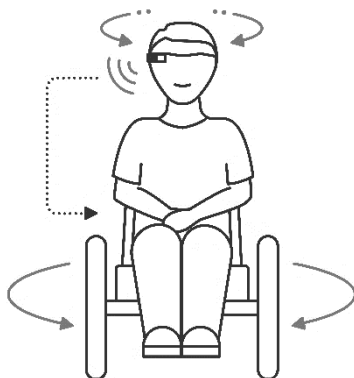




Instruction manual

munevo DRIVE

Stick on label with serial number here

munevo GmbH
Agnes-Pockels-Bogen 1
80992 Munich

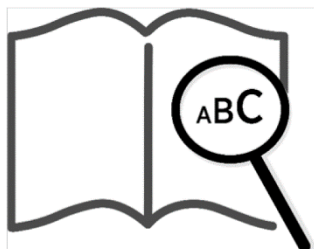
www.munevo.com
info@munevo.com
+ 49 89 55 06 49 04

List of figures

Figure 1-1: Start-up screen	4
Figure 4- 1: Sajama spectacle model - brown	13
Figure 4- 2: Avella spectacle model - grey ..	13
Figure 4-3: Switching on the glasses.....	16
Figure 4- 4: Menu structure.....	17
Figure 4- 5: Changing the direction of travel	17
Figure 4- 6: Change - Indoor/Outdoor.....	17
Figure 4- 7: Menu structure Media	20
Figure 4- 8: Camera menu.....	20
Figure 4- 9: Menu structure settings.....	21
Figure 4-10: Voice control menu.....	22
Figure 4-11: Language change warning.....	23
Figure 5- 1: Overview Smartglass.....	26
Figure 5- 2: Connecting the charging cable	27
Figure 5- 3: State of charge.....	27
Figure 14- 1: WLAN menu in the application	38

List of tables

Table 2- 1: Symbols used.....	11
Table 4- 1: Symbols in the display	24
Table 14- 1: Maintenance schedule	35
Table 14- 2: Troubleshooting.....	36
Table 14- 3: Status and warning notices.....	37
Table 14- 4: Immunity test level.....	39
Table 14- 5 : Immunity test level for HF electromagnetic fields.....	40
Table 14- 6: Residual risks.....	41



Visually impaired people can obtain these operating instructions in PDF format on:

www.munevo.com/service

Table of contents

1. General information.....	3	7 Maintenance and care.....	29
1.1 Foreword.....	3	7.1 Software updates.....	29
1.2 Intended use.....	3	7.2 Cleaning and care.....	29
1.3 Areas of application.....	4	7.3 Maintenance intervals.....	29
1.4 Contraindications.....	4	8 Malfunction/ Troubleshooting.....	29
1.5 Side effects	5	8.1 Error.....	29
1.6 Service.....	5	8.2 Defect/Failure.....	29
2 Security.....	5	8.3 Serious incidents.....	29
2.1 Meaning of the symbolism.....	5	9 Technical data.....	31
2.2 Standards and guidelines.....	5	9.1 European Device Information.....	31
2.3 General safety instructions.....	6	9.2 Adapter.....	31
2.4 Safety requirements for transport, storage and assembly	7	9.3 Google Glass.....	31
2.5 Safety during operation	7	10 System requirements.....	31
2.6 Network security.....	9	10.1 Network requirements	31
2.7 Safety requirements for care, maintenance and disposal.....	9	10.2 IT security measures	31
2.8 Requirement for the operator.....	10	11 Notes on reuse.....	32
2.9 Safety functions.....	10	12 Disposal.....	32
2.10 Warning and type plates.....	11	12.1 Disposal of the transport packaging	32
3 Scope of delivery.....	12	12.2 Disposal of the units.....	32
4 Operation.....	12	13 Legal notice.....	33
4.1 Fitting the glasses.....	12	13.1 Liability	33
4.2 Spectacle frames for prescription lenses.....	13	13.2 CE conformity	33
4.3 Gestures.....	13	13.3 Warranty	33
4.4 Voice control.....	14	13.4 Warranty conditions of munevo GmbH	34
4.5 Switching on the Smartglass.....	16	13.5 Licences.....	34
4.6 Menu structure.....	17	14 Appendix.....	35
5 Product description.....	26	14.1 Maintenance plan.....	35
5.1 Smartglass.....	26	14.2 Troubleshooting.....	36
5.2 munevo DRIVE adapter.....	28	14.3 Connecting Smartglass with WLAN	38
6 Transport and storage.....	28	14.4 Electromagnetic compatibility... ..	39
6.1 Transport.....	28	14.5 Residual risks.....	41
6.2 Storage.....	28	14.6 Gestures	45

1. General information



INFORMATION

Date of last update: **2024-07-10**
(YYYY-MM-DD)

- Read this document carefully.
- Observe the safety instructions.



INFORMATION

You can request these operating instructions as a PDF file from the customer service department at **support@munevo.com** or from the manufacturer's service department (see reverse for address).

- The PDF file can also be displayed in enlarged form.
- If you have any further questions about the instructions for use, please contact the specialist personnel who gave you **munevo DRIVE**.

1.1 Foreword

Dear **munevo** user,

Thank you for choosing **munevo DRIVE**. For the proper use of the system, the operating instructions provide you and the persons accompanying you with all the necessary knowledge about the structure, function, operation and maintenance of the product. Please familiarise yourself with the contents of the operating instructions to ensure safe and secure use of **munevo DRIVE**. In addition, you will receive information and tips on possible faults or malfunctions that may occur.

Knowledge of these instructions is essential for the safe use of **munevo DRIVE**. In particular, the chapter

"Safety" must be read carefully by the operator and accompanying person before using the device for the first time.

For reasons of better readability, the masculine form has been chosen in the text, nevertheless the information refers to members of all genders.



CAUTION

Users who cannot read (e.g. children of young age) must be instructed in detail about the symbols used in the application, their meaning and effect as well as about the contents of these instructions for use. In addition, extended practice time in the presence of an accompanying person is recommended.

1.2 Intended use

munevo DRIVE is exclusively for the individual use of people with walking disabilities for self-transportation indoors and outdoors and is to be used in conjunction with a power wheelchair. **munevo DRIVE** is used to control power wheelchairs, in particular driving, adjusting the seat position and controlling the emergency lighting and is based on the use of Smartglass technology. The **munevo** software on the Smartglass and the **munevo** adapter box controls a power wheelchair by recognising the head movements of the wheelchair user.

System requirements power wheelchair - control system:

- Curtiss-Wright - R-Net
- Dynamic Controls - LiNX
- Quantum Rehab - Q-Logic 3

General information

Any other use is considered improper. The manufacturer is not liable for any personal injury or damage to property resulting from improper use, but only the operator.

munevo DRIVE may only be used by a person who has read the instructions for use and is therefore a prerequisite for use in order to operate **munevo DRIVE** safely and without errors and to protect persons from danger.

The operational safety of **munevo DRIVE** is only guaranteed if it is used as intended, in accordance with the information in these operating instructions. The operator is ultimately responsible for accident-free operation.

 **WARNING**

Check head calibration, function and position of the emergency stop button daily before use. You will be reminded of this during system start-up.

WARNING!



Recalibrate regularly and when seating position changes!



Check emergency stop button before driving!

Figure 1-2: Start-up screen

1.3 Areas of application

The functional diversity of **munevo DRIVE** and its intuitive operability allow it to be used by people with walking disabilities:

- Paralysis
- Loss of limb (leg amputation)

- Limb defect/deformity
- Joint contractures/damage
- Other diseases

In the case of individual care, attention must also be paid to the following:

- Physical and mental condition
- Age of the disabled person
- Living conditions
- Environment

1.4 Contraindications

- Cognitive impairments and intellectual disability that preclude independent use of the wheelchair.
- Severely restricted freedom of movement ($< 3^\circ$) of the head around its three axes
- Limited vision that cannot be compensated by visual aids and leads to restrictions in everyday life
- Influence of interfering medicines (consult doctor or pharmacist)
- Circumstances that preclude the independent use of special controls

 **WARNING**

Persons with spasticity that leads to uncontrolled movements of the head and means that an EMERGENCY STOP button cannot be actuated by means of the head may only use **munevo DRIVE** when accompanied by another person. This person can stop the wheelchair in emergency situations.

 **WARNING**

People who suffer from narcolepsy or have a tendency to fall asleep involuntarily, which could cause the head to trigger uncontrolled driving

signals, may only use **munevo DRIVE** when accompanied by another person. This person can stop the wheelchair in emergency situations.

**WARNING**

Users who can control their wheelchair with **munevo DRIVE** but are unable to operate an EMERGENCY STOP button should have an accompanying person with them at all times.

1.5 Side effects

Headache

Looking at the Smartglass screen can cause eye muscle fatigue and a mild headache.

Tension in the neck muscles

The unfamiliar movements and range of motion can lead to fatigue and tension due to the exertion.

1.6 Service

**INFORMATION**

Service and repairs to the **munevo DRIVE** are only carried out by trained personnel authorised by **munevo**. In the event of problems, contact the specialist dealer who fitted the **munevo DRIVE** for you.

If you have any questions or if a problem cannot be solved despite consulting the operating instructions, please contact the medical supply store that sold and installed the control unit for you.

In terms of customer satisfaction, **munevo** strives to support customers in

every way so that they are satisfied with the product for a long time to come.

2 Security

2.1 Meaning of the symbolism

**WARNING**

Warnings of possible serious accident and injury hazards.

**CAUTION**

Warnings about possible risks of accident and injury.

**NOTE**

Warning of possible technical damage.

**INFORMATION**

Instructions for operation. Notes for service personnel.

2.2 Standards and guidelines

All safety information in this instruction manual refers to the currently valid national laws and regulations of the European Union. In other countries, the applicable laws and national regulations must be observed.

In addition to the safety instructions in these operating instructions, the generally applicable regulations of the Employer's Liability Insurance Association (BGV), the regulations for accident prevention (UUV) and for environmental protection must be observed and complied with. All information in these operating instructions must be followed without restriction at all times.

munevo DRIVE is built according to the currently valid rules of technology and is safe to operate. The safety of **munevo DRIVE** is confirmed by the CE mark and the declaration of conformity.

2.3 General safety instructions



WARNING

Danger of suffocation

Make sure that the packaging materials do not get into children's hands.



WARNING

Residual risks

Despite all measures to minimise the risks of using **munevo DRIVE**, residual risks cannot be excluded.

A list of the residual risks can be found in the appendix, under item 14.5



CAUTION

Risk of accident and injury due to non-observance or non-compliance with the safety instructions.

All safety instructions in these operating instructions and in all applicable documents must be observed and complied with. The instructions must be available to the operator at all times.



CAUTION

Risk of accident and injury due to improper use.

munevo DRIVE may only be used as intended and may only be used by people who have read the operating instructions



CAUTION

Risk of accident when driving without experience.

Driving without experience can unintentionally lead to collisions and other dangerous situations. Practise using **munevo DRIVE**, preferably on level, manageable terrain. Your medical supply store and **munevo** will be happy to answer any questions you may have about using **munevo DRIVE**.



CAUTION

Recalibration due to change in seating position due to fatigue

If the seating position changes significantly due to fatigue, recalibration should be carried out. It may be necessary to adjust the seat to prevent the body from slipping too much.



CAUTION

Recalibration due to change of seat setting (tilt)

If the seat setting is changed (tilting backwards), recalibration is necessary. A corresponding note in the application indicates this calibration.



CAUTION

Synchronicity between Omni and glasses

Attention should be paid to the Omni Display indications when opening other wheelchair modes to avoid unintentionally activating a different mode or profile than selected in the glasses. If a lack of synchronicity is noticed, the wheelchair should be switched off and switched on again after 30 seconds. If the problem

remains, a contact person at the responsible medical supply store should be contacted.

**INFORMATION**

Improper use of **munevo DRIVE** or failure to observe warnings will result in the loss of warranty claims.

**WARNING****Flame protection**

Plastic parts meet the requirements according to UL94.

2.4 Safety requirements for transport, storage and assembly

Transport and storage

**CAUTION**

Damage due to improper transport. Always transport the smartglass in the case provided to avoid damage.

For more information on correct transport and optimal storage conditions, please refer to chapter 6 "Transport and storage".

Assembly

**WARNING****Improper assembly**

munevo DRIVE may only be installed by authorised dealers to prevent improper installation.

The **munevo DRIVE** components may only be installed by a dealer authorised and trained by **munevo**. The dealer carries out the assembly according to the instructions in the service manual (assembly instructions).

Incorrect installation will invalidate the warranty or guarantee.

Furthermore, opening the components without having consulted **munevo** beforehand also leads to the exclusion of warranty or guarantee.

Any modification to the components will invalidate the CE certification.

2.5 Safety during operation

**WARNING****Risk of accident and injury due to faulty safety functions.**

The operator is obliged to satisfy himself of the safe and proper condition of **munevo DRIVE**, including the safety functions, before each use. **munevo DRIVE** may only be operated when all safety functions are in working order.

**WARNING****Risk of accident and injury due to modified wheelchair programming.**

Changes to the speed or acceleration parameters can lead to unpredictable and uncontrollable driving characteristics resulting in accidents. Always test the driving behaviour of your power wheelchair after completing the programming.

**WARNING****Risk of accident when driving without experience.**

Driving without experience can lead to collisions and other dangerous situations. Practice using **munevo DRIVE** in conjunction with your power wheelchair before using it for the first time on level, manageable terrain.

**WARNING**

Extreme caution should be exercised near unsecured landings, steep slopes or elevated surfaces. Unintentional movements or excessive speed in such situations can lead to injury and damage to property.

Reduce speed when travelling over uneven terrain as unintended head movements and manoeuvres may occur.

**WARNING****Danger of accident due to uncontrolled driving behaviour.**

When operating **munevo DRIVE** with your power wheelchair, uncontrolled movements may occur due to malfunctions. In this case, contact your authorised specialist dealer immediately. Immediately take **munevo DRIVE** out of operation if you detect faults, defects or other dangers that could lead to personal injury.

**WARNING****Observe health status when using four-directional driving.**

Use four-directional driving or the tilt-down gesture to drive with caution. If the user faints while driving in these two

modes, the wheelchair will continue to drive. If there are chances that fainting or exhaustion can occur while driving, using three-directional driving or the tilt-up to drive gesture is recommended, where the wheelchair will stop if the user faints while driving.

**WARNING**

In environments where there is a risk of collision with other objects, driving must not be deactivated.

**WARNING****Electromagnetic radiation**

When operating **munevo DRIVE**, interference may occur due to electromagnetic fields. Observe the following special features during operation:

Munevo DRIVE is tested according to the EMC regulations (EN 60601-1-2), but its functionality can still be affected by electromagnetic fields.

Switch off the power wheelchair in case of unexpected operation or in case of unintentional release of the brakes as soon as this can be done safely. In this case, contact your authorised specialist dealer immediately. - Further details on the conformity of **munevo DRIVE** with regard to electromagnetic compatibility and the specific tests according to EN 60601-1-2 can be found in the appendix, under 14.4.

**WARNING****Interference with other units**

Please note that the components of munevo emit electromagnetic radiation. In very rare cases, this radiation can interfere with medical devices (such as

pacemakers or defibrillators). Please keep a sufficient distance to the devices or contact your doctor or manufacturer. Switch off **munevo DRIVE** if no function is required. If you notice a malfunction of another device, please stop using **munevo DRIVE**.

**WARNING****Interference from other accessories**

The use of ACCESSORIES, transducers and wiring other than those specified or provided by **munevo** for this unit may result in increased ELECTRICAL EMISSIONS or reduced electromagnetic immunity of the unit and may result in improper operation.

**WARNING****Interference from HF devices**

CARRIBLE HF communication devices (radios) (including their ACCESSORIES such as antenna cables and external antennas) should not be used at a distance of less than 30 cm from the **munevo DRIVE** parts and cables designated by **munevo**. Failure to observe this may result in a reduction in the performance characteristics of the device.

**WARNING****Using other functions**

Please only use the functions (camera, seat position) and settings provided by the **munevo DRIVE**, such as calibration, lighting, volume, hazard lights, language, WiFi, etc. when the wheelchair is parked in a safe place.

**NOTE****Damage due to overheating or cold.**

munevo DRIVE is only functional in the temperature range from 0 °C to +35 °C. It must not be operated outside this temperature range.

**INFORMATION**

When driving on public roads, the road traffic regulations must be observed.

**WARNING****Operating with sufficient feedback**

Use the smartglasses only when sufficient feedback can be received from the system. The glasses provide visual and auditory feedback. Ensure either one of the types of feedback is sufficient to operate the product safely. If visual or auditory feedback alone is not enough in certain situations, ensure that both feedback can be received during operation.

2.6 Network security

Information on network security can be found in section 10.2 "IT security measures".

2.7 Safety requirements for care, maintenance and disposal

**CAUTION****Risk of accident and injury due to incorrect maintenance, repair or adjustment.**

Maintenance of **munevo DRIVE** may only be carried out by personnel authorised and trained by **munevo DRIVE**. This also applies to all repairs and adjustments to the **munevo DRIVE**.

Box. Incorrect adjustment can lead to loss of functionality.

**CAUTION****Check for updates regularly**

Please check regularly whether updates are available for the munevo DRIVE application by synchronizing the application (Support -> Sync). (see 4.6.7.3)

**CAUTION****Risk of injury due to uncontrolled movements.**

Always remove the fuse when carrying out any maintenance work with the battery cover open.

**NOTE****Damage to the electronics due to water penetration.**

Under no circumstances should **munevo DRIVE** be cleaned with a water jet or high-pressure cleaner. Avoid direct water contact with electronics at all costs.

**INFORMATION**

munevo DRIVE must be checked at least once a year by an authorised specialist for functionality and driving safety.

2.8 Requirement for the operator

**CAUTION****Risk of accident and injury due to improper operation.**

The **munevo DRIVE** may only be used by a competent operator. The operator and any accompanying person therefore read the operating instructions fully before the use of **munevo DRIVE**.

The operator must have read the complete operating instructions. Operation while overtired, under the influence of alcohol or medication is not permitted. The operator must not have any mental impairment that temporarily or permanently impairs attention or judgement.

**CAUTION**

Mental impairment or taking medication, both prescription and over-the-counter, may affect your ability to use the wheelchair safely. Consult your doctor about taking medication.

2.9 Safety functions

In order to be able to stop the wheelchair in dangerous situations, an EMERGENCY STOP button is fitted to the wheelchair. The wheelchair can always be switched off and on again with this button.

**WARNING****Risk of accident and injury due to faulty safety functions.**

The operator is obliged to check the proper condition of the safety device, EMERGENCY STOP button, before each

use. **munevo DRIVE** may only be operated if the **EMERGENCY STOP** button is functional.



WARNING

Risk of accident and injury in emergency situations.

The **EMERGENCY STOP** button serves as an **EMERGENCY STOP**. In emergency situations such as uncontrolled driving behaviour of the power wheelchair, the **EMERGENCY STOP** button must be actuated. The **EMERGENCY STOP** button must be attached to the wheelchair in such a way that it can be easily operated and reached by the user at all times.

Fall detection:

If the glasses fall down during use, this is recognised as a fall and the wheelchair is stopped immediately. To prevent further unwanted functions from being performed, the glasses lock themselves. Before further use, the glasses must be unlocked by tilting the head to the left for 3 seconds. (see 4.6.10)

2.10 Warning and type plates

The type plate is located on your **munevo DRIVE** adapter box and on the front of this instruction manual. The type plate shows the exact model, serial number and other technical data.

When contacting your specialist dealer or **munevo GmbH**, please always have the serial number ready.

Symbols used according to EN ISO 15223-1

	Manufacturer
	Date of manufacture
	Serial number
	Product reference number
	Batch number
	Medical device
	Authorised representative, e.g. for Switzerland
	Storage temperature range
	Examine the instructions for use for important safety-related information.
	Follow the instructions for use
	Protect from moisture
	Note on disposal in accordance with the WEEE Directive.
	CE marking "European Conformity"

Table 2-1: Symbols used

3 Scope of delivery

The scope of delivery includes:

Fitted to the wheelchair:

- **munevo DRIVE** adapter
- Serial cable - D-Sub 9
- If necessary, mount the adapter box
- If necessary, 2xM6 screws and nuts for fastening the bracket

For you:

- Operating instructions
- **munevo** Smartglass
- Case
- Power supply unit
- Smartglass charging cable

4 Operation

4.1 Fitting the glasses



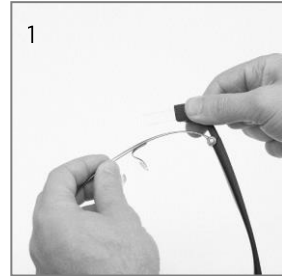
CAUTION

If the glasses are not positioned correctly, the display may obstruct your view and cause an accident. If positioned too low, you may tend to tilt your head upwards when looking straight ahead. This may cause neck strain and blurred vision if you wear glasses with prescription lenses.

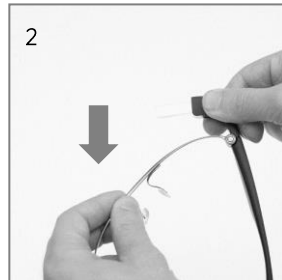
The **munevo** Smartglass is worn like normal glasses. The display should be just above the line of sight of the right eye.

The glasses are delivered with a titanium frame. If prescription lenses are required to compensate for a visual impairment, the titanium frame can be replaced with an appropriate spectacle

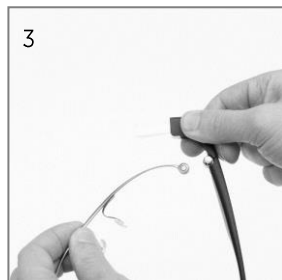
frame, see 4.2. The following describes how the frame can be replaced:



1. Hold the glasses with your right hand just behind the "display" as shown in "1".



2. With your left hand, fold the frame towards you.



3. Now you can replace the frame with another one.
4. Attaching the frame: Place the frame back on the joint and fold it forward until it clicks into place ("click").

4.2 Spectacle frames for prescription lenses

Instead of the titanium frame, there are two spectacle frames to which the Smartglass can be clipped. The frames (brown, grey) are shown below:



Figure 4- 1: Sajama spectacle model - brown



Figure 4- 2: Avella spectacle model - grey

For both frames there is also a right temple to wear them without the Smartglass. When removing the temple, proceed as described in 4.1, hold the spectacles as described in 1. However, do not hold the spectacles in front of the hinge, but hold the button of the hinge pressed down when closing.

4.3 Gestures

The **munevo DRIVE** application is operated using head movements. A distinction is made between driving signal input, i.e. gestures that result in movements of the wheelchair, and

menu control, i.e. gestures to control the application menu. In addition to head movements, the menu can also be controlled via voice control. In addition, the touchpad on the side of the glasses can be helpful, especially for caregivers/assistants.

The following head movements are used to operate the app and drive the wheelchair.

1. Application



- a. Head movement - horizontal head nodding is used to switch between menu items.



- b. Head movement - vertical head nod
 - i. Up - back to the previous menu
 - ii. Down - Confirm

2. Driving mode



- a. Head movement - Lateral head tilt is used for turning right and left or cornering. The more the head is tilted, the tighter the turn.



- b. Head movement - Backward tilt of the head is used to drive the wheelchair forward or backward (depending on the selected driving mode). From version 3.4.5 it is possible to change the direction of the tilt for driving. In the Admin menu there is a menu item "Driving gestures" in which "tilt down" can also be selected.

For more information on operating **munevo DRIVE**, various instruction videos can be viewed at www.munevo.com

4.4 Voice control

Munevo DRIVE can also be controlled using voice commands. Voice control can be activated under "Settings". Before the first use, it must be confirmed that the instructions in the user manual have been read.

To use voice commands, a dialogue must be activated **by tilting upwards for two seconds** or the **wake word "ok munevo"**. An acoustic signal now confirms that a voice command can be given. You have 10 seconds to do this. If

no voice command is given during this time or if the user tilts downwards, the voice control dialogue is closed, and the glasses do not wait for a command.

In addition, the voice control dialogue can be closed with the word "cancel".

Closing the voice control dialogue is also confirmed by an acoustic signal. This signal can be heard both after a correct voice command has been given and when the voice control dialogue is cancelled, or an incorrect voice command has been given.

Under Settings you can select whether voice commands can be initiated by a "wake-up word" or a "tilt movement". Only one of these two possibilities can be active at the same time.

A small symbol at the top of the screen indicates that the voice control is switched on and which initiation option has been selected. "Tilt up" is indicated by a small arrow next to the microphone, the wake-up word by OK next to the microphone.



Figure 4-3: Difference voice control

Further information on the setting options of the voice control is provided in the following chapter 4.6.

4.4.1 New version

If a new version of the voice control is available, this is indicated by an orange dot next to the Settings and Voice Control menu. The download only runs when the voice control screen is open. The download may take several minutes, depending on the speed of your internet connection.

4.4.2 Available Voice Commands

All menu items can be selected by voice commands. "Go to settings", for example, will navigate to the settings menu. The command "Open" can be used to select the menu items directly. Examples are:

- "Open Calibration"
- "Please open gallery"
- "Open Add-ons"

Likewise, actions in the menu can be carried out directly by voice control. Examples of this are:

- "Switch on hazard lights"
- "Establish a connection with the WiFi".
- "Start the tilt calibration".

Starting application version 10.14.5, it is possible to navigate directly to seat profiles on the glasses. Note that the voice commands such as "go to ...", "open ..." or "navigate to ..." will all navigate to the respective seat profile and the profile will need to be activated by a nod down to change the position. The voice commands support most common seat profile names such as "recline", "backrest", "footrest", etc. It is not possible to use custom seat profile names. In such situations where custom seat profile names are configured on the

wheelchair, it is recommended to use the seat profile position instead of the name. Example commands can be found in the text below.

The following is an overview of the possible voice commands. Please note that the commands can be varied and not only used as described below. As an example, we have described the commands differently in the various categories. The following list is only a selection of voice commands.

Navigate through the menu:

- "Go to Settings"
- "Open Drive"
- "Seat Setting"
- "Open Add-Ons"
- "Turn on the light"

Camera:

- "Photo please"
- "Take a picture"

Calibration:

- "Start Tilt Calibration"
- "Please Calibrate Nod"

Volume:

- "Change the volume to 0"
- "Change the volume to 10".

The volume can be adjusted in the range 0 (mute) - 10 (loud).

Voice commands:

- "Show the commands"
- "Open wake word"
- "Voice control off"

Language:

- "Switch to German"
- "Switch to English"
- "Select French"
- "Select Dutch"

- "Go to language"

Internet:

- "Connect to the Internet"
- "Connect to the WiFi"
- "Scan for Internet Connection"

Sync:

- "Start Sync"
- "Update the glasses"
- "Sync the app"
- "Update the device"

Seat:

- "Go to tilt"
- "Open recline"
- "Go to footrest"
- "Open seat height"
- "Go to seat 1"
- "Go to memory 4"

Seat positions can be used instead of seat profile names. Positions 1 through 14 and memory positions 1 through 6 are supported.



Figure 4-4: Switching on the glasses

4.5 Switching on the Smartglass

If the Smartglass was switched off, it must be started via the button on the inside of the battery module (behind the right ear) (press for 2 seconds). After the start-up process, the user is in the main menu of the application. The glasses can be switched off by holding the button for 2 seconds. If the goggles do not start despite previous charging, press and hold the button for 10 seconds to perform a reset. Then press again for 2 seconds and the glasses should start.

4.6 Menu structure

The menu structure is explained in detail below. In order to achieve better operability, it is possible to navigate to the left as well as to the right in most menu items. munevo DRIVE is available in the three versions "Driving only", "Basic" and "Advanced". The menu items displayed depend on the version selected. The version can be changed in the Admin menu. After starting the glasses, you are automatically in the main menu, at "Driving".

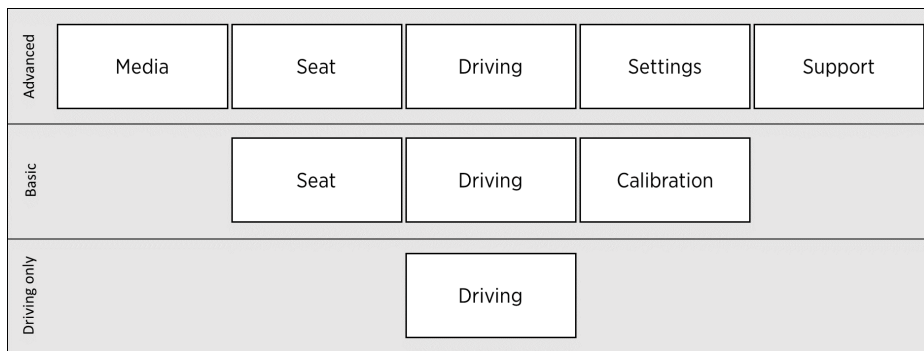


Figure 4- 5: Menu structure

4.6.1 Driving

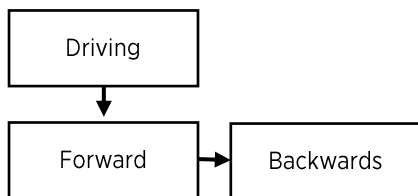


Figure 4- 6: Changing the direction of travel

In the "Driving" menu, the normal driving mode ("Forward") and the reverse mode ("Reverse"), as well as different driving profiles can be selected. By nodding left, one switches between the indoor and outdoor mode, by nodding right, one can switch between the forward and reverse mode. The reverse mode can also be selected in the activated driving state by nodding to the right, provided the head is in the zero position (see also 4.6.12).

4.6.1.1 Profiles

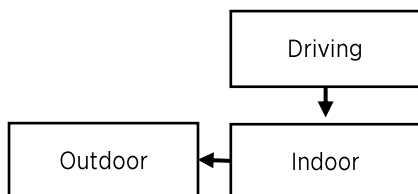


Figure 4- 7: Change - Indoor/Outdoor

Two driving profiles with different wheelchair speeds can be selected:

Indoor - slow profile to be able to ride safely and in control indoors.

Outdoor - faster profile to cover long distances outdoors.

**WARNING**

Before driving, the driving profile and speed levels must be checked.

4.6.1.2 *Activate drive*

Nod down in the driving menu to activate munevo DRIVE. An orange profile symbol and arrows a little further apart indicate this on the display. Now you can control the wheelchair by tilting your head (see section 4.6.10). Nod down again to deactivate munevo DRIVE. The profile symbol is now white again and the arrows are closer together. Only in deactivated mode can you change the profile and select all other menu items. If "Drive" is activated and you are in the zero position (the wheelchair is not moving), you can still switch between forward and reverse mode by nodding right.

While driving, the screen is not visible, so you can concentrate better on driving and battery consumption is reduced. As soon as you stop, the screen reappears on the display.

4.6.1.3 *Simplified driving mode*

From application version 10.9.1, the application supports a new driving mode called "Simplified mode". With the simplified mode, as soon as the driving screen is opened, driving is activated. Driving profile selection is removed from the simplified mode. The simplified mode can be used with one of two options, a four-directional and a three-directional control. The three- or four-directional control can be activated from the Admin menu using the "Drive mode" screen.

4.6.1.4 *Four-directional driving*

With this mode, all four directions to control a wheelchair can be accessed easily with head tilts. Unlike the three-directional driving mode, there's no need to change the driving direction with a right nod to drive forwards/backwards. Driving can be deactivated when the head is in neutral position. This can be visualized by the dot or the driving profile in the middle of the arrows, which when visible, indicates that the head is in the neutral position. From application version 10.14.5 onwards, the four-direction driving mode can be activated for any application mode (drive-only, basic, advanced) through the Admin menu.

4.6.1.5 *Three-directional driving*

This is the default driving mode since the first version of the application. This mode allows driving the wheelchair using three directions: left, right, up/down (depending on if tilt-down to drive is activated). If tilt-down to drive is deactivated from the Admin menu, tilting the head upwards will drive the wheelchair in the forwards direction if forward direction is active, and in the reverse direction if reverse direction is active. However, if tilt-down to drive is activated from the Admin menu, tilting the head downwards will drive the wheelchair in the forwards direction if forward direction is active, and in the reverse direction if reverse direction is active. Tilting the head left/right will drive the wheelchair in the left/right direction. Driving can be deactivated when the head is in neutral position.

This can be visualized by the dot or the driving profile icon in the middle of the arrows, which when visible, indicates that the head is in the neutral position.

4.6.1.6 *Neutral position calibration*

Starting application version 10.14.5, an additional setting is available in the Admin menu to enable calibrating a new neutral position before driving starts. For drive-only, basic and advanced driving modes, if the head position is different than the calibrated neutral position when activating driving, a calibration screen is shown for a moment to calibrate the new neutral position. For the simplified driving mode, the neutral position recalibration screen is shown as soon as the driving screen is opened. This calibration only recalibrates the new neutral position and takes a just few seconds. The user's calibration is then adjusted to the new neutral position so the user can drive the wheelchair with ease. Once the calibration finishes, driving is activated, and the user can start driving the wheelchair.

If neutral position recalibration setting is deactivated in the Admin menu, a warning message is shown instead to inform that the head position when activating driving is different than the calibrated neutral position. From this warning screen, the user can either choose to continue driving anyways, or can recalibrate the new head position before driving.

4.6.1.7 *Drive Settings*

From application version 10.9.1, there is an option to customize drive settings from the Admin menu. You can choose between two control types (Admin > Control type) and further customize settings for one of the options.

Default:

This is the default control type that munevo DRIVE came with from the beginning.

Custom:

This is a new mode (starting version 10.9.1) that offers customization to drive function compared to the default mode. With this mode you can customize the deadband while driving the wheelchair, which makes the control of the wheelchair smoother, depending on the selected deadband value.

Deadband:

This setting offers to customize the deadband in the left/right direction while driving. The value can be chosen from 0% to 50%, where 0% means there will be no deadband in the left/right when driving the wheelchair, offering the most precise control in the left/right direction. The higher this value is, the more deadband there will be for the left/right direction, offering more room for the

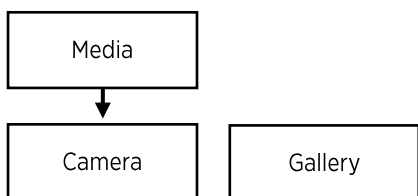
head to tilt left or right without changing the direction of the wheelchair, when you want to drive the wheelchair straight.

4.6.2 Seat adjustment

The seat setting can be adjusted via this menu item. The different seat modes can be selected by nodding sideways. Nodding downwards activates the selected mode, tilting to the left and right (identical to the driving gestures) changes the corresponding seat position. Nodding upwards exits the submenu of the activated seat mode. It is then possible to change the mode or exit the menu.

After changing the seating position, you should recalibrate the gestures for controlling the wheelchair, as the tilt of the head may have changed as a result. However, you will also be informed of this when you activate the driving mode. You can still activate the driving mode by nodding downwards. However, only do this if you are sure that your current zero position does not deviate significantly from your calibrated position, otherwise the wheelchair will start moving. To recalibrate the zero position, nod to the right and then down when the warning is displayed. For a more detailed explanation of calibration, see 4.6.12.

4.6.3 Media



The camera and the gallery can be accessed via the menu item "Media".

Figure 4- 8: Menu structure Media

4.6.3.1 Camera

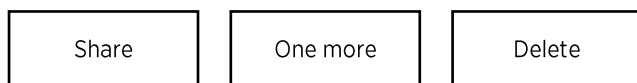


Figure 4- 9: Camera menu

Using the camera, you can easily take a photo of your surroundings or other people. As soon as the menu item "Camera"

is activated, you have 5 seconds to position your head accordingly before the photo is taken. You can see the section of the camera or the subsequent photo on the screen of the Smartglass. If a photo has been taken, this is automatically shown on the display. By nodding downwards, you open a new menu. You have the option of taking another photo, deleting the photo you have just taken or sharing it. To do this, your medical supply store or munevo must store an e-mail contact who will receive the photos by e-mail.



INFORMATION

Frequent use of the photo function can, under certain circumstances, greatly reduce the battery life.

4.6.3.2 Gallery

In the gallery, you can view, share or delete the photos via the screen. The pictures can be shared to an email address that is set for the glasses. To configure the email address, please contact **munevo**.

4.6.4 Settings

In the menu item Settings, the calibration and Smartglass settings, such as volume and language, can be adjusted. The lighting of the wheelchair is also controlled here.

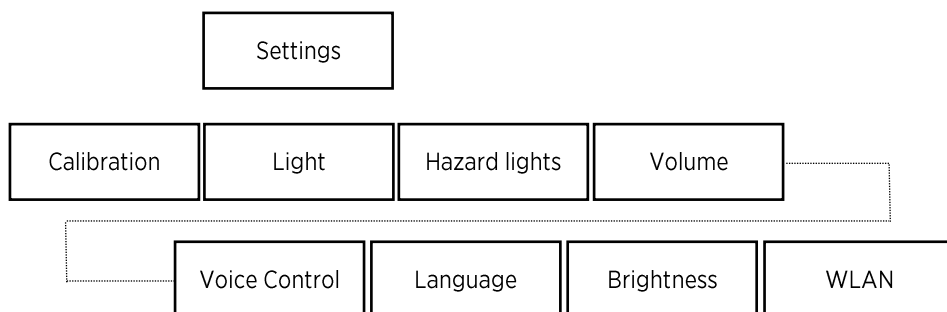


Figure 4- 10: Menu structure settings

4.6.4.1 Calibration

In this submenu, the calibration of the sensors can be carried out, both for the menu control gestures and for the driving gestures. The exact calibration procedure is explained on the screen and via the loudspeaker. The chapter Calibration (4.6.12) goes into more detail.

4.6.4.2 Light

You can switch the lighting of your wheelchair on and off via the menu item Light. Nodding to the right switches on the headlights and rear lights of your wheelchair, nodding to the right again switches them off. Nod upwards to leave.

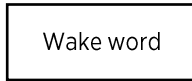
4.6.4.3 Hazard lights

The warning lights of the wheelchair can be switched on and off via the menu item Warning lights. Nodding to the right switches the warning lights on, nodding to the right again switches them off. Nod upwards to leave.

4.6.4.4 Volume

The volume of the application can be set via this menu item. The desired volume level can be selected by nodding sideways (right or left). To exit, nod upwards.

4.6.4.5 Voice control



This menu item can be used to change the settings of the voice control. You can select whether the voice control

Figure 4-11: Voice control menu

can be activated with a wake-up word or by tilting. In addition, the voice control of munevo DRIVE can be deactivated here.

Tilt up activation

Under this menu item, you can set the voice control to be activated by tilting upwards and holding for two seconds. To do this, "Tilt up activation" must be selected by nodding downwards. In the screen that now opens, the tilting can be activated or deactivated by nodding to the right.

Wake word

You can set the voice control to be activated by the wake word "ok munevo". To do this, select "wake word" by nodding downwards. In the screen that now opens, the "wake word" can be activated or deactivated by nodding to the right.

Commands

Some examples of voice commands and their function can be displayed under "Commands".

4.6.4.6 Language

The language of the application can be set via this menu item. You can switch between **German, English, French, Dutch, Spanish and Italian by nodding** sideways. The selection is confirmed by nodding downwards. The app then restarts in the selected language. If the menu items are not displayed in the correct pronunciation, connect the Smartglass to the Internet and carry out the language selection again.



CAUTION

The selected language is also used for voice control. When the language is changed, a corresponding note appears in the glasses which must be confirmed.

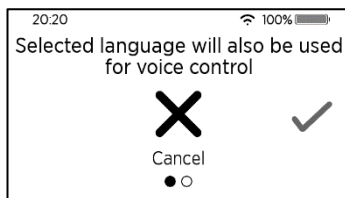


Figure 4-12: Language change warning

4.6.5 Brightness

 **WARNING**

Using the glasses with the display turned off is only recommended if the audio feedback while operating the glasses is audible for daily usage. If the glasses are operated in noisy environments, it is recommended to turn the display on to rely on visual feedback of the glasses.

In this screen, the display brightness can be adjusted between 5 levels. From the minimum brightness level, the display can also be completely turned off. Operating the glasses with the display completely turned off will provide maximum battery life. The application will function in the same manner as it does with the display turned on. Navigating through the application in screen-off mode can be done using audio feedback that the glass provides. Note that if the volume of the glasses is set to zero, enabling screen-off mode will turn the volume up to 30% so that audio feedback can be heard to operate the glasses. If the volume level is too low for use, please turn the volume up to a level where you can comfortably hear the audio feedback.

4.6.6 WiFi

In this menu item, the glasses can be connected to a WiFi access point so that they can access the Internet. This is necessary, for example, to update to the latest version of the application (more information on updating under Sync, section 4.6.7.3). You need someone's help for this. More on this in the appendix, under O.

4.6.7 Support

The Support menu provides individual information about the unit and the software. The emergency function is very important.

4.6.7.1 Emergency

The emergency function allows the user to send a message to his or her emergency contact if an internet connection is available (e.g. via a smartphone). In the emergency menu, the sending of the message can be confirmed by nodding downwards. A nod upwards allows the user to exit the menu without sending the emergency message.

4.6.7.2 App Info

Information about the unit can be accessed via this item. To exit, a nod of the head upwards is performed as usual.

4.6.7.3 Sync

The munevo app can be updated to the latest version by synchronisation. You will be informed about new versions or changes by e-mail or via your specialist dealer. An internet connection is required for synchronisation.

Update your app every month to ensure you have the latest version installed.

4.6.8 Standby

Tilting to the **right** for 3 seconds locks the application. Tilting to the **left** for 3 seconds unlocks it again (see 4.6.11). After 1 minute, the glasses automatically go into sleep mode and switch off the display to reduce battery consumption. To use the glasses again, tilt the head to the **left** for 3 seconds.

4.6.9 More symbols

Symbol	Meaning
	Lock symbol
	Unlock symbol
	Symbol for state of charge
	Low battery level

Table 4- 1: Symbols in the display

4.6.10 Driving gestures

The wheelchair can be driven by tilting the head. Tilting the head backwards/upwards causes the wheelchair to move forwards. If you bring the head to the starting position/zero position, the wheelchair stops. By tilting the head to the right or left, the wheelchair can be steered accordingly. The speed of the wheelchair or the turning radius can be controlled proportionally via the strength of the tilt. For example, the more the head is tilted, the tighter the curve. The maximum positions are set with the help of the calibration. The starting position can also be individually adjusted via this.

Summary of gestures:

- Tilt backwards/upwards - driving the wheelchair straight ahead.
- Lateral tilt - turning the wheelchair to the right and left. In combination with the backwards/upwards tilt, curves of different radii can be driven.

4.6.11 Lock mode

If the driving mode is deactivated, you can move your head without the wheelchair driving. However, it can happen that nodding movements open the menu and menu items are selected without this being intentional. In conversations, for example, you often move your head up and down. To prevent this from selecting a driving mode and driving off unintentionally, there is a lock mode. Tilting to the **right for 3 seconds** locks the application. Tilting to the **left for 3 seconds** unlocks

it again. If the application is locked, this is indicated by the orange lock. (See illustration under 4.6.9).

You can always lock the application when the small white lock is visible at the top centre.

Starting version 10.9.1, locking starts after a brief moment of tilting the head to the right instead of starting to lock right away. This is to ensure that no unintended locking starts while using the application. The same goes for unlocking the application, where it starts unlocking after a brief moment of tilting the head to the left.

4.6.12 Calibration



INFORMATION

Calibrate the glasses regularly. A change in the seating position can have an influence on the initial position of the head. When activating driving, this can result in unintentional driving off.

4.6.12.1 Menu calibration ("nod")

The purpose of this calibration is to record the possible nodding movements of the head that are used for menu control. After selecting the menu item "Nod", you are asked to hold your head still. This serves to measure the minimum movement, for example due to a tremor. Thereupon, the nodding movements are performed three times in succession in all directions; the directions are given on the screen. A green dot and a beep signal the readiness for the movement. For the pitching movements, the rotation speeds are decisive; they should be selected so that they can be performed

without effort. An orange tick confirms the calibration.

4.6.12.2 Driving calibration ("Tilt")

During this calibration, the maximum values of the tilt of the head are recorded. It is important that the maximum possible tilt angles are not necessarily carried out. Rather, the inclination that is comfortable should be selected. After selecting the menu item "Tilt", the head must also be held still here. The position of the head corresponds to the later starting position/zero position in which the wheelchair stands still. It can be calibrated as comfortable as you like. The tilt angles for the three directions, backwards, to the right and to the left, are then calibrated. Unlike the menu calibration, one tilts the head in the prompted direction to the desired maximum position and holds it for 5 seconds. When the calibration is complete, an orange tick appears.

Starting application version 10.9.1, the downward tilt gesture can be calibrated in the tilt calibration screen. This step is going to be active when any of the screens requiring the downward tilt is activated on the glass:

- Four-way driving
- When downward tilt for driving the wheelchair is active
- Any screen that has a four-way control for add-ons
- When voice control is active

5 Product description

5.1 Smartglass

5.1.1 Overview

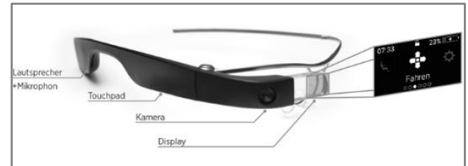


Figure 5- 1: Overview Smartglass

INFORMATION

Charge the battery. Before using the Smartglass or if the Smartglass has not been used for a long time, the battery must be charged.

WARNING

Danger of explosion. Only use chargers, batteries and cables approved by **munevo** to charge the Smartglass. The use of non-approved chargers or cables may cause the battery to explode or damage the Smartglass.

WARNING

Heat when charging the glasses
It is normal for the battery to generate heat when charging. The batteries in our glasses are protected against overheating.

5.1.2 Charging the Smartglass

1. Connect the USB cable to the USB power supply. Then connect the other end of the USB cable to the Smartglass.



Figure 5- 2: Connecting the charging cable

2. Plug the USB power supply unit into a mains socket.
3. When the Smartglass is fully charged, first disconnect the cable from the glasses and then disconnect the charger from the mains socket.

NOTE

- Use the supplied USB cable and USB power adapter. A third-party charger may not charge the Smartglass properly.
- Incorrect connection of the charger or use of an unapproved charger may cause serious damage to the unit. Damage caused by improper use is not covered by the warranty.

INFORMATION

- To save energy, please unplug the charger when not in use.
- The charger supplied does not have an on/off switch. It must therefore be disconnected from the socket so that no energy is wasted.

5.1.3 State of charge

The charge status of the battery can be read in the display. It is shown by a small battery in the upper right corner. If the charge level falls below 30 %, you will be informed of this by means of visual feedback and if the charge falls below 20% you will be informed by means of acoustic feedback as well.

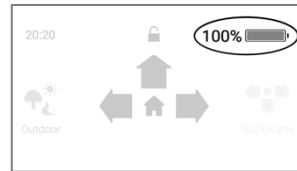


Figure 5- 3: State of charge

5.1.4 Battery care

Before first use, a new battery should be charged to 80 - 100 %. In principle, a battery should not be completely emptied before it is recharged. A memory effect, which occurred with earlier batteries, does not exist with modern batteries.

Excessive heat and cold can affect the longevity of the battery, so the goggles should only be stored in a temperature range of -20 to 45°C. Make sure that the battery is charged to 30 - 50% if you do not use the goggles for a longer period of time. This protects the battery from deep discharge.

5.1.5 Use of the glasses in wet conditions

NOTE

External force, such as a blow or a fall, can damage the housing and the unit may no longer be water resistant as a result.

It is recommended not to expose the glasses to rain, especially heavy rain or water, for a long period of time.

5.2 munevo DRIVE adapter

The **munevo DRIVE** Adapter receives the driving signals from the Smartglass via **Bluetooth** radio technology and forwards them to the wheelchair as control signals via the input module (Curtiss-Wright OMNI, input module from LiNX or enhanced display for Q-Logic 3). To enable use outside buildings, the **munevo DRIVE** adapter is protected against splash water.

5.2.1 Splash and dust protection according to IP65 and IP53

Please note that the following instructions only refer to contact with water and dust, other liquids are not covered by this. The adapter and the smart glass can be damaged by the ingress of water or dust. Follow these instructions to prevent damage to the unit.

NOTE

External force, such as a blow or a fall, can damage the housing and the unit may no longer be dust and water resistant as a result.

The **munevo DRIVE** adapter fulfils the conditions of the IP65 protection class (according to DIN EN 60529). The first code number "6" indicates that the adapter is fully protected against contact. The second code number "5" means that the adapter is protected against water jets from any angle and

can therefore be used without restrictions even in the rain.

The **munevo** Smartglass meets the conditions of the IP53 protection class (according to DIN EN 60529). The first code number "5" indicates that the glasses are protected against dust and foreign bodies in harmful quantities. The second code number "3" means that there is protection against falling water spray up to 60° from the vertical. It can be worn outdoors. In the event of rain, seek dry ground as soon as possible to avoid damage.

6 Transport and storage

6.1 Transport

When transporting the Smartglass, please always switch off the Smartglass and use the case provided to avoid damage. Transport this case in such a way that it is protected against falling and other violent impacts. Avoid permanent direct exposure to sunlight.



CAUTION

Damage due to improper transport.
Always transport the smartglass in the case provided to avoid damage.

6.2 Storage

Optimally, store the Smartglass at a temperature between -20°C and 45°C. If possible, avoid storage in a humid environment. Do not store the product in direct, permanent sunlight.

7 Maintenance and care

7.1 Software updates

When a new version of the **munevo DRIVE** software is available, you will be informed of this by e-mail. If major changes are made as a result of a software update, you will gladly receive an updated version of the operating instructions by e-mail.

7.2 Cleaning and care



NOTE

Do not use aggressive cleaning agents, chemical substances or hard brushes to clean the products. Under no circumstances should cleaning be carried out with a water jet or high-pressure cleaner.

The components of **munevo DRIVE** must be cleaned at regular intervals, depending on their use and the degree of soiling. Please use a soft, slightly damp cloth and a mild cleaning agent to clean the products.

7.3 Maintenance intervals



INFORMATION

If you need a spare part, please contact your medical supply store. Only spare parts from **munevo** may be used. Non-observance will result in the loss of warranty claims.



INFORMATION

If problems occur during maintenance, please contact your medical supply store.

Before each use, the functionality of the

control unit must be checked. The activities specified in Appendix 1 must be carried out by the user or a caregiver in accordance with the intervals.



NOTE

In some cases, effects on performance cannot be prevented if maintenance and storage are not carried out in accordance with the instructions given here.

8 Malfunction/ Troubleshooting

8.1 Error

Appendix 2 is intended to help you correct errors. If it is not possible to rectify the problem, please contact your medical supply store.

8.2 Defect/Failure

If one of the components of **munevo DRIVE** no longer works, please also contact your medical supply store.

8.3 Serious incidents

In the event of a serious incident, both the manufacturer and the competent supervisory authority must be informed immediately.

The competent, assessing supervisory authorities for **munevo DRIVE** can be contacted as follows:

Austria - Federal Office for Safety in Health Care

Radetzkystr. 2, 1030 Vienna, Austria

T: +43 1 71100 4206

E-Mail: meddev@bmfgf.gv.at

Belgium - FAMHP - Federal Agency for Medicines and Health Products Place

Victor Horta 40, Box 40, 1060 Brussels, Belgium
T: +32 2 528 4259, F: +32 2 528 4120
E-mail: meddev@afmps.be

Cyprus - Ministry of Health, Cyprus Medical Devices Competent Authority

1 Prodromou & 17 Chilonos Street, 1448 Nicosia, Cyprus
T: +357 22605572/735 – F: +357 22468427
E-mail: cymda@mphs.moh.gov.cy

Denmark - Danish Medicines AgencyAxel

Heides Gade 1, 2300 Copenhagen, Denmark
T: +45 44 88 9667
E-mail: med-udstyr@dkma.dk

France - Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM)

143 - 147 Boulevard Anatole France, 93285 Saint Denis Cedex, France T: +33 1 55 87 37 75, F: +33 1 55 87 37 42
E-mail: dmcddiv@ansm.sante.fr

Germany - Federal Institute for Drugs and Medical Devices (BfArM)

Kurt-Georg-Kiesinger-Allee 3, 53175 Bonn, Germany
T: +49 228 207 5355, F: +49 228 207 5207
E-mail: medizinprodukte@bfarm.demedizinprodukte@bfarm.de

Ireland - Health Products Regulatory Authority (HPRA)

Kevin O'Malley House, Earlsfort Centre,

Earlsfort Terrace, Dublin 2
T: +353 1 676 4971
E-mail: info@hpra.ie

Netherlands - Health and Youth Care Inspectorate

Postbus 2518, 6401 DA Heerlen, The Netherlands+31
88 1205000, F: +31 88 1205001
E-mail: meldpunt@igj.nl

Norway - Norwegian Medicines Agency

Postboks 240 Skøyen, 0213 Oslo, Norway
T: +47 22 89 77 00
E-mail: meddev-no@noma.no

Spain - Agencia Española de Medicamentos y Productos Sanitarios

C/ Campezo 1, Edificio 8, ES – 28022 Madrid
E-mail: sgps@aemps.es

Switzerland - Swissmedic - Medical devices

Hallerstr. 7, 3012 Bern, Switzerland
T: +41 58 462 02 11, F: +41 58 462 02 12
E-Mail: medical.devices@swissmedic.ch

Switzerland Representative
Easy Medical Device
Bernoulistrasse 20, 4056 Basel - Switzerland
E-mail: swiss@easymedicaldevice.com
Phone: +41 799036836

A serious incident is present at:

- a malfunction
- a failure
- a change in the characteristics or performance
- improper labelling
- improper instructions for use

which has led, could have led or could lead (un)indirectly to the death or serious deterioration of the state of health of a patient, a user or another person.

9 Technical data

9.1 European Device Information

UDI-DI:	04260691380003
SRN:	DE-MF-000006277

9.2 Adapter

Dimensions	85 x 45 x 34 mm (LxWxH)
Plastic housing	ABS
Connectivity	Bluetooth (2.402-2.48 GHz)
Maximum radiated power	6.31 mW
Protection class	IP65

Subject to technical changes

9.3 Google Glass

Display	640 x 360 Px
Camera	8 MP
Connectivity	Wi-Fi - 802.11 b/g 2.4GHz Bluetooth 5.0 (2.402-2.48 GHz)
Maximum radiated power	5.2 mW
Memory	3GB LPDDR4 32GB eMMC Flash
Operating temperature range:	0 – 35°C
Storage temperature range:	-20 – 45°C Keep dry

Battery	800 mAh,
Charging cycles	550
Protection class	IP53

Subject to technical changes

10 System requirements

10.1 Network requirements

- Wireless router: to use all functions of **munevo DRIVE**, especially the update function, you should have a functioning WLAN (wireless network); IEEE 802.11b/g/n/ac
- Internet connection: **munevo DRIVE** has been designed to provide software updates via your internet connection. For best performance, use DSL, cable or fibre optic.

Instructions on how to connect the glasses to the Internet can be found in the appendix, under O

10.2 IT security measures

10.2.1 Security of Bluetooth wireless technology

The communication via Bluetooth Low Energy between the Smartglass and the adapter is secured by a proprietary algorithm that does not allow manipulation of the data.

The data transmission and the data itself are encrypted using the AES-128 bit standard. This high standard enables the user of **munevo DRIVE** to have secure and trustworthy signal communication.

10.2.2 Device safety

The device must not be used for the installation and use of any application

other than the **munevo DRIVE** application. The complete **munevo DRIVE** system is designed in such a way that any kind of modification is excluded. This applies to both the Smartglass and the adapter.

10.2.3 Network security

All communication on our website takes place in a secure network with SSL encryption. Through these and other measures, the highest standard of protection for your personal data can be offered. In addition, **munevo** continuously takes various measures to protect the system against attempted data modification, eavesdropping or similar.

11 Notes on reuse

The special control **munevo DRIVE** is suitable for reuse. The features and performance must not change in such a way that the safety of patients and, if applicable, third parties is endangered during the service life.

Based on market observation and the state of the art, the manufacturer has calculated the use of the product to be 5 years, taking into account the intended use and the service and maintenance specifications. Periods of storage at the specialist dealer or cost unit are not included. It should be clearly emphasised that the product is reliable far beyond this defined period of time with appropriate care and maintenance. If the service life is reached, the user or a responsible assistant should contact the specialist personnel who adapted the product or the manufacturer's

service department (for address see back cover).

The components of the **munevo DRIVE** must be thoroughly cleaned and disinfected before being used again. Afterwards, the entire product must be checked by **munevo** or an authorised specialist for condition, wear and damage.

Any worn and damaged parts as well as components unsuitable/inappropriate for the new user must be replaced.

12 Disposal

12.1 Disposal of the transport packaging

Packaging materials should be recycled according to national and local regulations. If recycling is not possible, all packaging elements can also be disposed of in residual waste (household waste).

12.2 Disposal of the units

If **munevo DRIVE** is the property of the health insurance fund, it is returned to the health insurance fund for disposal.

If **munevo DRIVE** is privately owned, the following instructions apply to disposal:

- The disposal guidelines of the country of manufacture apply.
- For disposal in other countries, the country-specific disposal and environmental protection regulations apply.



INFORMATION

In the event of disposal, all components and materials of the special control unit must be disposed of in an environmentally friendly manner and in accordance with the legal requirements or recycled.

munevo offers an end-of-life disposal programme for electronic products in accordance with WEEE regulations. For detailed information, please call: +49 89 55 06 49 -04



13 Legal notice

13.1 Liability

munevo GmbH is only liable if the product is used under the specified conditions and for the specified purposes. **munevo** recommends to handle the product properly and to maintain it according to the instructions for use. The manufacturer is not liable for damages caused by components and spare parts that have not been approved by **munevo**. Repairs may only be carried out by authorised specialist dealers or by the manufacturer himself.

13.2 CE conformity

The product complies with the requirements of Directive 2017/745 (MDR). Based on the classification criteria for medical devices according to Annex VIII of the directive, the product has been classified as Class I. The declaration of conformity was therefore drawn up by **munevo GmbH** under its

sole responsibility in accordance with Directive 2017/745 (MDR) Annex IX.

13.3 Warranty

The statutory warranty valid at the time of delivery shall apply.

Prerequisites:

- There is a manufacturing or material defect.
- The cause of the change in the product is not natural or function-related wear or ageing.
- The damage was not caused by the fact that **munevo DRIVE** was not used as intended.

Excluded from warranty:

- Damage caused by improper use and force majeure.
- All parts that are subject to wear or ageing to the usual extent due to their function, insofar as these are not production or material defects.
- Damage caused by improper or inadequate care and repairs, conversions or replacement of parts not carried out professionally.
- Accidental damage or other external influences, insofar as these are not due to information or product defects.
- Damage caused by improper or inadequate care (e.g. cleaning the components with a strong water jet).

- Fluctuations in consumption and battery performance as well as a decrease in capacity due to age. They are normal in traffic, technically unavoidable and as such not a material defect.

13.4 Warranty conditions of munevo GmbH

munevo GmbH provides a 2-year warranty from the date of purchase for material and manufacturing defects of the product. Excluded from the warranty are:

- Damage resulting from improper use
- Wear parts
- Damage that is attributable to the customer's own fault

The Smartglass battery is guaranteed for 1 year from the date of purchase.

A warranty claim is void if the units have been opened by unauthorised persons.

13.5 Licences

Information on the licences we use and a reference to current versions can be found at www.munevo.com.

14 Appendix

14.1 Maintenance plan

Maintenance and inspection intervals	daily	weekly	monthly	annual
Check function and position of the emergency stop button	X			
Clean all components with a soft cloth and a mild detergent.		X		
Checking the cables - Has the cable been crushed or kinked? - Connections on input module and adapter tight?			X	
Check housing for damage - by medical supply store				X
Check adapter bracket for damage - by medical supply store				X
Check all screws for tightness - by medical supply store				X

Table 14- 1: Maintenance schedule

14.2 Troubleshooting

Error	Possible cause	Remedy
Glasses do not turn on	Battery not charged	Please connect the glasses to a mains socket using the charging cable and mains adapter supplied and wait for approx. 10 minutes.
	Battery charged for a long time, yet the glasses do not start up	Press and hold the on/off button for 10 sec., wait 2 sec. and then start the glasses as usual by pressing the button for 2 sec. If the glasses still do not switch on, please contact your dealer.
Glasses do not connect with adapter.	Adapter not supplied with power	• Check whether the wheelchair is switched on • Check cable to adapter for damage or kinks • Is the cable correctly connected to the input module?
	unknown	Switch off the wheelchair and glasses and switch them on again after a short waiting time.
	Adapter defective	LED does not light up despite carrying out the previously mentioned measures; contact your specialist dealer.
When changing the seating position, the goggle display does not show the same seating profile as in OMNI.	• Incorrect seat profiles stored in OMNI. • Application was not synchronised after a visit to the medical supply store to change the seat profiles.	Try to synchronise the application first and restart the wheelchair. If the seat profiles in the application still differ from those of the OMNI, contact your medical supply store or munevo customer service to update the seat profiles.
Pictures from the camera or the gallery cannot be shared.	No e-mail address is stored	In order to be able to share pictures, you need to deposit a friend/family member's email address. To change this address, please contact munevo customer service. You must then synchronise the device.
My emergency messages are not delivered to my carer	There is no email -address on file	In order to be able to send the emergency message, you must store an e-mail address of your carer. To change this address, please contact munevo customer service. You must then synchronise the device.
The application sometimes crashes or hangs	Current version of the application?	Please try to synchronise the application to get the latest version. If the problem persists, contact your medical supply store.
My glasses heat up very quickly.		A certain amount of heat is normal, especially during charging. If the heat from the glasses is uncomfortable, please contact your medical supply store.

Table 14- 2: Troubleshooting

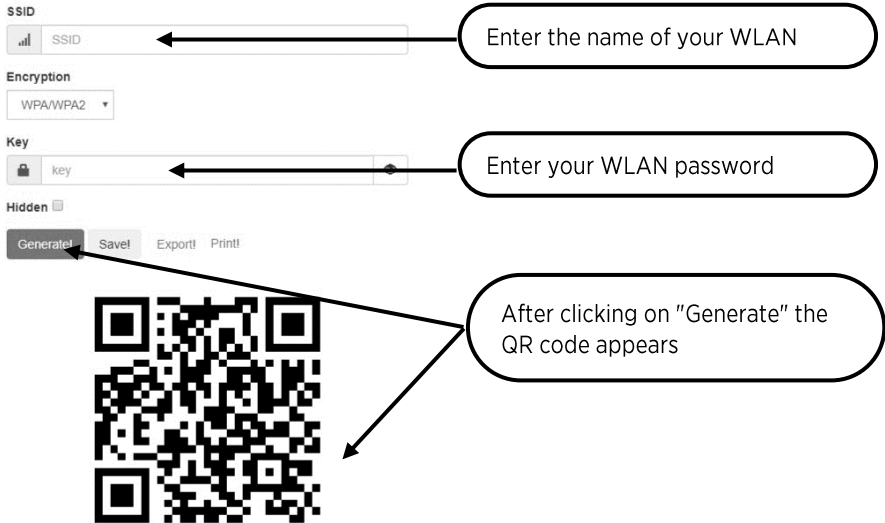
Status and warning notices in the application and their meaning.

Status/warning notice	Meaning
Scanning for the adapter	The Smartglass tries to establish a Bluetooth connection with the adapter. The wheelchair must be switched on for this.
Scan again	If no connection could be established between the smartglass and the adapter, the scan mode (the two devices search for each other) can be started again. To do this, nod downwards. If this is not desired, the glasses can be locked or you can exit the corresponding submenu by nodding upwards.
Scanning not possible. Please restart the glasses.	If you cannot establish a connection after several attempts, it may help to restart the glasses and adapter (wheelchair).
Bluetooth connection lost	If the glasses lose the Bluetooth connection to the adapter, this warning is displayed. The wheelchair cannot be controlled at this moment.
No seat profiles found. Nod down to synchronise the device.	The seat does not find any stored seat profiles when opening the seat menu. Synchronising will load these onto the glasses if they have been created. If they have not been created, contact your sales representative.
No email from the supervisor found. Nod down to synchronise the device.	The eyewear does not have a stored e-mail address for sending the emergency e-mail. A synchronisation will load this to the glasses, if they have been created. If not, contact your responsible field staff member.
The battery should be at least 20% to update the application.	Synchronisation of the application is only possible when the battery is at least 20% charged.
New version available. Please nod down to synchronise the device.	If there is a new version of the application and you have an internet connection, nod down to update to the new version.

Table 14- 3: Status and warning notices

14.3 Connecting Smartglass with WLAN

1. In order to connect the Smartglass to the Internet, you must create a QR code of your WLAN and then scan it with the glasses. To do this, go to the following website:
<https://www.qifi.org>



SSID

Encryption: WPA/WPA2

Key

Hidden

Buttons: Generate, Save, Export, Print

QR code

Callouts:

- Enter the name of your WLAN (points to SSID field)
- Enter your WLAN password (points to Key field)
- After clicking on "Generate" the QR code appears (points to Generate button and QR code)

2. As of version 3.4.5, there is a menu item "WLAN" in the "Settings" menu, which can be used to open the QR code scanner by tapping on the touchpad. Open it and scan the previously generated QR code by pointing the camera at the QR code. You can see the section of the camera on the display of the Smartglass and can position it accordingly. A short sound signal confirms successful scanning. The glasses then automatically connect to the WLAN.



Figure 14- 1: WLAN menu in the application

Note: If you have other security functions active that do not allow devices to connect to your WLAN, make sure that these are at least temporarily deactivated.

14.4 Electromagnetic compatibility

Munevo DRIVE is tested according to IEC 60601-1 and CISPR 11, Class B, Group 1:

Immunity test level

Phenomenon	EMC basic standard or Test method	IMMUNITY TEST LEVEL
DISCHARGE OF STATIC ELECTRICITY	IEC 61000-4-2	± 8 kV Contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air
High-frequency electromagnetic fields ^a	IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz
High-frequency electromagnetic fields in the immediate vicinity of wireless communication devices	IEC 61000-4-3	See Table 14- 5
Magnetic fields with energy- technical MEASUREMENT frequencies	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz

Table 14- 4: Immunity test level

Immunity test level for high-frequency electromagnetic fields

Test frequency MHz	Modulation	Maximum Power W	Distance m	INTERFERENCE RESISTANCE- CHECKING CONDUCT V/m
385	Pulse modulation 18 Hz	1,8	0,3	27
450	FM ± 5 kHz stroke 1 kHz sine	2	0,3	28
710	Pulse modulation 217 Hz	0,2	0,3	9
745				
780				
810	Pulse modulation 18 Hz	2	0,3	28
870				
930				
1 720	Pulse modulation 217 Hz	2	0,3	28
1 845				
1 970				
2 450	Pulse modulation 217 Hz	2	0,3	28
5 240	Pulse modulation 217 Hz	0,2	0,3	9
5 500				
5 785				

Table 14- 5: Immunity test level for HF electromagnetic fields

14.5 Residual risks

Risk/danger situation	Risk reduction measure	Remaining risk
Alteration or loss of the Bluetooth connection between the Smartglass and the adapter may result in loss of control of the wheelchair.	Using the EMERGENCY STOP button (see 2.9), the wheelchair can be stopped and switched off to avoid dangerous situations caused by unintentional movements of the wheelchair. If the adapter box detects a loss of Bluetooth connection, it switches on the wheelchair's hazard warning lights.	If the user has to operate the EMERGENCY STOP in a dangerous situation (e.g. in heavy city traffic), a residual risk cannot be excluded. With some wheelchairs, the hazard warning lights are switched off when the wheelchair is switched off, so that the wheelchair would not be clearly visible despite the measure. If the EMERGENCY STOP is activated before the adapter can switch on the hazard warning lights, the wheelchair would also be poorly visible and thus exposed to a residual risk of not being seen. The presence of a third person / companion who can intervene can further minimise the residual risk.
Risks related to electromagnetic interference are explained in 2.5 These interferences can lead to the loss of connection described above.	munevo DRIVE was developed and tested according to the specific requirements of IEC 60601-1-2 and ISO 7176-21.	Although the risks have been mitigated as far as possible, electromagnetic interference may still occur and pose a residual risk.
Battery defect in the Smartglass and associated ignition or acid leakage.	Google Glass, a high-quality product, is used as part of munevo DRIVES. The Google Glass battery is fully enclosed, leakage is very unlikely.	Although the risk has been mitigated as far as possible, leakage or ignition may still occur as the battery still contains appropriate materials.

Table 14- 6: Residual risks

14.6 Gestures



1. menu gestures

Vertical head nod (nodding in agreement, "yes")

- Down - Menu selection & activate/deactivate driving)
- Up - back, to the previous menu



Horizontal head nod ("no" movement)

- Right - next menu item
- Left - previous menu item



2. driving gestures

Tilt up

- Accelerate, forward or backward depending on mode



Lateral tilt

- Cornering and turning the wheelchair



3. lock/unlock

Tilt right for 3 sec -> Lock

Tilt left for 3 sec -> Unlock

Advanced	Media	Seat	Driving	Settings	Support
Basic		Seat	Driving	Calibration	
Driving only			Driving		



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