

αCARE SENS™

USER'S MANUAL

Revision – 2.0



For additional languages go to

<https://www.alphaomega-eng.com/αCare-V2-0>



Defining Neuroscience Technology

CE 0297

Copyright © 1996-2022 Alpha Omega Engineering Ltd. All Rights Reserved

PROPRIETARY NOTICE

This publication, or parts thereof, contains information proprietary to Alpha Omega Engineering and may not be reproduced, recorded, or transmitted in any form, by any method, for any purpose without written permission from Alpha Omega Engineering.

Alpha Omega Engineering Ltd. makes no warranty, expressed or implied, including but not limited to any implied warranties of merchantability or fitness for a particular purpose or use, regarding these materials and makes such materials available solely on an “as-is” basis.

In no event shall Alpha Omega Engineering Ltd. be liable to anyone for specific, collateral, incidental, or consequential damages in connections with or arising from the purchase or use of these materials. The sole and exclusive liability to Alpha Omega Engineering Ltd., regardless of the form of actions, shall not exceed the purchase price of the materials described herein.

For additional information on the device, including questions on infection control procedures, please contact: info@alphaomega-eng.com

CONTENTS

WARNINGS.....	4
1. OVERVIEW	5
2. PRODUCT DESCRIPTION AND PERSPECTIVE	7
3. LOG IN	8
4. CONTACT US	10



WARNINGS

- Only qualified personnel, who have been trained by Alpha Omega Ltd., should be allowed to operate this equipment.
- To prevent data loss, in the device running αCARE SENS™, do not let the device out of your sight.
- Setup screen saver and unlock by password/pattern to prevent data leakage from idle device
- Do not install on the device any application or software of untrusted or unknown sources.
- Do not click on any untrusted links, websites or icons with risks.
- Timely update the operating system, firewall and the browser when notified by the service provider.
- Install antivirus software and at least do virus scanning once a month.
- Do not let the device out of your sight. Please log out of αcare or lock your device when you are not using.



CAUTIONS

- US federal law restricts the sale of this device to or on the order of a physician.
- Discard according to the local regulations and law.

NOTES

- When using tablet, and for a better user experience, αCARE SENS™ Software should be visualized in Landscape view mode.
- αCARE SENS™ Software works best in screens larger than 10".
- Tablet should be set to lock screen autorotation.

1. OVERVIEW

A platform supporting the neurologist and the patients through the different stages of the Patient's Health Care Journey with movement disorder, by documenting electrophysiological mapping and informative data regarding programming sessions, resulting in making more objective and relevant decisions.

Reliable & informative data about the patient is documented:

- **From the OR** – Electrophysiological advanced mapping, lead placement, Lead electrophysiology and other information regarding planning, anesthesia time measurements and more.
- **In Clinic** – Detailed data of Monopolar Review process, stimulation parameters and symptoms changes across sessions

1.1. REGULATORY

1.1.1. FDA System Classification

Product Code: OUG

CFR Section: 21 CFR 880.6310

Regulation Name: Medical Device Data System

Trade Name: αCARE SENS™

Classification: Class I

1.2. INTENDED USE

αCare SENS™ is a medical device data system (MDDS) intended for transferring and cloud-base storage of electronic data collected during intraoperative DBS implantation, preoperative Neurology Clinics visits and post-operative programming sessions or from home during Activity of Daily Living .

The αCare SENS™ allows DBS programmer to produce informative data including measurements of disease symptoms and side effects to the benefit of patient programming.

1.3. CONDITIONS OF USE

The device may be used by medical personnel within a hospital, laboratory, clinic, or nursing home setting, or outside of a medical facility under direct supervision of a medical professional. The following are the αCare SENS™ Software use conditions:

Frequency of use: As per the specific case

Mobility: Mobile

Internet Connectivity:

Bandwidth	Bandwidth between 7-70Mb upload
Frequency and power	2.4GHzL 36 dBm/4w 5 GHz: 23–30 dBm / 0.2 - 1.0 w
Operating distance	~50m
Security	WPA2/WPA3

2. PRODUCT DESCRIPTION AND PERSPECTIVE

αCare SENS™ is an online platform that displays intraoperative data (Electrophysiological mapping, implantation depth and track, lead confirm results) for Neurologist during programming session, allowing DBS programmers to make an informative use of such MER intra-operative electrophysiology data.

αCare SENS™ provides an easy-to-use tool to document programming procedure including documentation of symptoms and side effects.

αCare SENS™ can be used together with tools and accessories to document patient symptoms and side effects during regular activity of daily life (ADL) and present reports to Neurologist to make an informative use of this data for tweaking stimulation parameters or medication intake.

3. LOG IN

3.1. SUCCESSFUL LOG-IN

The log-in page (figure 1) will be presented when accessing αCare web portal:

https://acus.alphaomega-eng.com/login_page

Use the credentials provided with the system for successful log-in.

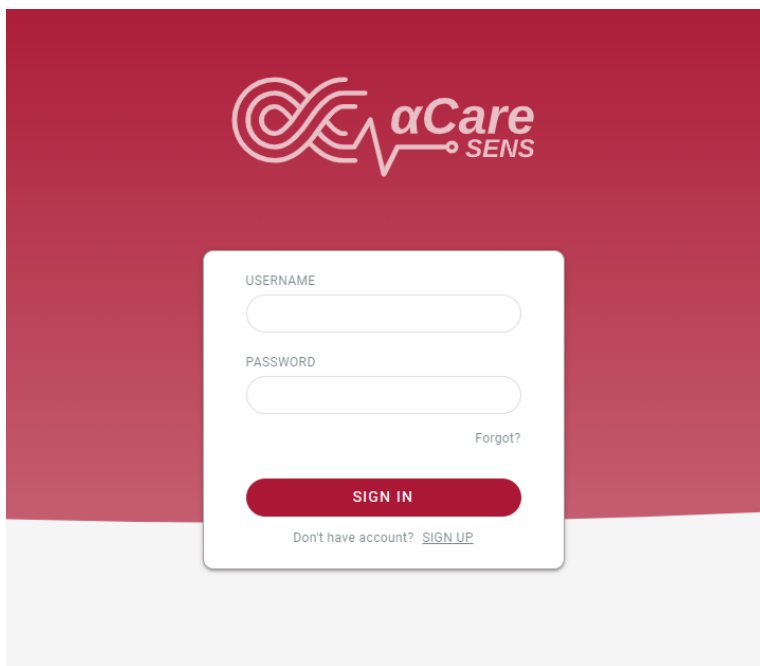


Figure 1: log-in page

At a successful log in you will get to αCARE SENS home page, where you can see list of patients, and today's appointments. Figure 2.

Patients can be filtered according to the patient's disease (1), neurosurgeon (2), and the date of the surgery (3).

Patient can be searched by his/her name in the searching box "search patients".

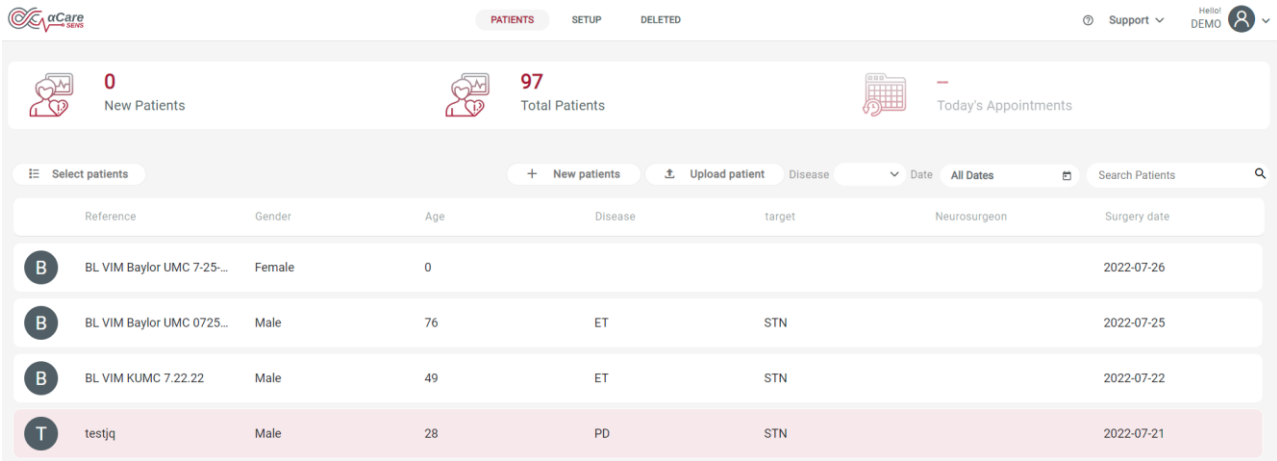


Figure 2: Homepage

3.2. ACARE SENS™ INSTRUCTIONS

Click “Support” to access DEMO instructions:

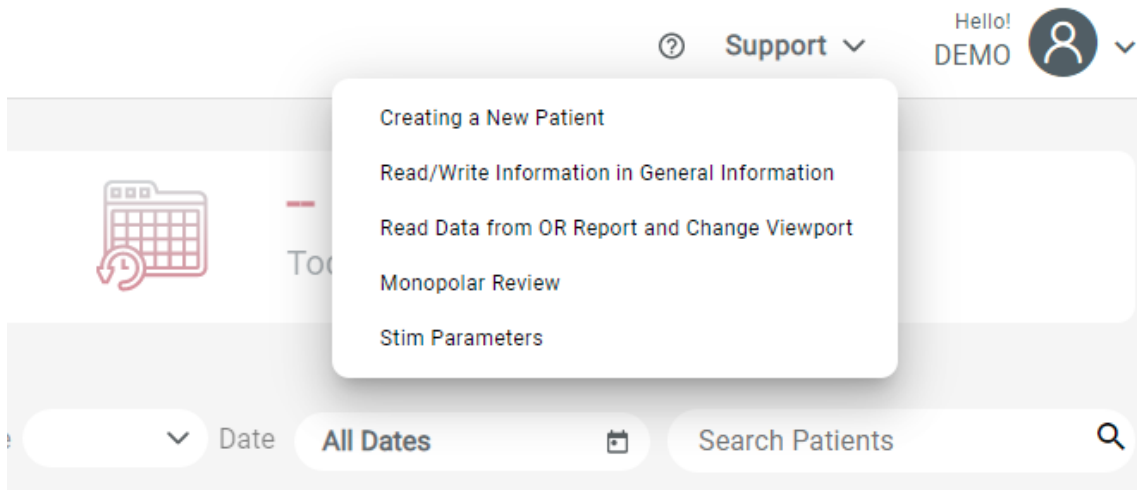


Figure 3: DEMO

4. CONTACT US

info@alphaomega-eng.com // www.alphaomega-eng.com

Americas

Alpha Omega Co. USA
5755 North Point Pkwy., Unit 229
Alpharetta GA 30022,
USA
Toll Free (877) 919-6288
Fax (877) 471-2055
info@alphaomega-eng.com

Asia Pacific & Middle East

Alpha Omega Engineering Ltd.
Hamerkava St. 6 ,Tsiporit Industrial Zone
Nof HaGalil (Nazareth Illit) 1789062,
Israel.
Tel 972-4-656-3327
Fax 972-4-657-4075
info@alphaomega-eng.com

Europe

 A Authorized Representative in
the EC: Alpha Omega GmbH
Ubstadter Str. 28
76698 Ubstadt-Weiher
Germany
Tel: +49 (0) 7251-4406620
Fax: +49 (0) 721-2391034
info@alphaomega-eng.com

China

Guangzhou Alpha Medical Technology
Co., Ltd.
Unit 202-10, Level 2, No. 6 Spiral Third
Road
Guangzhou International Biological Island
Guangzhou, China
Tel: +86 13322815872
info@alphaomega-eng.com

Australia

Emergo Australia
Level 20, Tower II, Darling Park
201 Sussex Street
Sydney NSW 2000

CE 0297