PEGASUS ZORG BV, 2516 AJ THE HAGUE, THE NETHERLANDS

Clinical Evaluation for Mobile devices

The document is established according to the MEDDEV 2.7.1 Rev 3. „Guidelines on medical devices: Clinical Evaluation: a guide for manufacturers and notified bodies“

1. General Details

The manually powered wheelchair, type: Varia is classified as a 12 22 03 Bimanual wheel-propelled wheelchair according to ISO 9999:2011. Varia is a wheelchair base frame suitable for Orthese and Modular seating systems. Its purpose is to transport people that are not able to walk on their own for longer distances or cannot walk permanently. The Varia is not used by the wheelchair driver. The product is basically sold worldwide.

Varia is assembled at Pegasus Zorg bv, Melkwegstraat 16, 2516 AJ, The Hague, The Netherlands.

Due to the fact that the Varia has no therapeutic or diagnostic purpose as it is not used by the wheelchair driver himself, the evaluation was directed toward the state of the art, existing, well-established technologies on manually propelled wheelchair design, conform use, safe use and reporting of negative side effects known in literature.

Varia

2. Description of the device

The product described does not perform any therapeutically or diagnostic purpose.
The product is used to:

- Assist in transport for persons with disability.

2.1 Clinical

Intended use:
No clinical use for the wheelchair driver.
Contradictions:
No contractions known

Application range:
Manually propelled wheelchairs are medical devices due to the MDD 93/42/EEG, they are ranked as devices to the compensation of injuries and/or handicaps. According to MDD 93/42/EEG manually propelled wheelchairs are class 1 devices. CE marking applies to all manual wheelchairs in accordance with the guideline.

Moreover, the product is classified according to EN 12183:2009 as 12 22 03 Bimanual wheel-propelled wheelchair (for use in indoor and outdoor areas). These indoor and outdoor products are able to overcome many obstacles in outdoor areas. All technical data, such as turning radius, safe climbing ability, dimensions, maximum obstacle height and operating conditions can be found in the user manual. The vehicle is successfully tested according to international standards concerning its safety.

User group:
For the Varia the maximum user weight is 120kg. Slopes and gradients up to 5% can be safely crossed (depending on the user´s weight).

Age of user group:
There are no age restrictions known for this device.

Place of application:
The place of application is related to the class according to EN 12183:2009, which covers the Varia wheelchair (for use in indoor and outdoor areas). Dangerous ground and dangerous situations as described in the user manual are to be avoided.

Physiology:
The attending person operating the Varia is not handicapped.

2.2 Technical

Conditions of use:
The Varia is well suited for indoor and typical middle European weather conditions. The Varia is suitable for the use on sidewalks and on public roads (not for use on the highway). Appropriate environmental conditions (like climbing ability and max. obstacle height) of use are described in the user manual.

Design:
The Varia wheelchair is a well-designed, easy to use wheelchair. Pegasus Zorg doesn't deliver directly to the consumer but through wholesale.
For transportation purposes, the armrests can be easily dismantled without the use of tools, as described in the user manual. The heaviest component does not weight more than 1.6 kg, which makes transportation light and simple.

Ergonomic product design makes the Varia very comfortable for indoor and outdoor use (Class I, EN 12183:2009).

The steering is done manually by the attendant.

Specifications:
All technical data, such as turning radius, safe climbing ability, maximum obstacle height and permissible operating conditions can be found in the user manual.

Technical Data		
Maximum user weight	120	kg
Seating width	54-62	cm
Seating depth	45.5	cm
Seating height	42.61	cm
Back height	51	cm
Total width	45	cm
Total length	62	cm

Wheels		
Front wheels	200 x 30	Solid tyre
Rear wheels	12 ½ x 2 ¼	Pneumatic tyre

The Varia wheelchair standard includes:
- Wheelchair base frame
- Armrest unit

2.3 Biological

Main points addressed are biological compatibility with skin touching surfaces. Cytotoxicity tests according to DIN EN ISO 10993-5:2009-10 have been carried out and successfully passed for fabrics which could get in contact with the skin during use.

3. Results from risk assessment

3.1 Potential risks from risk assessment

Risks originate mainly from technical, material, foreseeable misuse and mechanical characteristics of the product. Basis for the review was the risk analysis due to DIN EN ISO 14971:2004.

Main points considered are:

Energy hazards:
- Thermal energy
- Moving parts
- Acoustic energy

Hazards related to information:
- Inadequate labelling
- Inadequate operating instructions
- Inadequate maintenance
- Inadequate warnings

Operational hazards:
- Functional hazards
- Use hazards
- User weight above the defines maximum weight

Biological and chemical hazards:
- Biological hazards
- Breakage of aged product due to missing or incorrect maintenance
- Animal tissue
- Liquids
- Irritation of skin

For all the risks mitigation actions were defined and implemented where the risks were not acceptable to the user.

The potential risk associated with the use of a manually propelled wheelchair while being operated by an attendant is generally significantly lower than the risk associated with the use of a wheelchair that is operated by the handicapped person himself. The Varia is always and only operated by the attendant of the wheelchair, thus by persons without handicap.

3.2 Post market information on claims, complaints and vigilance reporting

The findings are supported by the report 'Device Bulletin, Adverse Incident Reports 2008, DB2009(02), March 2009'. This medical device adverse incident annual report, published as Device Bulletin DB 2009(02), provides an overview of medical device related adverse incidents reported to the MHRA in 2008, and records recent developments in incident reporting.
Concerning powered mobility the following results were reported:

Wheelchairs and children's buggies
Adverse incident reports concerning all types of powered and non-powered wheelchairs used by children and adults decreased in 2008 by 17% to 703.
Investigations led to many changes in designs and instructions for use and 11 Medical Device Alerts were issued. MDAs 2008/014, 035, 050, 052, 070, 072 and 077 involved issues concerning the wheelchair being used as a seat in a motor vehicle, MDAs 2008/029 and 076 covered problems with stability and MDAs 2008/044 and 078 involved failure of the wheelchair backrests.
Please note that the Varia is not intended to be used as a seat in any vehicle.

4. Method

4.1 General

Selection, identification, evaluation and collection are described for evaluation of the studies.

4.2 Target

The document has the purpose to prove the efficiency and effectives of powered and non-powered wheelchairs.

The conformity assessment is done following the requirements of the Medical Device Directive 93/42/EEG.

Functional user assessment and tests proved the effectiveness of the Varia as a trustable product that meets the needs of persons with walking disabilities.

Experience can also be drawn from the Varia, the 5th manually propelled wheelchair designed and produced by Pegasus Zorg from 2002-2014, and the previous model: type Dego II which has been produced from 2004 - 2014. In addition to the long experience in production, reconditioning and use of this product and other spare parts like therapy tables, headrests and legrests Pegasus Zorg performs customer surveys on a regular basis.

All required standards and technical documents for medical products were applied.

Nevertheless, further evaluation is done by a literature search that is described from chapter 4.3 to chapter 6 of this Clinical Evaluation.

Due to the fact, that products as a manually propelled wheelchair have no therapeutic or diagnostic purpose, the application (mechanism of action) cannot be accessed. Therefore, the target of the clinical evaluation was to assess:

- Possible negative side effects
- The safety of the product
- Technological aspect

4.3 Identification of data

For the review main focus for the literature search was on “pier reviewed” articles.
Database used:

- www.scholar.google.com and
- www.elsevier.com

To ensure the medical relevance of the findings.

The key word used for the desk research was: “manual wheelchair”.

If the search on above mentioned databases had not led to relevant findings, additional research would have been performed in the following databases, using the same key word:

- Pubmed: http://www.ncbi.nlm.nih.gov/pubmed
- Amedeo: http://www.amedeo.com
- PEDro: http://www.pedro.org.au
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4.4 Data evaluation

The reviewed documents are evaluated according the below ranking system:

Ranking	Description
1	Intended use, application and technology identical
2	Intended use, application and technology similar
3	Intended use, application and technology comparable
4	Technology comparable
5	Eventually comparable
6	Not comparable

5. Literature search

Find the listing of articles found with the search criteria:

Nr.	Author	Title	Published	Remark	Rank
1	Michalle M. DiGiovine, BS, Rory A. Cooper, PhD, Michael L. Boninger, MD, Brad M. Lawrence, MS, David P. VanSickle, PhD, Andrew J. Rentschler, BS	User assessment of manual wheelchair ride comfort and ergonomics	2000-04-04		2
2	Anna-Liisa Salminen, PhD1, Åse Brandt, PhD2, Kersti Samuelsson, PhD; Outi Töytäri, Msc; Antti Malmivaara, PhD	Mobility devices to promote activity and participation: A systematic review	J Rehabil Med 2009; 41: 697–706		3
3	Dan Ding, PhD; Elizabeth Leister, MS; Rory A. Cooper, PhD; Rosemarie Cooper, MPT, ATP; Annmarie Kelleher, MS, OTR/L, ATP; Shirley G. Fitzgerald, PhD; Michael L. Boninger, MD	Usage of tilt-in-space, recline, and elevation seating functions in natural environment of wheelchair users	JRRD, Journal of Rehabilitation Research & Development Volume 45, Number 7, 2008 Pages 973–984		2
4	Richard C. Simpson, PhD, ATP; Edmund F.	How many people would benefit from a	JRRD, Journal of Rehabilitation		2

	LoPresti, PhD; Rory A. Cooper, PhD	smart wheelchair?	Research & Development Volume 45, Number 1, 2008 Pages 53–72		

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6. Critical Evaluation

6.1 General Comments

Of all abstracts found in the data bases using the key word “manual wheelchair”, for further evaluation of the Varia only the abstracts were used originating from sources that dealt with similar or identical products. Abstracts considered relevant had to have the following similarities:

- Intended use (manual wheelchair, ..)
- Usage is similar (wheelchair, similar technology, …)

For the evaluation itself, only abstracts were considered with a ranking from 1-3. Studies with very view propends (<3 people) were excluded, because of the reduced validity.

Studies in non-English language were not taken into consideration. As the outcome of the research in the data bases was rather limited, and due to the fact that manual wheelchairs as such have been on the market for a long time without having to undergo significant changes in the basic design principles, all otherwise relevant studies published within the last 30 years have been taken into consideration.

Short summaries of the abstracts and articles taken into account are presented in the following chapter are presented in the next part of the evaluations.

6.2 Abstracts/Summaries of relevant articles

Nr. 1	**Abstract**
Source: American Congress of Rehabilitation 2000 **Remark:** **Author(s):** Michalle M. DiGiovine, BS, Rory A. Cooper, PhD, Michael L. Boninger, MD, Brad M. Lawrence, MS,	DiGiovine MM, Cooper RA, Boninger ML, Lawrence BM, VanSickle DP, Rentschler AJ. User assessment of manual wheelchair ride comfort and ergonomics. Arch Phys Med Rehabil 2000;81:490-4. **Objective:** To examine wheelchair-user perceived ride comfort during propulsion and to compare the ride comfort of ultralight and lightweight manual wheelchairs. An ultralight wheelchair is defined as having a high degree of adjustability, whereas a lightweight wheelchair has minimal adjustability. **Design and Participants:** Repeated measures design of a sample of 30 community-dwelling manual wheelchair users evaluating 7 different manual wheelchairs over an activities of daily living course. **Setting:** A rehabilitation engineering center.

David P. VanSickle, PhD, Andrew J. Rentschler, BS **Title:** User assessment of manual wheelchair ride comfort and ergonomics	There are differences in perceived ride comfort and basic ergonomics between the designs of the wheelchairs
Nr. 2	**Abstract**
Source: J Rehabil Med 2009; 41: 697–706 **Remark:** **Author(s):** Anna-Liisa Salminen, PhD1, Åse Brandt, PhD2, Kersti Samuelsson, PhD; Outi Töytäri, Msc; Antti Malmivaara, PhD **Title:** Mobility devices to promote activity and participation: A systematic review	The best study in methodological terms (20, 21) showed that powered wheelchairs clearly increased activity and participation as well as quality of life in stroke patients. Three studies reported adverse effects, i.e. difficulty in disassembly (26), low accident rate (25) and slightly increased falls (29). The outcomes are presented in Table IV. In this article we learned that stroke patients have a low accident rate but had difficulties to disassemble the products.
Nr. 3	**Abstract**
Source: JRRD, Journal of Rehabilitation Research & Development Volume 45, Number 7, 2008 Pages 973–984 **Remark:** **Author(s):** Dan Ding, PhD; Elizabeth Leister, MS; Rory A. Cooper, PhD; Rosemarie Cooper, MPT, ATP; Annmarie Kelleher, MS, OTR/L, ATP; Shirley G. Fitzgerald, PhD; Michael L. Boninger, MD **Title:** Usage of tilt-in-space, recline, and elevation seating functions in natural environment of wheelchair users	This study examined the usage of powered seating functions, including tilt-in-space, backrest recline, and seat elevation, among a group of wheelchair users during their typical daily activities. Twelve individuals who used a power wheelchair with seating functions participated in the study. They drove their own wheelchair and used the seating functions as needed in their community environment for about 2 weeks while the seating function usage was recorded with a portable device. We found that subjects occupied their wheelchair for 11.8 +/– 3.4 hours a day (all data shown as mean +/– standard deviation). While occupying their wheelchairs, they accessed tilt-in-space, backrest recline, and seat elevation 19 +/– 14 times a day for 64.1% +/– 36.8%, 12 +/– 8 times for 76.0% +/– 29.8%, and 4 +/– 4 times for 22.5% +/– 34.9%, respectively. Subjects chose to stay in tilted and reclined positions in their wheelchair for 39.3% +/– 36.5% of their time each day. They spent little time in a fully upright position. Subjects changed their seating positions every 53.6 +/– 47.0 minutes. Time spent in positions of different seating pressures varied among subjects. The information collected could enhance clinical practice of wheelchair provision, resulting in better compliance with clinical instructions and appropriate use of seating functions among wheelchair users. The study showed that subjects consistently accessed the seating functions throughout the day and spent most of their time in tilted and/or reclined positions; however, most did not reposition themselves as frequently as recommended in the clinical practice guideline.
Nr. 4	**Abstract**
Source: JRRD, Journal of Rehabilitation Research & Development Volume 45, Number 1, 2008 Pages 53–72	Independent mobility is important, but some wheelchair users find operating existing manual or powered wheelchairs difficult or impossible. Challenges to safe, independent wheelchair use can result from various overlapping physical, perceptual, or cognitive symptoms of diagnoses such as spinal cord injury, cerebrovascular accident, multiple sclerosis, amyotrophic lateral sclerosis, and cerebral palsy. Persons with different

Remark: **Author(s):** Richard C. Simpson, PhD, ATP; Edmund F. LoPresti, PhD; Rory A. Cooper, PhD **Title:** How many people would benefit from a smart wheelchair?	symptom combinations can benefit from different types of assistance from a smart wheelchair and different wheelchair form factors. The sizes of these user populations have been estimated based on published estimates of the number of individuals with each of several diseases who (1) also need a wheeled mobility device and (2) have specific symptoms that could interfere with mobility device use. An estimated 2.3 million people aged 15 and older used a wheelchair or electric scooter in 1999 [104]. The projected population of smart powered wheelchair users of 1.4 to 2.1 million represents 61 to 91 percent of all wheelchair users. This projection does not mean, of course, that 61 to 91 percent of wheelchair users need a smart wheelchair all the time. It simply means that 61 to 91 percent of individuals would benefit from a smart wheelchair at least some of the time. The number of wheelchair users has grown at an average annual rate of 5.9 percent a year [104]. At that rate, by 2010, wheelchair users will increase to 4.3 million, with 2.6 million to 3.9 million of these users benefitting from a smart wheelchair. Much like cruise control or Global Positioning Systems in automobiles, which people use a fraction of the time they are driving, the capabilities of a smart wheelchair may initially be sold as a luxury for high-end wheelchairs and slowly move toward greater market penetration.

6.3 Product Literature and Instructions for Use

We found our product literature and operating instruction to be consistent with the clinical data, covering all hazards and other clinically relevant information that might have an impact on the use of the Varia wheelchair.

7. Conclusions

According to all tests performed and all literature evaluated, manual wheelchairs as the Varia bear neither additional positive therapeutically side effects nor risks for their users . The quotations highlight:

- the clinical evidence demonstrates conformity with relevant Essential Principles;
- the performance and safety of the device as claimed have been established;
- the risks associated with the use of the device are acceptable when weighed against the benefits to the patient and user; and

(To support the understanding the positive aspects are highlighted in green and the negative aspects in red)

As a central remark, it has to be kept in mind that the purpose of the product was not to create a therapeutically benefit, neither has its design a diagnostic purpose.

The devices evaluated in this study were designed for attendants of persons whose ability to walk is impaired. By this the wheelchair driver is enabled to participate in the

community's day-to-day life better. As the wheelchair driver does not push or manoeuvre the device by himself, it would have been a surprise if any therapeutically benefit had been found in the course of this clinical evaluation.

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