

# ***NUSHU***

**Instructions for Use - IFU**

# Content

Signs and Symbols .....	3
Product description and intended use .....	4
Intended User Profiles and Intended Use environments .....	5
Warnings and important notes.....	6
Initial Use / Before Using the Device First Time .....	7
Using Magnes Nushu / Performing an Activity .....	16
Vibrational Cueing .....	23
Managing Accesses to your Data .....	24
Upgrading the Device Firmware .....	26
Managing Your Account.....	27
Cleaning and Maintenance .....	29
Warranty .....	29
Troubleshooting .....	31
Technical Specification .....	32

# 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 intended to be used for collecting data about patients' gait and activity as well as for cueing and/or notifying patients about gait events while they are walking by vibrations. Magnes Nushu has two operation modes: data collection modes and vibration feedback modes.



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 for making diagnostic or therapeutic decisions solely based on data collected by Magnes Nushu.

# Intended User Profiles and Intended Use Environment

## Intended user profiles:

- Users (including patients) wearing Magnes Nushu. They generate data while walking and get notifications by vibrations.
- Healthcare professionals (HCPs), who provide Magnes Nushu to patients. They collect data from patients and analyze the data.

## 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 make the shoes totally wet (e.g. river-crossing, nautical activities, strong rain or snow).

# Warnings / Important Notes



Users shall carefully read and understand these instructions for use prior to the usage of Magnes Nushu. Questions regarding usage of Magnes Nushu, users should get in contact with Magnes AG or their treating physician for advice.

	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 (please refer to the corresponding section of this manual).
	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 shoes exposed to direct sunlight during storage.
	No modification of this equipment is allowed.
	Use with caution on slippery and wet floor.
	If devices do not connect to the Nushu App refer to Troubleshooting on page 31.

# Initial Use / Before Using the Device First Time

## 1. Included in Delivery

- These Instructions for Use (IFU)
- A pair of shoes with embedded Magnes Nushu
- 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. Mounting the charging station

The charging station is composed of two pieces. These pieces need to be mounted to each other like two pieces of a puzzle. Figure 1 shows the mounted charging station composed of the two pieces (1 and 2).

# Initial Use / Before Using the Device First Time

After the charging station is mounted together, place the charging station on a flat surface and connect the two charger cables to the power adapter.

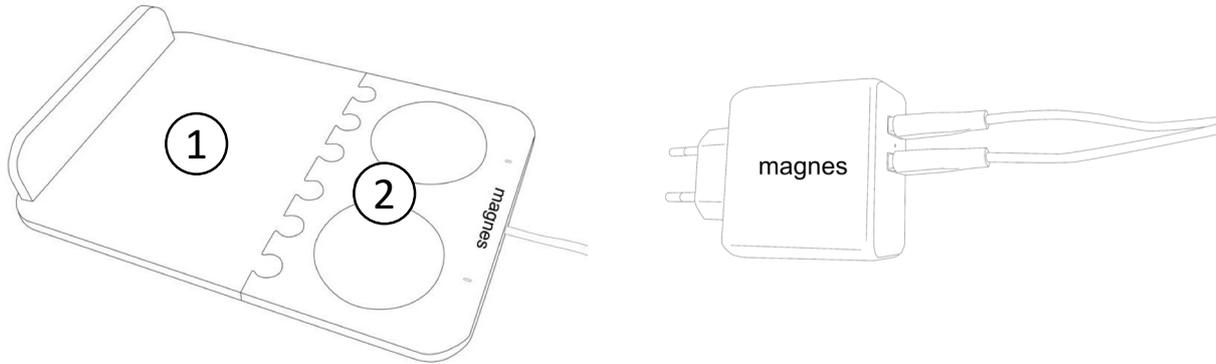


Figure 1 Setting up the charging station.

To charge Magnes Nushu place the shoes onto the charging station with the back of the shoes (heels) fully covering the round discs.

- If the shoes are placed correctly a white LED will light up for each device and will start blinking **slowly**. The LEDs will continue blinking while the shoes are charging.
- If the shoes are fully charged the LED will remain on (not blinking). **A full charge can take up to 5 hours.**
- **If LED is blinking very fast, this means the shoes are not positioned correctly onto the charging station.**

Figure 2 illustrates the correct positioning of the shoes onto the charging station.

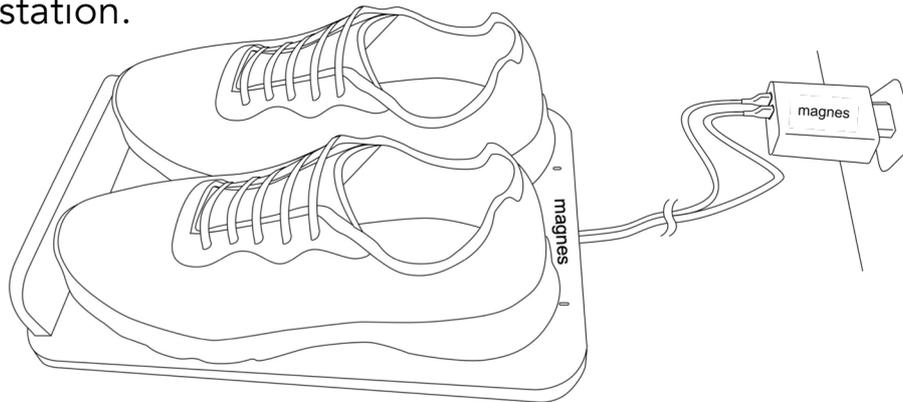


Figure 2 Placing the shoes on the charging station.

#### 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 10 seconds. The shoes will vibrate two times when they are on.

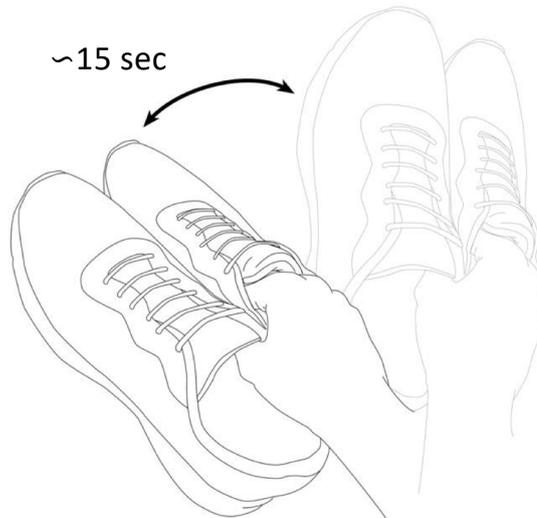


Figure 3 - Turn on the shoes by gently shaking them for 15 seconds.

You can see whether your device is on in the Nushu App if your devices are already paired with the Nushu App. You can wear your shoes and start using Magnes Nushu after turning them on.

## 5. Turning Off Magnes Nushu

In order to turn off the Magnes Nushu you have to switch off the Nushu App.

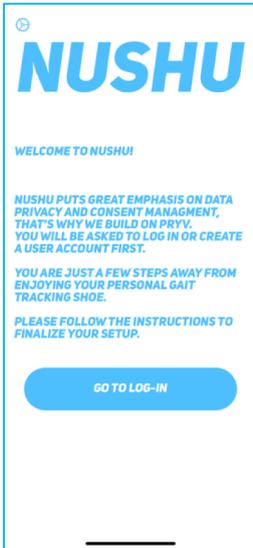


If you do not switch off the Nushu App, your shoes will stay on and this will drain their battery.

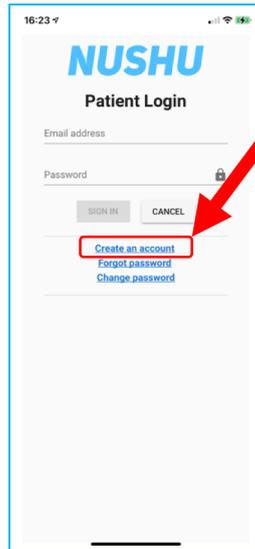
## 6. Installing Nushu App

Download the [Nushu](#) app from the App Store (iOS devices) and follow the installation instructions.

## 7. Logging In

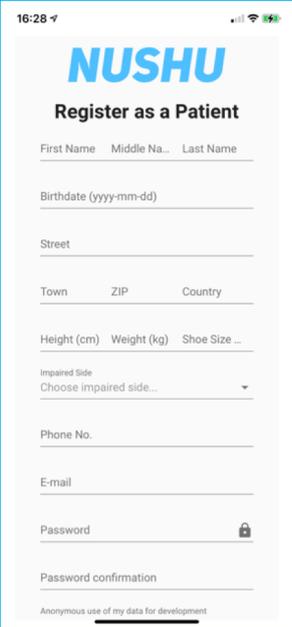


- Click the Nushu App to start. You will be greeted by a welcome page.
- Click on "Go To Log-In"



- If you are a new user tap on "Create an account" and follow the instructions on page 13.
- 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' with the title 'Register as a Patient'. The form includes the following fields: First Name, Middle Na..., Last Name; Birthdate (yyyy-mm-dd); Street; Town, ZIP, Country; Height (cm), Weight (kg), Shoe Size ...; Impaired Side (Choose impaired side...); Phone No.; E-mail; Password (with a lock icon); and Password confirmation. At the bottom, there is a checkbox for 'Anonymous use of my data for development'.

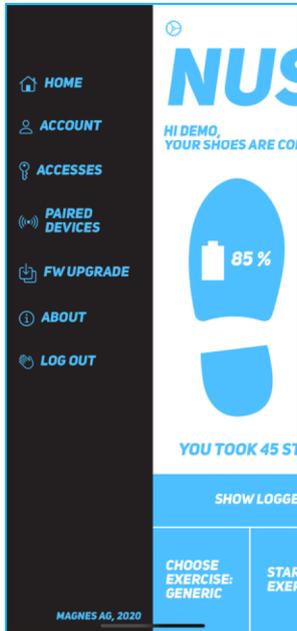
- If you have not created a Nushu account before, you can create one by clicking on “Create an account” on the “Patient Login” page.
- You will be redirected to the “Register as a Patient” page. Please fill in all required fields. Choose a strong password and confirm it by writing it 2nd time in the “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 button
  - Start a new exercise button
  - Download files button
- Menu Page can be accessed by tapping on Nushu logo at the top of the Nushu App screen.

## 10. Connecting Magnes Nushu with 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 shoes 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

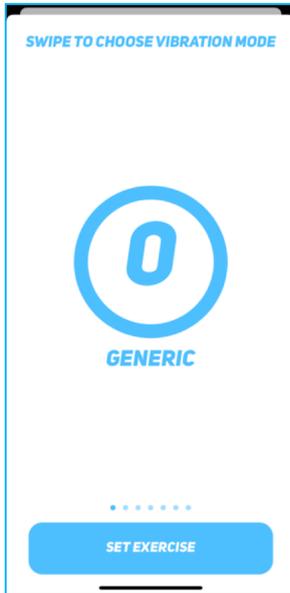


- On successful pairing, your connected shoes will appear on the screen.



- 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 for Collecting Data



- To collect data, tap on the button "Choose Exercise: Type". Swipe left and right to choose your desired type of exercise and click on "Set Exercise".

### 3. Starting an Activity for Collecting Data



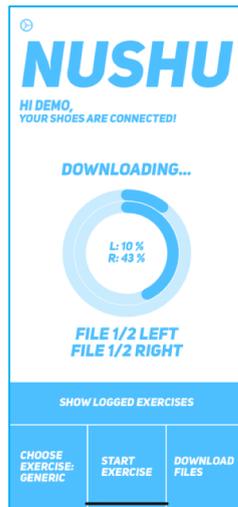
- Tap on “Start Exercise”. The button will change its colour to orange and two memory card icons will appear in the heels of both shoes on the screen. This indicates a successful start of data collection.
- When you have performed your walk or exercise, simply tap on “End Exercise” to finish the recording.
- You can repeat the previous two steps as many times as you like.

## 4. Download Data for Analysis

- You will have to download the data after an exercise so that they can be analysed. Simply tap on “Download Files”.

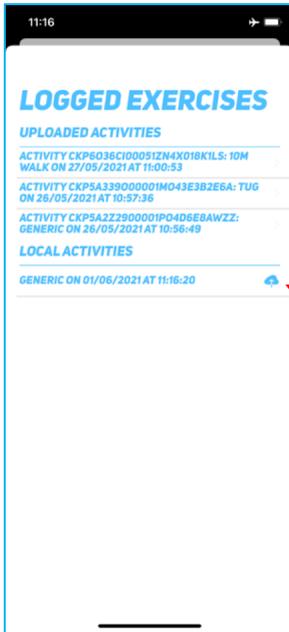


- A message will be prompted to “Join” the connection to the shoes’ WiFi network. By accepting the connection, the download of your collected data will begin.



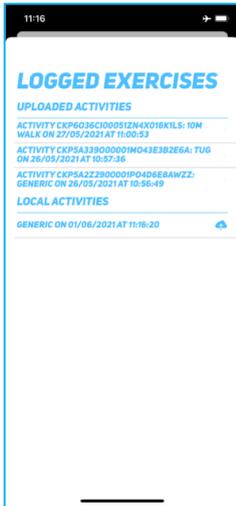
- You will see the progress on your screen.
- Upon completion, the app will upload the data to the database. This requires that your iOS device has access to the internet (either a WLAN or mobile data). Magnes AG is not responsible for extra costs caused by the upload of data via the Magnes Nushu App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

## 5. Show analysed activity

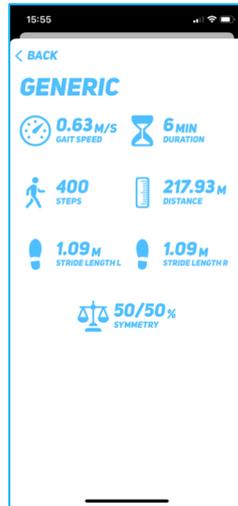


- You can check if and which activities have been uploaded by tapping on “Show Logged Exercises” on the home screen
- A list will appear that will show activities already in the database (“Uploaded Activities”) and activities that are still local on your phone (“Local Activities”).
- Activities under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

## 6. Show Analysed Activity



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



- Calculated parameters:
  - Gait speed
  - Duration of the activity
  - Steps
  - Distance
  - Left and Right stride length
  - Stride Symmetry
- Please note that the analysis and calculation of the parameters can take several minutes.

## 7. Show Statistics

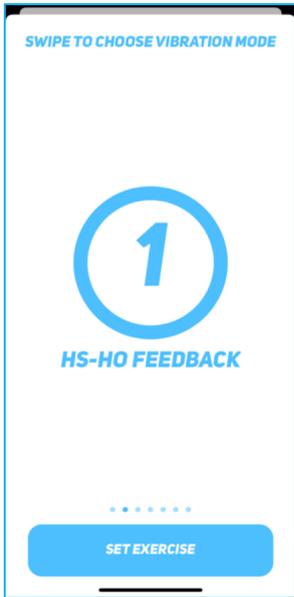


- You can check your weekly, monthly and overall performance by clicking on “You took # steps this week” on the home screen.



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

# Vibrational Cuing

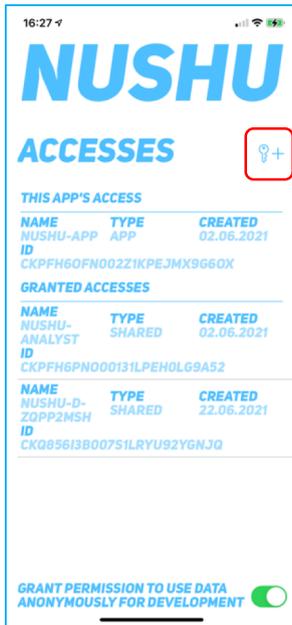


- The “HS-HO Feedback” exercise type offers vibrational cuing on Heel Strike (HS) and Heel lift-Off (HO) to the user.
- The user experiences 2 vibration alerts for every stride; i.e. for every heel strike and heel lift-off event.



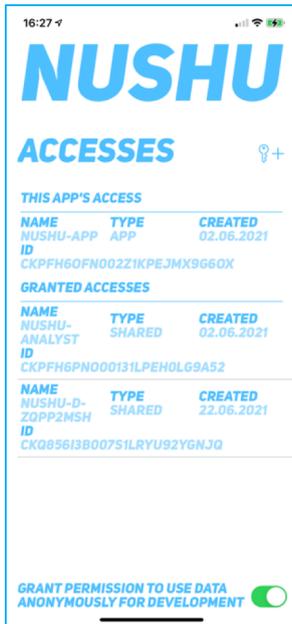
Please talk to your treating physician before using exercises with vibration feedback.

# 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 your therapist or doctor. Once the QR code is read, the access will be created.

# Managing Accesses to your Data



- To delete an access, simply 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").
- You can opt in or out of any future support for development (chosen during registration) in "Managing Accesses".

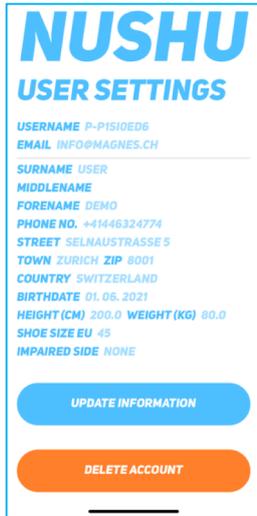
# Upgrading the Device Firmware



- Your shoes are running a 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".

# Managing Your Account

## 1. Viewing and Changing Account Information



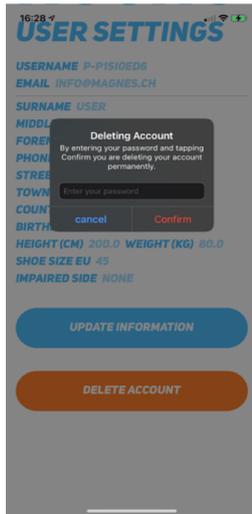
- To view or change your account information, go to the main menu by tapping on the Nushu logo at the top of the app. Choose “Account”.



- 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 lost and in order to continue using Magnes Nushu you will need to create a new account.

# Cleaning and Maintenance

Clean Magnes Nushu regularly, i.e. remove dirt residuals 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 oven.

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).

# Warranty

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  
Selnaustrasse 5  
8001 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

<b>Problem</b>	<b>Cause</b>	<b>Action</b>
Device not detected	Bluetooth inactive	Turn on the Bluetooth of your mobile smart device.
Device not detected	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
Device not detected	Device in sleep mode	Wake up the device by shaking Magnes Nushu for about 10 seconds
Data not uploaded to database	No internet connection available	Check mobile data or WiFi internet connection
Server cannot be reached	No internet connection available	Check mobile data or WiFi internet connection

# Technical Specifications

## Magnes Nushu

Gait events accuracy	<ul style="list-style-type: none"><li>• Heel Off, Flat Foot – 60 ms</li><li>• Toe Off, Heel Strike – 20 ms</li></ul>
Gait parameters accuracy	<ul style="list-style-type: none"><li>• Gait velocity – 0.08 m/s</li></ul>
Power Supply / Capacity	Li-ion battery 3.7 V / 750 mAh IEC 62133-2:2017
Memory	25 Days of Recording
Wireless Communication	BLE, WiFi
Battery charging rate	Regular: 260 mA, Precharge (low voltage): 52 mA
BLE power	3 dBm
WiFi power	19.5dBm
MD class	CLASS 1 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°

## 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

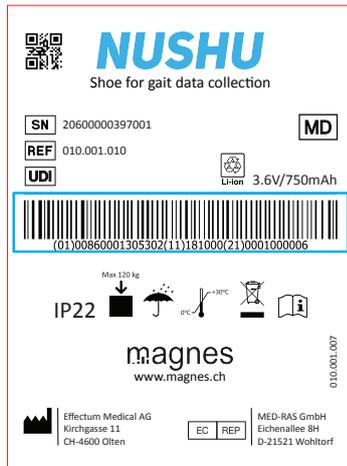
# Technical Specifications



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



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



Label description:  
(01) – Device identification  
(11) – Manufacturing date  
(21) – Serial Number

# Technical Specifications

Mobile RF communication devices may compromise the operation of other medical electrical devices. Maintain a safe distance between Magnes Nushu and any high-frequency emitting device to prevent the possibility of malfunction. This equipment complies with the IEC 60601-1-2 for the electromagnetic compatibility of the equipment and/or medical electrical systems.

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>11.11.2021</u>