NUSHU

User manual EN

Version 1: 2026-06-22

Software Version: 1.0

Digital version available for download

https://magnes.ch/documents/nushu-fda/

Contents

1 Support

For the best experience, carefully read and understand this user manual prior to using NUSHU.

For any inquiries, please reach out to Magnes.
Email: `support@magnes.ch`

For Europe and rest of the world

Magnes AG, Hardturmstrasse 253, 8005 Zurich, Switzerland.

For USA

Magnes Inc, 2261 Market Street STE 5508, San Francisco, CA 94114, USA.

2 Warnings / Important Notes


Users shall report any serious incident to Magnes AG and the authority having jurisdiction in their locale.


The product is NOT intended to come into contact with bare skin or wounds. Users must wear socks when using NUSHU.


Make sure NUSHU are charged.


Do not use NUSHU while they are charging.


NUSHU shall not be exposed to loads exceeding 120 kg (264 lb).


Transport and store NUSHU between 0°C (32°F) and 30°C (86°F).


Maximum humidity should not exceed 70%.


Do not leave your NUSHU exposed to direct sunlight during storage.


No modification of NUSHU is allowed.


Use with caution on slippery and wet floors.


Keep out of the reach of children.


WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of NUSHU, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.


Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.


WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.


It is possible that high levels of interference due to close proximity or due to the power of a source, disrupts the operation of this device. Medical electrical devices require special precautions regarding electromagnetic compatibility and all devices must be installed and put into service in accordance with the information specified in this user manual.


Please keep the shoe box with the label for future reference.

3 Product Description and Intended Use

NUSHU smart shoes, consisting of one pair of connected footwear and a mobile application, are intended to measure, record, and analyze walking parameters in patients with gait impairments. The shoes may be used either at home or in the clinic. NUSHU can also assist gait by providing patients with haptic notifications via tactile vibrations and exercise. NUSHU smart shoes are compatible with the NUSHU web application as part of the connected NUSHU medical device system.

The NUSHU web application is a software medical device intended for use by healthcare professionals (HCP) only, for assisting in the review of gait data to support the management of patients with gait impairments. Gait data is not intended to provide diagnostic conclusions independent of clinical judgment. The NUSHU web application is compatible with NUSHU smart shoes as part of the connected NUSHU medical device system.

It can be accessed at https://portal.nushumedical.com.


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


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


Please stop using the shoes and talk to your healthcare professional (HCP), if using them causes any discomfort.


Users shall report any serious incident to Magnes AG and the authority having jurisdiction in their locale.

4 Intended Use Environment

The NUSHU smart shoes may be used in the clinic and home environments. The usage can be indoors and outdoors.

The NUSHU web application is intended for clinic use only.


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


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

5 Technical Requirements

The Web Application https://portal.nushumedical.com 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.

6 Log In to the Web Application

When logging in for the first time (1), you need to register (2) as a clinical user.

Fill in all the fields with an *. Make sure to use an affiliated email address belonging to the institution you are working at.

After registration, log in (1) with your new account.

⚠ Every Web Application user is a clinical user. Users are uniquely identified by their email address. This ensures that an email address can be used for only one application (mobile or web application). If you want to use a single email address for both applications, use the built-in email aliasing feature (see Section 7.3).

⚠ The system only allows affiliated email addresses from verified domains to register. To verify your domain, reach out to support, if needed (see Section 1).

7 Add Patients to the Web Application

After the first login, click on the QR code button at the center of the page. If at least 1 patient was added before, click on "Add Patient" (1).

7.1 Add Patients via QR Code

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

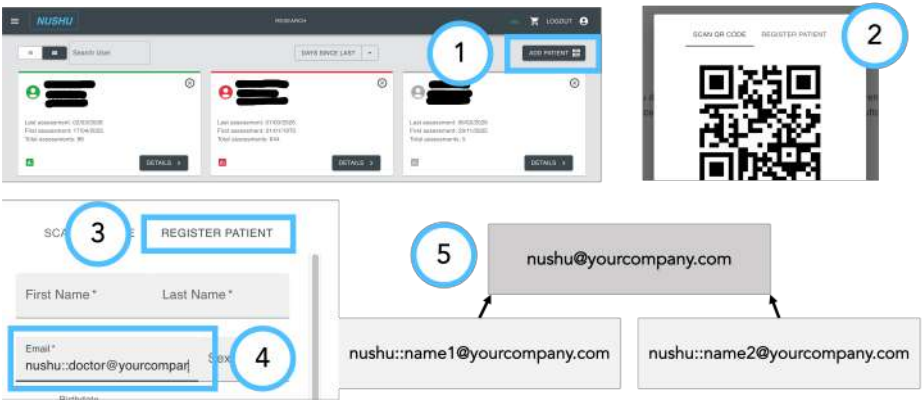
7.2 Register Patients Directly

To add patients to the web application and also register them in the mobile app, in the pop-up, go to the "REGISTER PATIENT" tab (3). Fill in all the details to proceed with the registration.

7.3 Multiple Accounts with One Email

It is also possible to create multiple accounts based on one main email address. Assuming the main email address is nushu@yourcompany.com, register additional accounts as nushu::name1@yourcompany.com (4). This way, multiple accounts can be manged through one main email address.

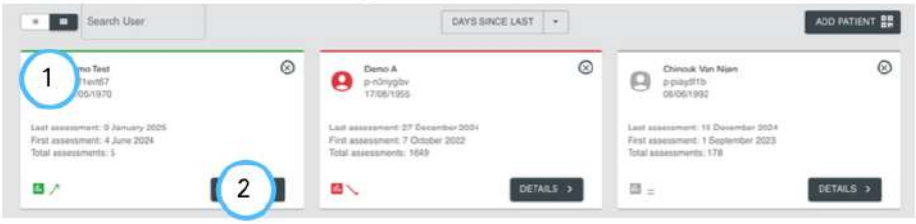
All emails of that account will be sent to nushu@yourcompany.com (5). To log into that account, ensure to use the full email nushu::name1@yourcompany.com. Email aliasing works across the whole NUSHU platform.



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

⚠ When using multiple accounts with one email, ensure that the main email account exists and that you have access to it. Access is required to reset the password and for account deletion.

8 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 color of the patient card reflects the user's assessment trend. It compares the assessments of

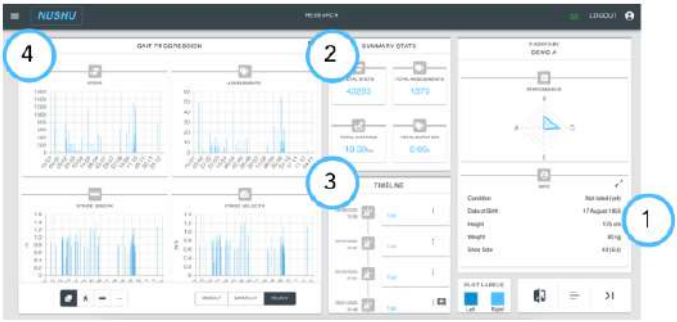
the past seven days to the preceding seven days and colors the card
Green: Increase in the number of assessments,
Grey: No change in the number of assessments,
Red: Decrease in the number of assessments.

To navigate to the Patient Page (see page 8), click on the respective "Details" button (2).

9 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.

9.1 General Information

This includes

1. **User information** from the mobile app (1)
2. **Calendar**: Heat map of the assessment dates (2), the darker the color the more assessments have been performed.
3. **Navigation panel** (3)

Calendar (2)

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 9). The symbols mean the following:
Green check mark: Activity analyzed
Orange warning sign: Data could not be analyzed
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 9.3 (see page 9).

9.2 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.

9.3 Assessment Page

Click on any analyzed activity, either from the calendar view or the navigation panel (see page 9).

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].

[1] Reference ranges are given for all but two gait parameters (strike angle and heel clearance),

The color (3) reflects the symmetry (left vs. right) of the mean values. Green, gray, orange and 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.

Button to (un-)mark the assessment (5) for comparison (see 10.2) and to download the pdf report.

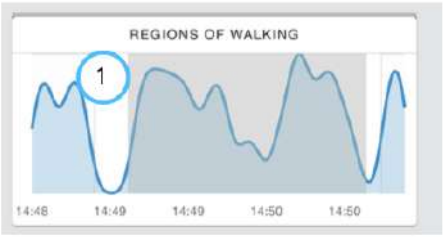
Button (6) to jump back to Patient Page (see 9).

Overall assessment details (7), 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 (8) that can be edited (same as in the mobile application). The comment is also displayed on the report.

The navigation tool bar (9) allows you to navigate to the previous/next assessment using the arrows, jump to a specific assessment using the assessment list or go to Comparison Page using the comparison icon (see 10.2).

10 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).

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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 $\pm$ 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.

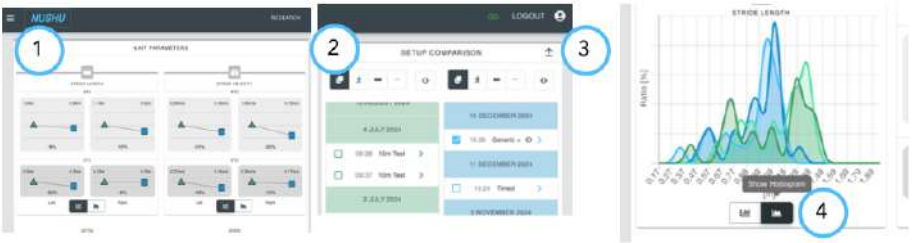
10.1 Freeze Index

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.

10.2 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.

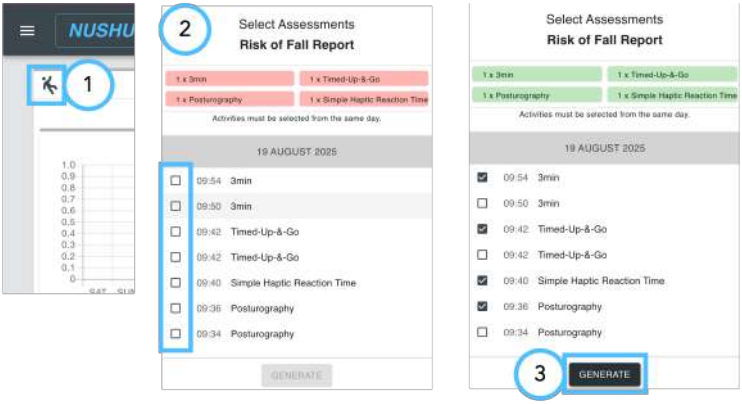
Select the two groups of assessments to compare (2) and generate the comparison using the button below.

At the bottom of the panel (3) are an upload button to upload saved comparisons, a save button for the selected comparison, a download button to download a comparison report.

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

10.3 Fall Risk Report

To generate a Fall Risk Report, first open the Patient View and click the icon located in the top-left corner of the screen (1). This will open the report creation window (2).



Select the following four activities, ensuring they are from the same day to generate a valid report:

- 3-Minute Walk
- Timed Up and Go
- Posturography
- Simple Reaction Time

When all required activities have been selected, click on Generate (3) to generate the report and automatically save it to your Downloads folder.

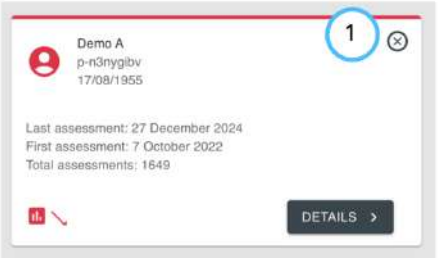
11 Menu Bar

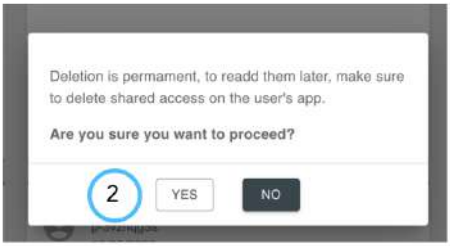
Click on the **menu button** (1) in the left top corner to open the menu.

The **About** page (2) contains the label, information about data privacy and contact details.

The **Documentation** page (3) contains information about the gait parameters and the link to this manual.

12 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 NUSHU mobile app.

13 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 not visible	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://portal.nushumedical.com to be opened. Also ensure that cross-origin resource sharing (CORS) is enabled for the same site.

14 Explanation of Symbols Used

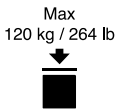
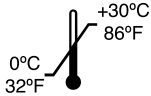
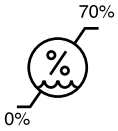
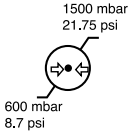
1			
A 	B 	C 	D 
E 	F 	G 	H
I 	J 	K 	L 
M 	N 	O 	P 
Q 	R 	S 	T 
U 			

Fig.	Title	Description	Standard (Ref. Nr.)
1A	Caution	Important safety or operating instructions	ISO 15223-1 (5.4.4)
1B	Read the user manual	—	ISO 15223-1 (5.4.3)
1C	Separate Collection of WEEE	Do not dispose in household waste	Directive 2012/19/EU / BS EN 50419 (—)
1D	Serial number	—	ISO 15223-1 (5.1.7)
1E	CE marking	European conformity	EU Regulation 765/2008 (—)
1F	FCC mark	Compliance with FCC rules and regulations	47 CFR FCC Rules (—)
1G	Dust- and waterproof rating	See Technical Specification	IEC 60529 (IP22)
1H	Keep dry	Keep away from rain	ISO 15223-1 (5.3.4)
1I	Maximal applicable load	—	ISO 7000 (0630)
1J	Temperature limit	Transport and storage temperature	ISO 15223-1 (5.3.7)
1K	Humidity limitation	—	ISO 15223-1 (5.3.8)
1L	Atmospheric pressure limitation	—	ISO 15223-1 (5.3.0)
1M	Manufacturer	—	ISO 15223-1 (5.1.1)
1N	Recycling	Battery disposal information	ISO 7000 (1135)
1O	Mains electricity is double insulated	—	IEC 60417 (5172)
1P	Indoor use only	—	IEC 60417 (5957)
1Q	Reference number	For identification of product at manufacturer	ISO 15223-1 (5.1.6)
1R	Unique device identifier	—	ISO 15223-1 (5.7.10)
1S	Date of manufacture	Manufacturing date	ISO 15223-1 (5.1.3)
1T	Keep out of reach of children	—	ISO 7010 (M055)
1U	Prescription use only	Restricted to sale by or on the order of a licensed HCP	21 CFR 801.109 (—)