

Test Report 061405DM

Electrically driven wheelchair

TEST	CATEG	ORY:
VERIF	CATIO	N
F	PASSED	\boxtimes
F	AILED	

Client:	IVCR International South Road Bridgend Industrial Estate Bridgend CF32 4BU +44 0 1656 664 321			
Manufacturing location:	Invacare Corporation 1200 Taylor Street Elyria, Ohio, USA 44035			
Test object:	Electrically powered wheelchair Model: M61 Maximum Rated User Capacity: 300 lbs (136 kg)			
Test specifications:	EN 12184: 1999-03			
Additional information:	Received Date:			
	Location of test:	Corporate Reliability Test Laboratory 38683 Taylor Parkway North Ridgeville, Ohio 44039 2005/June/14 to 2005/November/17		
	Test period: Report Date:	2005/November/17		
	Project manager:	Tom Tuckowski		
	Requester:	Dave Mahilo		
	Performed by:	Kevin Hankins		

Attachments: Risk Analysis Rev. D, Manual (English translation 10/5/05), TUV Certificate No. Z1 04 06 12941 098, Certificate Declaration No:HDAL-5HLSBF; Rev: 7.00, Information disclosure in manufacturer's specification sheets, Prints

Tested by: Kevin Hankins

Approved by: Dave Mahilo

Definitions:

N/A = Not Applicable

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INVAC4RE

Technical Data:



M61 Power Chair with Reference Loader Gage From Invacare Test: 061505KH and This Test

Total length incl. footrests:

990 mm minimum, 1030 mm maximum

Total length without footrests:

875 mm

Width:

650 mm minimum, 770 mm maximum

Height:

1055 mm minimum, 1280 mm maximum

Stroke:

127 mm maximum

Seat width:

465 mm

Seat depth:

410 mm minimum, 460 mm maximum

Seat surface height at front edge:470 mm minimum, 595 mm maximum

Brakes:

Motor type spring loaded disc brake

Drive wheels:

-size

3.00-4

-tires

air-filled \(/\ rubber \(\)

Air-filled tires are available. Non-air-filled tires were used for all testing because they are worst-case for all tests.

Steering wheels:

-size

152 mm (6 inch)

-tires

air-filled 🗌 / rubber 🔯



Power electronics:

Dynamic Controls Ltd.

Controller Model DK-PMB21, Invacare Part No. 1139643 Control Device Model DK-REMD11, Invacare Part No.1139644

Certificate Declaration No:HDAL-5HLSBF; Rev: 7.00

Declaration of Conformity to

European Community Medical Devices Directive, MDD 93/42/EEC

Conformance to EN12184:1999 Conformance to EN12182:1999

Motor:

Permanent magnet 2-pole gearmotor

Stroke motor:

COP CCL permanent magnet 2-pole gearmotor

Batteries:

MK Battery Model MU-1, type: SLDA AGM 2 x (12 v, 27.6 Amp-Hour rating (5 hour rating))

Battery charger:

Off-board Charger

CTE Corporation Part# BAT-GC0812 Mains: 1.3 Amp 200 to 250 vac 50 Hz Supply to Chair: 24 v DC 8 Amp

TUV Certificate No. Z1 04 06 12941 098 Conformance to EN 12184:1999



Item	Requirement Fulfilled
1 Scope EN 12184:1999 Clause 1.	
This present European standard specifies requirements and test procedures for electrically powered wheelchairs and scooters with a maximum speed not exceeding 15 km/h intended to carry one person whose mass does not exceed 100 kg, including the following classifications from EN ISO 9999:1998: Classification no. / title:	The M61 Electric Wheelchair is designed with a maximum rated speed of 6.8 km/h (4.25 mph) and maximum rated user capacity of 136 kg (300 lbs). Invacare Tests 050205JT.1 061505KH Front Wheels Load = 40kg Mid Wheels Load = 131kg Rear Wheels Load = 63kg
12 21 21 Powered attendant-controlled wheelchairs 12 21 24 Electric-motor-driven wheelchairs with manual steering	
12 21 24 Electric-motor-driven wheelchairs with manual steering 12 21 27 Electric-motor-driven wheelchairs with powered	Unladen Mass = 98kg
	Max User Mass = 136kg
steering	
2 Normative References	
See EN 12184:1999 Clause 2.	
3 Definitions	
See EN 12184:1999 Clause 3.	
4 Test equipment	
See EN 12184:1999 Clause 4.	
5 Type classes EN 12184:1999 Clause 5	
Electrically powered wheelchairs shall be classified in one or more of the following three classes, dependant upon their intended use.	
Class A: Compact, maneuverable wheelchairs not necessarily capable of negotiating outdoor obstacles.	Class A 🖂
Class B: Wheelchairs sufficiently compact and maneuverable for some indoor environments and capable of negotiating some outdoor obstacles.	Class B
Class C: Wheelchairs, usually large in size, not necessarily intended for use indoors but capable of travelling over longer distances and negotiating outdoor obstacles.	Class C



Item	Requirement Fulfilled
6 General Requirements	
•	Product Risk Analysis: Pronto M61
The wheelchair shall conform to the requirements of EN	Part No.: 1127273 Rev. D, attached.
12182:1999 for:	
a. Risk analysis 12182:1999 4.1	
al. EN 1441:1997 Risk Analysis	N/A Yes No Remark
((EN 1441 was obsoleted by) ISO 14971
a2. 12182:1999 5.2 Biocompatibility and to deity	N/A Yes No Remark
a3. 12182:1999 5.4.2 Animal tissues	N/A Yes No Remark
a4. 12182:1999 5.5 Resistance to corrosion	N/A Yes No Remark
a5. 12182:1999 6 Noise and vibration	N/A Yes No Remark
a6. 12182:1999 8.2.1 Battery housings	N/A Yes No Remark
	N/A Yes No Remark X
includes 12182:1999 8.1 Electrical safety	Battery Charger TUV Certificate No. Z1 04 06
0. 10100 1000 10 0. 0	12941 098, Conformance to EN 12184:1999
	N/A Yes No Remark N/A Yes No Remark Remark
a9. 12182:1999 22 Ergonomic principles	N/A Yes No Remark Invacare Test 071405KH.1 Passed includes 7176-
	14 Forces to operate controls.
-10 10100-1000 14 Dealersing	N/A Yes No Remark
a10.12182:1999 24 Packaging	N/A Yes No Remark
b. 12182:1999 4.2 Intended performance and technical	See Clause 8 below.
documentation c. 12182:1999 4.3 Clinical evaluation	N/A Yes No Remark
d. 12182:1999 4.4 Aids that can be dismantled	N/A Yes No Remark
	N/A Yes No Remark
e. 12182:1999 4.5 Single use fasteners f. 12182:1999 5.2 Biocompatibility and toxicity	N/A Yes No Remark
g. 12182:1999 5.2 Biocompatibility and toxicity	N/A Yes No Remark
h. 12182:1999 5.4 Infection and microbiological	N/A Yes No Remark
contamination	Non-sterile product. May be cleaned.
	N/A Yes No Remark
liquids	No liquid storage other than batteries.
j. 12184:1999 12 Safety of moving parts	N/A ☐ Yes ☒ No ☐ Remark ☐
	N/A Yes No Remark
body	
	N/A Yes No Remark
	N/A Yes No Remark
7 Design Requirements EN 12184:1999	
7.1 Footrest and legrests	
7.1.1 Requirements for footrests and legrests	
15	
The wheelenan share of tapasis of	N/A Yes No Remark
preventing the user's feet from sliding backwards.	Heels strap or footrest lip are provided.
If for atmosts and largests can be adjusted as mayed from ano	
If footrests and legrests can be adjusted or moved from one	
position to another they shall have provision to locate them	N/A Yes No Remark
securely in any operating position.	
If the layout of footrests and legrests can be adjusted they shall	
the layout of rootrests and legrests can be adjusted they shan have increment adjustments not exceeding 25 mm.	
lave morement adjustments not exceeding 25 mm.	N/A Yes No Remark



Item	Requirement Fulfilled
If the wheelchair is fitted with a separate footrest for each foot:	
a) the gap between the footrests shall not exceed	M
35 mm for wheelchairs intended for adults; 25 mm for wheelchairs intended for children; when tested as specified in 7.1.2;	
or	
b) the footrests shall be fitted with means for preventing the user's feet from sliding into the gap.	N/A ☐ Yes ☒ No ☐ Remark ☒ b. Heels strap (separate footrests are optional).
7.2 Requirements for pneumatic tires	N/A ☐ Yes ☒ No ☐ Remark ☒
If the wheelchair is fitted with pneumatic tires, they shall have identical valve connections.	Air-filled tires are available. Non-air-filled tires were used for all testing because they are worst-case for all tests.
7.3 Requirements for fitting a seat belt	
The wheelchairs shall have provision for a seat belt to be fitted.	N/A Yes No Remark
7.4 Requirements for armrests and backrests	
If armrests and backrests can be adjusted or moved from one position to another they shall have provision to locate them securely in any intended operating position.	N/A Yes No Remark
7.5 Requirements for wheelchairs designed for use as seats in motor vehicles	
If the manufacturer claims the wheelchair is intended for use as a seat in a motor vehicle, the manufacturer's information shall identify the wheelchair tiedown and occupant restraint systems (WTORS) that are suitable and the attachment points on the wheelchair.	N/A 🛛 Yes 🗌 No 🗌 Remark 🗍



Item	Requirement Fulfilled
7.6 Requirement for braking systems	OPY
The wheelchair shall be fitted with a braking system that includes the following:	
 a) a service brake, which operates independently of tire wear and inflation pressure and operation of which is possible by the user and/or the attendant; 	N/A Yes No Remark
 b) an automatic brake, which operates independently of tire wear and inflation pressure and is operated by putting the speed control input device set for zero speed; 	N/A Yes No Remark
c) a parking brake, which can be operated independently of tire wear and inflation pressure and when there is no battery power and/or motor drive is disconnected (i.e. in freewheel mode) and which can be operated by the user and/or attendant.	N/A Yes No Remark The means to re-engage each gearbox is achieved by re-engaging the freewheel lever.
NOTE: These braking functions may be combined in one device and/or operated by reconnection of the motor drive system.	
 d) if the wheelchair has no service brake operational when in free-wheel mode, parking brakes shall be operable during motion. 	N/A Yes No Remark Arrange each gearbox is achieved by re-engaging the freewheel lever.
If parking brakes are subject to wear from any friction surfaces, tires, etc, they shall have provision for adjustment for any wear that have taken place to the point of replacement as recommended in the manufacturer's documentation and for any wear occurring during the tests specified in 8.2.2.	N/A 🛛 Yes 🗌 No 🗌 Remark 🗍
7.7 Requirement for component weight	
If the wheelchair is intended to be dismantled for ease of carrying:	
a) any component that has a mass greater than 10 kg, shall be provided with suitable handling devices (e.g. handles):	N/A 🛛 Yes 🗌 No 🗌 Remark 🗍
 b) the user manual shall indicate the points where the component part can be lifted safely and/or a method for handling during assembly. 	N/A 🛛 Yes 🗌 No 🗍 Remark 🗍



Item	Requirement Fulfilled			
7.8 Requirements for battery enclosures If batteries are used for the wheelchair propulsion a) they shall be accessible without tools for inspection, service and replacement operations as recommended by the	COPY			
manufacturer;	N/A Yes No Remark			
and b) all battery enclosures shall be ventilated at the highest point by an opening or openings which total not less than 100 mm² in area. NOTE: The openings are to permit escape of gas.	N/A Yes No Remark			
7.9 Battery containers				
7.9.1 Resistance to corrosion				
Battery containers shall be resistant to corrosion caused by battery gases and acid.	N/A Yes No Remark			
7.9.2 Resistance to leakage from battery containers				
If the wheelchair is fitted with batteries containing liquid electrolytes, the battery containers shall not leak when tested according to 7.9.3.	N/A Yes No Remark No The M61 wheelchair is fitted with batteries containing non-liquid electrolyte.			
7.10 Audible warning device	N/A ☐ Yes ☒ No ☐ Remark ☒ Conformance to EN12184:1999			
The wheelchair shall be equipped with an audible warning device.	Conformance to EN12184:1999 Conformance to EN12182:1999 Declaration No:HDAL-5HLSBF; Rev: 7.00			



Item	Requirement Fulfilled
8 Performance requirements	- OPY
	P(0)15 B
8.1 Static impact and fatigue strength	\mathcal{S}
The wheelchair shall comply with the requirements specified in	NA D V NA D Daniel M
ISO 7176-8:1998. The wheelchair shall be tested as specified in	N/A Yes No Remark
ISO 7176-8:1998.	T A ANOLDTONIA WO V-1 1000
	Invacare Tests to ANSI/RESNA WC Vol. –1998
	Section 8 in part or in whole: 062005KH Passed.
	7176-8 Static and Impact Strengths
Wheelchairs of Type Class A (see 5) are excluded from the Drop	061605TM.1 Passed.
Test, ISO 7176-8:1998 Clause 10.5.	10.4 Drum with 300 lbm user mass
Further requirements and tests beyond those specified in ISO	10.5 Drop with 300 lbm user mass
7176-8:1998 are considered to be necessary and may be	050205JT.1 Passed.
considered for a future development of this standard. These	10.4 Drum with 300 lbm user mass
include the following: - Impact strength of anti-tip levers;	10.5 Drop with 300 lbm user mass
 Impact strength of anti-tip levers; Impact strength of curb climbers; 	111804JM.2 Passed.
- Fatigue strength of brake mechanisms, other than	10.4 Drum with 300 lbm user mass
manually operated brakes;	10.5 Drop with 300 lbm user mass
- Strength of steering mechanisms (e.g. manual handle bar	
steering systems for scooters).	Class: A
Steeling systems are all the steeling systems	
8.2 Parking brake performance and strength	
0.2 Tailing brance personners	
8.2.1 Requirements for parking brakes	N/A Yes No Remark
•	See Remark in 7.6
8.3 Control input devices	
	N/A Yes No Remark
8.3.1 Requirement for fatigue strength of joystick and lever	Conformance to EN12184:1999
operated control input devices	Conformance to EN12182:1999
	Declaration No:HDAL-5HLSBF; Rev: 7.00
8.4 Performance of driving characteristics	
The Label and the driving performance	Class: A
The wheelchair shall meet the driving performance requirements specified in Table 2 for the Type Class(es) of use	Class. A
for which the wheelchair is intended.	
for which the wheelchair is intended.	
Requirements for ability to climb maximum safe slope	
The wheelchair shall be capable of climbing at a minimum	
speed of 2 km/h	
- the appropriate maximum safe slope specified in Table 2;	
or	
- any greater maximum safe slope claimed by the	
manufacturer, whichever is the greater.	
The wheelchair passes the test specified in 8.4.2.2 if it	
achieves or exceeds a speed of 2 km/h after traveling 5 m up	
the specified maximum safe slope.	



Item				Requirem	ent Fulfil	led			
	Minimum								
		Type Class			C1		d by Taylorani		
		A	В	c		Maximum 9 degrees		pe ciaime	ed by Invacare is
Maximum safe sl	one	3°	6°	10°		9 degrees	•		
iviaxillium sale si	Орс					N/A □	Yes 🖂	No 🗌	Remark 🔀
						Invacare 7			
Dynamic Stability	v: ISO 7176-2								
		M	inimum	slope		Class: A			
Dynamic Stability	/		Type C						
		A	В	C		N/A □	Yes 🖂	No 🗌	Remark 🔀
starting forwards	uphill *	3°	6°	10°		Invacare T	Tests:	140	Remark 🖂
stopping forwards	s uphill *	3°	6°	10°		121404JM 012505JM			
stopping forwards	downhill *	3°	6°	10°		N/A	Yes 🖂	No 🗌	Remark 🔀
stopping backwar	ds downhill *	3°	6°	10°	_	See above N/A	Yes 🖂	No 🗌	Remark 🔀
turning on horizon	ta1 **		tipping ance poi			See above	Yes 🖂	No \square	Remark 🔀
turning on nonzon	emmer of the second	Jun	occui			See above	8 41 4 54		
			,, , ,,,			N/A See above	Yes 🛚	No 🗌	Remark 🔀
* Limiting stability is any visible lifting of all uphill wheels ** Test does not apply to manually steered wheelchairs					~ 1	<u>.</u> .			
50000000 1 (000000000 1 1 1				~ ((0)/1				
Lateral dynamic stability while turning in circles, ISO 7176-2:2001 10.3 was measured to be 0 m during this Test. This			176-		$_{2}(\bigcirc)/_{2}$	5			
2:2001 10.3 was m	easured to be to	om au and is	iring un stable v	s Test. vhile doi	iiis ig so.	((
wheelchair turns on its own axis and is stable while doing so.					<i></i>				
Static stability: ISO/FDIS 7176-1:1997				Note: Usin	g 7176-1:	1999. 199	7 Rev unavailable.		
	Type Clas	s	Min	n. Slope					
All Directions	A			6°					
All Directions	В			9°	_				
All Directions	С			15°					
Forward									
						2000 - 10	Yes 🛚	No 🗌	Remark 🛚
a) Front wheels unlocked				Invacare T 121404JM 012505JM	ests:				
b) Front wheels locked			The state of the s	Yes 🛚	No 🗌	Remark 🛚			
Rear									
c) Front wheels unlocked			N/A See above	Yes 🛚	No 🗌	Remark 🔀			

4				
	INV	S .	RE	
	Remark	\boxtimes		

Item			Requirement Fulfilled		
d) Front wheels locked			N/A ☐ Yes ☒ N See above	No ☐ Remark ⊠	
1 116			N/A ☐ Yes ⊠ N See above	io 🗌 Remark 🔀	
1	right		A CONTRACTOR OF THE CONTRACTOR	lo ☐ Remark ⊠	
	Stab	pility direction	Actual Tipping angle, degrees		
			Least stable	Most stable	
	Forward	Front wheels locked	18	21	
		Front wheels unlocked	18	23	
	Rear	Rear wheels locked	14	15	
		Rear wheels unlocked	>25	>25	
S	Sideways	Left	20	24	
		Right	20	24	
8.4.1 EN 12184 Table 2, continued Brake effectiveness ISO 7176-3:2003 Parking Brake Requirement: A: 6 degrees, B: 9 degrees. Automatic Brake Requirement: A: 6 degrees, B: 9 degrees.			See Remark in 7.6 N/A ⊠ Yes □ N	No	
6 Clause	10 (settings specif	ISI/RESNAWC/Vol.2-1998 Section fied by the manufacturer).	Class: A (All Classes sa	me Requirements)	
a) forwards horizontal: 15 km/h max measured: 6.4 km/h			N/A ☐ Yes ⊠ N Invacare Test 081605KI		
 b) reverse horizontal: Maximum allowed is equal to 70% of max fwd speed of the wheelchair or 5 km/h, whichever is lower. measured: 2.9 km/h 			N/A ☐ Yes ⊠ N Invacare Test 081605KI	lo □ Remark ⊠ H Passed.	
Obstacle climbing ability ISO 7176-10 Class A: 15 mm min measured: 60 mm			N/A Yes N Invacare Test 071405KI The M61 power chair cl obstacle with & without disclosure only, the M6 from a 60 mm high obst had a measured ground	imbed a 60 mm high 0.5 m run-up. For l power chair descended acle without tipping and	



Item	Requirement Fulfilled		
Turn-around width between limiting walls ISO 7176-5			
Class A: 1300 mm max Measured: 495 mm	N/A Yes No Remark No Invacare Test 061505KH Passed.		
Minimum turning radius ISO 7176-5			
Class A: Measured: 495 mm 1000 mm max	N/A ☐ Yes ☒ No ☐ Remark ☒ Invacare Test 061505KH Passed.		
Range ISO 7176-4	Class: A		
Class A: 15 km min. measured: 20.47 km	N/A ☐ Yes ☒ No ☐ Remark ☒ Invacare Test 050205JT.1.		
Deceleration ISO 7176-6			
Requirement: Maximum value of deceleration peak lasting more than $0.03 \text{ s} = 4 \text{ m/s}^2$ Measured: 0.5 m/s^2	N/A ☐ Yes ⊠ No ☐ Remark ⊠ Invacare Test 081605KH Passed.		
Stopping distance ISO 7176-6			
Requirement: Maximum horizontal stopping distance = 1.2 m (EN 12184:1999 Table 3 for 4.25 m/hr = 6.84 km/hr)			
Measured: 0.8 m	N/A Yes No Remark No Invacare Test 081605KH Passed.		
8.5 Surface temperature EN12182			
Surfaces which can come into constant direct contact with the user's skin during normal use and including at least those within the envelope illustrated in Figure C.1 shall not exceed 41° C as measured by the method specified in EN 12182:1997, Surface temperature.	N/A ☐ Yes ☒ No ☐ Remark ☒ Maximum ambient operating temperature = 50 degrees C per 7176-9:2001. Product Risk Analysis: Pronto M61 Part No.: 1127273 Rev. D, attached.		
8.6 Noise			
When the wheelchair is tested as specified in EN 12184:1999 8.6.2, the sound pressure level shall not exceed: - Class A: 65 dB(A) - Class B and C: 75 dB(A)	Class: A N/A ☐ Yes ☒ No ☐ Remark ☒ Invacare Test 063005KH Passed.		



Item	Requirement Fulfilled
8.7 Environmental protection	
8.7.1 Operating and storage temperature The wheelchair shall comply with the operating and storage temperature requirements of ISO 7176-9:2001.	N/A ☐ Yes ☒ No ☐ Remark ☒ Invacare Test 071405KH.2 Passed.
8.7.2 Water resistance	
When tested as specified in EN 12184:1999 8.7.2.2 the wheelchair shall perform as follows: a) immediately after application of the water and switching on the controller no unexpected movements shall occur; b) the steering, driving and braking functions of the wheelchair shall operate as specified by the manufacturer after intervals of i) 5 min +- 1 min; ii) 60 min +- 5 min; and	COPY
iii) 24 h +- 30 min, after applying water.	N/A ☐ Yes ☒ No ☐ Remark ☒ Invacare Test 071405KH.2 Passed
8.8 Resistance to ignition	
If the wheelchair is equipped with upholstered parts it shall conform to the ignition requirements of ISO 7176-16:1997.	N/A Yes No Remark No Invacare Test 060105.B by Omega Point Laboratories Passed.
9. Electrical requirements	
9.1 General requirements	
The wheelchair shall conform to the requirements of ISO 7176-14:1997.	N/A Yes No Remark No Invacare Test 071405KH.1 Passed. Load the wheelchair using 300 lbm user mass. Use ANSI/RESNA WC/Vol.2-1998 Section 6 Clause 10 (settings specified by the manufacturer).



Item	Requirement Fulfilled
COPY	Exceptions to ISO 7176-14:1997 called by EN 12184:1999 sub-Clause 9.1: - ISO 7176-14:1997 subclause 6.11 specifies a battery set. Use a variable voltage d.c. power supply instead ISO 7176-14:1997 specifies 5+-0 degrees for the inclined plane for subclauses 6.13, 6.15, and 6.17. Use any angle between 1 and 11 degrees.
	Invacare Tests to ANSI/RESNA WC Vol. –1998 Section 14 in part or in whole: 111804JM.1 Passed
Wheelchairs which include battery chargers that cannot be removed without the use of tools and/or are permanently connected to the wheelchair battery shall conform to the electrical requirements of IEC 60601-1 and the requirements of ISO7176-14:1997.	N/A Yes No Remark Off-board charger. Wheelchair does not include any battery charger that cannot be removed without the use of tools and/or are permanently connected to the wheelchair battery.
NOTE: ISO 7176-14:1997 excludes wheelchairs with on board battery chargers from its scope. The combination of the above clauses from this standard and the requirements of IEC 60601-1 provide a suitable combination of requirements.	
9.2 Requirement for controller switch	
Provision shall be made for the user to switch the controller on and off.	N/A Yes No Remark Conformance to EN12184:1999 Conformance to EN12182:1999 Declaration No:HDAL-5HLSBF; Rev: 7.00
9.3 Requirement for power indicator	
The wheelchair shall be fitted with a device to indicate to the user when power is turned on so that the wheelchair is ready to drive. This indication shall conform to the requirements of IEC 60073.	N/A Yes No Remark Conformance to EN12184:1999 Conformance to EN12182:1999 Declaration No:HDAL-5HLSBF; Rev: 7.00

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Item	Requirement Fulfilled			
9.4 Requirements for circuit protection				
Circuits connected to batteries in the wheelchair shall be protected against excessive current. The following functions of the wheelchair shall not be affected by the grantian of the means of protection of any other fireuity.	N/A ☐ Yes ☒ No ☐ Remark ☒ Invacare Test 071405KH.1 Passed.			
by the operation of the means of protection of any other circuit:				
- driving, braking and steering;	N/A ☐ Yes ☒ No ☐ Remark ☒ Conformance to EN12184:1999 Conformance to EN12182:1999 Declaration No:HDAL-5HLSBF; Rev: 7.00			
- lighting, direction Indicators and hazard warning flashers.	N/A ⊠ Yes ☐ No ☐ Remark ⊠ No such components.			
9.5 Requirements for disengagement of automatic				
brakes It shall not be possible to drive the wheelchair with its own	N/A ☐ Yes ☒ No ☐ Remark ☒ The spring-loaded brake on each motor is always engaged unless wheelchair is commanded to			
motor drive system if the automatic brakes are disengaged.	drive. Conformance to EN12184:1999			
NOTE: This requirement overrides part of 7.2 of ISO 7176-	Conformance to EN12182:1999 Declaration No:HDAL-5HLSBF; Rev: 7.00			
14:1997, concerning requirements for non-powered mobility.	Declaration No.115/15 3115551; Nev. 7.00			
9.6 Requirements for connections to batteries				
Intermediate connections to batteries connected in series shall not be used to supply power.	N/A ☐ Yes ☒ No ☐ Remark ☒ Invacare Test 071405KH.1 Passed.			
Connections to battery terminals shall be insulated when batteries are enclosed in a battery container.	N/A Yes No Remark No Invacare Test 071405KH.1 Passed.			
9.7 Requirements for battery chargers	Off-board charger:			
•	CTE Corporation Part# BAT-GC0812			
	Mains: 1.3 Amp 200 to 250 vac 50 Hz			
	Supply to Chair: 24 v DC 8 Amp			
	TUV Certificate No. Z1 04 06 12941 098			
	Conformance to EN 12184:1999			
Battery chargers for wheelchairs and scooters shall conform to the requirements of clause 9 of ISO 7176-14:1997,	N/A Yes No Remark			
together with the following provisions:				
 Battery chargers shall indicate when charging is in progress and when charging is complete; 	N/A Yes No Remark			
 Battery chargers shall have the capability of charging batteries discharged to 70% of their nominal voltage; 	N/A Yes No Remark			
c) Trickle charging current shall not exceed 500 mA (NOTE: Some chargers may provide a pulsed trickle				



Item		Requirem	ent Fulfill	ed	
d)	charge where the peak current exceeds 500 mA but the average current measured over one pulse period is less than 500 mA); Battery chargers shall operate without the need for intervention or supervision apart from connecting and	N/A 🗌	Yes 🔀	No 🗌	Remark 🗌
	turning on at the start of charging and disconnecting at the end of charging.	N/A 🗌	Yes 🔀	No 🗌	Remark 🗌
9.8	Electromagnetic Compatibility (EMC) EN 12184:1999 Clause 9.8	N/A Yes No Remark Invacare Test 071405KH Passed Performed EN 12184:1999 pertaining to EN 12184:1999 clause 9 sub-clause 9.8. Exceptions: 9.8.2.2 electromagnetic immunity: IEC 6100 3:2002 allows use of GTEM, in which the lopoints of the wheels are not constrained to be a height of 0.8 m. 9.8.2.2 electromagnetic immunity: Test at the higher level required by ANSI/RESNA WC 2-1998 Section 21: 20 v/m (vs EN 12184:1998)			
	Electromagnetic emission while driving EN 12184:1999 Clause 9.8.1	10 v/m). N/A []	Yes 🛚	No 🗌	Remark [
	Electromagnetic immunity, standby (not driving) EN 12184:1999 Clause 9.8.2 a	N/A 🗌	Yes 🖂	No 🗌	Remark
	Electromagnetic immunity while driving EN 12184:1999 Clause 9.8.2 b	N/A 🗌	Yes 🔀	No 🗌	Remark
	Electrostatic discharge (ESD), Human Body EN 12184:1999 Clause 9.8.3.2.1	N/A 🗌	Yes 🛚	No 🗌	Remark
	Electrostatic discharge (ESD), Charged Frame EN 12184:1999 Clause 9.8.3.2.2	N/A 🗌	Yes 🛚	No 🗌	Remark



Item	Requirement Fulfilled
10 Information to be supplied by the manufacturer	
10.1 General	
The wheelchair shall be provided with the documentation and labelling that conform to the requirements in EN 1041:1998 and ISO 7176-15:1996.	N/A ☐ Yes ☒ No ☐ Remark ☒ See attached Information disclosure in
EN 1041:1998:	manufacturer's specification sheets.
4.1.1 Information supplied by the manufacturer and intended for direct visual recognition shall be legible when viewed under an illumination of 215 lx using normal vision, corrected if necessary, at a distance which takes into account the specifics and size of the individual medical device.	N/A Yes No Remark
NOTE 1 The information presented should be understandable by the intended user and/or other persons, where appropriate. NOTE 2 If there is insufficient space on the container or the device, the relevant information may be given on an insert, accompanying document or on the next layer of packaging, as applicable. The recognition of certain markings on small or specialized devices may require the use of methods other than visual, for example, electronic	COPY
 4.1.2 Any symbols used in the information supplied by the manufacturer with the medical devices shall either: a) conform to those specified in harmonized standards, or b) in areas for which no harmonized standards exist, have their meanings explained in the information supplied by the manufacturer with the device. NOTE Examples of harmonized standards are EN 980 and EN 60601. 	N/A ☐ Yes ☑ No ☐ Remark ☐
 4.1.3 Any identification colors used in the information supplied by the manufacturer with the medical devices shall either: a) conform to those specified in relevant harmonized standards, e.g. medical gas cylinders; or b) where no harmonized standard exists, be described together with their meanings in the information supplied by the manufacturer with the device. NOTE Reference to standards which include color coding is given in EN 1041:1998 Annex A. 	N/A ☐ Yes ☑ No ☐ Remark ☐
4.1.4 The information supplied by the manufacturer shall not be presented in such a manner that it obscures other essential information. NOTE The information supplied by the manufacturer should	

INVACARE

Item Requirement Fulfilled				
not be presented in such a manner that it may be confused with other essential information.	N/A □	Yes 🖂	No 🗌	Remark
4.1.5 Any units of measurement units shall be expressed in SI units as specified in ISO 31, or other legal units. NOTE 1 Attention is drawn to Council Directive 80/181/EEC as amended, see EN 1041:1998 Annex A, and to ISO 1000 which gives further guidance on the application of SI units. NOTE 2 This requirement does not preclude the additional use	(N	
of other units as allowed by harmonized standards.	N/A	Yes 🖂	No 🗌	Remark
4.1.6 As far as is practicable and appropriate, the information needed to use the device safely shall be set out on the device itself and/or on the packaging for each unit, or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information shall be set out in	N/A □	Yes ⊠	No 🗍	Remark [
the leaflet supplied with the device(s).	IVA L	103 🖂	110	Remark
4.1.7 User adjustable controls shall have their function clearly specified.	N/A □	Yes 🛚	No 🗌	Remark 🗌
4.1.8 Any detachable component, intended by the manufacturer to be used separately from the original device, shall be identified by its batch code, or by other appropriate means.	N/A ⊠	Yes 🗌	No 🗌	Remark 🗌
4.1.9 The address of the manufacturer shall be provided in sufficient detail to enable contact to be established NOTE Specific legal requirements apply to devices imported into the European Union, see EN 1041:1998 Annex C, 13.3a).	N/A 🗌	Yes 🔀	No 🗌	Remark [
4.1.10 Any date shall be expressed in the format YYYY-MM-DD, or YYYY-MM, or YYYY, in accordance with EN 28601. NOTE The choice of format will be determined by the requirements of the relevant Directive(s) and the specific nature of the device itself.	N/A ⊠	Yes 🗌	No 🗌	Remark [
Manage CV, MC 237, CC 105-12-1				



Item		Requirement Fulfilled				
10 I	nfor	mation to be supplied by the manufacturer, continued				
		eral, continued				
ISO	7176	5-15:1996 7.3 Contents of user manual		~<	$\sqrt{1}$	
				(D)	//	
Use	r man	ruals shall contain the following information:	(A)	()	U	
		ls of the warranty, or if no warranty is provided, a		\bigcirc		
	state	ment to that effect;	N/A	Yes 🛛	No 🗌	Remark
b)	gene	ral characteristics as follows:				
50020	i)	description of the wheelchair type, accompanied by				
		pictures or drawings of the wheelchair and a non-				
		technical description of how the wheelchair is				
		intended to be used,	N/A 🗌	Yes 🖂	No 🗌	Remark
	ii)	description of the intended user, including maximum		00.00	5000000000	
		occupant mass,	N/A 🗌	Yes 🖂	No 🗌	Remark
	iii)	the environment in which the wheelchair is intended				
		to be used and any environmental conditions that				
		might be harmful to the wheelchair, such as		_		
		temperature and humidity,	N/A	Yes 🖂	No 🗌	Remark
	iv)	if pneumatic tires are fitted, the recommended				-
		inflation pressure or pressure range, given in	N/A ⊠	Yes 🔝	No 🔙	Remark 🛚
		kilopascals;				ranslation to US
						ire pressure is
						e." This ensures
		heelchair is marketed for user-assembly, the	correct inf	lation if the	e tire is cha	anged.
	follo	wing information:		🗀		
	i)	a list of components;	N/A ⊠	Yes [No 🗌	Remark 🗌
	ii)	information about any tools or equipment needed to	27/4 57	v . 🗆	N []	D 1 [
	•••	assemble the wheelchair,	N/A ⊠	Yes 🗌	No 🗌	Remark
	111)	instructions on how to inspect for missing or	N/A ⊠	Yes \square	No 🗌	Remark
		damaged parts,	N/A 🖂	1 62 🗀	NO [Kelliark []
	10)	instructions for assembling, installing and removing any parts supplied by the manufacturer;	N/A	Yes 🖂	No 🗌	Remark
)	instructions how to prepare the wheelchair for	IVA 📋	1 63 🖂	140	Remark
	٧)	storage, shipment or travel, for example removal of				
		any batteries;	N/A 🗍	Yes 🖂	No	Remark
d) in	etruet	tions for operation of the wheelchair as follows:	11/11	100 2	.,.	Komark 🗀
u) III	i)	complete operating instructions for safe use				
	1)	including:				
		- instructions for operating the wheelchair on				
		surfaces likely to be encountered by the user,	N/A	Yes 🛛	No 🗌	Remark
		- instructions for transfer of the user to and from the		-		
		wheelchair,	N/A	Yes 🛛	No 🗌	Remark
		- illustrations to clarify these instructions	N/A	Yes 🛛	No 🗌	Remark
		NOTE – Illustrations should be given for the				
		following situations: ramps, steep terrain, curbs				
		and steps, and transfer.				
	ii)	any common misuse of the wheelchair known by the				
	ń	manufacturer that might lead to personal injury or				
		damage to the wheelchair;	N/A	Yes 🛛	No 🗌	Remark



Item	Requirement Fulfilled			
e) maintenance instructions accompanied by annotated			$\sim \Pi$	
illustrations, and the following information:		~ 100	VI	
i) details of any maintenance, including:				
- any service, maintenance and/or fault-finding for		O 0		
which the manufacturer intends the user to be				
responsible,	N/A	Yes 🛛	No 🗌	Remark
- information about the type of tools or equipment	N/A 🛛	Yes 🗌	No 🗌	Remark 🛛
needed to repair and service the wheelchair,	Manual di	rects user t	o qualified	Dealer.
- frequency of maintenance,	N/A	Yes 🖂	No 🗌	Remark
- a list of materials necessary, including any part	N/A 🔯	Yes 🗌	No 🗍	Remark 🔀
numbers and procurement information,		rects user t	o qualified	
- identification of circumstances in which an			3	
operation should be undertaken by the				
manufacturer, distributor or service agent,	N/A 🗌	Yes 🖂	No 🗌	Remark
ii) instructions on methods of cleaning,	N/A	Yes 🖂	No 🗍	Remark
iii) for parts that the manufacturer intends to be readily	1071	. 40 🔼		
replaced, the following:	Manual di	rects user t	o qualified	Dealer:
- ordering information,	N/A ⊠	Yes 🗌	No 🗌	Remark
- instructions for access removal,	N/A ⊠	Yes	No 🗍	Remark
- replacement and testing, and	N/A	Yes 🗌	No 🗌	Remark
- annotated illustrations of the parts (including tires	N/A ⊠	Yes 🗌	No 🗆	Remark
	14/11/25	1 00 🗀	110	rtomark
and batteries) and their location, iv) information on how to perform potentially hazardous				
maintenance operations, such as battery servicing and	N/A □	Yes 🖂	No 🗌	Remark
	IVA [1 63 2	110	remark
tire inflation;	N/A 🗌	Yes 🖂	No 🗌	Remark
f) instructions for carrying out performance checks; g)description of wheelchair repair procedures as follows:	MAL	1 63 🖂	110	remark
i) identification of parts that are intended to be repaired	N/A ⊠	Yes 🗌	No 🗌	Remark
	11//1	103	1,0 🗀	Roman C
by the user ii)identification of parts that have to be serviced by the				
manufacturer or an authorized service facility in order				
to maintain warranties and service ability,	N/A 🗌	Yes 🖂	No 🗌	Remark
to maintain warrantes and serviceability,	IVIA [1 63 2	110	Roman
iii)identification of any parts that can be removed and				
sent to the manufacturer/distributor or other party for	N/A 🖂	Yes \square	No 🗌	Remark
repair,	MYM	1 63 🗀		Roman K
iv)identification of circumstances in which the				
manufacturer, distributor or service agent should	N/A 🗌	Yes 🖂	No 🗌	Remark
undertake the repair,	N/A [103	140	Romark
v) a list of authorized service facilities (If this				
information is not known, a clearly marked space for				
this information to be added by the supplier should be	N/A 🗌	Yes 🖂	No 🗌	Remark
provided.),	N/A	i es 🖂	110	Remark
vi) information on whether or not any replacement units	NI/A 🖂	Yes 🗌	No 🗌	Remark 🖂
are available,	N/A ⊠ Manual di			
		rects user to		
vii)packing and shipping instructions when necessary.	N/A ⊠	Yes 🔝	No	Remark

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Item		Requirement Fulfilled			
10.2	User Manual	6	>0[PY	
	Idition to the requirements of 10.1, the manufacturer shall in the user manual the following:	0		•	
•	The wheelchair classification (Type Classes A, B or C);	N/A 🗌	Yes 🛚	No 🗌	Remark
۰	The maximum safe slope;	N/A 🗌	Yes 🔀	No 🗌	Remark
٥	The maximum climbing ability when on a slope facing upwards;	N/A 🗌	Yes 🛚	No 🗌	Remark
۰	The maximum obstacle climbing ability;	N/A 🗌	Yes 🛚	No 🗌	Remark
9	The battery type, capacity, size, max current and connector configurations;	N/A 🗌	Yes 🖂	No 🗌	Remark [
•	The charger specification;	N/A 🗌	Yes 🛚	No 🗌	Remark [
•	A warning that any transportation on a slope may be dangerous, if the automatic brakes are disengaged;				Remark 🔀 otor is always mmanded to drive.
•			Yes 🏻	No 🗌	Remark 🗌
۰	A warning that the wheelchair itself can disturb the performance of electromagnetic fields such as emitted by alarm systems of shops:	N/A 🗌	Yes 🖂	No 🗌	Remark 🗌
•	II willing of risks in connection with the suppose	S. Company	Yes [] l electrolyte	No 🗌	Remark 🔀
•	A recommendation for the recycling of used batteries;	N/A 🗌	Yes 🔀	No 🗌	Remark [
•		N/A ⊠ This whee only.	Yes [] chair conta	No 🗌 iins a seat _l	Remark 🔀 positioning strap
•	The method of attaching anti-tip devices, if they are supplied;	N/A ⊠	Yes 🗌	No 🗌	Remark
	if a curb-climbing device is needed, the type of device recommended and instructions for its use;	N/A ⊠	Yes 🗌	No 🗌	Remark
	if the manufacturer claims the wheelchair is designed for use as seat in motor vehicles, the method of attaching wheelchair tie down and occupant restraints and				

					A CONTRACTOR AND A CONT	
Ite	m	Requirement Fulfilled				
	recommendations about suitable tie down and restraint systems;	N/A ⊠	Yes	No 🗌	Remark	
•	if a wheelchair is fitted with special driving/braking adjustment devices, the recommended settings of these devices;	N/A ⊠	Yes 🗌	No 🗌	Remark 🗌	
9	if a programmable controller is fitted, the method of programming the controller, who should carry out the programming and what effect it has on driving performance;	N/A Manual re	Yes ⊠ efers to Elec	No 🗌	Remark ⊠ anual.	
•	a warnings if the wheelchair is capable of climbing slopes steeper than the maximum safe slope and on the risks when driving and manoeuvring forward and, especially, backward on these slopes;	No claim	Yes of capabilit naximum sa		Remark ⊠ ing slopes steeper	
•	a warning that the wheelchair may interfere with kerbs when mounting or dismounting if anti-tip devices are fitted	N/A ⊠	Yes 🗌	No 🗌	Remark 🗌	
•	a warning if driving characteristics can be adjusted outside safe limits specified in Table 2 and 3 (EN 12184:1999 page 30-31 and 32);	N/A ⊠	Yes 🗌	No 🗌	Remark 🗌	
•	a warnings if instability can arise during turning, e.g. for manually steered wheelchairs;	N/A ⊠	Yes 🗌	No 🗌	Remark	
9	wheelchairs of class C with a turning radius exceeding 1.500 mm shall bear a warning that it may be difficult to turn in front of lifts or building entrances, since they contradict standards for buildings.	N/A ⊠ Not Class	Yes C. Turnin	No 🗌 g radius no	Remark 🛭 st exceeding 1.5mm.	
10.3	Labeling					
	ddition to the requirements of 10.1, the manufacturer shall y the following labeling:					
1	devices for disengagement of the automatic brakes shall be marked clearly, showing engaged and disengaged positions and marked with a warning, that caution must be taken on slopes;				Remark 🔀 otor is always ommanded to drive.	
• 1	the information and connection details specified in clause 9 of ISO 7176-14:1997 shall be displayed on the front of the	N/A TUV Cert	Yes ⊠ ificate No.	No Z1 04 06 1		

Conformance to EN 12184:1999

battery charger.



Item	Require	nent Fulfil	led	
10.4 Specification sheet				
In addition to the information specified in ISO 7176-15, manufacturers shall disclose the following information in their specification sheets:	See attached Information disclosure in manufacturer's specification sheets.			
 the maximum height of kerb which the wheelchair can descend; 	N/A 🗌	Yes 🛚	No 🗌	Remark [
• the maximum height of obstacle which will pass underneath the wheelchair;	N/A 🗌	Yes 🛚	No 🗌	Remark 🗌
• the turning space.	N/A 🗌	Yes 🛚	No 🗌	Remark 🗌
Requirements for protection against single fault EN 12184:1999 A.4.4	2 of a contract of the contrac			
The wheelchair should not move after a single fault has occurred in the drive circuit and the joystick has returned to its neutral position.	N/A 🗌	Yes 🏻	No 🗌	Remark
Additional requirements from TUV PPP 03/96:		,	M	
Controller Single Fault		$ \mathcal{C}^{0} $		
The wheelchair shall at least conform to the principle of "Dead Man" stopped by a protection system independent from the controller when a Single Fault occurs in safety-relevant components of the electronic controller for driving and		9		
steering. This means that the wheelchair shall stop safely when the joystick is released.	N/A 🗌	Yes 🛚	No 🗌	Remark [
If no complete exclusion of errors in the independent protection system is possible, it shall be possible that its function can be tested prior to starting a drive.	N/A ⊠	Yes 🗌	No 🗍	Remark 🗍
The test shall start automatically when the main switch is	1111	. • • •	,,,	
switched on or the user shall perform the test at least once a day without any problems.	N/A □	Yes 🛛	No 🗌	Remark 🗌
The test handling shall differ from the controller handling so that mis-operations are avoided.	N/A 🗌	Yes 🛚	No 🗌	Remark 🗌
If a safety-relevant error is recognized during the test, it shall not be possible to start the drive mode.	N/A 🗌	Yes 🛛	No 🗌	Remark 🗌



Item	Requiren	ient Fulfill	ed	
If an automatic test of the controller and the steering is performed when the wheelchair is switched on, it must not be possible to start the drive mode, if a safety-relevant error was recognized.	N/A 🗌	Yes 🔀	No 🗌	Remark 🗌
The operating instructions shall contain clear reference to the performance of this test.	N/A ⊠ This test is	Yes totally aut	No 🗌 omated.	Remark 🛚
Errors which occur in the protection system being independent from the controller during the drive mode shall not influence safe road performance. They should be displayed; however, they should not cause an immediate switching off.	n/a 🗌	Yes ⊠	No 🗌	Remark [
Actuating of operating elements shall not lead to unintended malfunctions, which cause dangers (not Single Fault), when the wheelchair is in normal mode.	N/A 🗌	Yes 🛚	No 🗌	Remark [
If operating elements of additional drives e.g. seat adjustment are released, the movement shall automatically stop (not Single Fault).	N/A 🗌	Yes 🛚	No 🗌	Remark 🗌
The controller shall work completely, even if the battery is completely discharged.	N/A 🗌	Yes 🛛	No 🗌	Remark 🗌
If the battery is not completely discharged, no malfunctions of	N/A 🗌	Yes 🛛	No 🗌	Remark



14	Other
Test	quipment calibration on-file.
	1
Addition to the second	
-	
-	
(1)	
<u> </u>	
	