Manager Guide

brAIn™ Shoulder Positioning

Shoulder Surgery Planning Tool

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AVATAR MEDICAL

Manufacturer Name: Avatar Medical SAS

Software Name: brAIn™ Shoulder Positioning

Software Version: FDA.1.1.1

Document Number: BSP_FDA_MG

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Table of Contents

Introduction

Document scope

This document focuses exclusively on the **Admin Console interface** of the brAIn™ Shoulder Positioning software. It is separate from the User Manual, as access to the Admin Console is restricted to authorized users only.

Software information

Name of device: brAIn™ Shoulder Positioning

This Manager Guide can be consulted in the following formats:

- PDF format. The PDF can be opened by web browsers (Microsoft Edge version 120.0.2210.133 or above, Google Chrome version 120.0.6099.217 or above, Mozilla Firefox version 121.0.1 or above, Chromium 8.0.552.0 or above) and with Adobe Acrobat Reader version 2023.008.20458 or above.
- In paper form upon request within 7 days and free of charge.

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Directions for Use

For more information, please refer to the section *brAIn™ Shoulder Positioning Directions for Use* of the User Manual.

Acronyms and Definitions

Term	Definition
API	Application Programming Interface

BSP	brAIn™ Shoulder Positioning
Tenant	A Tenant refers to a group of users or an organization that shares access to a specific instance of software or a service. Each tenant has its own isolated environment, meaning their data, settings, and resources are kept separate from other tenants, even though they are using the same system.
User Manual	This refers to the BSP_FDA_UM User Manual document for software version FDA.1.1.1

Recommendations related to the Admin Console

Like all brAIn™ Shoulder Positioning interfaces, the Admin Console requires an Internet connection for access. To ensure a smooth experience, we recommend using a wired connection or a stable WiFi connection, detailed in the *Network requirements* section of the User Manual.

In this Manager Guide, useful information and tips are highlighted using the following style:

💡 Helpful information example

General warnings related to the Admin Console

In this Manager Guide, warnings and information that may impact device performance are highlighted using the following style:

⚠ Warning example

They are listed in the table below, organized by section:

Section	Warning
Authentication	If not logged in or if logged in as a User-profile user, the user can still click on the different panels but will be prompted with an error footer. The contents of each panel will remain hidden.
Logout	After 10 minutes of inactivity, the user is automatically logged

	out.
Organization	Upon clicking on the Organization button, a Manager-profile user will be prompted with an error footer. It is a normal error notification.
Account creation	The email address must be unique among all existing user accounts. Attempting to create a duplicate account with an already existing email address will generate an error message on the top right corner of the page.
Account deletion	This action is irreversible. All user-related information, including account details and plans, will be permanently deleted.
Plan deletion	This action is irreversible. The plan will be permanently deleted.

Application Access

Web interface

The Admin Console interface of the brAIn™ Shoulder Positioning software is available at the following link: https://console.fx.avatarmedical.cloud. Detailed information on application accessibility can be found in the *Web browser compatibility* section of the User Manual.

Manager account

A Manager-profile account can see and delete any Plans created by any user (see Plan deletion section).

A Manager-profile account can also manage User accounts:

- They can create User-profile user accounts (see Account creation section)
- They can delete any accounts regardless of the profile (see Account deletion section)

Authentication

Homepage

The homepage of the Admin Console Interface is accessible without being authenticated in brAIn™ Shoulder Positioning with a user account, however the contents of the different panels can't be accessed without being logged in.

> ⚠ If not logged in **or** if logged in as a User-profile user, the user can still click on the different panels but will be prompted with the following error footer:
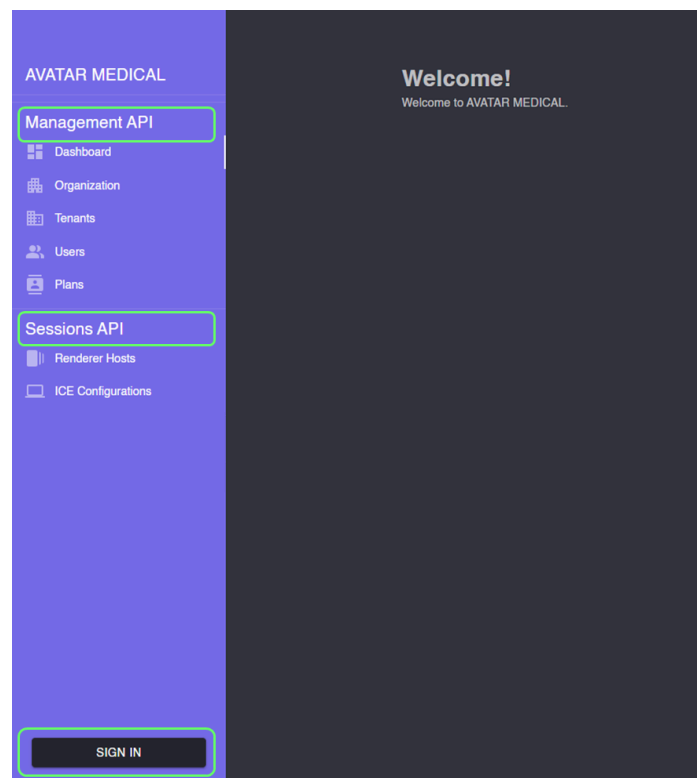>
> An unhandled error has occurred. Reload   ✕
>
> The contents of each panel will remain hidden.
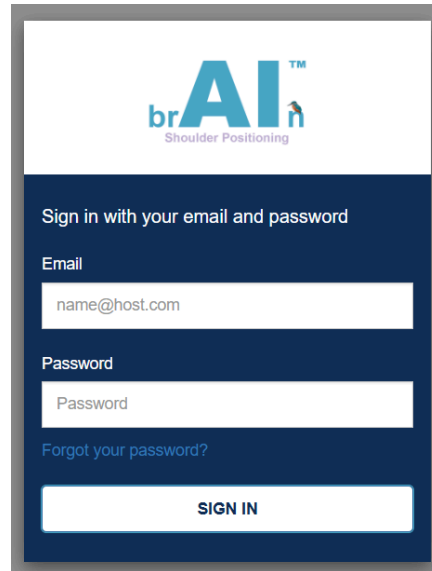
Clicking on any panel header will automatically redirect the user to the Login interface.

The homepage consists of two sections: the Management API for user and plan management and the Sessions API for session management, each containing different information panels.

Login

To log in to the Admin Console Interface of brAIn™ Shoulder Positioning, the user can either click on the "SIGN IN" button in the bottom left corner of the homepage **or** click on any panel header. The user will be redirected to the Connect Interface, where they must enter their email and password and click the "SIGN IN" button:


If their email and password are correct, the user will be redirected to the Dashboard of the Admin Console Interface and will now be able to access authorized panels.

> 💡 If a user is already logged in the brAIn™ Shoulder Positioning application, when accessing the Console webpage they won't need to log again and will be redirected automatically to the Dashboard.

Logout

To log out of brAIn™ Shoulder Positioning from the Admin Console Interface, the user must click on their username menu in the bottom left corner of the webpage, and click the "Sign Out" link:
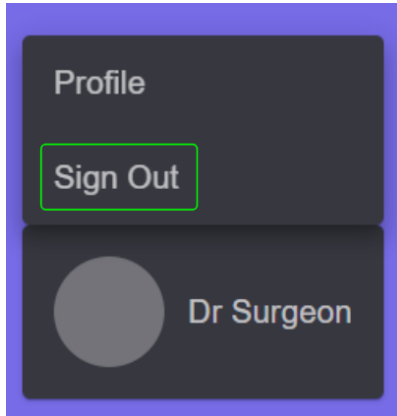
> ⚠ After **10 minutes of inactivity**, the user is automatically logged out.

Password forgotten

The procedure to retrieve one's password is described in the *Password forgotten* section of the User Manual.

Management API

Dashboard

Clicking on the Dashboard tab returns the user to the Homepage.

Organization

The Organization panel contains identification information on the cloud platform where brAIn™ Shoulder Positioning is hosted. This panel contains 3 columns ("Id", "Unique Identifier" and "OrganizationName") whose contents remain empty to Manager users, as shown below:

Organization Info

| Id | Unique Identifier | OrganizationName |

⚠ Upon clicking on the Organization button, a Manager-profile user will be prompted with the following error footer:

An unhandled error has occurred. Reload ✕

It is a normal error notification.

Tenants

The Tenants panel displays the list of existing Tenants and allows the Manager-profile user to visualize them. Each Tenant is characterized by its Unique ID, its Name, its Creation Time and its Status. A Manager-profile user can only visualize the information on existing Tenants, but **cannot create a new Tenant**, nor Archive/Delete an existing Tenant.

If a Manager-profile user attempts to create a new Tenant by clicking on the "+" button as shown above, a popup window will appear where the new Tenant Name can be written:
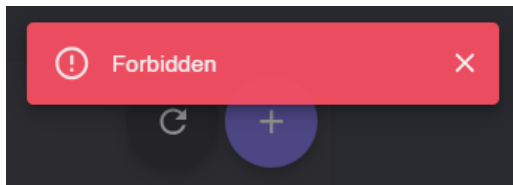
However, clicking on "OK" will prompt the Manager-profile user with the error message "Forbidden". This error message is expected.

Users

The Users panel, displayed below, allows a Manager-profile user to:

● View the list of current user accounts, sorted by creation time from most recent to oldest
● Create new user accounts with a User-profile
● Delete any existing users
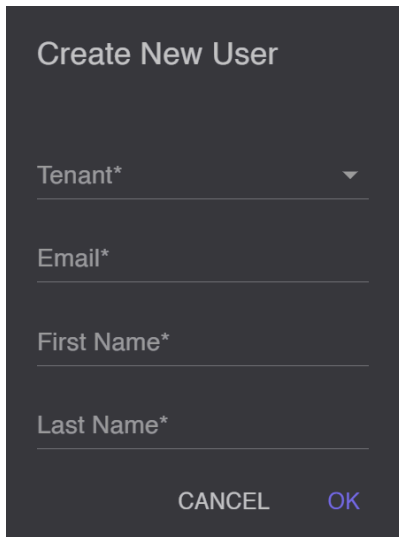
The information displayed for each user are:

● their Name: Firstname Surname
● their Email address
● the Tenant they belong to (always the same value as brAIn™ Shoulder Positioning is deployed with a single Tenant)
● the Plan Count, corresponding to the number of plans successfully created by the user, excluding those with an Error Step or that have been deleted
● their Profile type: User, Manager or Organization
● the Creation date of their account.

Account creation

To create a new User-profile user account, the Manager should click on the "+" button as shown above. The Manager will be prompted with a popup window, where the following mandatory information have to be filled in order to create a new user account:

- Tenant: will be chosen from a dropdown menu with existing Tenants Names (only one item as brAIn™ Shoulder Positioning is deployed with a single Tenant)
- Email address: will be used as username to log in to the software. It must be a valid email address since the first-time connection password will be sent to that email.
- First name of the user to be created
- Last name of the user to be created

After clicking on "OK" upon full completion of the form, a green popup window as shown below will appear, confirming the creation of the new user account. Within a few minutes after account creation, the new user will receive a welcome email with a first-time connection password. See *First connection* section of the User Manual for more details.
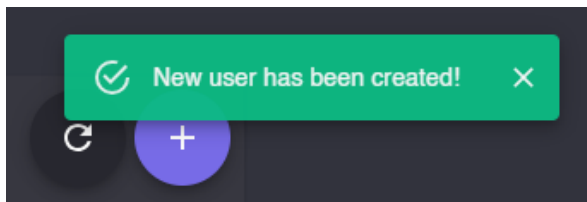

⚠ **The email address must be unique** among all existing user accounts. Attempting to create a duplicate account with an already existing email address will generate an error message on the top right corner of the page, as shown below.
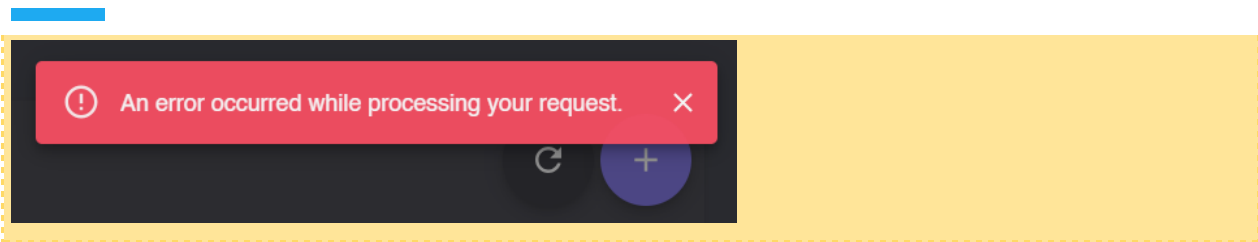
To upgrade the new user to a Manager-profile user, please contact contact@avatarmedical.ai.

Account deletion

A Manager-profile user can delete any user by clicking on the corresponding bin icon at the end of each row. A Warning popup window as shown below will appear. If the Manager-profile user confirms the deletion by clicking on "DELETE", the user selected will be irreversibly deleted.
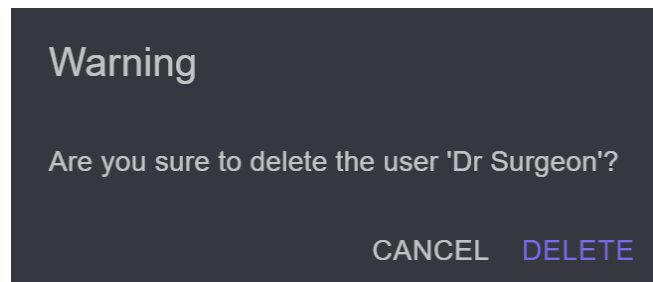
⚠ This action is irreversible. All user-related information, including account details and plans, will be permanently deleted.

If a Manager-profile user ever attempts to delete their own account, an error message (shown below) will appear, upon which their account will be deleted. A deleted Manager-profile user won't be able to do any actions anymore on the Admin Console and all panels' contents will be hidden.
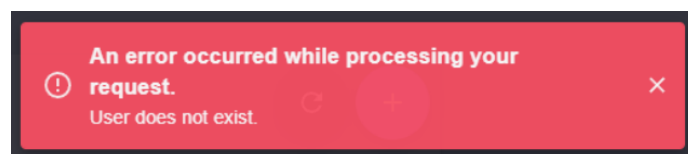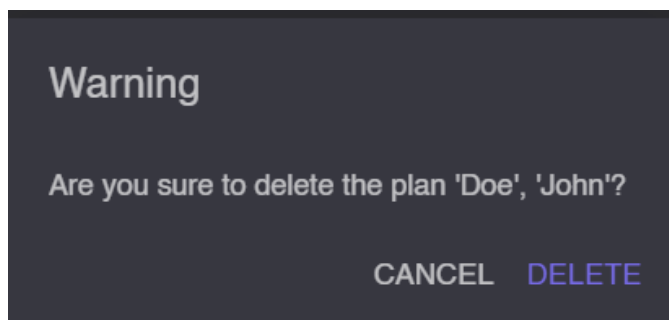

Plans

The Plans panel displays all the existing plans, sorted by creation time from most recent to oldest, and allows Manager-profile users to delete existing plans.
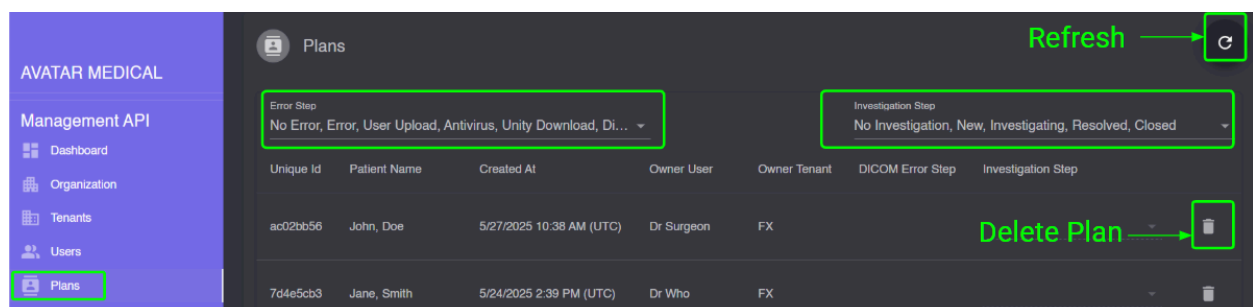
Created Plans

A new row corresponding to a new created plan appears upon completion of the "Create New Plan" procedure in the **brAIn**™ **Shoulder Positioning** application (see the section *Creating a plan* of the User Manual). Each plan has a unique ID: the first 8 characters are shown in the 'Unique Id' column, with the full ID available in the tooltip. If the plan does not appear, please use the Refresh button to update the list of plans. The table autorefreshes itself.

Plan deletion

By clicking on the trash bin icon at the end of each row, the user will be prompted with a Warning window shown below. By clicking on "DELETE", the plan will be irreversibly deleted.

⚠ This action is irreversible. The plan will be permanently deleted.

DICOM Error Step

Authorized users can sort the created plans by DICOM Error Step and Investigation Step.

By clicking on the Error Step scrolling window shown above, the user can unselect the undesired options. By default, all the options available are pre-selected. They are detailed below in the chronological order of their occurrence during the planning.

Error Step	Description
No Error	No error encountered
Error	None of the errors below apply
User Upload	Error during the loading of DICOM series from the webpage (frontend) to the server endpoints (backend)
Antivirus	The DICOM series uploaded did not pass the antivirus scan
Unity Download	Error in information sending from Data Storage to the Renderer (due to network issues for example)
Dicom Conversion	An error occurred during the conversion of the DICOM series to the internal format
Segmentation	The segmentation step failed
Tessellation	Error when creating the 3D surfaces of the segmented shoulder anatomies
Unity Upload	Error in information sending from the Renderer to AWS S3 (due to network issues for example), opposite of Unity Download
Segmentation Rejected	Rejection of the segmentation by the user
Morphology Analysis	Failed detection of the shoulder landmarks
Shoulder Side	User has confirmed that there is a shoulder side detection error

💡 Plans created without any error can be filtered out by selecting only the option "No Error" in the DICOM Error Step scrolling window.

Investigation Step

The pre-selected options in the Investigation Step scrolling window are:

- No Investigation
- New

- Investigating
- Resolved
- Closed (for dropped cases, resolved cases communicated to the client, and cases without client feedback over a certain period)

Sessions API

The content of the **Renderer Hosts** panel and the **ICE Configurations** panel in the Sessions API section are **not accessible for a Manager-profile user**. A red error footer "An unhandled error has occurred. Reload" and a red notification "Forbidden" will both appear.
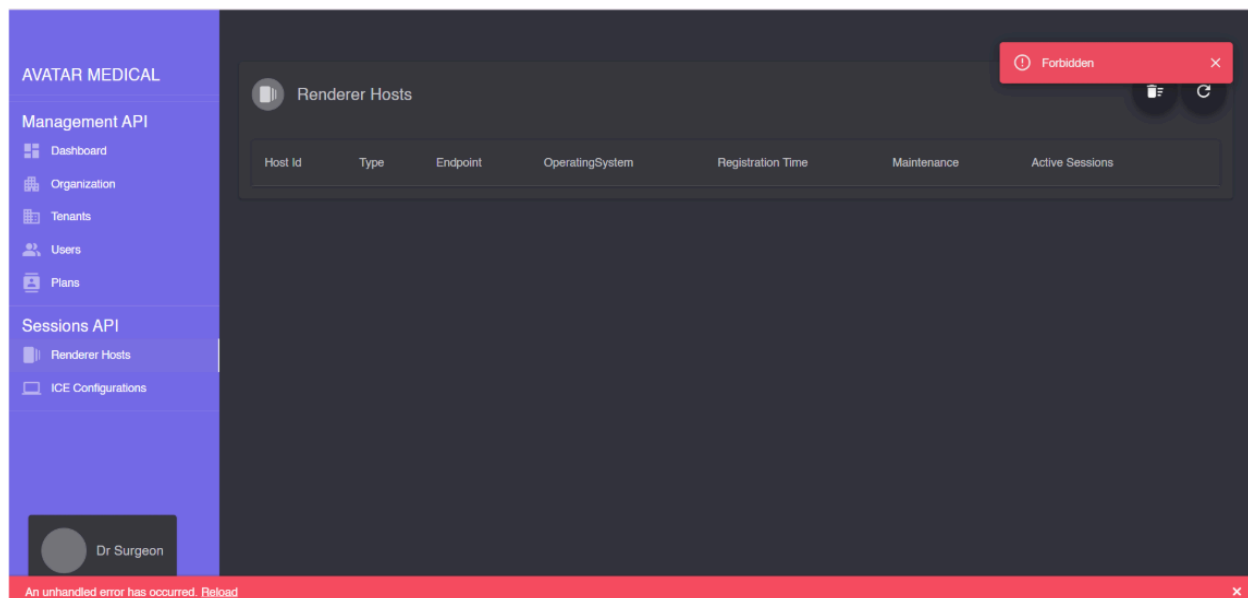
System and data protection recommendations

Please refer to the section *System and data protection recommendations* of the User Manual for more information.

Troubleshooting & Contact Information

For any plan-specific questions that arise during the review or to report software anomalies, contact Avatar Medical Customer Support to ensure prompt resolution and maintain optimal software performance:

Avatar Medical SAS - Customer Support

Address: 11 rue de Lourmel, 75015 Paris, France

Email: contact@avatarmedical.ai

Phone Number: +33 9 74 67 00 15

Website: https://avatarmedical.ai

In case of detection of a cybersecurity event, please contact using the email address provided below.

Any serious incident related to the device should be reported to Avatar Medical using the email address provided below and to the competent authority of the Member State.

Vigilance Contact: vigilance@avatarmedical.ai