Device category	Walking Aids

Clinical Evaluation Report

Device category:
Walking aids

Group	Product name
Rollator	Alpha
	Banjo
	Delta
	Futura
	Gloss
	Jazz1
	Jazz2
	Legacy
	Maxi
	Melody
	Soprano
	Symphony
Walking Frames	Actio
	Asteria
	Aventia
	Brio
	Escort
	Foria

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This report is established according to MEDDEV 2.7.1; Clinical Evaluation and MDR 2017/745.

1 Clinical Evaluation Scope and Plan

Aids for walking are used by persons / "users" who need to stabilize themselves during transfer or regular walking. It could be in all combinations related to standing and moving, mainly without assistance from a caregiver.
The walking aid could either be with or without wheels.

The devices in the category are classified as Class I products according to the requirements of the European Medical Device Regulation 2017/745.
As these products have no therapeutic or diagnostic purpose, the evaluation was directed towards the state of the art existing, well-established technologies, safety and reporting of negative side effects known in literature.

For Devices in the Category, see attachment 1.

1.1 Description of the device

Product description

Aids for walking are designed to support a movement made by the user with the purpose to make the movement as safe as possible as the user needs additional stabilization. They are used both in institutions as well as in private homes.

The Walking frames are used mainly indoors/ even ground and the Rollators both indoors and outdoors. Both product groups have handgrips/ underarm supports that are height adjustable and are aimed to be both a balance support as well as used as the pushing area.

The category can be divided in the following groups:

Walking frames: Are equipped with four fixed "legs" with or without small fixed front wheels. The frame is either completely fixed or has side wise "joints" resulting in that one side could be slightly lifted whilst the other side is being moved forwards. To change direction whilst walking, the Walking frame needs to be lifted.

Rollators: Have three or four larger wheels, where the four wheeled one is the most usual one. They all have hand brakes and two or all four wheels swivel. The three wheeled one can be turned easier but is at the same time more unstable (in this version, the front wheel is the one that swivels).

To change direction, the rollator is being turned in the direction where the user prefers to walk. For some of the rollators, a seat plate is optional so the user can sit and rest during the walk. As other alternatives instead of handgrips, underarm supports are being used as push area.

The larger the wheels the more suitable is the rollator for outdoor walks on uneven ground.

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Intended use

In general, the intended use is to support during walking. Most walking aids have height-adjustable handgrips or underarm supports.
Rollators are intended to support a continuous walk where the users "steer" the Rollator in the direction that they would like to travel. If the user becomes tired whilst walking and the Walking aid has an optional seat plate, the user can lock the Rollator and sit and rest a while. When using a Walking frame, the user needs to stand still and lift the Walking frame forwards after each step. The walking frame requires the user to have a trustworthy balance.

Group	Product name	Intended use		
Rollator	Alpha	To support a person during walking and may also serve as a resting seat	To be used both indoor and outdoor on even ground.	The weight of the user must not exceed the maximum weight, see UM and product label.
	Banjo			
	Delta	To support a person during walking.	Only for indoor use	
	Futura	To support a person during walking and may also serve as a resting seat.	To be used both indoor and outdoor on even ground.	
	Gloss			
	Jazz1			
	Jazz2			
	Legacy			
	Maxi			
	Melody			
	Soprano			
	Symphony			
Walking frame	Actio		Only for indoor use	
	Asteria	To support a person during walking.		
	Aventia			
	Brio			
	Escort			
	Foria			

- Invacare presume a Medical professional (MP) and care team have made an individual assessment of the user to determine the patient's risk level or therapy requirements. Dealers and caregivers have assessed that the Rollators and Walking frames give the required support and have an adjustment where there is no risk using them for the user. Further that caregivers and users have been appropriately trained by the MP on how to use the device correctly and safely.

Intended users

The typical user is a person who has balance issues with or without insufficient muscle tone. It affects the walking ability and makes the users unsure whether they are able to stabilize themselves well enough for an independent walk. Many users have a walking stick for shorter distances but for longer stretches, they need a more stable support.
The users' need to have the ability and strengths in their hands (or underarms for the Alpha) to handle the Rollator and respectively the Walking frame as it is being maneuvered by the hands.
Here follow the most usual diagnoses: CVA (Cerebral Vascular Accidents), Dementia, Muscular diseases, Trauma (Traumatic Brain injuries), Parkinson, Neuromuscular diseases, Cancer or Patients after surgical procedures.
Another user group is elderly persons who would need a support whilst walking due to the natural aging process where both balance and muscle strengths are affected.
The Alpha is designed for users with inadequate hands like Rheumatoid Arthritis (RA) providing specially shaped underarm supports.

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The largest user group is frail elderly persons with multi diagnoses where the condition is deteriorating.

Indications and contra indications

Indication: A person who has balance or/ and issues with muscle strengths and needs additional support whilst walking.

Contra indications: There are no contraindications if the support substitutes the lack of balance and muscle force the individual user has. Considerations must be done if the condition is deteriorating even further.

Clinical performance or clinical safety

Invacare constantly offers free Clinical training through our clinical team and European Product Managers. The free trainings are targeting both customers like Clinicians, Dealers, Caregivers and internally our sales representatives ensuring good support in the decision making of the appropriate device.
It is essential for Invacare through these trainings to help the customer select the Walking aid based on customer requirements and at the same time receive feedback on how our product range is used ensuring optimized performance.
Evaluations are being done by our customers and enclosed is an evaluation done by a Danish customer in relation with a tender request, See attachment 2.

2 Identification of clinical data

The clinical knowledge of the Invacare category Aids for Walking are obtained by the following:

- Case studies and trainings as described above
- Ongoing literature studies as described in chapter 2.2
- The main competitors are:

Group	Product name	Competitors
Rollator	Alpha	Human Care, Sunrise, Vermeiren, Dietz Reha
	Banjo	Drive Medical, Thusane, Dietz Reha, B&B, Primo
	Delta	Drive Medical, Vermeiren, Sunrise
	Futura	Topro, Sunrise, Dietz Reha, Human Care, Drive Medical
	Gloss	
	Jazz1	Topro, Human Care, Drive Medical
	Jazz2	
	Legacy	Human Care, Vermeiren, Dietz Reha, Drive Medical
	Maxi	Sunrise, Dietz Reha, Drive Medical, Tous Ergo
	Melody	Topro, Sunrise, Dietz Reha, Human Care, Drive Medical
	Soprano	Topro, Sunrise, Dietz Reha, Drive Medical
	Symphony	Topro, Dietz Reha
Walking Frames	Actio	Drive Medical
	Asteria	Drive Medical, Herdergen, Dietz Reha, Sunrise
	Aventia	
	Brio	Drive Medical, Aidapt
	Escort	Drive Medical, Herdergen, Dietz Reha, Sunrise
	Foria	Drive Medical, Vermeiren

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2.1 Clinical data generated and held by the manufacturer

Data held by the manufacturer, generated from Risk Management activities and the PMS system;

Number of Vigilance reports and sales per product line
Year 2014 - May 2019

Group	Product name	Vigilance reports	Sales in units
Rollator	Alpha	18	11 372
	Banjo	23	657 948
	Delta	3	55 113
	Futura	464	173 052
	Gloss	0	0
	Jazz1	15	9 650
	Jazz2	6	39 190
	Legacy	17	279 794
	Maxi	38	62 758
	Melody	61	20 415
	Soprano	15	5 871
	Symphony	17	3 804
Walking Frames	Actio	1	200 173
	Asteria	2	105 371
	Aventia	1	15 731
	Brio	0	16 285
	Escort	2	82 343
	Foria	0	10 125
TOTAL		**683**	**1 748 995**

Out of the 18 products, there have been 683 Vigilance cases reported of a total sale of 1,7M units of Walking Aids. The majority of the reports come from the Rollator Futura. Out of the 464 reports, 351 relates for breakage of fork. 10% of the total sales of all Walking aids comes from Futura. 0,2% have become a Vigilance case due to the issue with the front fork (and wheel).
Invacare distributed new front forks (including wheels) with improved design to the customers, together with a Field Safety Notice explaining that for affected devices both front forks (including wheels) needed to be exchanged and the exchanged forks needed to be scrapped.

The issue with the fork or/ and ball bearing of the fork has generated most of the overall reports.

Ball bearings, forks and as well wheels have been a subject for improvement where the material has improved, or the parts have changed completely, see above for the Field Safety Notice.

For the user, the main reports speak about no injury alleged however there have been two deaths reported but no clear explanation of what happened is presented.

For improving and minimizing the risks the following product improvements have been done:

- Invacare are constantly working on optimizing instructions of use like Manuals, Trainings and videos. It is however the responsibility of the Medical personal to ensure that the products´ knowledge is in accordance with what is requested. If more information is needed, Invacare has, as mentioned, trainings to offer.

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The residual risks are being cared for as follows:

Main risks:

- Misuse or wrong assembly or exceeding product specifications
- Worn components
- Components failure

Risk reduction / risk control:

- Verification according to ISO 11199-1:1999
- Verification according to ISO 11199-2:2005
- Information / warning in UM
- Labelling
- Manufacturing control processes -> incoming, online and final inspection

2.2 Clinical data from literature

For Current knowledge/ the state of the art the following standards and norms were consulted:

Relevant standards

Group	Product name	Standards
Rollator	Alpha	ISO 11199-2:2005
	Banjo	
	Delta	
	Futura	
	Gloss	
	Jazz1	
	Jazz2	
	Legacy	
	Maxi	
	Melody	
	Soprano	
	Symphony	
Walking Frames	Actio	ISO 11199-2:2005
	Asteria	ISO 11199-1:1999
	Aventia	
	Brio	
	Escort	
	Foria	

Data retrieved from literature needed for the clinical evaluation and sources used for the research to ensure medical relevance of the findings:

- https://www.ncbi.nlm.nih.gov/pubmed
- https://www.cochranelibrary.com/
- https://www.hindawi.com/

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2.3 Scope of literature search

The literature search was based on the key words as follows;
Walking with support, Rollators, Walking frames, Walking aids, Mobility assistive technology,

2.4 Methods

The search was performed in 2019 by the evaluator, Pia Hindersson, and was based on the general research on category performed in Aids for Walking. Period covered by search is year 2015 to date and reflects the key words relevant for the research.

Literature sources used to identify data are displayed in the table under section 2.5 as well as the websites accessible through the hyperlinks in section 2.6.

Internet search and deemed relevance of literature, when cross reading articles have been judged relevant only if the key words were placed in the context of "intended use" and included a clear statement concerning the use and selection of the Walking Aid Category.

2.5 Literature search

Find the listing of articles found with the search criteria:

Ref.no	Author	Title	Published (Year)	Rank
1	Carver J[1], Ganus A[1], Ivey JM[1], Plummer T[1], Eubank A[1].	The impact of mobility assistive technology devices on participation for individuals with disabilities	2015	1
2	Costamagna E[1], Thies SB[2], Kenney LPJ[2], Howard D[3], Liu A[2], Ogden D[4].	A generalizable methodology for stability assessment of walking aid users.	2017	2
3	Takuji_Adachi,[1] Kuniyasu_Kamiya,[2] Yuji Kono,[3] Kotaro_Iwatsu,[4] Yuko_Shimizu,[5] Ikumi_Honda,[5] and Sumio_Yamada	Predicting the Future Need of Walking Device or Assistance by Moderate to Vigorous Physical Activity	2018	2

For easier interpretation of the articles, positive aspects are shown in green and negative aspects are shown in red.

2.6 Appraisal of data

The reviewed documents are evaluated according to an internal ranking system described in EW-0902.

The referenced data from literature and data held by the manufacturer are based on equivalent devices with the characteristics described in EW-0902 and have the ranking 1 or 2;

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Abstracts of relevant articles/white papers

Ref.no. 1	**Conclusion**
Title: The impact of mobility assistive technology devices on participation for individuals with disabilities **Source:** https://www.ncbi.nlm.nih.gov/pubmed / 25815679	This study aims to address the gap in research and contribute to the body of knowledge on the perspectives assistive technology device users have toward their devices. Quantitative data from this study indicate that users of MATD are satisfied with the way in which their devices enable maneuvering indoors, while qualitative data suggest otherwise. Healthcare professionals must be cognizant of the impact of the environment and/or environmental barriers when prescribing.
Ref.no. 2	**Conclusion**
Title: A generalizable methodology for stability assessment of walking aid users. **Source:** https://www.ncbi.nlm.nih.gov/pubmed/ 28684213	To assist balance and mobility, older adults are often prescribed walking aids. Nevertheless, surprisingly their use has been associated with increased falls-risk. To address this finding, we first need to characterize a person's stability while using a walking aid. To measure these parameters, we have developed an instrumented Walking frame with a load cell in each foot which we use together with pressure-sensing insoles and a camera system. *- The result was not presented*
Ref.no. 3	**Conclusion**
Title: Predicting the Future Need of Walking Device or Assistance by Moderate to Vigorous Physical Activity **Source:** https://www.hindawi.com/journals/bmri/2018/1340479/	A 2-Year Prospective Study of women aged 75 Years and above who could independently walk without assistance. 330 women participated. Their moderate to high physical activity (MPVA) was measured through an accelerometer. The receiver operating characteristics analysis identified a 7.9 min/d of MPVA as the cut-off value. The results of this study suggest the importance of promoting daily MVPA for preventing mobility limitation in older women aged 75 years and above.

3 Analysis of data

The appraised data demonstrates compliance with each of the GSPR pertaining to the clinical performance and clinical safety of the devices in the category, when the devices are used according to their intended purpose.

3.1 Requirement on Safety (MDR GSPR 1, 2, 3)

Risks identified in the risk management documentation and literature have been adequately addressed.

There is full consistency between current knowledge/ the state of the art, the available clinical data, the information materials supplied by the Invacare, and the Risk Management documentation for the device.

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3.2 Requirement on acceptable benefit/risk profile (MDR GSPR 1, 2)

The benefit for the user who needs some type of support whilst walking allows the person to be independent and limits the need of a caregiver. It gives the user the opportunity to live as "normal" as possible and participating in social life and at the same time preserve the mobility, as highlighted in one of the literatures studies concerning the importance of physical activity.

The number of vigilance cases in relation to sales volume is low.

The mentioned contraindications in chapter 1.1 are part of the evaluations the prescriber does when selecting the right Walking aid for the user.

If the recommendations, standards and Invacare product information are used as supplied, the benefit for the users is greater than the risks.

3.3 Requirement on acceptability of side-effects (MDR GSPR 8)

The data available is of sufficient amount and quality for the detection of undesirable side-effects and their frequency. Based on the data analyzed there are no undesirable side-effects for the category.

As mentioned in the CER report, Invacare presume a Medical professional has been part of the selection of the right product for the user, when needed, individual assessments have been made and that risk and safety information, as instructed by Invacare, is being followed.

4 Conclusion

The clinical evidence demonstrates conformity with applicable General Safety and Performance Requirements;

- in the literature found principles are, if applicable for the product, implemented in the product design
- 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.
- Based on the evaluated Clinical data the technical documentation and user manual of the manufacturer are consistent.

5 Qualification of the responsible evaluator

The clinical evaluation is conducted by;

Established by: Pia Hindersson
Location: Invacare in Spånga, Sweden
Position: Clinical Manager
Education: BA in Marketing;
Diploma as Certified Occupational Therapist
Experience: Occupational Therapist – 6 years:
Sales and Marketing mainly as European/ Global Product Manager for Manual Wheelchairs - 35 years

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Following aspects have been taken into consideration:

The evaluators possess knowledge of the following:

- research methodology
- regulatory requirements
- medical writing

With respect to the device/ category under evaluation, the evaluators have knowledge of:

- the device technology and its application;
- management of the conditions intended to be managed by the device
- knowledge of medical alternatives, standards and technology

6 Approvals

Approval and release	
Evaluator: Pia Hindersson	**Signature:** 
Date: 2019-Aug-22	
Group Product Manager: Ashton Evans	**Signature:** 
Date: 2019-Aug-21	

Change history (add numbers of rows as needed)		
Version	**Description**	**Date:**
1	Initial Issue according to MDR 2017/745	21. August 2019

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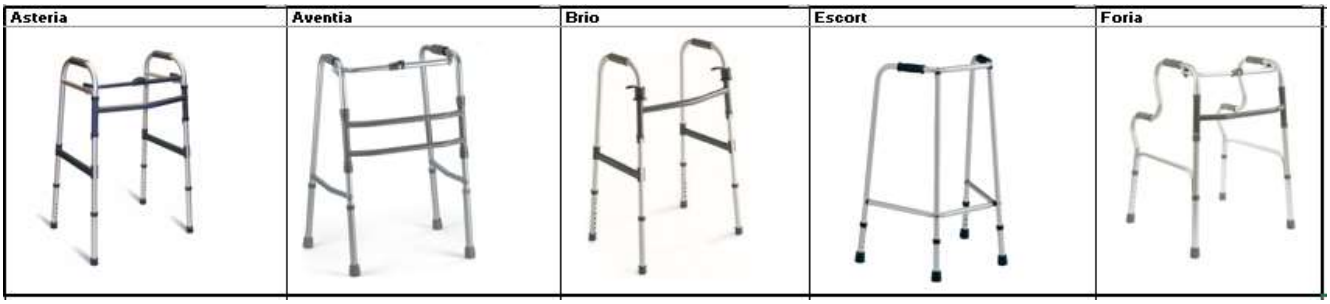
Attachment 1

Devices in the category

Rollators:

Walking Frames:



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Attachment 2

Komudbud 2019 – Futura

A good assessment is given for the comfort criterion for the citizen.

The walker is very stable and the tip is also reasonably stable, though not optimal. The turning radius is too large and it does not rotate sharp enough to maneuver around easily.

Handles are nice and the hand rests well. However, they are difficult to adjust with the thumbscrew and because they smoke in the bottom when you loosen the screw. It is negative that there is infinite adjustment because it presents a greater risk of error.

The walker is nice to go inside, but you can hit it front wheel in connection with turns.

It takes effort to slow down as it is quite tight and the surface is very small. There are therefore not many different ones applications / ways of braking by hand, such as to do it by wrist. However, the hardness can be set.

The seat is stable and you do not slip on it. However, you do not sit so good because the seat cuts slightly against the thighs.

The rollator is easy to handle in collapsed mode and is lightweight to collapse as you can do it from the handle side. The hook is easy to get on and it is good it is red.

The daily cleanliness is good, the seat is easy to dry because it is not a net. The basket is difficult to wipe because it is one metal mesh. Otherwise nicely rounded and easy to get to.
For the accessories, the basket is easy to get in and there is a small pocket, which is very positive for the citizen. The basket sits far down, but works fine to get citizens' own bag in.

The tray is easy to lie on, but it is not properly / stable.

The cane holder is unstable and the cane falls off several times driving over small edges and outside.

A good assessment is given for the Management Criteria sub-criterion for custodial staff.

It is easy to clean the rollator.

Accessories are easy to attach and remove, it is easy to lay the tray on for depot. Stick holder is reasonably simple to put on velcro, but it is not very simple to make it sit tight
enough.

It is difficult to change brakes because cable is not visible. Brake probably needs to be adjusted more often because they have to be loosened at the start for the sake of the citizen.

It is easy to change wheels.

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Evaluation Jazz - Copenhagen 2016

The Resource Center has paid special attention.

Quality:
• The walker is made of good materials.
• There is a very good warranty period for the product.
• The walker has a very contemporary design.
• Rocker pedal is fitted as standard.
• The rollator has very little resistance on the wheels and has a very low weight of 6.8 kg.

Functionality:
• The walker has a large setting range for push handles.
• The backrest can be adjusted in length without the use of tools.
• The rollator has a low weight, which makes it easier for users to include the rollator in e.g. bus and train.
• Good step-by-step brake that is easy to use. Enclosing grip for brake.
• Good locking mechanism in the folded state, as well as good points to hold when carrying the rollator in the folded state.
• It is very easy to install accessories on the rollator.
• There is a very large and useful other range.

Evaluation of your offer:

Below you can see which elements of your offer were particularly decisive for the overall evaluation price. Positive: green, Negative: red.
Quality:
• There is a good warranty period of 36 months.
• Not contemporary design as the walker looks a bit clumsy.
• The walker has good operational safety.
• The walker is problematic to clean and prepare for the next occupant due to the internally placed brake cable.

functionality:
• Height adjustment of the push handle is stepless and good, with clear indications.
• The walker is quite heavy (7.8 kg) and therefore heavy handling.
• The basket is also quite small and sits very low, so citizens with disabilities cannot bend down to the basket.
• The internal brake cables make it more difficult for the technicians to change the brake cables.

• The range offered under other products is limited.

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Evaluation Futura – Copenhagen 2016

Quality:
• The walker is solidly designed and good for the user. The handles are turned so that the user will tend to hold the rollator close to the body, thereby avoiding unnecessary strain on the arms, shoulders and back.
• The walker is stably built with low maintenance. There are very few places where rust can occur.

Functionality:
• Solid seat is deep and wide, so the user feels secure when sitting on the seat.
• The seat is stable and can be folded up so that the user can go very close to the rollator.
• Good step-by-step brake that is easy to use. Good enclosing grip for brake for better grip.

• Easy height adjustment of push handle. Continuous adjustment of the push handle with clear indications makes it easy to fine-tune the push handle.