

NUSHU

Instructions for Use

v3.2 18.09.2023

To be used with the Magnes NUSHU app V2

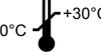
Content

Signs and Symbols	4
Product Description and Intended Use	5
Intended User Profiles and Intended Use environments	6
Warnings and Important notes.....	8
Initial Use / Before Using the Device First Time	9
Using Magnes NUSHU/Performing an Activity	18
1. Home screen with connected devices	18
2. Select activity type	19
3. Select vibration (biofeedback) mode	23
4. Starting an activity for collecting data	24
4.1 Starting an activity – Timed 25 feet test.....	26
5. Download data for analysis	27
6. Show analysed activity	28
7. Show statistics	30

Content

Managing Accesses to your Data	31
Upgrading the Device Firmware	33
Managing Your Account.....	34
Cleaning and Maintenance	36
Warranty.....	36
Troubleshooting	38
Technical Specification	40

Signs and Symbols

	Important safety instructions or operating instructions		Medical Device
	Read the instruction for use (IFU)		Dust- and water-proof rating
	Dispose the device in accordance with EC Directive – WEEE (Waste Electrical and Electronic Equipment)		Maximal applicable load
	Serial Number		Keep away from rain
	Reference Number		Transport and storage temperature
	Unique Device Identifiers		Li-ion battery disposal information
			Manufacturer
			Authorized Representative
			European Conformity

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.



The performance of Magnes NUSHU may be incorrect when it is used outside the defined intended use.



Magnes NUSHU is not intended to be used to make diagnostic or therapeutic decisions based only on data collected by Magnes NUSHU.

Intended User Profiles and Intended 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 above 12 years of age.

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

Intended Use Environment:

Device is meant for indoor and outdoor walking.



Device is **not** meant for high-impact activities, e.g. running, jogging, or doing other sports.



Do **not** immerse the shoes in water or use them in conditions that drench the shoes (e.g. river-crossing, nautical activities, strong rain or snow).

¹ See the Magnes Nushu Dashboard '*MSD-03-01-03 User Manual HCPs*' for more information.

Intended User Profiles and Intended Use Environment

Indications:

Magnes Nushu will be used by patients who have problems or symptoms related to their gait. This includes the following patients:

- Parkinson's disease patients
- Alzheimer's disease patients
- Multiple Sclerosis patients
- Dementia patients
- Stroke patients
- People with brain or spine injury
- Elderly people
- People with brain disorders
- People with walking (gait) disorders
- Patients of Sarcopenia
- Patients of Cachexia
- Muscular atrophy patients
- Pediatric patients
- Orthopaedic patients
- Contraindications

Contraindications:

- none

Warnings / Important Notes



Users shall carefully read and understand these instructions for use prior to using Magnes NUSHU. Any questions can be asked to Magnes AG² or their treating physician.



Users shall report any serious incident to the legal manufacturer³ 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 Magnes NUSHU.



Make sure Magnes NUSHU is charged (see page 10 for more details).



Do not use Magnes NUSHU while they are charging.



Magnes NUSHU shall not be exposed to loads exceeding 120 kg.



Transport and storage temperature needs to be between 0°C and 30°C.



Maximum humidity should not exceed 85%.



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



No modification of Magnes NUSHU is allowed.



Use with caution on slippery and wet floors.

²Magnes AG, Hardturmstrasse 253, 8005, Zurich, e-mail: support@magnes.ch

³Effectum Medical AG, Kirchgasse 11, CH-4600 Olten, www.effectummedical.com, e-mail: info@effectummedical.com

Initial Setup of the Magnes NUSHUs

1. Included in delivery

- These Instructions for Use (IFU)
- A pair Magnes NUSHUs
- Wireless charging station
- Power cable for the wireless charging station

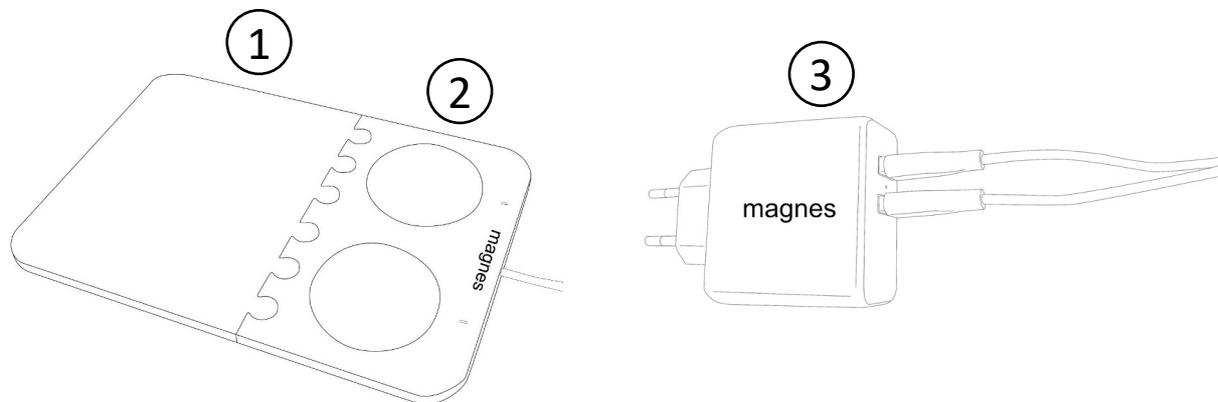
2. Required items

A smart device (phone, tablet) running iOS 14 or newer is needed to install NUSHU App

3. Setting up the charging station

The charging station is composed of two pieces. These pieces need to be connected to each other like a puzzle. The figure on the following page illustrates this procedure.

After the charging station is put together (1 & 2), place the charging station on a flat surface and connect the two charging cables to the power adapter (3).



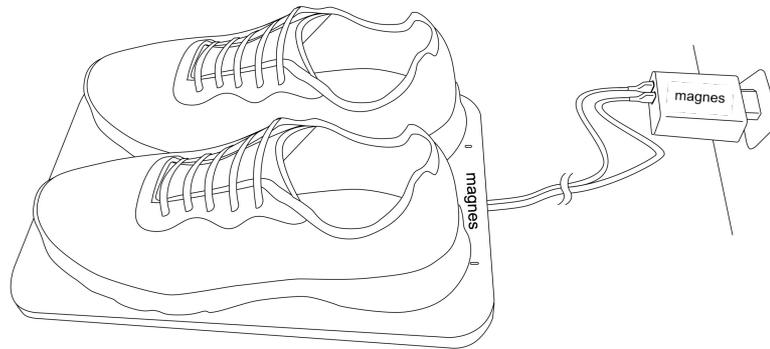
To charge Magnes NUSHU place the shoes onto the charging station with the back of the shoes fully covering the round discs.

Do not use another charging station than the one delivered with NUSHU.

The shoes are being charged if a white LED will lights up for each device and is blinking slowly. The correct shoe placement is shown in the figure below.

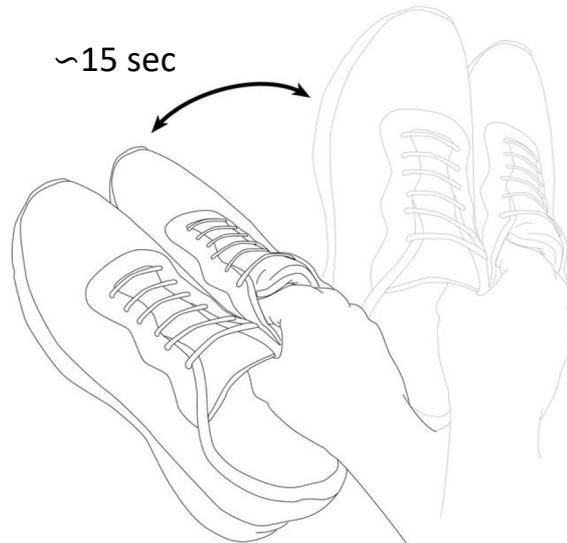
Once fully charged the LED will remain on (not blinking). Fully charging them can take up to 5 hours.

If an LED is blinking very fast, this means the shoes are not positioned correctly onto the charging station.



4. Turning on Magnes NUSHU and wearing the shoes

Magnes NUSHU can be turned on by moving the shoes (e.g. gently shaking them up and down) for at least 15 seconds. The shoes will vibrate twice when they are on.



You can see whether your device is on in the NUSHU App. They either connect directly to your phone or are available for pairing.

5. Turning Off Magnes NUSHU

If connected, you can turn off Magnes NUSHU by closing the NUSHU App. If not, they will power down on their own after 5' of inactivity.

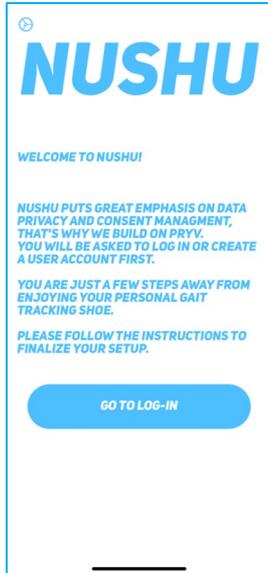


If you close the NUSHU App, your shoes will stay on and this will drain their battery.

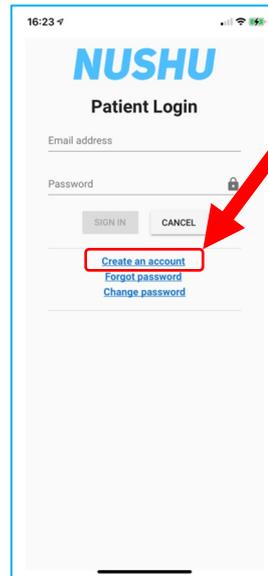
6. Installing NUSHU App

Download the app from the App Store for iOS devices and follow the installation instructions.

7. Logging In

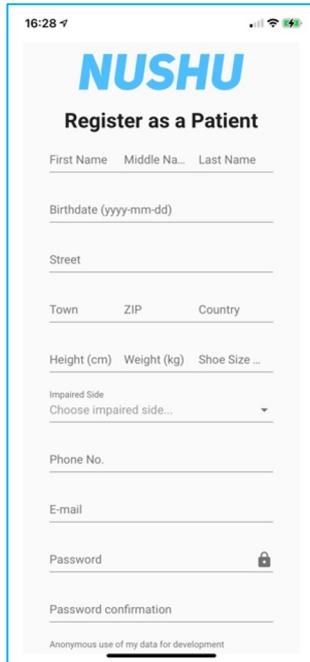


- Click the NUSHU App icon to start. You will be greeted by a welcome page.
- Click on "Go To Log-In"



- If you are a new user tap on "Create an account" and follow the instructions on page 14.
- If you already have an account, please enter your email address and your password to login.

8. Creating an Account



The screenshot shows a mobile application interface for NUSHU. At the top, the time is 16:28 and there are icons for signal strength, Wi-Fi, and battery. The NUSHU logo is prominently displayed in blue. Below the logo, the text "Register as a Patient" is centered. The form consists of several input fields: "First Name", "Middle Na...", and "Last Name" (all on one line); "Birthdate (yyyy-mm-dd)"; "Street"; "Town", "ZIP", and "Country" (all on one line); "Height (cm)", "Weight (kg)", and "Shoe Size ..." (all on one line); "Impaired Side" with a dropdown menu showing "Choose impaired side..."; "Phone No."; "E-mail"; "Password" with a lock icon; and "Password confirmation". At the bottom, there is a link that says "Anonymous use of my data for development".

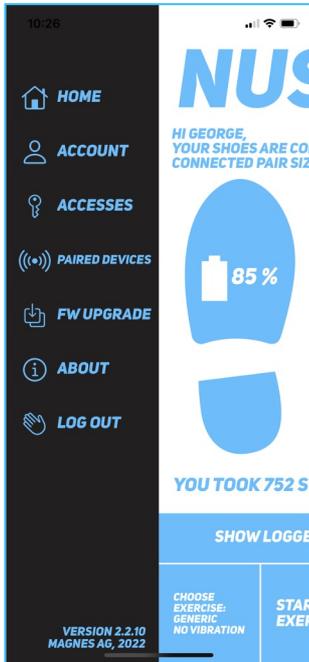
- Please fill in all required fields. Choose a strong password and confirm it by writing it 2nd time in the “Password Confirmation” field.
- Click on “Create”. You will be notified if your registration was successful with a green message on screen.
- A welcome email will be sent to you with your anonymised username.
- To log in with your newly created account click on “Go to Sign in” and follow the steps in Section “Logging In” in this document.

9. Home screen at Initial Login



- On successful login you will see the app's home screen.
- You can see following buttons:
 - Show Logged Exercises button
 - Choose exercise: No Logging, No Vibration button
 - Choose valid combination button
 - Download files button
- A Menu Page can be opened by tapping on NUSHU logo at the top of the screen.

10. Connecting Magnes NUSHU with the NUSHU App



- Go to the menu by tapping (once) on NUSHU logo at the top of the screen.
- Select “Paired Devices” and then click on “Pair new device”.
- A list of devices will appear where you will have to select your Magnes NUSHU pair and click on “Set this pair”.
- If your shoes do not appear, ensure that you have turned the shoes on and that they are charged.

Using Magnes NUSHU / Performing an Activity

1. Home screen with connected devices



- On successful pairing, your connected shoes will appear on the screen.



- You can monitor the battery level of each shoe. If the shoes are charging a lightning symbol will appear instead of the Battery symbol.

2. Select activity type



To select an activity type, tap on the button “Choose Exercise: No Logging, No Vibration button” in the bottom left of the screen. Scroll up and down to choose your desired type of exercise and click on “Set Activity Type”.

All available activity types are explained on the following pages.

2. Select activity type



No Data logging mode: No data will be collected in this mode.



Generic walking: Start the exercise and start walking. Can be used for long activities of walking indoors and outdoors.



Timed Up and Go (TUG): Sit on a chair, start exercise, then get up from the chair and walk straight for 3m at a comfortable and safe pace, turn and walk back to the chair and sit down and stop the exercise.



6min walking: Walk for 6', the activity will be stop automatically after the timer has reached 6'.



3min walking: Walk for 3', the activity will stop automatically after the timer has reached 3'.

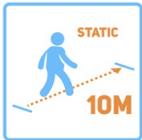
2. Select activity type



Timed 25 Foot walk: Please see the detailed instructions on page 25.



10 Meter walk: Start the exercise and then walk for at least 12m, then come to a stop. The analysis discards the first 1.5m of walking and then returns the gait analysis for the subsequent 10m.



Static 10 Meter walk: Start the exercise and walk straight, stop walking after 10m and stop the exercise.



Dual Task 10 Meter walk: Start the exercise and walk straight, while walking count backwards starting from 100 in steps of 7, stop walking after >12m and stop the exercise.

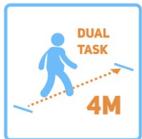


4 Meter walk: Same as the 10 Meter walk, but with a minimum walking distance of 6m.

2. Select activity type



Static 4 Meter walk: same protocol as for the static 10 meter walk, but with a minimum walking distance of 4 meters.

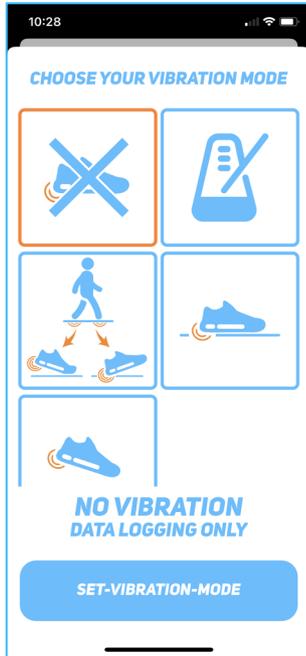


Dual Task 4 Meter walk: same protocol as for the Dual Task 10 Meter walk, but with a minimum walking distance of 6 meters.



Stair Climb: Start the exercise and then begin climbing a set of stairs. Note, that this exercise type is only meant for climbing stairs and shouldn't be used otherwise.

3. Select vibration (biofeedback) mode



To select a Vibration mode, swipe up and down and choose your desired mode and click on "Set-Vibration-Mode".



Please talk to your treating physician before using exercises with vibration feedback.

3. Select vibration (biofeedback) mode



No Vibration: In this mode the shoes will not vibrate while walking.



Metronom: You can set a frequency at which the shoes vibrate. By moving the slider, the frequency can be adjusted.



HS-HO Feedback: In this mode vibrational feedback is given at each heel off and at each heel strike.

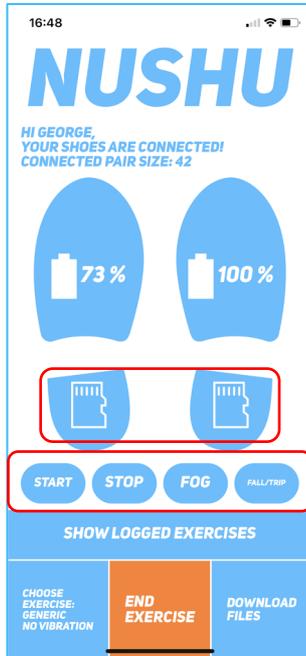


Ground Vibrate: In this mode the shoes give vibrational feedback when the shoes are in contact with the ground.



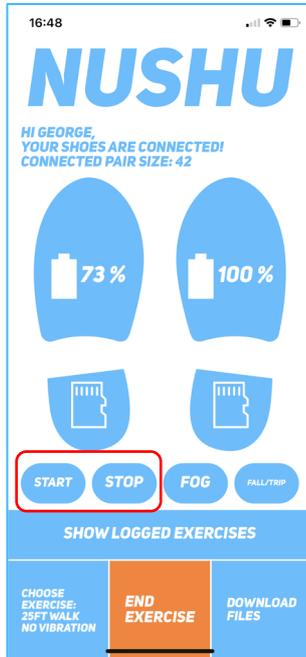
Swing Vibrate: In this mode the shoes provide vibrational feedback during the swing phase while walking.

4. Starting an activity for collecting data



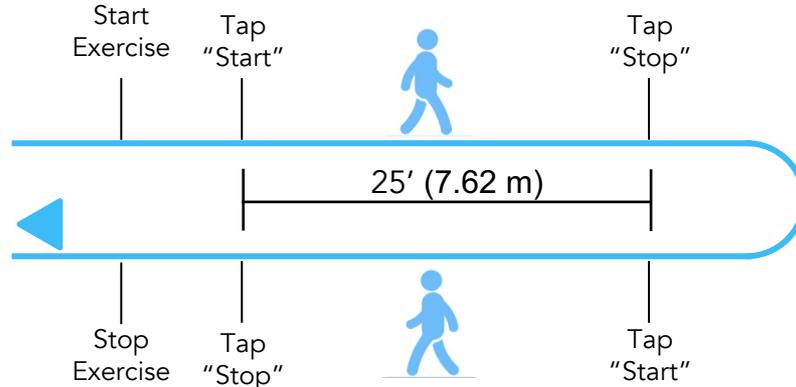
- Tap on “Start Exercise”. The button will change its colour to orange and two memory card icons will appear in the heels of both shoes on the screen. This indicates a successful start of data collection.
- Four Buttons will appear: **Start**, **Stop**, **FOG**, **Fall/Trip**. Start and Stop button are only to be used with the 25 Foot test. FOG and Fall/Trip will record a Freezing of Gait or Fall/Trip event and saved in the database.
- When you have performed your walk or exercise, simply tap on “End Exercise” to finish the recording.

4. Starting an activity – Timed 25 feet test



Step by step Guide:

1. Select under activity types "25FT".
2. Select under vibrations modes "No Vibration".
3. Tap on "Start Exercise".
4. Start walking and tap on "Start" when transiting the start-mark, keep walking past the stop-mark and tap on "Stop" when transiting it.
5. Turn around, rest, and repeat the procedure by returning to the starting point. Again mark the transitions by tapping on "Start" and then on "Stop"
6. Press "Stop Exercise".



5. Download data for analysis

- Download the data after an exercise so that they can be analysed. Simply tap on "Download Files".



- A message will be prompted to "Join" the connection to the shoes' WiFi network. By accepting the connection, the download of your collected data will begin.



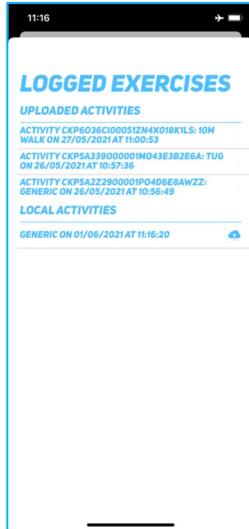
- You will see the progress on your screen.
- Upon completion, a check mark will appear and the app will try to upload the data to the database. This requires that your iOS device has access to the internet (either a WLAN or mobile data).
- Magnes AG is not responsible for extra costs caused by the upload of data via the Magnes NUSHU App using mobile data.

6. Show analysed activity



- You can check if and which activities have been uploaded by tapping on “Show Logged Exercises” on the home screen
- A list will appear that will show activities already in the database (“Uploaded Activities”) and activities that are still local on your phone (“Local Activities”).
 - Activities under “Local Activities” have to be manually uploaded by simply tapping on the little cloud icon on the right. Indicated with a red arrow.

6. Show analysed activity



- You can click on one activity to visualize the calculated parameters.



- The calculated parameters include:
 - Gait speed
 - Duration of the activity
 - Steps
 - Distance
 - Average Left and Right Stride Length and the coefficient of variation (COV)
 - Average Left and Right Heel Clearance and COV
 - Average Left and Right Swing-Stance Ratio and COV



Please note that the analysis and calculation of the parameters can take several minutes.

7. Show statistics

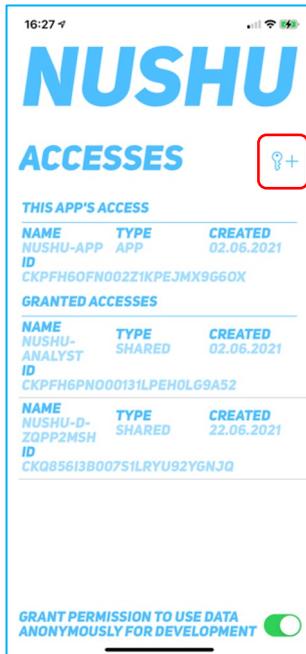


- You can check your weekly, monthly and overall performance by clicking on “You took # steps this week” on the home screen.



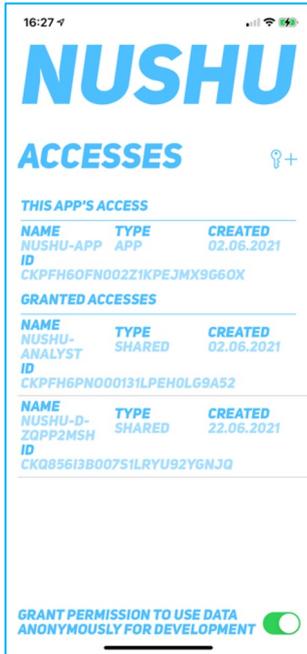
- By swiping left or right you can switch between the parameters.
- By scrolling up or down you get back to the home screen.

Managing accesses to your data



- To view, add, or delete who has access to your data, go to the main menu by tapping on the NUSHU logo at the top of the app. Choose "Accesses".
- The app's own access will be shown under "This App's Access".
- Should you wish to create a new access for a treating doctor, tap on the ADD SYMBOL (key with a plus) symbol.
- The app will ask to open your camera. Point your camera at the QR code that you received from the HCP. Once the QR code is read, the access will be created.

Managing accesses to your data



- To delete an access, swipe left on an access and confirm your deletion.
- To view any access' details, just tap on the access in the list.
- Per default, the access "NUSHU-Analyst" is created upon login to the app. This access is needed by Magnes NUSHU to process your data and to provide you with the analysis results.
- "NUSHU-Analyst" does not have access to your personal "Profile" account information (see "Viewing and Changing Account Information" on page 33).
- You can opt in or out of any support for future development by toggling the slider at the bottom of the screen.

Upgrading the device firmware



- Your shoes are running firmware which is driving the sensors, communication and storage. The devices support upgrading of the firmware over the air.
- In order to check for available upgrades, tap the NUSHU logo on the top of the app. Tap on “FW Upgrade” in the menu.
- You will be shown the firmware version running on each device. Should you happen to have the newest firmware installed, the screen will inform you accordingly.
- Should there be a new firmware version available, tap on “Upgrade FW”.



The update might take several minutes. Please wait until the process is finished.

Managing Your Account

1. Viewing and Changing Account Information



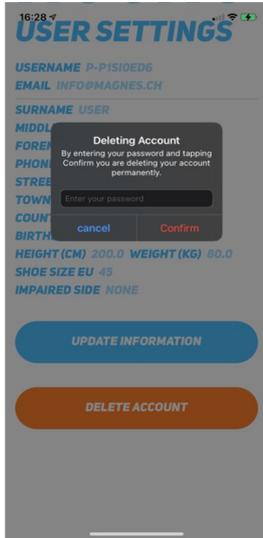
- To view or change your account information, go to the main menu by tapping on the NUSHU logo at the top of the app. Choose “Account”.



- Should you wish to change any of the provided information, simply tap on “Update Information”.
- After tapping on “Update Information”, the fields will become editable.
- By tapping on “Save Information” the information will be saved and updated in your account.

Managing Your Account

2. Deleting your Account



- Should you wish to delete your account for any reason, navigate to the “Account” page and tap on “Delete Account”.
- You will be warned that this step is irreversible.
- By entering your password and clicking on “Confirm” your account will be permanently deleted. To cancel the process tap on “Cancel”.



If you confirm, all your data will be deleted and in order to use Magnes NUSHU you will need to create a new account.

Cleaning and Maintenance

Clean Magnes NUSHU regularly, i.e. remove any dirt with a damp cloth (dampen cloth with ambient temperature tap water) and leave to air dry.



Do not use any detergents. Do not machine wash. Do not use sharp utensils. Do not dry shoes in direct sunlight, oven, and/or microwave.

The maintenance of Magnes NUSHU must not be carried out by the user. In case of a malfunction, please contact your distributor or the manufacturer.



Device contains a Lithium Ion battery. Dispose the device in accordance with EC Directive – WEEE (Waste Electrical and Electronic Equipment)

Warranty

Magnes NUSHU has a limited warranty of 2 years from the date of purchase. During the warranty period, should this product prove to be incomplete or defective in functionality in accordance with the provisions given in Instructions For Use, Magnes AG shall carry out a repair or a replacement delivery free of charge. The warranty covers manufacturing defects and DOA (dead on arrival) cases. Defect products shall be returned to the return address specified below for further inspection. In no case shall the user modify the devices in any way (or even just try to do so).

Cleaning and Maintenance

Any such action will void the warranty. Instances of force majeure are beyond the scope of this warranty. For disputes, Swiss law shall apply.

Return address:

Magnes AG

info@magnes.ch

Hardturmstrasse 253

8005 Zurich

Switzerland

The following are explicitly excluded from this warranty:

- Deterioration due to normal use or consumption of the product
- Accessories supplied with the product which are worn out or used up through proper use (e.g. shoes, rechargeable batteries)
- Products that are stored, used, or cleaned improperly or contrary to the provisions of the instructions for use
- Products modified or repaired by the customer or by a service center not authorized by Magnes AG
- Products that are damaged during transportation between manufacturer and customer, or between service center and customer

Troubleshooting

Problem	Cause	Action
Devices not detected	Bluetooth inactive	Turn on the Bluetooth of your mobile smart device.
Devices do not connect	Battery is empty	Fully charge your Magnes NUSHU.
Device not detected	Electromagnetic interference	Try using your device in a place free of other Bluetooth and wireless devices.
Devices do not connect	Device in sleep mode	Wake up the device by shaking Magnes NUSHU for about 15 seconds.
Data not uploaded to database	No internet connection available	If data was download from the shoes, they will be saved under "Local Activities" under "Logged Exercises". Check mobile data or WiFi internet connection.
Server cannot be reached	No internet connection available	Check mobile data or WiFi internet connection.

Troubleshooting

Problem	Cause	Action
Data download is not responding	Connection issue	Double tap on the NUSHU icon. If the problem persists, close the app completely.
Can not connect to the NUSHU WiFi	Connection issue	Retry to connect. If the problem persists, close the app completely.
Profile data are not shown correctly	Connection issue	Logout and close the app completely.

Technical Specifications

Magnes NUSHU

Lifetime	24 months
Gait events accuracy	Heel Off, Flat Foot – 60 ms Toe Off, Heel Strike – 20 ms
Gait parameters accuracy	Gait velocity – 0.08 m/s
Power Supply / Capacity	Li-ion battery 3.7 V / 750 mAh IEC 62133-2:2017
Memory	32 GB (~600h of recordings)
Wireless Communication	BLE, WiFi
Battery charging rate	Regular: 260 mA, Precharge (low voltage): 52 mA
BLE power	Bluetooth 4.2, 2.4 GHz, max. 1 mW, 3 dBm
WiFi power	19.5dBm
MD class	CLASS IIa MDR
Weight	40g for each side
Water and Dust Proof	IP22 – Protection against objects and particles >12.5mm and dripping water when tilted at 15°
Electrical Safety	Class II (Internally Powered)

Technical Specifications

Charging Station

Mains voltage	110 – 240 V at 50 – 60 Hz
Valid inputs	5V/3.0A, 9V/2.0A, 12V/1.5A
Output power	15W each, 30W total
Wireless charging standard	Qi

If the performance of the device starts to degrade, please send it back to the distributor or to Magnes AG, Hardturmstrasse 253, 8005 Zürich, Switzerland.

Magnes NUSHU fulfils following EMC Tests:

- EN 61000-4-4, EN 61000-4-5, EN 61000-4-6,
- EN 61000-4-8, EN 61000-4-11, EN 55011, EN 61000-3-2 and EN 61000-3-3 .



The device conforms with the European health, safety, and environmental protection standards. CE conformity to Medical Device Regulation 2017/745.



Manufacturer, Effectum Medical AG, Kirchgasse 11, CH-4600 Olten



NUSHU
Shoe for gait data collection

SN XX XXXX
REF 010.001.010
UDI

MD CE 0297

Max 120 kg

IP22
0°C - +30°C
3.6 V 750 mAh
Li-Ion

magnes
www.magnes.ch

Effectum Medical AG
Kirchgasse 11
CH-4600 Olten

MED-RAS GmbH
Eichenallee 8H
DE-21521 Wohltorf

010.001.007.v1



(01)XXXXXXXXXXXXXXXX(11)XXXXXX(21)XXXXXXXXXXXX

Label description:

- (01) – Device identification
- (11) – Manufacturing date
- (21) – Serial Number



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 Magnes NUSHU, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.



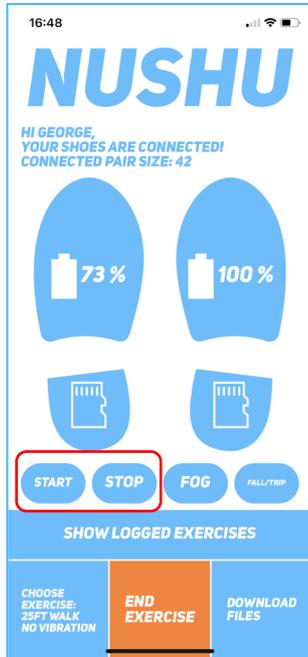
WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

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 manual.

Document Version History

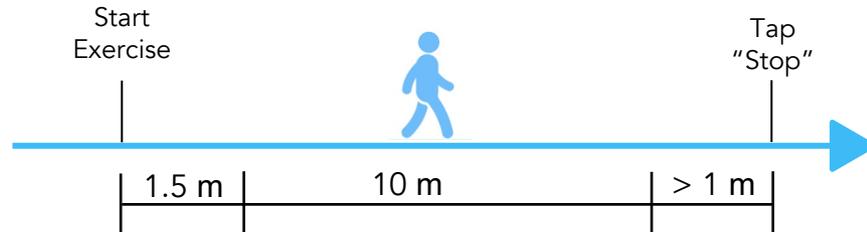
Version	Author	Comments
1.0	George Chatzipirpiridis	Initial version completed on <u>04.10.2021</u>
2.0	George Chatzipirpiridis	Completed on <u>21.05.2022</u>
3.0	George Chatzipirpiridis	Completed on <u>22.09.2022</u>
3.1	George Chatzipirpiridis	Completed on <u>05.10.2022</u>
3.2	George Chatzipirpiridis	Completed on <u>18.09.2023</u>

4. Starting an activity – 10m test



Step by step Guide:

1. Select under activity types “10m”.
2. Select under vibrations modes “No Vibration”.
3. Tap on “Start Exercise”.
4. Tell the patient to start walking. After 1.5m the 10m data collection starts. The patient will need to walk 1.5m + 10m + at least 1m.
5. Press “Stop Exercise” when the patient has at least performed 12.5m of walking distance in total.



4. Starting an activity – 10m test

Step by step Guide:

1. Select under activity types “10m”.
2. Select under vibrations modes “No Vibration”.
3. Tap on “Start Exercise”.
4. Tell the patient to start walking. After 1.5m the 10m data collection starts. The patient will need to walk 1.5m + 10m + at least 1m.
5. Press “Stop Exercise” when the patient has at least performed 12.5m of walking distance in total.