MEDICAL DEVICE PASSPORT SMOOV

IMPORTANT INFORMATION FOR MEDICAL DEVICE CONSULTANTS AND SPECIALIST DEALERS REGARDING PRODUCT HANDOVER (INITIAL SUPPLY AND REUSE) WITH CHECKLIST ON THE REVERSE

IMPORTANT INFORMATION FOR SPECIA-LIST DEALERS AND USER INSTRUCTORS

- Please fill in the fields in the medical device passport carefully.
- Alber and its specialist dealers as service providers are legally obliged by the German Medical Devices Act to monitor their products. This medical device passport is necessary for ensuring complete traceability of our products.
- Instructions may only be given by trained persons. Alber does not accept any liability for damage caused by instruction or advice given by untrained persons.
- To allow us to exclude improper use and incorrect operation of our products, please confirm the instruction with your signature in the medical device passport. The signed document must be filed safely!
- Alber's warranty terms and conditions are printed on the reverse of your carbon copy. In case of service, you should always have your medical device passport to hand to enable faster processing.
- The checklist for the instruction is printed on the reverse of this information sheet.

IMPORTANT INFORMATION FOR THE INSTRUCTOR

- Fill in the fields on the reverse on a firm surface with a ballpoint pen. Please have the persons who have received instruction sign the confirmation of instruction form.
- Distribute copies of the document as follows:
 - Original copy to the instructor
 - White carbon copy to Alber
 - Red carbon copy to the specialist dealer
 - Yellow carbon copy to the end customer
- Please return the white carbon copy to Alber for registration purposes using the pre-paid return envelope enclosed.
- Keep the medical device passport and your copy of the confirmation of instruction form in a safe place. Please have these documents to hand in case of service or if you have any questions about the product.

GENERAL SAFETY INSTRUCTIONS

- Prior to first use, read and observe the operating manual and the safety instructions contained therein.
- Use SMOOV one only if you are in good physical and mental condition.
- The maximum obstacle height, maximum person weight, maximum gradeability of the SMOOV one and the wheel-chair manufacturer are to be observed.
- Only approach and tackle obstacles at an appropriate speed and at a right angle to the obstacle.
- Prior to using the push rims for braking, deactivate the assistance from the drive. Reduce speed prior to cornering. Caution: Risk of toppling!
- Avoid stairs, drops, bodies of water and other such hazardous areas!
- Prior to each use, check that the drive unit and control unit are charged. Check that the brackets are firmly attached to the wheelchair, check that they have not loosened during the service life, and check that they are not completely missing.
- Switch off the drive and control unit during transport, remove it from the wheelchair, and secure it when in a car.
- Only move persons when the SMOOV one is switched off or undocked and when the parking brakes are activated.
- The SMOOV one may only be used with a wheelchair. Such a wheelchair must be equipped with two parking brakes and a pair of anti-tippers.
- Repairs may only be carried out by the Alber Service Centre or by persons authorised by Alber.

THE USER IS TO RECEIVE THOROUGH INSTRUCTION IN THE HANDLING OF THE SMOOV ONE. SUCH INSTRUCTION IS AN ESSENTIAL PART OF THE HANDOVER OF THIS MEDICAL DEVICE. SPECIAL CONSIDERATION IS TO BE GIVEN TO POTENTIAL HAZARDOUS SITUATIONS THAT MAY ARISE DURING PRODUCT USE. ALLOW SUFFICIENT TIME FOR THE INSTRUCTION.

CHECKLIST FOR THE INSTRUCTION OF THE WHEELCHAIR USER

To be ticked by the instructor following demonstration ${old V}$

Explain potential hazards	Undertaking your journey safely: inform the customer of the general safety instructions (see front).
Explain the display and signals of the drive and control unit	 On/Off switch of the drive unit lights up green when ready for operation. Brief acoustic signals confirm that the drive/control unit has been switched on/off. Five white LEDs on the drive unit indicate the current charge status of the drive unit battery. Five white LEDs on the control unit indicate the current charge status of the control unit battery. The coloured LED provides information about the charge status of the control unit battery. These LEDs flash in the event of error messages or warnings. Observe the information in the operating manual or in the mobility app in this regard.
Explain how to attach the drive unit	 Apply the parking brakes. This secures the wheelchair against rolling away. Only for folding wheelchairs: Insert the adapter axle between the ends of the stub axle. Caution: The red marking on the right and left in the adapter axle must not be visible following insertion! Roll the drive unit across the ground towards the rear and let it click into place in the bracket. Caution: Do not lift the drive unit behind the wheelchair – Risk of toppling! Check that the drive unit is firmly seated in the bracket by moving the housing (top).
Explain how to attach the control unit	 Insert the control unit in the bracket only when it is switched off and let it click into place. Check that the control unit is firmly seated in the bracket by moving the housing.
Explain how to switch on the drive unit	Switch on the drive unit by pressing and holding (for approx. 2 seconds) the On/Off switch on the top. The On/Off switch lights up green. The charge status of the battery is indicated by means of five white LEDs.
Explain how to switch on the control unit	Switch on the control unit by pressing and holding (for approx. 2 seconds) the rotary knob. The Bluetooth connection to the drive unit is established automatically, mean-while an LED on the control unit flashes blue. When the connection is active, a coloured LED indicates the charge status of the control unit battery and five white LEDs indicate the charge status of the drive unit battery. Caution: The SMOOV one is now ready for use!
Explain how to use the SMOOV one	 Turning the rotary knob forwards accelerates the drive. Turning it backwards reduces the assisted speed. Note: If the control unit is mounted on the left side of the wheelchair, the setting must be adjusted using the SMOOV mobility app. Briefly press the rotary knob to switch off the assistance immediately. Caution: switch off the drive assistance in advance of an obstacle, in advance of slopes and in advance of a hazardous area! As is the case with a manual wheelchair, the wheelchair's push rims are used for braking and steering. Caution: The SMOOV one does not assist you when steering or braking! If the drive wheel is turned out of position, this is indicated by a flashing middle LED. Caution: The drive assistance cannot be activated in this state!

CHECKLIST FOR THE INSTRUCTION OF THE WHEELCHAIR USER

	 Prior to navigating slopes, switch off the drive assistance by pressing the rotary knob. Caution: The drive does not provide assistance when braking. The push rims are used for braking! With regard to moving off on inclines, secure the wheelchair using the parking brake, then move off using the push rims and switch on the drive assistance using the rotary knob. Caution: No assistance is possible if the drive wheel is turning. The SMOOV one does not provide protection against rolling backwards! Carry out steering exercises and braking to a standstill in the various usage modes in a flat, open area. Practice navigating inclines with a helper if necessary. Deactivate assistance from the drive on slopes.
Explain how to remove the control unit	 Apply the parking brakes. This secures the wheelchair against rolling away. Switch off the control unit, press the button at the bottom of the bracket and remove the control unit. Stow the control unit securely. Unintentional switch-on should be prevented.
Explain how to remove the drive unit	 Apply the parking brakes. This secures the wheelchair against rolling away. Pull the handle on the drive unit upwards and release the drive unit from the bracket. Roll the drive unit across the ground in front of the wheelchair. Caution: Do not lift the drive unit behind the wheelchair – Risk of toppling! Only for folding wheelchairs: Push the adapter axle together and remove it. Stow the drive unit securely. Caution: The drive could be hot!
Explain how to charge the drive unit and control unit	 Switch off the control unit and drive unit. Plug in the charger socket and put the magnetic plug in the charger socket. The white LEDs on the drive unit indicate charging and the charge status. It is only permitted to charge the drive unit with the SMOOV one charger included in the delivery. The control unit can be charged via the socket above the red position light of the drive unit using the USB-C cable included in the delivery. The control unit can also be charged via an external charger with max. 5 volt and max. 1.5 ampere. Caution: After charging, the cover for the socket on the drive/control unit needs to be closed again!
Explain the Mobility App	The mobility app first needs to be connected to the smartphone. This connection is established via the connect icon in the top right of the app. Once the connec- tion has been established, the individual functions can be selected via the menu icon in the top left. The SMOOV mobility app offers a number of functions and extensions. For example, switching off the red position light of the drive unit, adjustments to SMOOV one such as left-hand operation or extensions for the SMOOV one are possible via the SMOOV mobility app. Caution: Settings are possible that make handling characteristics significant- ly more active. Following a change, first always check (in a safe environment) that the wheelchair can still be steered and braked safely!

CONFIRMATION NOTE

I have been instructed in how to use the product and i have been made aware of potential hazardous situations.

Name, First Name of the User/End Customer

Place, Date, Signature of the User/End Customer

The instruction was carried out by:

Name, First Name

Place, Date, Signature of Specialist Dealer

DEAR SPECIALIST DEALER, PLEASE FILE THE SIGNED COPY OF THIS DOCUMENT IN YOUR CUSTOMER FILE.

