

<p align="center"><b>TEST REPORT</b></p> <p align="center"><b>PPP 31025A:2011 Rev. 2</b></p> <p align="center"><b>TUV SUD Test Report for power and control systems for electrically powered wheelchairs and scooters</b></p>	
Report No.:	713186854-1
Date of issue:	2021-04-09
Project handler:	Matthias Müller
Testing laboratory:	TÜV SÜD Product Service GmbH
Address:	Masurenweg 1-3, 30163 Hanover, Germany
Testing location:	as above
Client:	SANO Transportgeraete GmbH
Client number:	5010787488
Address:	Am Holzpoldlgut 22, 4040 Linz/Lichtenberg, Austria
Contact person:	Stefan Schaubmair
Standard:	ISO 7176-14:2008
TRF number and revision:	PPP_31025A:2011, Rev. 2 of 2018-10
TRF originated by:	TUV SUD Product Service, Mr. Michael Steinmann ( <i>product specialist</i> )
Copyright blank test report:	<p>This test report is based on the content of the standard (see above). The test report considered selected clauses of the a.m. standard(s) and experience gained with product testing. It was prepared by TUV SUD Product Service.</p> <p>TUV SUD Group takes no responsibility for and will not assume liability for damages resulting from the reader's interpretation of the reproduced material due to its placement and context.</p>
General disclaimer:	<p>This test report may only be quoted in full. Any use for advertising purposes must be granted in writing. This report is the result of a single examination of the object in question and is not generally applicable evaluation of the quality of other products in regular production.</p>
Scheme:	<input type="checkbox"/> TUV Mark <input checked="" type="checkbox"/> without certification <input type="checkbox"/> EU-Directive
Non-standard test method:	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes, see details under Summary of testing
National deviations:	N/A
Number of pages ( <i>Report</i> ):	20
Number of pages ( <i>Attachments</i> ):	N/A
Compiled by: Matthias Müller/ Andrei Ninu	 SIGN-ID 499444 09.04.2021
Approved by: Andrei Ninu/ Matthias Müller	 SIGN-ID 327264 2021-04-09

Test sample:	StoriX ID: HAN-540766-1
Type of test object:	Stair climbing device
Trademark:	
Model and/or type reference:	PT-S 160
Rating(s):	See copy of marking plate
Manufacturer:	SANO Transportgeraete GmbH
Manufacturer number:	5010787488
Address:	Am Holzpoldlgut 22, 4040 Linz/Lichtenberg, Austria
Sub-contractors/ tests (clause):	N/A
Name:	N/A
Order description:	<input checked="" type="checkbox"/> Complete test according to TRF
	<input type="checkbox"/> Partial test according to manufacturer's specifications
	<input type="checkbox"/> Preliminary test
	<input type="checkbox"/> Spot check
	<input type="checkbox"/> Others:
Date of order:	2020-03-03
Date of receipt of test item:	2020-12-21
Date(s) of performance of test:	2020-12-21 to 2021-04-08
Test item particulars: Electrically powered stair climbing device, type PT-S 160	
<b>Purpose of the product</b> (Description of intended use): The PT-S 160 is a mobile stair climbing device with a integrated seating system. It enables persons with walking disability to navigate over steps by an authorized assistant.	
<b>Characteristic data</b> (not shown on the marking plate): N/A	

Attachments:

Attachment	Description	Pages
Kept in file	EMC Test Report (stair climbing device) EMV Consulting Test Report No. EMVC 2020-07-12-Rev_1, 2021-02-05	43
Kept in file	EMC Test Report (external power supply) EMV Consulting Test Report No. EMVC 2020-11-08, 2020-01-05	44
Kept in file	IEC 60335-2-29 Test Report Hongcai Testing Test Report No. HCT16HR-1116S, 2016-08-25	114
Kept in file	IP21 Test Report (external power supply) Waltek Testing Group Test Report No. WTH21F03018385S, 2021-03-25	8
Kept in file	User manual Liftkar PT (Stand: 01/2021)	62

General remarks:

"(see remark #)" refers to a remark appended to the report.  
"(see appended table)" refers to a table appended to the report.  
Throughout this report a **comma** is used as the decimal separator.  
The test results presented in this report relate only to the object tested.  
This report shall not be reproduced except in full without the written approval of the testing laboratory.

**Summary of testing:**

The product fulfils the requirements of ISO 7176-14:2008

- ☐ deviation(s) found  
☒ no deviations found

**Additional information on Non-standard test method(s)**

Sub clause: --

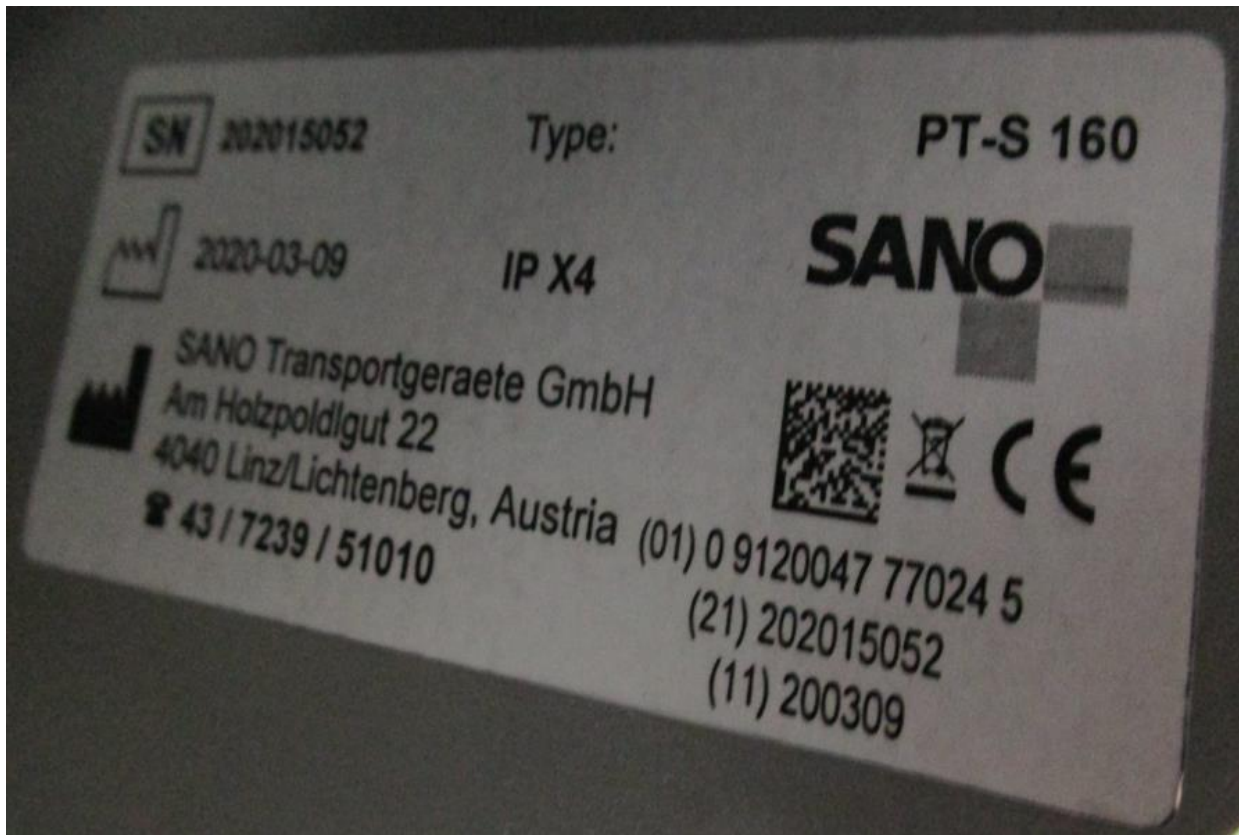
Page: --

Rational: --

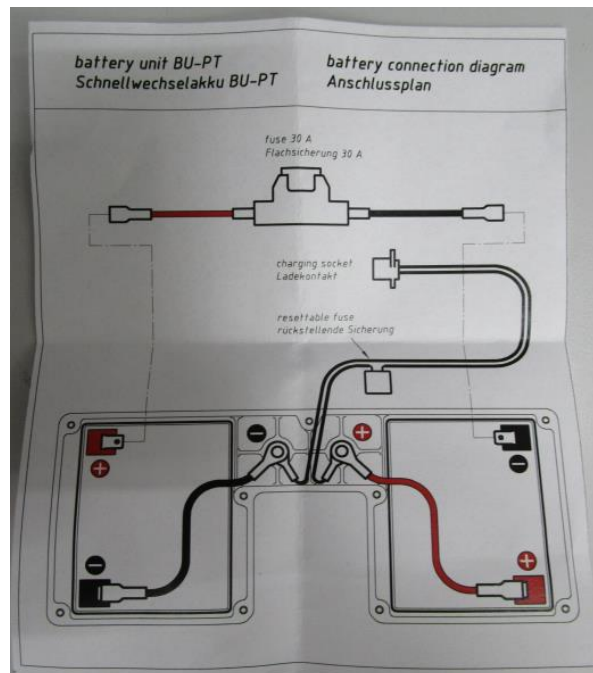
**If additional information is necessary, please provide**

N/A

Copy of marking plate:



Battery connection diagram:



**Picture of the product:**



**Name and address of factory (ies)** *(only if certification is provided):*

N/A

**Possible test case verdicts:**

test case does not apply to the test object: N/A (not applicable / not included in the order)

test object does meet the requirement: P (Pass)

test object does not meet the requirement: F (Fail)

**Possible suffixes to the verdicts:**

suffix for detailed information for the client: C (Comment)

suffix for important information for factory inspection: M (Manufacturing)

Clause	Requirement + Test	Result – Remark	Verdict
<b>5</b>	<b>Preparation of test wheelchair</b>		---
5.1	Wheelchair/scooter set-up in accordance with ISO 7176-22.	Stair climbing device	N/A
5.2	Mass and configuration of test load		---
	a) Dummy acc. ISO 7176-22		N/A
	b) Human combined with weights	82 kg combined with 80 kg	P
5.3	Wheelchair/scooter attributes		---
	Maximum speed $V_{MAX}$ on a horizontal surface (according to ISO 7176-6)		N/A
	Maximum stopping distance $L_i$ on inclined test plane (according to ISO 7176-3)		N/A
5.4	Obtain circuit diagrams for the wheelchair from the the wheelchair manufacturer.		P
5.5	Preparation records		---
5.5.a)	Equipment specified for test		P
5.5.b)	Position of adjustable parts (body support)		N/A
5.5.c)	Battery type and manufacturer	See appended table 9.7	P
5.5.d)	Safe working load (SWL):	160 kg	P
<b>6</b>	<b>Guidance for tests</b>		---
6.2	Batteries		---
	Nominal voltage of the battery set	$V_{NOM} = 24 V_{DC}$	P
	Cut-off voltage of the battery set	$V_{cut-off} = 10 V_{DC}$	P
6.3	Test conditions		---
	Ambient temperature ( $20\text{ °C} \pm 5\text{ °C}$ )	$T = 21.2\text{ °C} - 22.3\text{ °C}$	P
<b>7</b>	<b>Single fault safety</b>		---
7.1	Software testing addressed separately	Software developed and maintained in accordance with EN 62304 (see appended table 7.1)	P
	Means by which the wheelchair is made safe against single fault conditions	(see appended table 7.1)	P
7.2	Controller <b>command signal processing</b> failures		---
7.2.3.2	Open-circuit test at $0.5V_i$		---

Clause	Requirement + Test	Result – Remark	Verdict
	Open switch	No driving function, open circuit or short circuit leads to STOP, brakes activated, no movement	N/A
	Open switch (control device in stop position)		N/A
7.2.3.3	Short-circuit test at $0.5v_i$		---
	Open switch		N/A
	Open switch (control device in stop position)		N/A
7.2.3.4	Leakage current test		N/A
7.3	Controller <b>output device</b> failure		---
7.3.3.2	Open-circuit test at $0.5v_i$		---
	Open switch		N/A
	Open switch (control device in stop position)		N/A
7.3.3.3	Short-circuit test at $0.5v_i$		---
	Open switch		N/A
	Open switch (control device in stop position)		N/A
7.4	Ability to stop when power is removed		---
7.4.3.d	Stopping distance (control device in FWD direction)		N/A
7.4.3.e	Steering response		N/A
7.4.3.f	Stopping distance		N/A
7.4.3.i	Arithmetic mean stopping distance (d, e, f)		N/A
7.4.3.k	Stopping distance (control device in stop position)		N/A
7.4.3.m	Arithmetic mean stopping distance (k)		N/A

<b>8</b>	<b>Design</b>		---
8.1	There shall be available at least one means to switch on/off the wheelchair.		P
	On/Off switch marking	Symbol IEC 60417: 5007 and 5008	P
	Switching off does not cause drive wheels to revolve		P
8.2	Current consumption while switched off	$I_{2900} = C_{20} / 2900 = 1.72 \text{ mA}$ $I_{\text{measured}} = > 5 \mu\text{A}$	P
8.3	Control signal at switch on		---

Clause	Requirement + Test	Result – Remark	Verdict
	No moving if any control device is not in neutral position if the wheelchair is switched on.		P
8.4	Safe operation as the battery set becomes depleted		---
8.4.1	No hazardous situation when the battery set nears depletion.	Visual and acoustic signal	P
8.4.3.2	Upslope test		N/A
8.4.3.3	Downslope test		N/A
8.5	Over-discharge protection		---
8.5.2.2	Battery set test method (discharge)	See 8.5.2.3	P
8.5.2.3	Voltage source test (discharge simulation)	$U_{\min} = 16.1 \text{ V}_{\text{DC}}$	P
8.6	Controller over-voltage protection	$U_{\max} = 34.2 \text{ V}_{\text{DC}}$	P
8.7	Switch-off while driving		---
8.7.c	Switch-off at max. forward speed shall not create a hazardous situation	System STOP, no hazard	P
8.7.e	Switch-off at max. reverse speed shall not create a hazardous situation	System STOP, no hazard	P
8.8	Measuring devices		---
8.8.2.3	Indication that battery set is nearing depletion		P
8.8.2.4	Indication of remaining distance range (informative)		N/A
8.9	Drive inhibit during charging		P
8.10	Charging connection voltage drop		---
8.10.2	Voltage difference dU does not exceed 3.5 % of the nominal voltage of the battery set	Battery charger supplied with the device	N/A
	Charging current		---
	Entry point voltage		---
	Terminal voltages of batteries		---
	Total battery voltage		---
	Voltage drop		---
8.11	Non-powered mobility		---
	The force to disengage the braking system shall not exceed		---
	– 60 N for combined hand and arm operation;		N/A
	– 13,5 N for operation by one hand;		N/A
	– 5 N for operation by one finger;		N/A



Clause	Requirement + Test	Result – Remark	Verdict
	– 100 N for operation by pushing with a foot;		N/A
	– 60 N for operation by pulling with a foot.		N/A
	Max. pushing force to start the wheelchair loaded with SWL [ $F_{push} \leq 65 + (0.6 * SWL)$ ]		N/A
8.12	Brakes		---
8.12.3.c	Fault of brake system with the wheelchair/scooter facing up the slope		N/A
	Fault of brake system with the wheelchair/scooter facing down the slope		N/A
8.13	Battery enclosures		---
	Adequately ventilated ( $A = 0.005 * n * C_5$ )	Several holes, more than 0.05 cm <sup>2</sup>	P
	Leakage at 20° tilt (must be tested for non-spillable batteries)		N/A
8.14	Symbols		---
	Used symbols in accordance with IEC 60601-1		P
8.15	Safety of moving parts		---
	Electrically powered moving parts do not present a hazard		P
8.16	Use in combination with other devices		---
	If the wheelchair is intended by the manufacturer for use in combination with other devices that would be electrically connected to the battery set shall conform to ISO 7176-14		N/A

<b>9</b>	<b>Protection against shock, burns, fire and explosion</b>		---
9.1	Electrical isolation		---
9.1.3.2	Positive connection test	$I_{pos} \leq 0.1 \text{ mA (enclosure parts)}$	P
9.1.3.3	Negative connection test	$I_{neg} \leq 0.1 \text{ mA (enclosure parts)}$	P
9.2	Protection from non-insulated electrical parts		---
9.2.2	Battery terminals insulated	Closed battery system	N/A
9.2.3	Non-insulated electrical parts not touchable or no direct current above 5mA flows		N/A
9.3	Circuit protection		---
	Wiring and connection protected against excessive current flow		P

Clause	Requirement + Test	Result – Remark	Verdict
	No self-reset circuit protection device used		P
	No hazardous parts touchable when changing fuses (without using a tool)		N/A
9.3.3.2	Short circuit test for battery power wiring		---
9.3.3.2.a	Circuit protection device within circuit loop	30A car fuse (green)	P
9.3.3.2.d	Observed results after closing circuit breaker	Fuse blown immediately	P
9.3.3.3	Short circuit test for other than traction current wiring		---
9.3.3.3.a	Circuit breaker on test points B	Insulated contacts	P
9.3.3.3.b	Circuit breaker on test points C	Insulated contacts	P
9.3.3.3.c	Circuit breaker on test points D	Insulated contacts	P
9.3.3.4	Load current test for wiring that carries battery charging current		---
	Capacity of the circuit protection device (must be installed) that carries battery charging current	40 A resettable fuse	P
	Observed results after closing circuit breaker	fuse triggered	
9.4	Stalled condition protection		---
9.4.3.1	Initial stall test for 3 minutes (up to a maximum of five test cycles if circuit protection devices is triggered)	After one sec. system switched into error mode, no hot surfaces or damages, function as usual after switching up/down.	P
9.4.3.2	Extended stall test for 30 minutes	After one sec. system switched into error mode, no hot surfaces or damages, function as usual after switching up/down.	P
9.5	Surface temperatures		---
	Max. surface temp. within occupant reach space	No surfaces with changing temperatures within occupant reach space	P
9.6	Disconnection of battery system		---
9.6.2	Means for disconnecting battery set provided (without using a tool)		P
9.7	Resistance to ignition		---
9.7.2	Material classification	Lead-acid batteries	N/A
<b>10</b>	<b>Ergonomics</b>		---
10.1	User interface		---

Clause	Requirement + Test	Result – Remark	Verdict
	Correct marking (IEC 60601-1 / ISO 3287)		P
	Visual indicators with the colour red only used for warning		P
	All symbols, visual indicators and sounds described in the user manual		P
	Size and style appropriate for viewing distance		P
10.2	Operating forces		---
10.2.3.1	Lever to control speed and/or direction	$F_{\text{speed}} = 4 - 5 \text{ N}$ (switch)	P
10.2.3.2	Push button, rocker and keypad switches	$F_{\text{button}} = 4 - 5 \text{ N}$	P
10.2.3.3	Toggle switches		N/A
10.2.3.4	Pneumatic switches (sip and puff)		N/A
10.3	Display position		---
	Devices that present visual information positioned so that they are clearly visible by the occupant.		P
10.4	On/off indicator provided		P
10.5	Connectors		---
	Connectors can be connected and disconnected without the use of tools		P
10.6	Audible noise		---
10.6.3	Max. driving noise level	$L_{\text{drive}} = 55.9 \text{ dB (A)}$	P
10.6.4	Max. electrically adjustable body support components noise level		N/A
10.7	Acoustic warning device		---
10.7.3	Max. sound level [db(A)] and frequency [Hz]		N/A

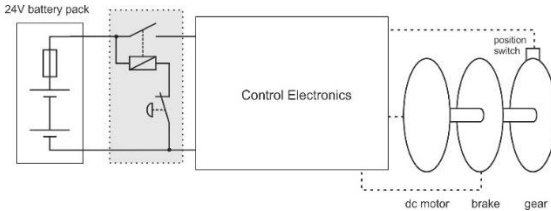
<b>11</b>	<b>Durability</b>		---
11.1	Control devices		---
11.1.2.2.b	Control device operates adequately		P
11.1.2.2.c	Operating force	See 10.2.3.2	P
11.1.2.2.d	Operating distance	$D = 4 \text{ mm}$	P
	1.5 million operating cycles test		N/A
11.2	Switches		---
11.2.2	100,000 operating cycles test		P
11.3	Connectors		---

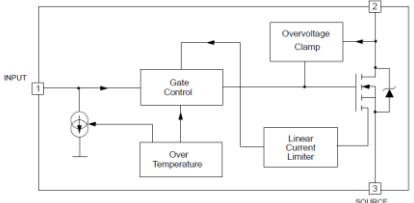
Clause	Requirement + Test	Result – Remark	Verdict
11.3.2	Connectors intended for daily use have adequately robustness (rated 4,000 cycles)	Charging connector	P
<b>12</b>	<b>Electrical connections</b>		---
12.1	Interchangeability of connectors		P
12.2	Wire routing secure		P
12.3	Wire colors		---
	All wires connected to the positive terminal of the battery set shall be red and permanently marked with a "+" symbol	Closed battery system, only for authorized personnel	N/A
	All wires connected to the negative terminal of the battery set shall not be red and shall be permanently marked with a "-" symbol	Closed battery system, only for authorized personnel	N/A
12.4	Intermediate battery connection power drains		---
	No power drawn from the battery set other than via the positive and negative terminals		N/A
<b>13</b>	<b>Environmental</b>		---
13.1	Protection against ingress of liquids min. IPX4 (according to ISO 7176-9)	IPX4	P
13.2	Protection against leakage of substances		N/A
13.3	Electromagnetic compatibility (according to ISO 7176-21)	See summary of contents	P
<b>14</b>	<b>Misuse and abuse</b>		---
14.1	Reversed polarity at the battery set	Closed battery system	P
14.2	Integrity of enclosures (IK10 impact test)	5 kg impact hammer applied	P

Clause	Requirement + Test	Result – Remark	Verdict
--------	--------------------	-----------------	---------

<b>15</b>	<b>Information provided with the wheelchair related to control systems</b>		---
15.1	Accompanying documents		P
15.2	Battery connection and circuit protection diagram		P
15.3	User manual provided with the following information:		---
15.3.a	Safety information provided as specified in 15.4		P
15.3.b	Statement that only specified products are to be used with the wheelchair		P
15.3.c	Safety performance of set up procedures		P
15.3.d	Information of properly set up		P
15.3.e	Correct use of brakes		N/A
15.4	Safety information with the following information provided to operators:		---
15.4.a	Consult accompanying documents		P
15.4.b	Warning for switch off before entering or exiting		P
15.4.c	Warning for possible sudden stop		P
15.4.d	Warning not to operate when behaving abnormally		P
15.4.e	Special environment storage condition		P
15.4.f	Interpretation of battery gauge		P
15.4.g	Warning not to operate with depleted batteries		P
15.4.h	Instructions for service (including intervals)		P
15.4.i	Safety warnings related to pinch points		P
15.4.j	Electromagnetic interference and possible effects		P
15.5	Correct fitting of removable parts		P
15.6	Information regarding residual risks		P
	All symbols, visual indicators and sounds described in the user manual (clause 10.1)		P

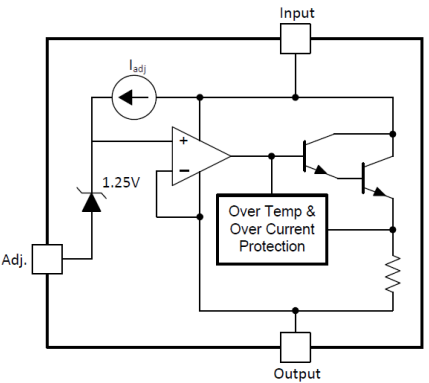
<b>17</b>	<b>Disclosure</b>		---
	The following information shall be disclosed as specified in ISO 7176-15:		---
17.a	product meets all requirements of ISO 7176-14		P
17.b	forces necessary to operate the control devices		N/A
17.c	pressures necessary to operate pneumatic switches (sip and puff operation)		N/A

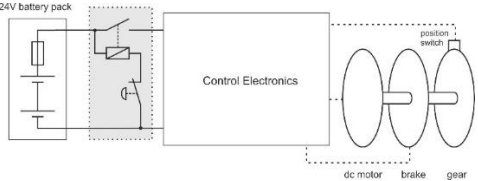
7.1	<b>TABLE: Single fault conditions <sup>1</sup></b>		P
	Test type and condition	Remarks and observed results	---
	Motor		--
	<p>One 24V DC Motor – 300W – AMT Schmidt</p> <p>Fault Injection: Short-circuit of the Power Stage =&gt; motor rotates continuously</p>	<p>Protection means: Short circuit detection (implemented in the motor driver) Details are provided – in the Risk Assessment – “20210130 Elektronik FMEA_PT_PTR” RISK ID 1.3.2/1.19.15</p> <p>The power stage of the control electronics has a short circuit protection realised in hardware by the gate driver. The used gate driver of type A3941 from Allegro Microsystems monitors the drain – source voltages VDS of all four MOSFET's in the power stage and switches of the MOSFET's when one of the voltages exceeds a set threshold level. Because of the resistive characteristics of the MOSFET's in the on state these voltages are proportional to the drain source currents IDS. In case of a short circuit the current IDS and therefore the voltage VDS reaches the threshold limit and the power stage is switched off. The fault condition is latched. The power stage can only be reactivated after a reset of the driver.</p> <p><b>1 Measurements see document “Measurements 2021-01-04 SFC- Treppensteiger #2” chapter “Measurements to subject ‘Motor’”</b></p> <p>Additionally, there is an emergency button for allowing the supervising person/user to timely stop the movement when a hazardous situation is identified. The emergency button is directly interrupting the connection to the battery, setting the safe state of the stair climber.</p> <p>Function chain for the emergency button: The grey block in the figure below highlights the power relay and the emergency button. The motor control electronics is disconnected from the battery when the emergency button is pressed.</p>  <p>Details are provided – in the Risk Assessment – “BA_de_PTR Bedienungsanleitung 10_2020 - SANO Deutschland” page 12</p> <p>Alternatively, the user/supervising person may lay down the stair-climber on the stairs. The motor will continuously move, but it will have, no consequences to the patient's safety.</p> <p>Details are provided – in the Risk Assessment – “BA_de_PT_Bedienungsanleitung 10_2020 - SANO Deutschland” page 46</p>	P

	Brake	--
	<p>A disk brake is used to set the safe-state of the stair climber, brake directly controlled by the SW/microcontroller.</p> <p>When unpowered, the brake is on – not allowing any motorized movement</p> <p>Fault Injection: The brake is continuously open due to a short-circuit of the solenoid driving the brake.</p> <p>“20210130 Elektronik FMEA_PT_PTR” Risk ID: 1.9.1/1.9.3</p> <p>Break output monitoring: In standby mode (stair climber switched on but not moving) the break output of the electronics is permanently diagnosed. If the output has a short circuit (results in an uncontrolled break release) or the break and cabling has an open circuit fault (the break cannot be released) no upstairs or downstairs operation is possible.</p> <p><b>2 Measurements see document “Measurements 2021-01-04 SFC- Treppensteiger #2” chapter 2.1. “Monitoring of brake output”</b></p> <p>Please provide a more detailed description of the inherent safety mechanism implemented to mitigate failures of the breaking system – i.e. the transistor VNN3NV04P-E.</p> <p>Details are provided – in the Risk Assessment – “20210130 Elektronik FMEA_PT_PTR” RISK ID 1.9.3</p> <p>The break control output of the electronics is realised by a fully autoprotected power MOSFET of type VNN3NV04P-E. This MOSFET has the following protective mechanism:</p> <ul style="list-style-type: none"> <li>• Linear current limitation</li> <li>• Thermal shutdown</li> <li>• Short circuit protection</li> <li>• Integrated voltage clamp</li> <li>• ESD protection</li> </ul> <p>Internal block diagram of the autoprotected MOSFET:</p>  <p>In case of a short circuit or an overload at the output due a defective or incorrectly wired brake the transistor will not be damaged.</p> <p><b>3 Measurements see document “Measurements 2021-01-04 SFC- Treppensteiger #2” chapter 2.2. “Fully autoprotected MOSFET”</b></p> <p>Besides of the mechanical brake, there is a second means to softly brake the stair-climber, i.e. by short-circuiting the driving motor and setting it in generator mode.</p> <p>Details are provided – in the Risk Assessment – “20210130 Elektronik FMEA_PT_PTR” RISK ID 1.9.3</p> <p>Whenever the stairclimber is in standby mode the electromechanical brake is applied. Additionally the power electronics short circuits the motor. In case of a failure of the electromechanical brake the short circuited permanent magnet motor produces enough torque at a relatively slow rotational speed to prevent an abrupt drop down of the load.</p> <p><b>4 Measurements see document “Measurements 2021-01-04 SFC- Treppensteiger #2” chapter 2.3. “Motor soft braking by short circuit”</b></p>	<p>--</p> <p>P</p>

	Fault Injection: Spring for closing the brake when unpowered – broken.	<p>PMS Data: 14600 Stair-climber as Medical Devices (25000 total also as non-MD) old since 2005.</p> <p>Dauertests –“PB-17-075-MP-PA028“ / “PB-17-075-R-PA094-08_2“ / “P-05-184-MP-PA 024-N3-03 (PT S 160 erfüllt) “</p> <p>Details are provided – in the Risk Assessment – “20210130 Elektronik FMEA_PT_PTR” RISK ID 1.9.3</p>	P
	Tilt sensor		--
	<p>A tilt-sensor has been integrated in the controller whose function is to supervise the tilt of the stair climber. In order to avoid the risk of tipping over, the stair-climber is active only within a predefined tilt range</p> <p>Fault injection: Calibration values of the tilt-sensor are corrupted/overwritten.</p>	<p>Corrupted calibration data – saved in EEPROM, is detected at PowerOn. All configurations saved in EEprom, e.g. current range, tilt-range, temperature, are protected by using a CRC mechanism.</p> <p>Details are provided – in the Risk Assessment – “20210130 Elektronik FMEA_PT_PTR” RISK ID 1.17.2/1.17.3/1.18.1</p>	P
	Fault injection: Defective Tilt-sensor/cable.	<p>Only a predefined range of the sensor’s voltage is valid. If the sensor signal exceeds the specifications, e.g. caused by a cable problem/interruption or short-circuit, the stair-climber is set in the safe-state.</p> <p>Details are provided – in the Risk Assessment – “20210130 Elektronik FMEA_PT_PTR” RISK ID 1.15.2</p>	P



	Power Supply	--
	<p>Battery – Lead 2 x 24V 5Ah – series</p> <p>From the 24V – the following voltages are derived: a 3,3V voltage supply for the microcontroller, 5V for drivers, 7V &amp; 12V</p> <p>Fault Injection: under-voltage 3.3V.</p> <p>The brown-out circuit will cut-off the voltage when below 2V (still within specs – ARM Cortex M3: STM32F101C6).</p> <p>Details are provided – in the Risk Assessment – “20210130 Elektronik FMEA_PT_PTR” RISK ID 1.17.3</p> <p>Details are provided – in the Risk Assessment – “20210130 Elektronik FMEA_PT_PTR” RISK ID 1.17.4</p> <p>The used voltage regulator of type LM317 is active on the market for about 40 years -&gt; reliable and mature technology. The regulator employs an internal current limitation and thermal shut down, making it essentially blow out proof. The nominal output current of the voltage regulator is 500mA. In the actually design only 29mA are needed. The oversized design implies a high reliability.</p> <p>Internal block diagram of the autoprotected voltage regulator LM317:</p>  <p>In case of a voltage regulator failure and therefore possible microcontroller malfunction the measures according to subclass “User Interface” may be carried out (PT: Lay down the stairclimber on the stairs; PTR: Push emergency button)</p> <p>Over-undervoltage for all other voltages in the system, 5V, 7V, 12V are detected by the microcontroller which is able to timely trigger the safe-state.</p>	<p>P</p>

	User Interface	--
	<p>A switch is integrated in the Control panel for changing the direction – forwards/backwards</p> <p>Fault Injection: Cable issue results in an unexpected movement/direction.</p> <p>Details are provided – in the Risk Assessment – “20210130 Elektronik FMEA_PT_PTR” RISK ID 1.13.5</p> <p>The motor changes the direction unintentionally.</p> <p>Prevention of unintentional changes of direction:</p> <p>PT: The two signals for “up” and “down” operation are low active, that is to say a low signal at the “up” or “down” input results in an upstairs or downstairs operation. A change of the direction during operation is not possible (e.g. if the “down” button is pressed or a cabling fault sets the “down” input low during upstairs operation the stairclimber stops). A low signal to start an upstairs or downstairs operation is only accepted when the stairclimber is in standby mode and the signals for “up” and “down” were high previously -&gt; in case of a cable issue the stairclimber will not change direction or start automatically after a stop.</p> <p>Unintentional change of direction during operation is inhibited</p> <p>PTR: The single signal for the change between “up” and “down” is low active. A change of the direction during operation is not possible. If the “up/down” button is pressed for a short time during operation the direction is not changed, only the green LED indicates that the preselected direction has changed. After a stop the stairclimber will move in the direction indicated by the green LED when operation is started again. If the “up/down” button is pressed permanently (e.g. due to a cabling issue) the operation is stopped and the stairclimber is switched off.</p> <p>Unintentional change of direction during operation is inhibited</p> <p><b>5 Measurements see document “Measurements 2021-01-04 SFC- Treppensteiger #2” chapter 3 “Measurements to subject ‘User Interface’”</b></p> <p>Additionally, there is an emergency button for allowing the supervising person/user to timely stop the movement when a hazardous situation is identified. The emergency button is directly interrupting the connection to the battery setting the safe state of the stair climber.</p> <p>Details are provided – in the Risk Assessment – “BA_de_PTR Bedienungsanleitung 10_2020 - SANO Deutschland” page 12</p> <p>Functional chain of the emergency button:</p>  <p>Alternatively, the user/supervising person may lay down the stair-climber on the stairs. The motor will continuously move, but it will have, no consequences to the patient's safety.</p> <p>Details are provided – in the Risk Assessment – “BA_de_PT Bedienungsanleitung 10_2020 - SANO Deutschland” page 46</p>	<p>--</p> <p>P</p>
<p><sup>1</sup> Individually set by test engineer depending on safety philosophy / safety requirements, existing component certificates and result of documentation assessment.</p>		
<p><b>Supplementary information:</b> N/A</p>		

7.2.3.4	<b>TABLE: leakage current tests</b>		N/A
Test point		Resistance value	Remark
<b>Supplementary information:</b> No driving mode			

9.7	TABLE: lists of critical component parts <sup>1</sup>					P
Object/part No	Manufacturer/ trademark	Type/model	Technical data	Standard	Mark(s) of conformity <sup>2</sup> )	
Battery charger	Soneil International Limited	2402SRM20	IN: 100-240 V <sub>AC</sub> , 50/60 Hz, 0.7 A OUT: 24 V <sub>DC</sub> , 1 A	EN 60335-2- 29	--	
Battery	Long	WP5-12	2 x 12 V <sub>DC</sub> , 5 Ah (C <sub>20</sub> )	--	--	
Drive motor	AMT	SLB	24 V <sub>DC</sub> , 12 A, 2500 RPM	--	--	
Resettable Fuse	Bours	MF-R Series – PTC resettable fuse	40 A, 30 V	--	--	
Fuse	MTA	uniVAL 0700370/40	30 A, 32 V	--	--	
<sup>1</sup> Safety relevant components can be programmable electronic controllers, fuses, fuseholders, plugs, sockets, motors, wiring, switches, temperature regulators and -switches, relays, battery chargers, component materials, enclosures etc.						
<sup>2</sup> an asterisk indicates a mark which assures the agreed level of surveillance						
Supplementary information: N/A						