (Figure 54).

Figure 54: Import button

If the data has been sent via AirDrop to an iPad, the OccluSense®-iPad-App will launch automatically. You will be asked if the received file should be saved for immediate or later import. If you decide to import the data later, the file can be imported by using the "Import" button in the edit mode of the patients list (Figure 54).
To avoid duplicates, the ID of the patient is being considered. If the patient already exists, the recordings are being synchronized. If the same ID is being used for a different patient you have to choose between the existing or imported patient.
New imported recordings will be added to the respective list of recordings, sorted by date. Updated notes of synchronized recordings are automatically being added.

SETTINGS

17 Menu “Settings”

17.1 Recording settings

The default settings for duration and frequency can be selected here. These settings will be applied whenever you set a new patient active, described in chapter 14.2, or when the “New recording” button in the patient management has been pressed.

17.2 Handheld firmware (and updates)

This view shows the firmware version of the connected handheld device as well as the latest available firmware version. If a new firmware version is available you can start the update. The handheld device will receive and install the update automatically. This might take a few minutes. During the update process the connection to the handheld will be lost and the WLAN data might be lost as well. To reconnect the handheld device, refer to chapter 10.2.

NOTE

- The update for the OccluSense®-iPad-App is provided by the Apple AppStore in the standard update process.

17.3 Terms and conditions

The terms and conditions of the app are listed here. You will be asked to accept these terms and conditions to register your handheld device, which is needed to use all functionalities of the app.

18 Menu “Imprint” (HELP -> Imprint)

The imprint contains all the important information about the legal manufacturer, further contact details and software license agreements.

When tapping on the e-mail address, the default mail app on the iPad will open.

TROUBLESHOOTING

19 Basic troubleshooting

19.1 Damages of the handheld

CAUTION

- In case of a mechanical damage, the device must be returned or disposed of properly.

19.2 Reset to factory default

To reset the handheld to factory default, you have to press and hold the reset button that can be accessed through a small hole inside the battery compartment (chapter 4.1). You will hear a sound when the reset has been initiated.
To access the button a very thin object (i.e. paperclip) is required. After resetting, the handheld is in factory configuration. No data in the OccluSense®-iPad-App is being deleted or changed.

19.3 Connection lost after Firmware Update

Updating the firmware of the handheld may cause a disconnection to the wireless network.
If the handheld device has lost information about the local wireless network, indicated by the missing name of the local wireless network at the handheld device connection indicator, switch the iPad's wireless network to the network of the OccluSense® handheld device. Then reconnect the handheld device to the local wireless network, for details refer to chapter 10.2.
If the handheld device does not reconnect automatically to the app when using the wireless network of the handheld device, establish the connection manually.

19.4 Entering wrong WLAN credentials

As described in chapter 10 the WLAN credentials have to be correct, otherwise the handheld will be out of reach for further connectivity attempts. If you have accidentally entered incorrect WLAN connection credentials, please reset the handheld as described in chapter 19.2 and try again.

19.5 Troubleshooting table

General (all components)

Error (symptom)	Cause	Action
Handheld, charging station, test sensor, screwdriver or OccluSense®-Sensors are missing.		• Consult Bausch (support@occlusense.com)
Handheld, charging station, test sensor, screwdriver or OccluSense®-Sensors are damaged. OccluSense®-Sensor Seal pack is damaged.		• Consult Bausch (support@occlusense.com)

OccluSense®-iPad-App

Error (symptom)	Cause	Action
The OccluSense®-iPad-App is not installed properly on the iPad.	• The user's iPad is not compatible with the OccluSense®-iPad-App • The iOS-version of the user is not compatible with the OccluSense®-iPad-App • The OccluSense®-iPad-App has not been downloaded correctly or completely from the appstore	• See operating instructions, "Hardware Requirements" • Update the iOS • Try to download the App again • Check internet access
The connection between OccluSense® -iPad-App and handheld is not possible.	• Another handheld is already connected to the app • The WLAN connection between iPad and handheld is insufficient or not available • The rechargeable batteries of the iPad or the handheld are not properly charged	• Disconnect the current inter-connection, see instructions for use (chapter 10.3.2) • Check (or let check) WLAN connection • Make sure that batteries are properly charged (chapter 8.1 and iPad user manual)
No connection can be established between iPad and handheld.		• Make sure that iPad and handheld are in the same WLAN and connected (Settings -> Handheld registration)
Only sample/demo data is visible.	• The registration process has not been performed	• Perform registration process, see chapter 10.2.4

Error (symptom)	Cause	Action
A recording of the bite force distribution can not be started.	• Patient file has not been created or activated in the OccluSense® -iPad-App	• Create patient file in the OccluSense®-iPad App (chapter 13.2) • Activate patient in the Occlu Sense®-iPad-App (chapter 14.2)
	• The regularly requested function test (with the test sensor) has not been performed	• Perform function test with test sensor (chapter 12)
	• The function test has failed	• Ensure correct position of the test sensor in the handheld! • Perform function test again • In case of further function test failures consult Bausch (support@occlusense.com)
	• A required update of the OccluSense® -iPad-App or the handheld firmware was not installed	• Ensure connection to the Apple AppStore • Perform update (chapter 17.2, 21.3)

OccluSense®-Handheld

Error (symptom)	Cause	Action
Handheld can not be switched on.	• There are no batteries in the battery compartment	• Insert batteries into the battery compartment (chapter 8.1)
	• The batteries have been inserted incorrectly	• Remove the batteries from the battery compartment and insert them according to the identification marks inside the battery compartment (section 8.1) • Ensure the firm contact of the the battery poles with the battery probes
	• The batteries are insufficiently charged	• Charge the batteries (chapter 8.1)
Batteries cannot be inserted into the handheld.	• Battery compartment cover can not be opened	• see manual (chapter 8.1)
	• There are no (suitable) batteries available	• Use of 3 x AAA NiMH rechargeable batteries, 1000 mAh (chapter 8)

Error (symptom)	Cause	Action
Battery compartment cannot be closed	• Battery compartment cover is defective or missing • Screwdriver is damaged or missing	• Consult Bausch (support@occlusense.com)
The connection between OccluSense® iPad-App and handheld is not possible.		• Connect handheld with iPad App (chapters 10) • Reset the handheld to factory default (chapter 19.2)
No connection can be established between iPad and handheld.	• The WLAN configuration has been set up incorrectly	• Reset the handheld to factory default (chapter 19.2) • Connect iPad App to the handheld (chapter 10) and re-enter WLAN credentials (chapter 10)
The recording of the bite force distribution cannot be started	• The registration process has not been performed • The regularly requested function test (with the test sensor) has not been performed or it has failed	• Perform registration process, see chapter 10.2.4 • Perform or repeat function test with test sensor (chapter 12) • Consult Bausch (support@occlusense.com)

OccluSense®-Charging station

Error (symptom)	Cause	Action
The charging station cannot be connected to the (local) power supply.	• The matching power supply plug is defective or missing	• Consult Bausch (support@occlusense.com)
The handheld batteries are not (correctly) charged.	• There are no batteries in the battery compartment • The batteries were inserted incorrectly • The handheld is not correctly positioned in the charging station • The charging station does not recognize the inserted handheld	• Insert batteries into the battery compartment (chapter 8.1) • Insert handheld into the charging station (chapter 8.1) • Make sure that the handheld's position in the charging station is correct and without any intermediate layer

OccluSense®-Test-Sensor

Error (symptom)	Cause	Action
Handheld does not recognize the OccluSense®-Test-Sensor	• OccluSense®-Test-Sensor is not properly inserted	• Check position of the test sensor in the handheld (chapter 12)

OccluSense®-Sensor

Error (symptom)	Cause	Action
The handheld does not recognize the OccluSense®-Sensor.	• OccluSense®-Sensor is not properly inserted • The used OccluSense®-Sensor is defective or manipulated	• Check position of the test sensor in the handheld and, if necessary, reposition the sensor (chapter 14.1.2) • Replace unrecognized OccluSense®-Sensor • Consult Bausch (support@occlusense.com)

Treatment

Error (symptom)	Cause	Action
The handheld turns off after a few recordings	• There are no suitable rechargeable batteries inserted in the battery compartment • The batteries are defective	• see manual (chapter 8.1) • Replace batteries use of 3 x AAA NiMH rechargeable batteries, 1000 mAh (chapter 8)
The recordings are assigned to another patient	• A patient other than the patient being treated is set active in the OccluSense®-iPad-App	• Create patient file in the OccluSense®-iPad-App (chapter 13.2) • Activate patient in the OccluSense®-iPad-App (chapter 14.2)

CLEANING

20 Cleaning and disinfection

The components of the OccluSense®-System (handheld, charging station and test sensor) must be cleaned and disinfected regularly after each treatment as part of general practice hygiene.
In principle, the following must be observed: "Requirements for hygiene in reprocessing medical devices Recommendation of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM)", Bundesgesundheitsblatt 2012 - 55:1244-1310.
Damaged system components may not be reused and must be disposed of properly if the warranty has expired.

The following system components must be stored dust-free after cleaning and disinfection.
Storage conditions:

Temperature range	0°C ... +80°C
Relative humidity	20% ... 90%
Atmospheric pressure	500hPa ... 1060hPa

20.1 Handheld

Clean and disinfect the handheld within max. 2 hours after treatment:

1. Switch off the handheld. To do this, press and hold button 1 (pink) for more than 2 seconds. Alternatively, the handheld switches itself off automatically after approximately 4 minutes.
2. Remove the sensor from the device and dispose it in accordance with official disposal regulations. (see also: Chapter 24 "Disposal instructions")
3. In case of any contamination, such as saliva, wipe off the surfaces with a damp cloth and dry the surfaces.
4. Visual inspection of the handheld for any damages
5. Disinfect the surfaces (also in the area of the sensor lid below the sensor) with disinfection tissues.

- Recommended disinfectant tissues: e. g. Kanizid Microspray-AF quick disinfectant tissues from Kaniedenta or appropriate disinfectants.
- Note: Cleaning agents and disinfectants containing formaldehyde may only be used after cleaning and disinfection in order to prevent a protein fixation.

20.2 Charging Station

1. Disconnect the charging station from the electric supply system.
2. Proceed as described in chapter 20.1, steps 3 to 5.

20.3 Test-Sensor

Cleaning and disinfection as described in chapter 20.1, steps 3 to 5.

20.4 Reusability

Frequent reprocessing has no effect or limitation on the system components of the OccluSense®-System, as the end of the product's life is determined by wear and tear and damage caused by use.
The use of damaged and dirty components is the responsibility of the user.
In case of disregard any liability is excluded.

NOTE

- The instructions of the manufacturer of the detergent and disinfectant must be followed strictly. In particular, the concentrations to be used and the application times must be observed!

CAUTION

- The components of the OccluSense®-System are not suitable for mechanical cleaning and thermal disinfection processes.
- The battery compartment cover must be closed during cleaning and disinfection.
- **Switch off** the handheld before cleaning/disinfection!
- It is mandatory that the contact time of the disinfectant product is being observed and that the unit is **NOT** switched on during this time.
- The OccluSense®-Sensors are disposable medical devices and must not be reused.

MAINTENANCE

21 Batteries, electrical safety, software updates

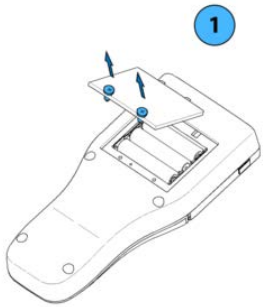
21.1 General

The OccluSense®-System is basically maintenance-free.
However, the system must be calibrated once a day (if used) in the form of a function test. If the function test runs successfully as described in chapters 11 and 12 "Safety test & function test with test sensor", no maintenance is required. However, if errors occur during the function test of the device, then there is probably a defect in the OccluSense®-System. In this case see chapter 19.

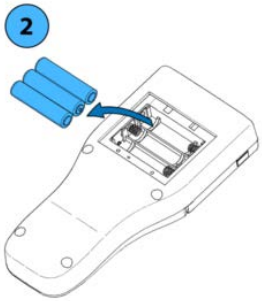
CAUTION

- Do not make any repairs or other changes to the system.
- The use of damaged and altered components is under the responsibility of the user.
- In case of disregard any liability is excluded.

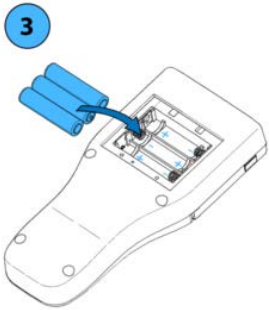
21.2 Replacing the batteries



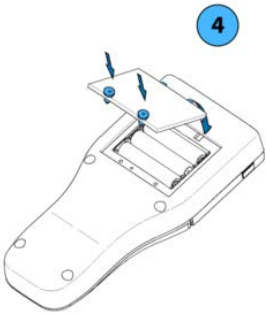
1. Loosen the screws of the battery compartment cover using a Torx IP 6 screwdriver (included) and remove the battery compartment cover.
The screws of the battery compartment cover are "captive", i. e. they remain on the battery compartment cover after opening.



2. Remove the batteries to be replaced and dispose of in accordance with the official disposal regulations (see chapter 24).



3. Insert new suitable AAA NiMh rechargeable batteries (with a capacity of at least 1000mAh each) in the correct arrangement (see markings in the battery compartment).



4. Insert the battery compartment cover and tighten the screws by hand.

CAUTION

- Batteries inserted inversely can reach high temperatures and damage the device.
- Pay attention to the marking in the battery compartment!

21.3 Software-Updates

For troubleshooting purposes, the OccluSense®-System supports updating the handheld firmware and the OccluSense®-iPad-App.
As soon as an update of the handheld firmware or the OccluSense®-iPad-App is available, a reminder for the update is automatically displayed and can be downloaded and installed by selecting:

"Settings" -> "Handheld Firmware"

NOTICE

22 Transport & Storage

In case of a longer storage of the OccluSense®-System, it is recommended to remove the batteries from the handheld and store them together with the other system components in the system case (included). The same applies to the transport of the system.

Transport and storage conditions:

Temperature range	0°C ... +80°C
Relative humidity	20% ... 90%
Atmospheric pressure	500hPa ... 1060hPa

23 Expected lifetime

The expected lifetime of the handheld is 5 years.
Expiry date of sensor: See label on the packaging.

24 Disposal Instructions

The components of the OccluSense®-System (handheld unit, charging station, test sensor) as well as the OccluSense®-Sensors must be disposed of in accordance with the applicable official disposal regulations. This means in detail:
Rechargeable Batteries: EU Directive 2006/66/EC; Law on the placing on the market, taking back and environmentally friendly disposal of batteries and accumulators (Battery Act - BattG)
Handheld equipment (without batteries), charging station and test sensor: EU Directive 2012/19/EU on waste electrical and electronic equipment (WEEE); Act on the marketing, take-back and environmentally sound disposal of electrical and electronic equipment (ElektroG)
OccluSense®-Sensor ("general"): Disposal in normal waste
OccluSense®-Sensor ("contaminated", e. g. HIV or hepatitis): disposal according to TRBA 250

25 Electromagnetic Compatibility

Changes or modifications of this system which are not expressively approved by the manufacturer may result in increased emissions or increased susceptibility to the equipment or system.
The system has been designed and tested to comply with applicable EMC regulations. It has to be operated only as described in chapters 8,10,12 and 15.

26 Warranty

From the date of purchase, a legal warranty of 24 months applies to all product components. The warranty for the battery functionality is 12 months.

This warranty covers repairs due to material and/or processing defects. Damage caused by improper use and/or cleaning & disinfection or caused by unauthorized service and repair providers or by the user himself during service or repair attempts will void the warranty.
Otherwise, the General Terms and Conditions of Dr. Jean Bausch GmbH & Co. KG apply.

27 Customer Service

Please use our support system and our knowledge database under the menu item "Help". You can contact our support team via the request form. An internet connection is required.

Alternatively, you can reach our support system at **help.occlusense.com**.

Phone support:

Germany & Europe	+49-221-982 59010 (multilingual)
The Americas:	+1 (844) 633-4002
Japan:	+81-50-3101-4161

Dr. Jean Bausch GmbH & Co. KG
Oskar-Schindler-Straße 4
D – 50769 Köln
GERMANY
www.occlusense.com
help@occlusense.com

28 Spare parts

- Charging Station	BK 5002
- Battery compartment cover	BK 5001-3
- Test Sensor	BK 5011
- Screwdriver	BK 5012
- Power supply adapter Europe	BK 5003
- Power supply adapter USA/Japan	BK 5004
- Power supply adapter UK	BK 5005
- Power supply adapter Australia	BK 5006
- Power supply adapter China	BK 5007

29 Notification of incidents

NOTE

- Serious incidents in connection with the application of the OccluSense®-System have to be reported to Dr. Jean Bausch GmbH & Co. KG [info@occlusense.com] and the respective authority of the EU member state!

NOTE

- The OccluSense®-System is an intensively tested product. Nevertheless, a malfunction may result in the incorrect display of the masticatory forces. The decision of therapeutic treatments must not be based solely on the data recorded by the OccluSense®-System. For this purpose, further information must be obtained in order to provide a comprehensive diagnosis. From the values of the recorded masticatory forces shown, no conclusions can be drawn about the absolute forces (absolute values). The recordings of the masticatory forces are relative value representations.

30 Declaration of Conformity

Please download the Declaration of Conformity for OccluSense® here:

www.occlusense.com/downloads

U.S.A.

U.S.A. & CANADA
MET Electrical Safety E114779

FCC ID: 2BAUV-OCCLUSENSE

Contains Microchip ATWINC1500-MR210PB - FCC ID: 2ADHKATWINC1500

The frequency band in which the appliance operates is 2.4 GHz.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications made to the Device Name device not expressly approved by Dr. Jean Bausch GmbH & Co. KG could void the user's authority to operate the equipment.
This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

CANADA

IC 30548-OCCLUSENSE

Contains transmitter module Microchip ATWINC1500-MR210PB - IC: 20266-WINC1500PB
This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following conditions:

- This device may not cause interference.
- This device must accept any interference, including interference that may cause undesired operation of the device.

Cet appareil contient un ou des émetteurs/récepteurs exempts de licence conformes aux RSS exempts de licence d'Innovation, Sciences et Développement économique Canada. Le fonctionnement est soumis aux conditions suivantes :

- Cet appareil ne doit pas provoquer d'interférences.
- Cet appareil doit accepter toutes les interférences, y compris les interférences susceptibles de provoquer un fonctionnement indésirable de l'appareil.

EUROPE

The ATWINC1500-MR210PB module is an R&TTE Directive assessed radio module that is CE marked and has been manufactured and tested with the intention of being integrated into a final product.

JAPAN

R 007 – AD0199

KOREA

R-CRM-mcp-WINC1510MR210P

TAIWAN

CCAN18LP0321T2

INDIA

ETA Certificate No: NR-ETA/5411-RLO(NR)

CHINA

CMIIT ID: 2018DJI1305

BRAZIL

Segurança
Compulsório
INMETRO

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