Magnes NUSHU

Web Application

Instructions for Use

V4 2025-02-04

Content

NUSHU

Support

For the best experience, carefully read and understand these Instructions for Use prior to using the Magnes NUSHUWeb Application.

The device conforms with the European health, safety, and environmental protection standards. CE conformity to Medical Device Regulation 2017/745.
Legal Manufacturer: Effectum Medical, Kirchgasse 11, CH-4600 Olten

For any inquiries, please reach out to Magnes.
E-mail: support@magnes.ch

For Europe and rest of the world
Magnes AG, Hardturmstrasse 253, 8005 Zurich, Switzerland

Use the latest version of these Instructions for Use to avoid discrepancies between the information contained herein and the Web Application.

Signs and Symbols

⚠	Important safety instructions or operating instructions
📖	Read the instruction for use (IFU)
CE	European Conformity
FC	Federal Communication Commission (FCC)
▲	Manufacturer

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 with notifications via vibrations on how they walk to assist normal walking. Magnes NUSHU allows to perform standard gait assessments and exercises.

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 at **https://dashboard.nushu.health.**

⚠️ Magnes NUSHU may NOT perform as expected if used outside of its intended use.

⚠️ Magnes NUSHU is NOT intended to be used for making diagnostic or therapeutic decisions.

⚠️ Please stop using the shoes and talk to your HCP, if using them causes any discomfort.

⚠️ Users shall report any serious incident to Magnes AG and the authority having jurisdiction in their locale. (see page 3).

Intended User Profiles and Use Environment

Intended User Profiles

Magnes NUSHU will be used by patients who have problems or symptoms related to their gait. It can be used by anyone equal to or above 6 years of age.

Gait data is collected during daily activities or at a clinic. The patients may use Magnes NUSHU on their own or with the guidance of a doctor, physiotherapist, nurse, other caretaker or a family member.

Intended Use Environment

Device is designed for indoor and outdoor activities only.

⚠ Magnes NUSHU is NOT designed for high-impact activities like running or jogging.

⚠ Magnes NUSHU is NOT designed for water sports. Avoid using Magnes NUSHU in heavy rain or snow.

Technical Requirements

The Web Application (**https://dashboard.nushu.health**) can be accessed by a device 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 the following browsers:

- Google Chrome v91.0+
- Mozilla Firefox v71.0+
- Safari v14.0+
- Microsoft Edge v90+

⚠ 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 application will behave in the intended way.
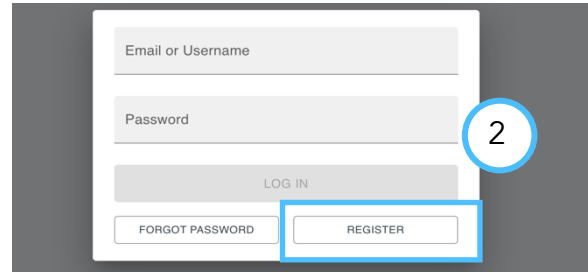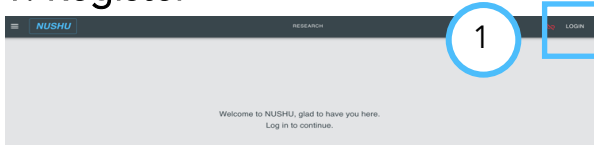
⚠ It is recommended to access the Web Application on a screen of at least 15" in diameter to ensure all text is legible and buttons are accessible.

Log In to the Web Application

When logging in for the first time, you need to register as a doctor-user[1].

1. Register

Fill in all the fields with an *. Choose the right affiliation. This shall be the clinic or research institution you are working at.

After registration, log in with your new account.

⚠️ 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 them to appear.
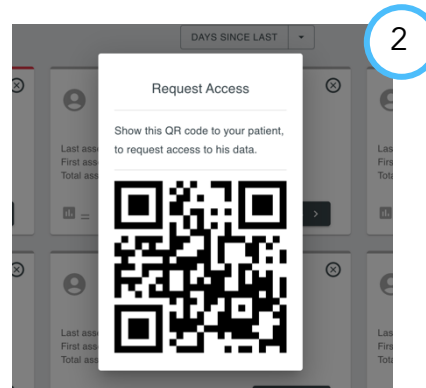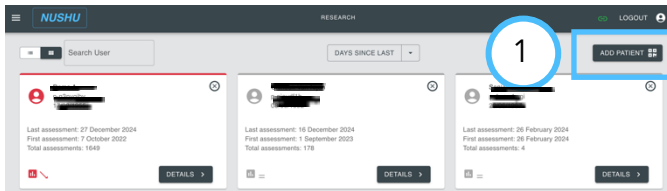
⚠️ [1] Every Web Application user is a doctor-user. Users are uniquely identified by their email, so you cannot have a patient-user (mobile application user) and a doctor-user for the same email address.
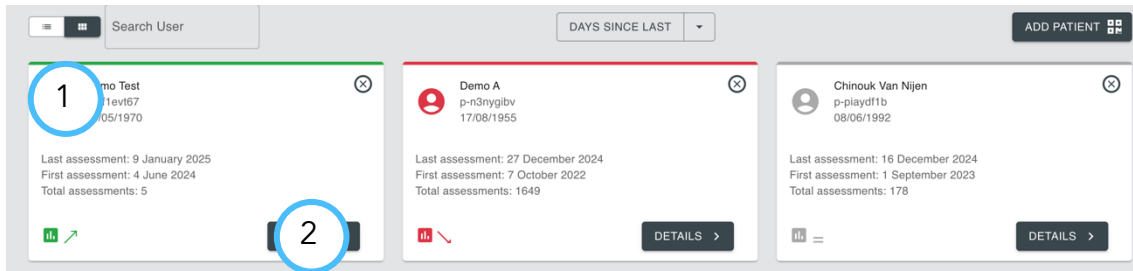
Adding Patients to the Web Application

1. Click on "Add Patient" (1). This option is only available, when at least 1 patient was added before. If no patient was added before, proceed to step 2.

2. Let the patient-user scan the QR code at the center of the page with the Magnes NUSHU app.

⚠ Refresh the page after the patient-user has scanned the QR code to see the patient-user on the Web Application.

Patient Overview Page

Patient-user's name, user ID and birthday are shown (1). When contacting Magnes support, always provide the user ID of the patient.

The colour of the patient card reflects the user's assessment trend. It compares the assessments of the past seven days to the preceding seven days and colors the card
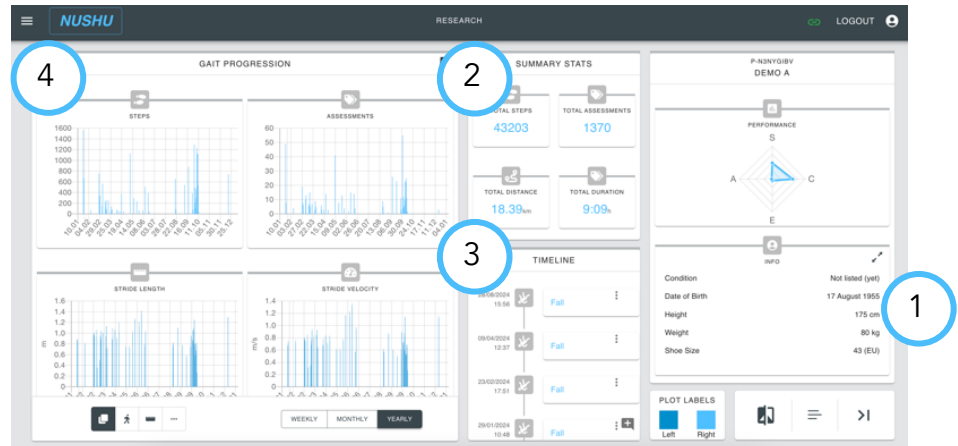- green: increase in the number of assessments
- grey: no change in the number assessments
- red: decrease in the number of assessments

To navigate to the Patient Page (see page 11), click on the respective "Details" button (2).
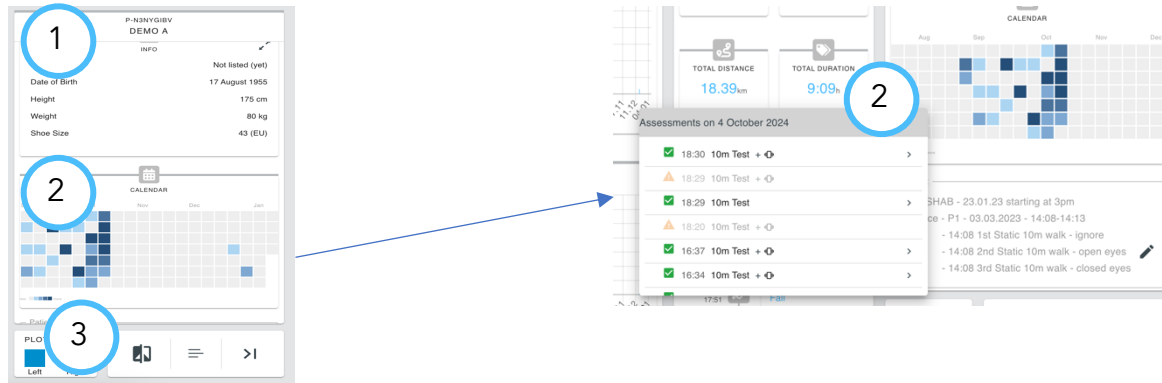
Patient Page

This shows a general overview of the data of the selected user.

1. General information
2. Summary statistics
3. Timeline
4. Gait progression

On smaller screens, not all elements (e.g., calendar in the 1. section) may be visible. If you cannot find a certain element, scroll up or down in the relevant section.

General Information

User information from the app (1)

Calendar: Heat map of the assessment dates (2), the darker the color the more assessments have been performed. Hover over the days to see the number of collected assessments or click to show a menu to navigate to specific assessments for detailed analysis (see page 14). The symbols mean the following: green check mark: activity analyzed; orange warning sign: data could not be analyzed for various reasons; grey hour glass: analysis still pending. Analyses should run within 10 minutes of uploading the data to the database from the mobile app.

Navigation panel (3): Jump to the Comparison Page (left), show all assessments (middle) or go to the patient's latest assessment (right). The latter two take you to the Assessment Page (see page 14).
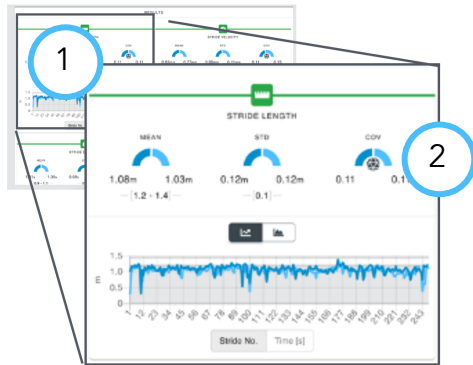
Gait Progression

This section shows the trend of multiple gait parameters by showing the average daily value for each gait parameter.

Click on Weekly, Monthly, Yearly (1) to see the progression of the different parameters over time.
By default the overall is taken across all walking assessment, but one can see the trends for specific assessment types by using the assessment type toggle (2).

Click on the report button (3) to download the Gait Progression Report. Select which assessments to include in the report.
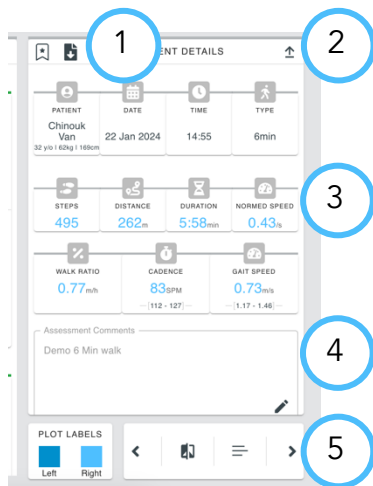
Assessment Page Part I

Click on any analyzed activity, either from the calendar view or the navigation panel (see page 12).

For every gait parameter, summary statistics (1) are given by the left and right mean, standard deviation (STD) and coefficient of variability (COV). Click on the graph icon below the COV statistic (2) to open a spider plot of all COV values. Reference ranges are shown for each parameter[1].

The color (3) reflects the symmetry (left vs. right) of the mean values (green/grey/orange/red indicate the range from high to low symmetry).

The gait parameter can be plotted against step number or time. Alternatively, the distribution of the values can be shown (4). All plots can be viewed in fullscreen by clicking on them.

Assessment Page Part II

Button to (un-)mark the assessment (1) for comparison (see page 31) and to download the pdf report.

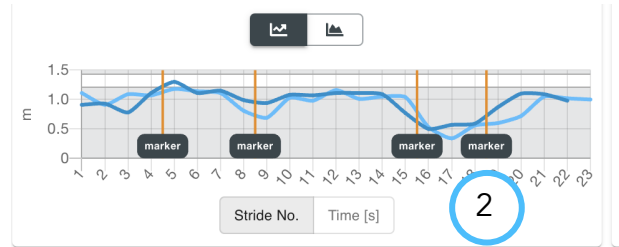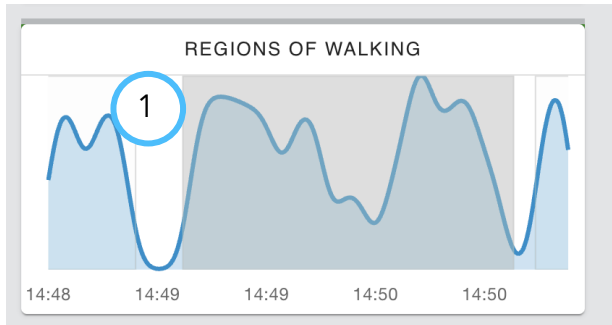Button (2) to jump back to the patient page (see page 18).

Overall assessment details (3), such as the date and time, the type and patient name. Performance statistics are given for the entire assessment. For cadence and gait speed, reference ranges[1] are given.

Assessment Comment (4) that can be edited (same as in the mobile application). The comment is also displayed on the report.

The navigation tool bar (5) allows you to navigate to the previous/next assessment using the arrows, jump to a specific assessment using the assessment list or go to the Comparison Page using the comparison icon (see page 18).

[1] Reference ranges are given for all but two gait parameters (strike angle and heel clearance), as well as for the overall cadence and gait speed. McKay *et al.* compiled the mean and standard deviation for each parameter by age group and sex. The ranges on the Web Application are given by mean ± standard deviation based on the user's sex and age. Reference: McKay, Marnee J., et al. "Spatiotemporal and plantar pressure patterns of 1000 healthy individuals aged 3–101 years." *Gait & posture* 58 (2017): 78-87.
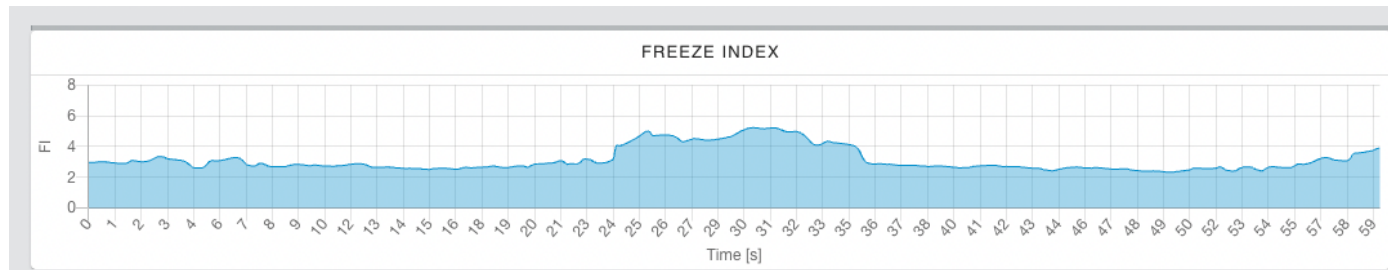
Generic Assessment

For generic assessments, regions of walking are shown on the right side (grey shading). Regions of walking indicate consistent walking periods of a user. The results in the report are restricted to the selected data segment. Click on another region of walking, delimited by the vertical lines (1), to change the region of walking.

When collecting a generic activity, it is possible to mark specific events, like start and end of a dual task using the "Mark" button in the mobile app. These marks are shown on the Web Application with marker lines (2).
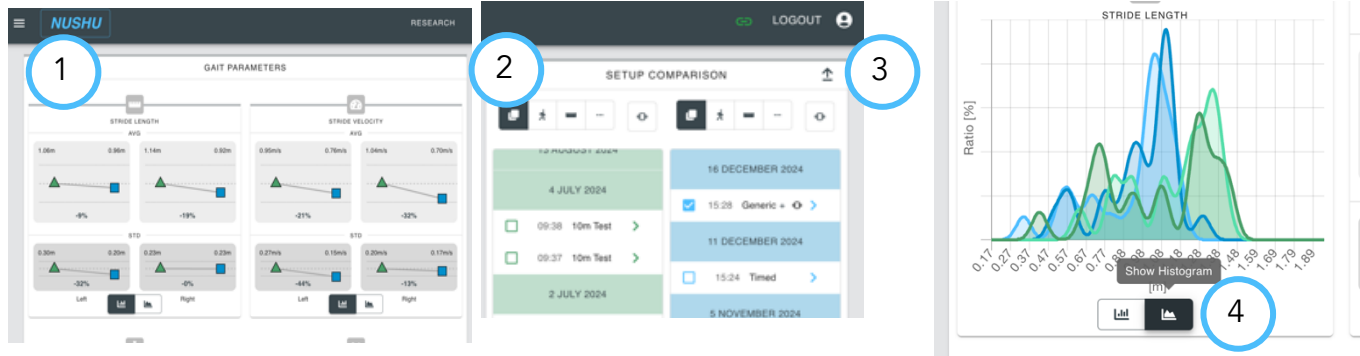
Freeze Index

FREEZE INDEX

The freeze index (FI) shows the likelihood of freezing at a given moment in time. If the user freezes, the FI shows a higher value, as shown in the figure between 24-36s.

The FI is only elevated, if the freezing period is longer than 5s.

⚠ The FI is automatically computed for each assessment. The interpretation of it is the responsibility of the HCP/Researcher.
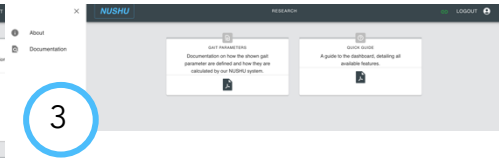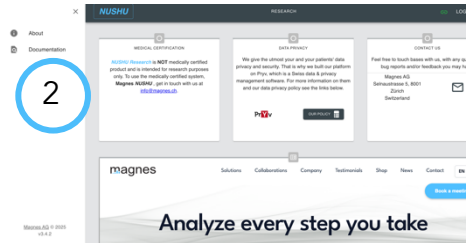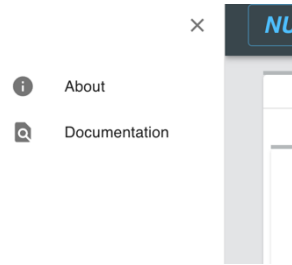
NUSHU

Comparison Page

The comparison page is a tool to compare and visualize (groups of) assessments to one-another in terms of their gait parameters (1). The average of each parameter is shown with the percentage difference between the two assessments.

Select the two groups of assessments to compare (2) and generate the comparison using the button below.

Click on the download button (3) to download the report or save the comparison.

Click on the distribution icon (4) to compare the parameter distribution of two assessments in more detail.
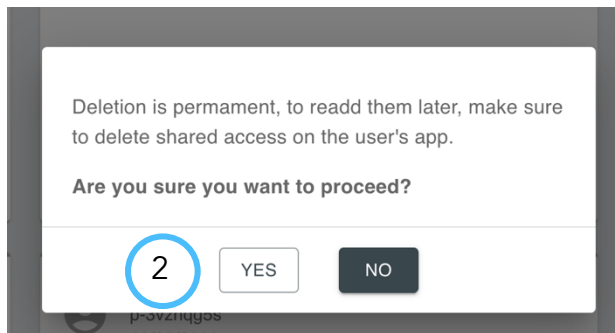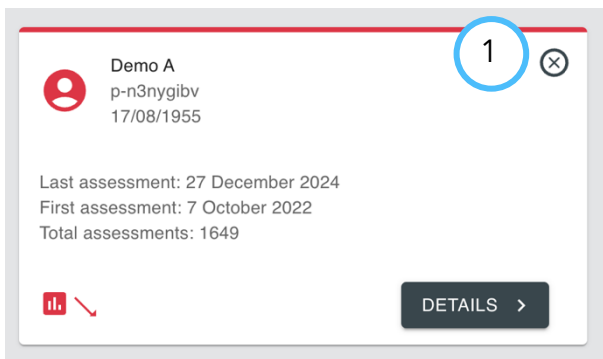
Menu Bar

Click on the menu button (1) in the left top corner to open the menu.

The "About" page (2) contains a disclaimer, information about data privacy and contact details.

The "Documentation" page (3) contains information about the gait parameters and the link to these Instructions for Use.

Delete User

To delete a user profile, go to the start page. Click on the "X" (1) in the right top corner of the patient card.

Confirm with "**YES**" in the pop-up window to delete the user profile or press "**NO**" to cancel the process (2).

⚠️ Deleting a user profile only deletes the access to that user's data from the Web Application. To delete that user's data from the database, the user account has to be deleted via the Magnes NUSHU mobile app.

Troubleshooting

Problem	Cause	Action
Activity not analyzed	Faulty data collection	Check analysis status in the calendar view
Activity not visible	Activity not uploaded	Upload activity via mobile app
	Activity collected with a non-corresponding mobile app	Make sure to collect the data using the corresponding mobile app to see all activities in the web application
Limited functionality available	Firewall blockage	The firewall of your institute can prevent some functionalities. Make sure your IT department allows https://research.nushu.health to be opened. Also ensure that CORS is enabled for the same site.

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