# NUSHU

## Web Application

## Instructions for Use
v3.0 - 18.09.2023

# Content

# Signs and Symbols

The following signs and symbols appear in this instructions for use (IFU) and on the device labels:

| | |
|---|---|
| ⚠️ | Important safety instructions or operating instructions |
| 📖ℹ️ | Read the instruction for use (IFU). |

# Product Description and Intended Use

Magnes Nushu is a medical device that enables patients to collect data on their gait and share this data with healthcare professionals (HCPs). Magnes Nushu can help patients with gait deficits by providing them notifications via vibrations on how they walk to assist normal walking.

Magnes Nushu Web Application is intended to be used by HCPs to visualize and track the walking parameters collected by patients using Magnes Nushu. The data collected by Magnes Nushu can be used to infer changes in the condition of patients.
It can be accessed over following link: https://dashboard.nushu.health/

⚠ Any serious incident, must reported to the legal manufacturer (see page 7) and the authority having jurisdiction in your locale.

⚠ Magnes Nushu Web Application is not intended to be used for making diagnostic or therapeutic decisions based on the gait analysis by Magnes Nushu.

# Product Description and Intended Use

**Intended User Profiles:**

Magnes Nushu Web Application has the following intended user profiles:
- HCPs, who provide Magnes Nushu to their patients.

**Intended Use Environment:**

The website can be accessed by a modern smart device that is connected to the internet and has a user interface through an internet browser. This includes a desktop computer, laptop or a tablet. It has been tested and runs properly on following browsers:
- Google Chrome v91.0+[1]
- Mozilla Firefox v71.0+
- Safari v14.0+
- Microsoft Edge v90+

[1] v91+, refers to the browser version 91 and the '+', indicates the stated version or higher.

# Product Description and Intended Use

⚠ It is not recommended to be accessed by a device with a screen size smaller than 9" as the website rendering will be cramped making buttons difficult to press and text too small to read easily.

⚠ Using a browser or a version not listed above, should be done at the user's own risk, as there is no guarantee that the website will behave in the intended way.

# Warnings / Important Notes

⚠ Users shall carefully read and understand these instructions for use prior to the usage of Magnes Nushu Web Application. For any questions regarding usage of Magnes Nushu Web Application, users should get in contact with:

Magnes AG, Hardturmstrasse 253, 8005, Zurich, www.magnes.ch, e-mail: support@magnes.ch

⚠ It's important to use the latest version of this manual not doing so may result in discrepancies between the manual and the website.

Legal manufacturer, Effectum Medical AG, Kirchgasse 11, CH-4600 Olten, www.effectummedical.com, e-mail: info@effectummedical.com

CE The device conforms with the European health, safety, and environmental protection standards.

# Opening the Website and Login

By opening the Magnes Nushu Web Application, you will be greeted by the home page of the website, as pictured in Figure 1. The Web Application can be seen to have an App-bar, i.e. the dark bar at the top, containing a number of buttons available across all subpages of the website. These are the following:

1. Menu List button: opens a small submenu list, this is explained further on page 36.
2. Nushu button: takes the user back to the Home page.
3. Database connection button: indicates if the dashboard is connected to the database. When pressed, it reloads all information from the database. If the connection is active, the icon is green; else the icon is red.
4. Login: Starts the login process, for more information see page 12. Once the user is logged in, the button switches to a Logout Button. For more information on logging out go to page 13.
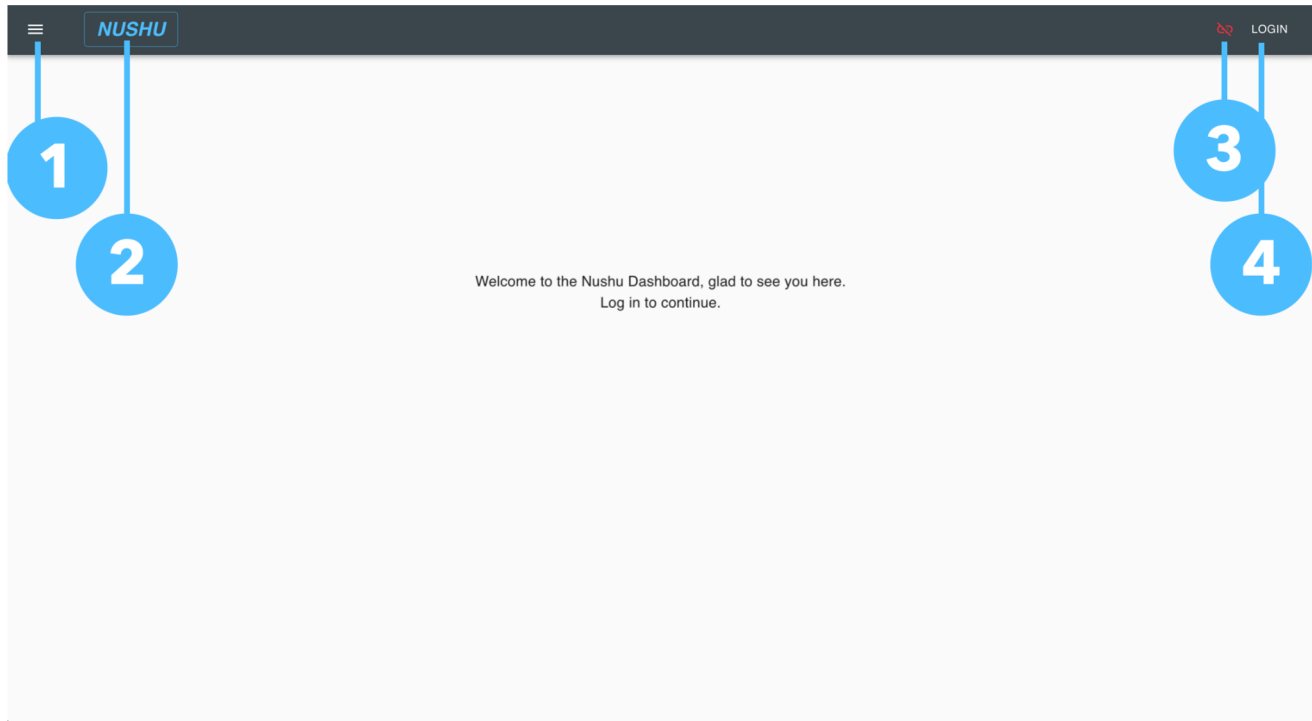
# Opening the Website and Login



Figure 1 - The welcome page.

# Opening the Website and Login

## Creating a Doctor Account

When accessing the page for the first time, the user is asked to create a doctor account. This is done by pressing the login button, located at the top right corner of the page (see Figure 1), which opens up the pop-up window shown in Figure 2, where the user is prompted to login. If the user already has a doctor account, skip to the subsection titled 'Log In' on page 12.

⚠️ Make sure your browser has pop-ups enabled to see the login pop-up. Newer versions of Safari, for example, block pop-ups by default, and the user has to give their permission for it to appear.

To create a new doctor's account, press the 'Create an account' button in the pop-up, which takes you to the 'Register as a Doctor' page presented in Figure 3. Here, the user is required to fill in all fields.

⚠️ You can only create one account for each email address. This means that the entered e-mail has to be unique amongst all existing doctor and patient accounts.

# Opening the Website and Login

Upon successful registration, the pop-up will display the message: New user successfully created: <username> and the user can navigate back to the pop-up's login page by using the 'Go to Sign In' button. Additionally, upon successful sign up, a welcome message is sent to the registered email address.
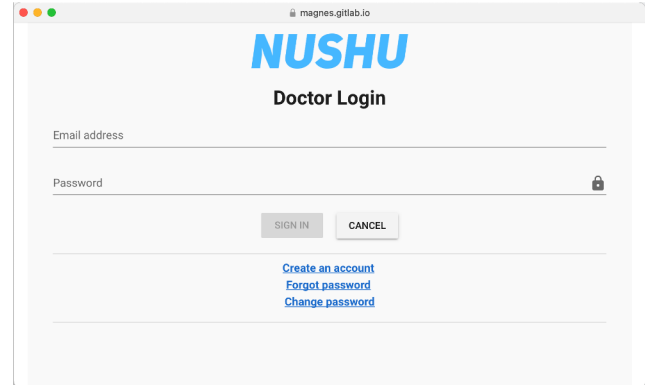


Figure 2 - Login pop-up.

Reception of a welcome email is not guaranteed as it can fail for some email providers. Even if this message wasn't received, the account is still fully functional if the "New user successfully created" message appears.

# Opening the Website and Login

## Logging in

To log in, the user has to enter their registered email address and the set password into the corresponding textfield of the login pop-up page, pictured in Figure 2. Upon successful login, the pop-up window will close automatically.

⚠️ Entering the wrong password or username will result in a warning at the bottom of the pop-up stating 'Not found'. To retrieve a lost password, click on the 'Lost Password' button of the pop-up and enter the registered email in the textfield and press 'Request Password Reset' and a reset link is sent to the provided email.

# Opening the Website and Login

## Logging out

If the user wants to logout, they have three options. The first is to click the logout button, which replaces the login button once the user has successfully logged in and subsequently confirm that they want to logout. The other option is to close the browser tab, in which the Magnes Nushu Web Application was in. Lastly, the entire browser can be closed, which also equates to a successful logout.

⚠ Failure to logout correctly, may leave certain artefacts of the website stored in the browser cache. This poses a vulnerability to data security, as later users of the browser can thus gain access to patient data not belonging to them.
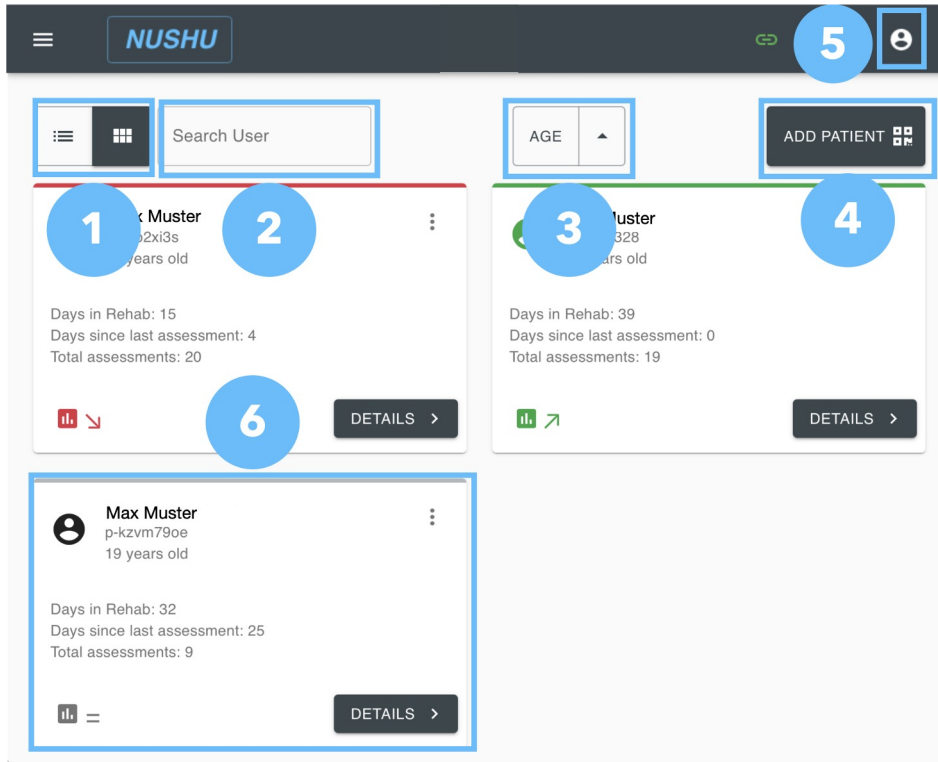
# The Home Page



Figure 3 - Home page.

# The Home Page

Upon successful authentication, the Home page is reloaded as shown on Figure 3. If the HCP has not yet registered any patients, the Home page will be empty apart from a button to add patients, which opens the QR code seen in Figure 4.

Otherwise it consists of following elements, labelled accordingly in Figure 3:

1. Toggle between table and card view of the patients.
2. Search bar, with which a patient can be searched for by their first or last name or their system username.
3. Button to reorder in what order patients are displayed. Available options are age (default), last name, days in rehab and total no of assessments.
4. Add patient button, used to add patients to the HCP. Its functionality is further detailed in the subsection 'Adding patients' (on page 16).
5. Show account info button, which brings an editable overlay of the doctor account's details.
6. Card view / Table view, depending on the toggle in 1, providing a gateway to the patient's unique Patient page. More details are given in the subsection 'Card / Table view' (on page 17).

# The Home Page

## Adding Patients

If no patients are registered, the user can add patients by pressing the add patients button in the center of the screen. If the user already has registered patients, the add patient button is found in the top right under the App bar. Pressing the add patients button, launches the dialog window seen in Figure 4.

Embedded within the QR code is the user account's username and its affiliation. A patient can scan the image using the Nushu App to grant access to their data[2]. The affiliation of the patient also determines the billing of the subscription to Magnes Nushu and it cannot be changed manually.



Figure 4 - Doctor's QR code.

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[2]For more information on granting access to an HCP from a patient's perspective, refer to the 'Managing Accesses' of the '*MSD-03-01-00-Magnes Nushu IFU Patients EN-master V3*'.

# The Home Page

## Card / Table View

Both views include information on each patient such as the their full name, username, age, days since last assessment and total assessments. Additionally, the card view is color coded to show if the patient has been doing more (green) / same (gray) / less (red) number of assessments in the past seven days compared to the seven days prior to that. By clicking on the patient (Table View) or on the 'Details' button (card view), the user is taken to the Patient Page (see page 18).

NUSHU

# The Patient Page

1. General Info (see page 19)
2. Summary Stats (see page 21)
3. Timeline (see page 22)
4. Gait Progression (see page 23)
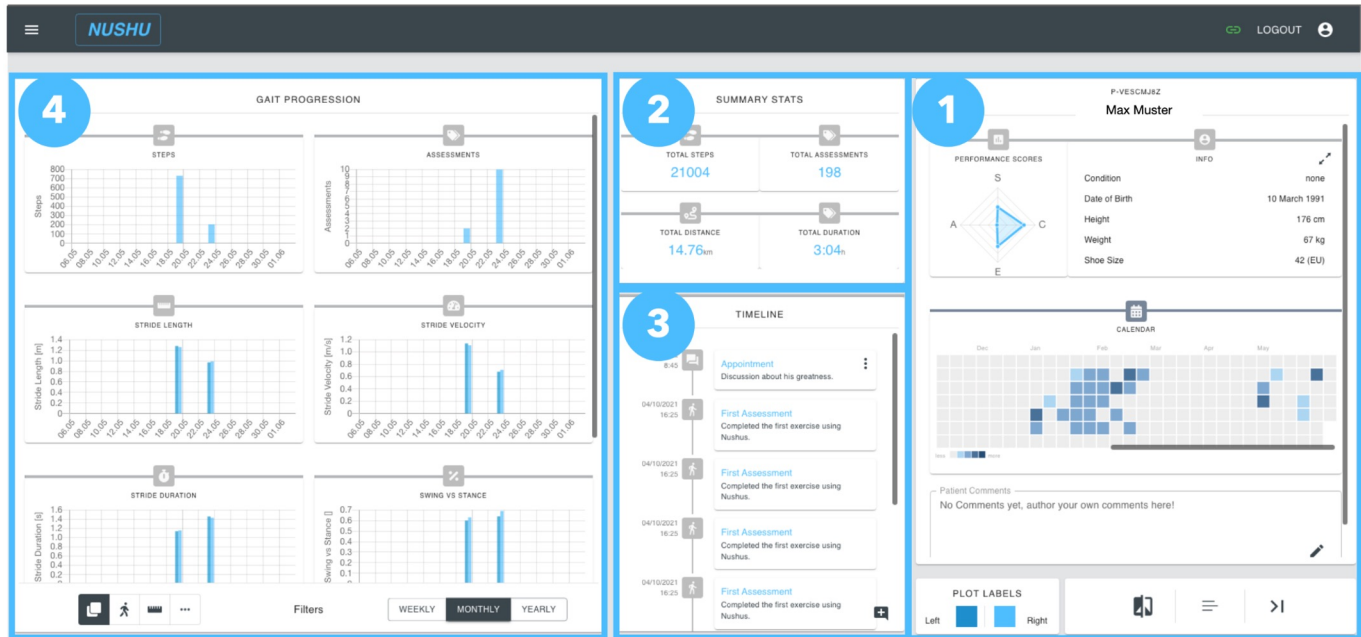


Figure 5 - The Patient Page

# The Patient Page

## General Info

1. Spider plot of the patient's recent symmetry (S), consistency (C), endurance (E), and activity (A).
2. General information on the patient. For more details a dialog is opened when clicking the expand button (see page 20).
3. Calendar heat map of the assessment dates, whereof each can be clicked on to bring up a menu to navigate to specific assessments.
4. Editable comment section.
5. Navigation panel, to jump to the Comparison Page (see page 32), show all assessments or go to the patient's latest assessment (see page 24)
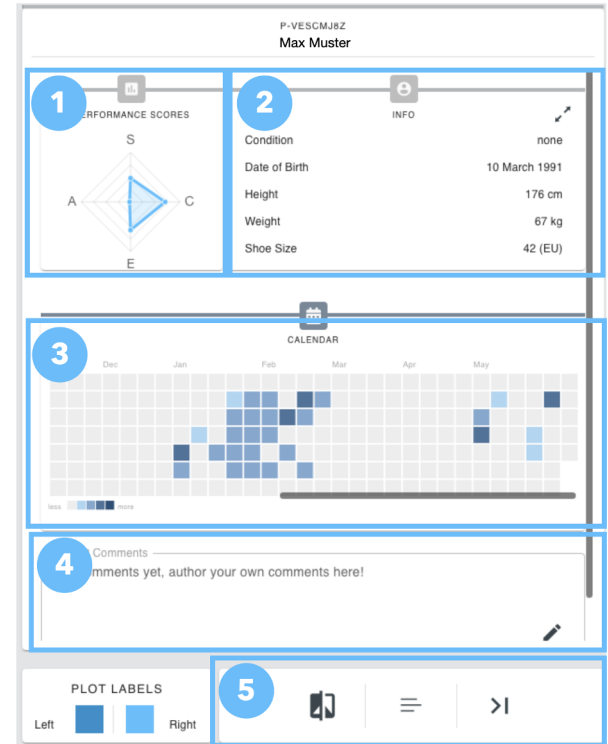


Figure 6 - The Patient Page – General Info.

# The Patient Page

## General Info – Patient Details

In addition to showing more information on the selected patient, this overlay (seen in Figure 7a) allows the HCP to edit the patient's condition. Clicking the edit button, brings up a list from which the HCP can select various conditions.



Figure 7a - Patient Details



Figure 7b - Patients Conditions

# The Patient Page

## Summary Stats

Shows the total number of taken steps, assessments, distance and time taken from all assessments. The values in green represent the totals over the past seven days.
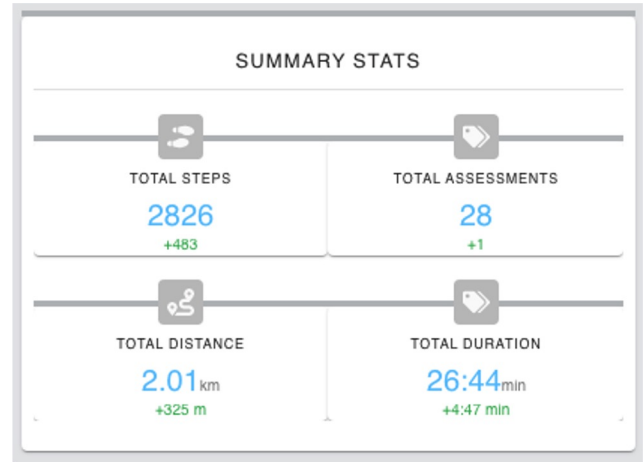


Figure 8 - The Patient Page - Overview.
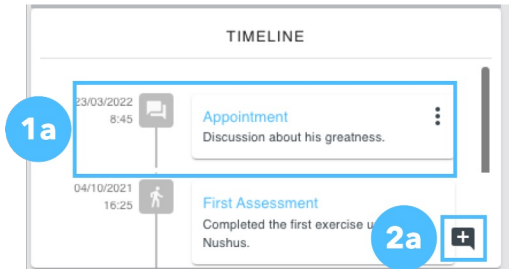
# The Patient Page

## Timeline



Figure 9a - The Patient Page - Timeline

1. An entry. To edit or delete an entry, click the three dots, note this is not possible for the default entries ('Registration' and 'First Assessment').
2. Add an entry button, which brings up the dialog in Figure 8b.
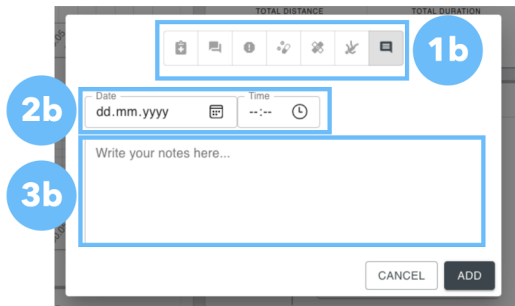


Figure 9b - The Patient Page - Add Entry

1. Toggle to select a preset entry type, by default, 'Comment' is selected.
2. Textfield to input a time and date which can be set by typing or by using the menu that is brought up, from the little icon.
3. Textfield to input the content of the entry.

# The Patient Page

## Gait Progression



Figure 10 - The Patient Page - Trends.

This section shows the trend of multiple parameters, by showing the average daily value for each gait parameter. By default the overall is taken across all activities, but one can see the trends for specific activity types by using the activity type toggle (1). The trends can be shown for the past 7, 28 or 365 days, by selecting WEEKLY, MONTHLY and YEARLY respectively (2).

All plots can be viewed in fullscreen by clicking on them.

If enough data is available, a trend line is shown, which is computed by a linear fit to the daily values.

# The Assessment Page

This view visualizes the gait parameters of a single Magnes Nushu assessment, i.e. an exercise.

To provide a clear overview of each element of the page, it is broken down into four separate elements, seen labelled in Figure 11 on the following page, which are the following:

1.  Assessment Details (see page 26)

2.  Walk Selector (see page 27)

3.  Navigation Panel to jump to the next or previous assessments

4.  Gait Parameter Stats (see page 28)

# The Assessment Page



Figure 11 - The Assessment Page

# The Assessment Page

## Assessment Details

1. Button to (un-)mark the assessment for comparison (see page 31) and to download the pdf report.
2. Button to jump back to the patient page (see page 18)
3. Overall assessment details, such as the date and time, the type and patient name.
4. Performance stats given for the entire assessment. For cadence and gait speed, a range of reference values is given (see page)
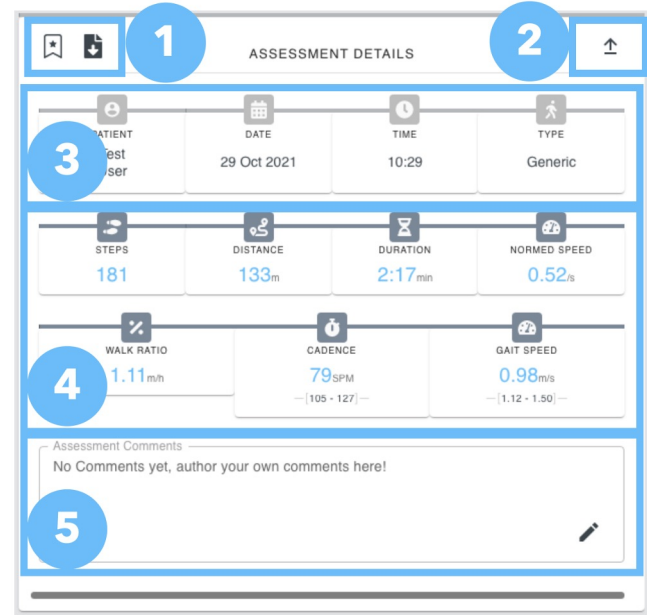5. Editable assessment comment.



Figure 12 - The Assessment Page - Assessment Overview.

# The Assessment Page

## Walk Selector



Figure 13 - The Assessment Page -  Walk Selector Element.

Each generic activity is divided into individual walks, for which statistics of the gait parameters are computed separately. All other activity types are treated as a single walk. If more than a single walk was detected, this element is shown, which allows the HCP to select which walk to view the stats for. What is shown is the frequency of recorded steps.
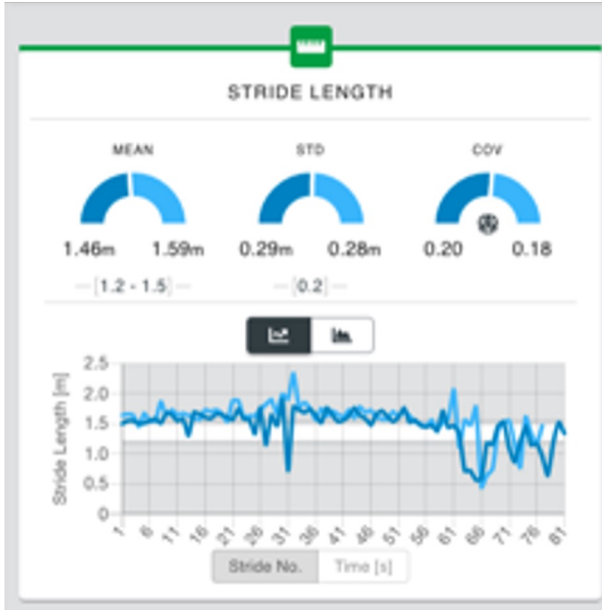
# The Assessment Page

Gait Parameter Stats



Figure 14 - The Assessment Page - Gait Parameter Stats

For every gait parameter, summary statistics are given by the left and right mean, standard deviation (STD) and coefficient of variability (COV). The little icon in the latter, brings up a spider plot of all COV values.

The symmetry (left vs. right) of the mean values is encoded in the card's color. Green, grey, orange and red signify good, ok, poor and very bad symmetry respectively.

The gait parameter can be plotted vs step number or time and includes the parameter's reference range (see page 37). Alternatively, the distribution of the values can be shown. All plots can be viewed in fullscreen by clicking on them.

# The Comparison Page

The comparison page is a tool to compare and visualize (groups of) assessments to one-another in terms of their gait parameters. The view can be broken into four sections, see Figure 15, namely:

1. Setup Comparison Panel (see page 31)
2. Load and Save Comparisons (see page 32)
3. Overall Stats Comparison (see page 33)
4. Gait Parameters Comparison (see page 34)

# The Comparison Page



Figure 15 - The Comparison Page

# The Comparison Page

## Setup Comparison Panel



Figure 16 - The Comparison Page - Select Assessments Panel

For each group (A & B) choose assessments to compare to each other from the patient's assessments list (2). Assessments marked for comparison, feature a little bookmark icon.

Filter the displayed assessments by type using the toggle above (1). Have assessments been selected for both groups, pressing the compute button (3) sums up the gait analysis stats by group.

# The Comparison Page

## Load & Save Comparisons

Comparisons can be saved, by clicking the save icon, which brings up the dialog shown in Figure 17a. Conversely, saved comparisons can be loaded by opening the dialog seen in Figure 17b by clicking on the cloud icon.
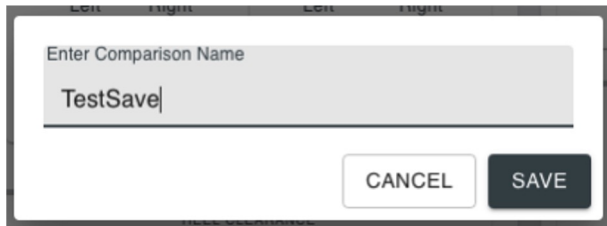


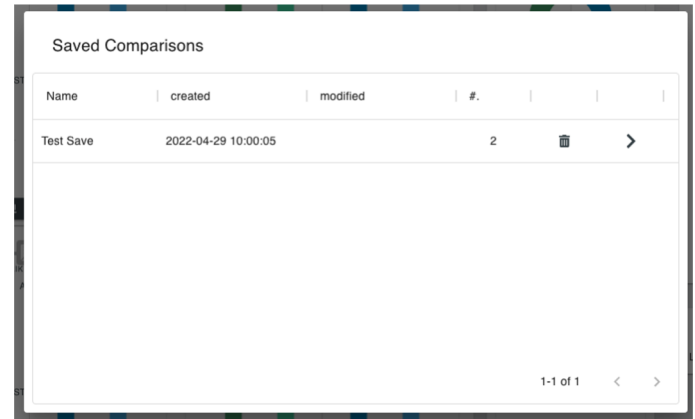Figure 17a - The Comparison Page - Load & Save Comparisons



Figure 17b - The Comparison Page - Load & Save Comparisons

# The Comparison Page

## Overall Stats Comparison

The performance summary statistics, such as overall step count, distance, duration, cadence and gait speed for the two groups.
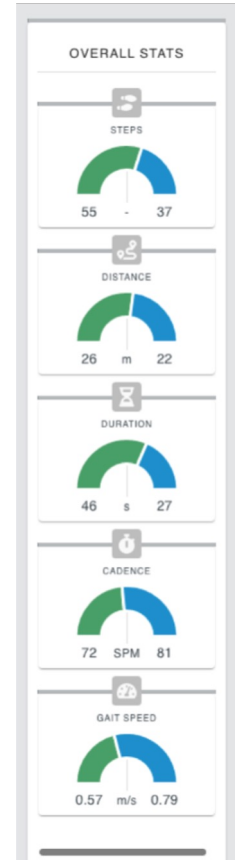


Figure 18 - The Comparison Page - Overall Stats Comparison

# The Comparison Page
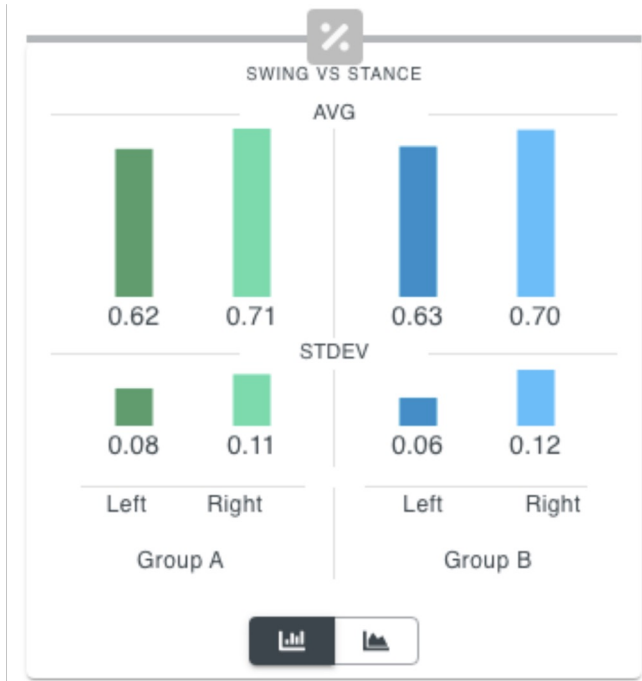
## Gait Parameters Comparison



Figure 19 - The Comparison Page - Gait Parameter Comparison

Each gait parameter comparison of Groups A and B is displayed in its own separate card. By default the comparison is shown in the form of bar plots of the average and standard deviations.

The view can be changed into a histogram of the underlying values by using the toggle present at the bottom of each card.

# Menu List

This section details the pages and functionalities found on the menu list, which can be opened by pressing the stack icon on the left edge of the App bar. The menu consists of buttons linked to additional pages, which are detailed in the following subsections. The linked pages are listed below:

1.  About Page (see page 36)
2.  Documentation Page, featuring links to helpful documents such as this manual and to a document describing the gait parameters, their definition and how they are computed by Magnes Nushu.

# Menu List

## About Page

1. Placeholder for medical certification label.
2. Link to platform's data privacy policy.
3. The platform's contact information, which can be used for bug reporting.
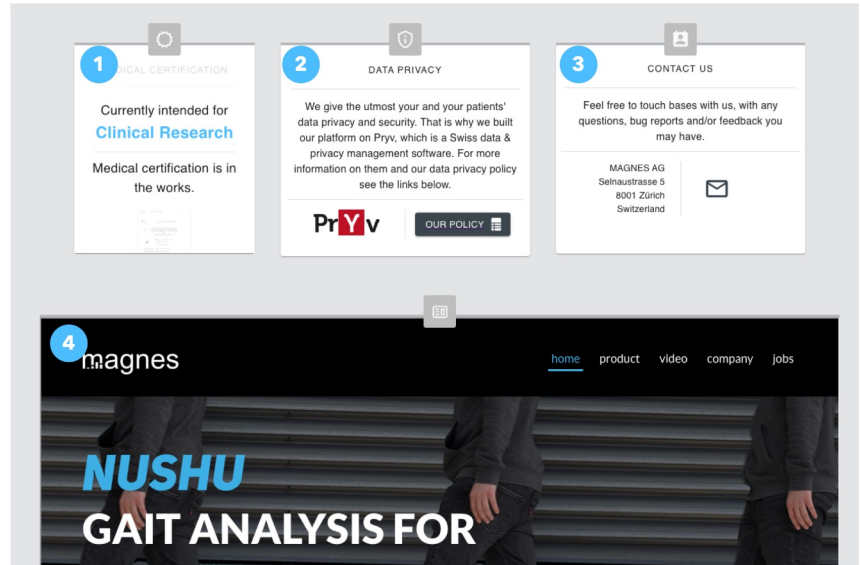4. In-page view of the Magnes AG company website.



Figure 20 - Menu List - About Page

# Reference Ranges

To ease interpreting and understanding the results given in the Assessment Page (see page 25) reference ranges are given for all but two gait parameters (namely strike angle and heel clearance), as well as for the overall cadence and gait speed.

The given ranges are based on the work of McKaya *et al.* who compiled the mean and standard deviation for each parameter by age group and sex[4]. The ranges shown on the dashboard are given by <MEAN> +/- <STD>, which are taken from the aforementioned table, based on the patients sex and age.

[4] McKay, Marnee J., et al. "Spatiotemporal and plantar pressure patterns of 1000 healthy individuals aged 3–101 years." *Gait & posture* 58 (2017): 78-87.

# Document version History

|  | Author | Comments |
|---|---|---|
| 0.7 | Henrik Maurenbrecher<br><br>Alessandro Schaer | Initial version completed on 21.07.2021 |
| 1.0 | Henrik Maurenbrecher<br>Barna Becsek | 31.08.2021 |
| 1.7 | Henrik Maurenbrecher<br>Alessandro Schaer | 28.10.2021 |
| 2.10 | Henrik Maurenbrecher<br>Alessandro Schaer | 15.09.2022, changed ID to<br>010.003.022.e |
| 2.11 | Henrik Maurenbrecher | 06.10.2022 updated intended purpose |
| 3.0 | Henrik Maurenbrecher | 18.09.2023 |

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