

# Sherpa

## Instructions for use

This document describes the instructions for use for the MS sherpa remote monitoring solution, hereafter mentioned as 'MS sherpa',









*version 16*

*28 August 2024*



This medical device is a product of health regulation which bears, under this regulation, the CE mark

## 1. MS sherpa label

MS sherpa	
	<b>Legal Manufacturer</b> Sherpa BV Transistorweg 7 6534AT Nijmegen The Netherlands <a href="https://www.mssherpa.nl/en/">https://www.mssherpa.nl/en/</a>
	<b>MS sherpa</b> MS sherpa digital remote self-monitoring solution
	<b>Production Date</b> 2024-08-30
	Basic UDI: <b>87202999688MSsherpaBZ</b> UDI: <b>(01)8720299968813(10)2.3.2</b> UDI-DI: <b>8720299968813</b> UDI-PI: <b>2.3.2</b>
	<b>Version Number</b> 2.3.2
	<b>CE-marking</b> Class I
	<b>Medical Device</b>
	<b>Electronic IFU</b> <a href="#">Click here</a>

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## 2. General Instructions for Use

MS sherpa Instructions for Use are supplied in electronic form and are accessible through the [MS sherpa Knowledge Library](#). Please carefully read the instructions for use provided below to ensure safe use of MS sherpa.

### 2.2 Hardware and Software Requirements

The minimal hard- and software requirements are as follows:

- MS sherpa App for persons with MS (pwMS), smart phone requirements:
  - version 9 or higher for Android
  - version 14.0 or higher for iOS.
- MS sherpa Clinician Portal, accessible via web-browsers (Windows and Mac), no restrictions

### 2.3 Languages

The instructions for use are available in the following languages:

- English
- Dutch
- German
- French

### 2.4 Current version of the Instructions for Use

Revision 16, approved 28 August 2024

### 2.5 Previous versions

Revision 15, approved 20 June 2024

### 2.6 Paper version

Paper versions of the Instructions for Use are available on request. To obtain a paper version, please send a request MS sherpa Support via [MS sherpa Support](#) and your request will be processed within 5 working days.

### 2.7 Medical emergency situations

There are no known emergency situations or other circumstances in which you need to consult your caregiver during the use of MS sherpa.

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## 2.8 MS sherpa and CE certification

### **Background**

Sherpa BV is an independent Dutch healthcare innovation company since 2016.

### **Product history and certification**

MS sherpa (version 1.0-2.3.x) is available on the market as a CE marked class I device under the MDD since 20 December 2019, and currently in transition to CE Class IIa under MDR. Since market entrance MS sherpa has been used by more than 300 individual users, mainly in the context of clinical investigations and the first users during clinical implementation. MS sherpa is considered a medical device under Directive 93/42/EEC (MDD) as well as under Regulation (EU) 2017/745 (MDR).

## 2.9 Privacy and Information Security

All personal information in MS sherpa is handled in accordance with the General Data Protection Regulation (GDPR) and our privacy and security guidelines, in accordance with the ISO27001 and NEN7510 standards.

Information regarding Privacy, Information security and User agreements are provided in the EULA and Privacy statements which are available in the MS sherpa app, MS sherpa caregiver dashboard and the MS sherpa knowledge library.

Both the MS sherpa app and MS sherpa caregiver dashboard are password protected (strong format required). For the MS sherpa caregiver dashboard also 2 factor authentication ('2FA') is in place. Additionally, regular security monitoring is conducted to detect and prevent any unauthorized access attempts promptly.

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## 3. Instructions for Use for persons with MS and MS Caregivers

### 3.1 Important Contacts

#### 3.1.1 MS sherpa Support

Supportive information and the option to contact MS sherpa can be found on the [MS sherpa website](#). The MS sherpa website contains an [Interactive tool](#) with frequently asked questions (FAQs) for clinicians, researchers and persons with MS. Here, step-by-step instructions are presented for general use, including pictures and videos. This IFU can also be found here in Pdf format.

If the FAQ is not sufficient or applicable to the occurring question or issue, the MS sherpa support team is available as a point of contact for any clinician or person with MS via [support@mssherpa.nl](mailto:support@mssherpa.nl)

#### 3.1.2 Regulatory Compliance

For any questions or comments regarding regulatory compliance, please contact: **Sonja Cloosterman** (Person Responsible for Regulatory Compliance (PRRC)) via [MS sherpa Support](#)

### 3.2 Error reporting

Users should report any serious incident that has occurred in relation with MS sherpa to Sherpa BV and/or competent authority (CA) of the country in which the user resides.

- To get into contact with MS sherpa, contact MS sherpa Support (see 3.1.1), who will duly process any incidents.
- CA of the country where the user/reporter resides:
  - [Contacts](#) (access '[contact points](#)' in section 'National competent authorities')

### 3.3 Intended Audience

The intended audience for these Instructions for Use are MS caregivers and persons with MS (18 years or older) who use MS sherpa.

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### 3.4 Intended Purpose (product claim)

*MS sherpa is a digital solution for remote self-monitoring for persons with Multiple Sclerosis (MS) and their professional caregiver team(s), intended to support the monitoring of presence and progress of symptoms related to MS in order to provide personalized insights over time.*

This intended purpose ('claim') is substantiated by the clinical data identified, appraised and analyzed in clinical evaluation of the Device, leading to a positive Benefit-Risk ratio.

With our clinical evaluation and investigations we confirmed the MS sherpa 'Clinical Benefit': MS sherpa is able to accurately monitor MS related symptoms and visualize these over time ('providing accurate information on MS'), expecting to support shared decision making between pwMS and professional caregivers.

Residual risks are part of the 'Limitations' (3.4.3) and Instructions (3.4.4, including specific 'Warnings & Precautions').

#### 3.4.1 MS sherpa components and subsequent functionalities

MS sherpa contains the following components:

##### 1. Three **validated clinical tests**

- Walking ability (2MWT)
- Cognitive processing speed (SDMT)
- Patient reported outcomes (PROs)

Serviced by

- a) A **pwMS smartphone app** (iOS or Android) for user interaction and data presentation for use by persons with MS (pwMS) in their home environment
- b) A web-based **Caregiver dashboard**, that provides an interface for viewing test results (curves) and usage statistics for MS sherpa on an insight-screen for use by MS caregivers

##### 2. '**Clinical engine**' with validated algorithms:

- to process the data for off-line analysis of the 2-minute walking test (2MWT),
- to process the collected data for 2MWT and SDMT into insight curves in the clinician dashboard.
  - The graphs on the insight screen contain model-based level estimates with a 95% confidence interval (CI) on top of the individual test results. The individual datapoints are used by the model to come to a personalized level estimate of the "true" 2MWT and SDMT test scores, given day-to-day variation and measurement error. If two points on the graph have non-overlapping 95% CI-bands around them, the 2MWT or SDMT level changed statistically significant in the timespan between these two points.

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### 3. Additional services, contract and user management

- Serviced by web-based **Admin dashboard**, that provides an interface for contract and user management, as well as any contract-specific functionalities or services.

### 4. Back-end and infrastructure

#### 3.4.3 Limitations of use

As MS sherpa's intended use is to support monitoring with the use of digital tests via a smartphone in normal clinical MS care setting, by the application of data analysis and algorithms to visualize the insights, limitations to its use apply. The Device is not intended:

- for diagnostic or therapeutic purposes or in any other manner for regular medical practice;
- to monitor patients in an emergency situation;
- to monitor patients who are clinically unsuited to be monitored at home, e.g. patients who are at risk of being unable to call for emergency help;
- to be used in house/inside a building when performing the 2MWT test
- to be used by pwMS younger than 18 years

Based on clinical evaluation of the Device, MS sherpa can be safely and effectively used by pwMS and caregivers.

To ensure clinical suitability, pwMS and caregivers must take the intended use and limitations of use of the Device into account. The final decision on clinical suitability of the patient is the responsibility of the MS caregiver.

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### 3.4.4 Warnings & precautions

This section describes the warnings, precautions and instructions for managing foreseeable unwanted situations with regards to use of the Device.

#### General:

- Abnormal/unintended use of MS sherpa (e.g. for diagnostic purposes) by a caregiver or pwMS can lead to clinical error. MS sherpa should be used within the limitations of use at all times.

#### MS sherpa smartphone App for pwMS:

- pwMS are advised to use a smartphone with version 9 or higher for Android or version 14.0 or higher voor iOS.
- pwMS receive an introduction mail for activating their account and installing the app (via App or Play Store) on their phone.
  - To receive new updates of the MS sherpa App, it is advised to turn 'automatic updates' for Apps to 'on'
  - In the App or Play store the latest version of MS sherpa can be checked, you can also always update the MS sherpa manually via the App/Play store.
- Mobile data connection or WiFi must be active to use the MS sherpa App
- When using MS sherpa for first time MS sherpa (after downloading from App store or Play store), ensure the following steps:
  - When you first start using MS Sherpa you will be asked to allow MS Sherpa to send you notifications. This option must be enabled to allow the app to use your GPS signal.
  - When starting the Walking ability test for the first time, confirm that MS Sherpa is allowed access to 'exercise and fitness activity'. This should be accepted with 'OK'.
  - Subsequently, confirm that MS Sherpa is allowed to access your 'location data'. This should be accepted with:
    - For *iOS*: **'While Using App'**.
    - For *Android*: **'Always'**
- Always read the information and instructions in the MS sherpa App in addition to this IFU
  - Follow these instructions while performing the tests. If you do not follow the instructions, it may result in inaccurate data
- Do the tests as often as agreed upon with your caregiver. Please note that self/remote-testing at home does not replace your regular visits with your caregiver.



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- **Walking ability test** (2 Minute Walking Test (2MWT)):
    - GPS is used to estimate the distance walked during your 2MWT, therefore:
      - Perform the 2MWT always outside (to ensure robust GPS connection) and in a straight line (resulting in the best performance of MS sherpa)
    - **Precautions:**
      - Do not perform in unsafe traffic participation
      - If the 2MWT is executed correctly, in rare events an error can still occur in the GPS data collection. In this case, the following message will be shown on the test result screen: “Oops, something went wrong. Unfortunately we do not consider the current test results as valid. Therefore, the result will not be saved. If you encounter invalid results frequently, please contact us through the ‘Support function’ “ (see 3.1.1).
      - Ensure that your battery is charged enough, and that the status is not in the ‘Battery Saving mode’
    - Walk as fast as safely possible, but do not run and/or jog
    - It is advised to walk the same path for each 2MWT test, this supports the comparison of test results
    - The use of a walking aid or ‘walker’ is allowed
    - Performing the 2MWT with mild fatigue can be continued, but do not continue with pain
  - **Cognition test** (SDMT):
    - Perform this test in a quiet room, so that you cannot be disturbed
    - Every time you start the cognition test there is the possibility to perform a 'practice session'. It is advised to fulfill this practice session, so that you are well prepared for the cognition test.
  - **Test Results** on ‘Today screen’:
    - In case the 2MWT test or SDMT was not performed as instructed (eg. you stopped walking due to an unexpected contact with a passerby/person, or you stopped the SDMT test as you were disturbed), the test can be removed from the ‘Today’ screen with providing the reason for removal.
    - It is not a problem if a single test result is missing, for example because it was marked inaccurate by the 2MWT algorithm (see above), or because you forgot to do the test. As long as you continue to use MS sherpa on a regular basis, your data can be used to optimize your MS care.
  - Information in **‘Insights’**:
    - Interpretation of the test results: It’s normal for the results to change over time, a lower score does not necessarily mean that your MS is more active
    - Please discuss your results with your caregiver as part of shared decision making.

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## Caregiver dashboard

- An internet connection is required for use of the MS sherpa caregiver dashboard. Without an internet connection caregivers will not be able to receive up-to-date insight screens.
- Caregivers will receive an introduction mail activating their account, including the link to the MS sherpa caregiver dashboard
- It is recommended that clinicians read and adhere to the available 'Care giver Manual', which is available via a link in the Caregiver dashboard and can also be found on: <https://mssherpa.atlassian.net/wiki/spaces/ESHERPA>
- Caregivers decide which pwMS starts with MS sherpa, these pwMS can be activated via the Caregiver dashboard, triggering the 'introduction mail' to the pwMS. It is recommended that Caregivers discuss the following topics with the pwMS, when MS sherpa is introduced:
  - Perform the MS sherpa tests at a weekly basis, this gives the best results for the insight curves in the Caregiver dashboard
  - It is important to explain to patients that it is normal that scores vary over time, and that eg. a lower score does not necessarily mean that the MS is more active
  - *Walking ability test (2MWT)*: If the Caregiver is unsure whether the patient can safely participate in traffic while doing the walking test, the walking test should be turned off

### Insight curves (2MWT and SDMT):

- MS sherpa is intended to support monitoring of persons with MS (see intended purpose in 3.4). If for example,
  - The curves display statistically relevant changes (see explanation in 3.4.1), or
  - A single outlier test data point is visible, or
  - No test data is available for a certain period of time
    - additional diagnostics may be necessary to confirm clinically relevant changes.
- Walking ability test (2 Minute Walking Test (2MWT)):
  - Due to the use of a validated algorithm (using GPS data) there is a certain inaccuracy in the position determination, as such the bandwidths of the 2MWT curves in the insight screens are typically slightly wider than those of the SDMT and changes in walking speed in general less quickly visible than changes in information processing speed (See also Caregiver manual, section 1.2.)

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### **End of use of MS sherpa**

In case the MS sherpa solution is no longer used, e.g. as decided by you and your caregiver or when a (research) contract has ended/completed, your account will be put on 'inactive'. The users will then not be able anymore to login to either the MS sherpa app or Dashboard.

For MS sherpa app users it is also advised to 'de-install'/remove the App from their phone, so that no data is kept unnecessarily on their phone.

### **2.4.5. Contraindications**

There are no contraindications for the use of MS sherpa.

### **2.4.6. Side-effects**

There are no known side-effects of MS sherpa.



**We are on an a mission to support  
personalized treatments based on  
real-world data and individual goals**



CEN-ISO/TS 82304-2 digital health ISO  
Certified by **orcha**



German Innovation award 2023  
Awarded by **German Design Council**



Dutch Digital Health Challenge  
Awarded by **Health Holland**

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