IN-EXON

IN-EXON®

Instructions for Use

Inflatable Exoskeleton for Aquatic Rehabilitation

Version 1.0

Model name: Gaia

Read these Instructions for Use carefully before operating the device.

ASSURE Medical Equipment Co., Ltd.

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Chapter 1

General Information

1.1 About IN-EXON®

IN-EXON® is an inflatable exoskeleton designed to support aquatic rehabilitation by improving body stability, buoyancy control, and assisted movement during therapeutic water-based activities. The device combines an ergonomic wearable structure with an adjustable pneumatic support system to facilitate rehabilitation exercises for individuals with reduced mobility.

The device is intended to assist patients during physiotherapy sessions performed in controlled aquatic environments under the supervision of qualified healthcare professionals. IN-EXON® is designed to improve patient positioning in water while supporting functional rehabilitation and reducing physical effort during assisted exercises.

IN-EXON® is not intended to replace conventional rehabilitation techniques but to complement therapeutic programs prescribed by qualified healthcare professionals.

1.2 Purpose of this Manual

This Instructions for Use (IFU) provides all information necessary for the safe handling, preparation, operation, cleaning, maintenance, storage, and disposal of the IN-EXON® device.

Compliance with the instructions contained in this manual contributes to reducing risks associated with improper use and helps ensure safe and effective operation throughout the expected service life of the device.

Failure to follow these instructions may result in serious injury to the user, damage to the device, or loss of therapeutic effectiveness.

1.3 Intended Users

This manual is intended for:

Table 1.1: Intended users of the IN-EXON® device.

User Category	Description
Physiotherapists	Qualified professionals responsible for rehabilitation treatment.
Rehabilitation Physicians	Medical professionals supervising rehabilitation programs.
Healthcare Professionals	Authorized personnel trained in the use of the device.
Caregivers	Individuals assisting the patient during therapy sessions.
Trained Assistants	Personnel trained in the correct use of the device.
End Users	Individuals who have received appropriate training.

The device shall only be used after the user and supervising personnel have carefully read and understood this manual.

Whenever uncertainty exists regarding the operation or suitability of the device, discontinue use and contact the manufacturer before proceeding.

1.4 Reading this Manual

Before operating the device:

- Read this manual completely.
- Pay particular attention to all safety-related information.
- Follow every instruction in the order presented.
- Keep this manual available throughout the entire service life of the device.

If the device is transferred to another owner or healthcare facility, this manual shall accompany the device.

1.5 Device Identification

Table 1.2: Device identification.

Item	Description
Device Trade Name	IN-EXON®
Version	Gaia 1.0
Device Type	Inflatable Exoskeleton for Aquatic Activities
Intended Purpose	Device for aquatic activities
Manufacturer	ASSURE Medical Equipment Co., Ltd.
Country of Manufacture	China
Lot Number (LOT)	See device label
Serial Number (SN)	See device label
Manual Version	IFU Rev. 1.0

Chapter 2

Safety Information

2.1 General Safety Principles

The safe operation of the IN-EXON® device depends on correct use, regular inspection, and continuous supervision by qualified personnel. Failure to comply with the instructions provided in this manual may result in serious injury to the user or damage to the device.

IN-EXON® is intended exclusively for therapeutic, rehabilitation and acquatic activities. The device shall only be used within its intended purpose and under the environmental and operating conditions specified in this manual.

Before each rehabilitation session, the supervising healthcare professional shall verify that the device is in safe operating condition and that the patient's clinical status is compatible with its intended use.

The user, caregiver, and healthcare professional shall read and understand this manual before using the device.

2.2 General Warnings

The following warnings identify situations that may result in serious injury or death if the device is used improperly. Read and understand each warning before operating the device.

WARNING

IN-EXON® is **not** a life-saving flotation device.

The device does not replace a certified personal flotation device (PFD) and shall never be used as lifesaving equipment.

Failure to comply with this warning may result in drowning, serious injury or death.

WARNING

The device shall only be used under the continuous supervision of a qualified physiotherapist, healthcare professional, or trained caregiver capable of providing immediate physical assistance.

Never leave the user unattended while wearing the device.

WARNING

Do not use the device if the user is unable to maintain the head and airways above the water surface without assistance.

Improper use may result in airway submersion and drowning.

WARNING

Immediately discontinue use if any loss of buoyancy, air leakage, structural damage, or unexpected malfunction is observed.

Safely remove the user from the water before inspecting the device.

2.3 Precautions

Observe the following precautions before each rehabilitation session:

Table 2.1: Pre-use safety checklist.

Inspection Item
Inspect the pneumatic chambers.
Check all valves.
Verify strap adjustment.
Confirm the correct device fit.
Inflate within the specified pressure range.
Verify that qualified supervision is available.
Ensure that the aquatic environment is suitable.

2.4 Foreseeable Misuse

The following uses are considered reasonably foreseeable misuse and may result in hazardous situations.

Table 2.2: Reasonably foreseeable misuse.

The device shall not be used for:
Diving or underwater activities.
Apnea training.
Running or jumping while wearing the device.
Use in rough water, strong currents, rivers, or uncontrolled aquatic environments.
Use together with non-certified flotation devices.
Use after unauthorized modifications.
Use under the influence of alcohol, recreational drugs, sedatives, or medications that impair judgment or reflexes.

2.5 User Limitations

The device shall not be used in the following situations unless specifically authorized by a qualified physician.

Table 2.3: Clinical limitations for device use.

The device shall not be used in the following situations:
Pregnancy.
Severe cardiac disease.
Severe respiratory insufficiency.
Uncontrolled epilepsy.
Open wounds.
Active skin infections.
Acute spinal instability.
Any medical condition incompatible with aquatic rehabilitation.

The device shall not be used outside the specified height, weight, or sizing limits.

2.6 Technical Safety

Before every use, inspect the device carefully.

Table 2.4: Conditions requiring immediate discontinuation of device use.

Do not use the device if any of the following conditions are observed:
Damaged pneumatic air chambers.
Air leakage.
Defective inflation valves.
Damaged straps or buckles.
Excessive wear.
Punctures.
Cuts.
Deformation of structural components.

Only manufacturer-approved accessories and inflation equipment shall be used.

Do not repair, modify, puncture, or disassemble the device.

Keep the device away from:

- sharp objects;
- excessive heat;
- open flames;
- concentrated chlorine;
- solvents;
- petroleum-based chemicals.

2.7 Environmental Conditions

IN-EXON® is intended for use only in controlled aquatic environments suitable for rehabilitation activities.

Before use, verify that:

- water temperature is appropriate for rehabilitation (typically 28–34 ℃);
- water visibility is adequate;
- the pool floor is free from hazards;
- surrounding structures do not present abrasive surfaces;
- qualified assistance is immediately available.

Do not use the device during adverse environmental conditions including waves, strong currents, storms, or poor visibility.

2.8 Emergency Procedures

Table 2.5: Situations requiring immediate termination of therapy.

Immediately terminate the rehabilitation session if any of the following occurs:
Sudden loss of buoyancy.
Air leakage.
Structural failure.
Breathing difficulties.
Dizziness or loss of consciousness.
Chest pain.
Severe fatigue.
Panic or psychological distress.

Safely remove the user from the water as quickly as possible.

If necessary, activate local emergency medical services and provide appropriate first aid according to institutional procedures.

Do not reuse the device until it has been fully inspected and confirmed to be in safe operating condition.

2.9 Residual Risks

Despite compliance with all instructions contained in this manual, certain residual risks cannot be completely eliminated.

These include:

- accidental loss of buoyancy;
- patient instability;
- falls during water entry or exit;
- hypothermia following prolonged exposure;

- improper fitting of the device;
- misuse contrary to the instructions provided.

Appropriate supervision, correct device preparation, and compliance with this manual significantly reduce these residual risks but cannot eliminate them entirely.

Chapter 3

Device Description

3.1 Device Overview

IN-EXON® is an inflatable wearable exoskeleton specifically designed to support aquatic rehabilitation and assisted mobility for individuals with reduced lower-limb motor function. The device combines a lightweight modular exoskeletal structure with an integrated pneumatic buoyancy system that provides whole-body biomechanical support during aquatic activities.

Controlled stabilization of the trunk and lower limbs promotes physiological body alignment, reduces gravitational loading and facilitates therapeutic movement in water.

By reducing the physical demands associated with conventional aquatic therapy, IN-EXON® enables healthcare professionals to deliver rehabilitation exercises in a safer and more controlled environment.

The device is intended to complement conventional rehabilitation programs and shall always be used under the supervision of qualified healthcare professionals.

The modular design allows the device to adapt to different patient body sizes while maintaining stability, comfort, and freedom of movement during acquatic activities and therapy sessions.

Front view

Back view

Figure 3.1: IN-EXON front and rear views.

3.2 Main Components

Table 3.1: Main components of the IN-EXON® device.

No.	Component	Description
1	Adjustable Waist Belt	Provides primary fixation around the pelvis, ensuring correct positioning and overall device stability.
2	Upper frontal section	Inflatable front section that stabilizes the upper body and contributes to whole-body buoyancy during aquatic rehabilitation.
3	Upper posterior section	Inflatable back section that stabilizes the upper body and contributes to whole-body buoyancy during aquatic rehabilitation.
4	Lower Leg Modules	Inflatable supports that assist lower-limb alignment while allowing controlled movement in water.
5	Adjustable Straps	Enable individualized fitting and secure fastening of the device to the user's body.
6	Inflation and Deflation Valves	Manual valves used to inflate and deflate the pneumatic chambers to the recommended operating pressure.
7	Valve Connectors	Connection ports used to attach the inflation pump to the pneumatic system.

Figure 3.2: Adjustable waist belt

Figure 3.3: Upper frontal section, shoulders and lateral straps, inflation and deflation valves

Figure 3.4: Upper posterior section, lateral straps

Figure 3.5: Lower leg modules with foot and leg straps

3.3 Principle of Operation

IN-EXON® operates through an integrated pneumatic buoyancy system that provides adjustable support to the user during aquatic rehabilitation.

After inflation, the internal air chambers generate controlled buoyancy forces that partially counteract the user's body weight while maintaining body alignment in the water. The distribution of buoyancy across the whole body contributes to improved postural stability and facilitates the execution of rehabilitation and swimming.

Unlike active robotic exoskeletons, IN-EXON® does not generate movement through motors or actuators. Instead, it assists natural body movement by providing passive biomechanical support and controlled flotation.

The modular configuration allows therapists to perform a wide range of rehabilitation activities while adapting the level of assistance according to the patient's clinical condition

and therapeutic objectives.

3.4 Technical Characteristics

Table 3.2: General technical characteristics.

Characteristic	**Description**
Device Type	Inflatable passive exoskeleton
Operating Principle	Pneumatic buoyancy assistance
Functional Support	Whole-body biomechanical support through controlled buoyancy
Adjustment	Adjustable straps and pneumatic pressure
Inflation System	Manual inflation through dedicated valves
Reuse	Reusable medical device
Operating Environment	Controlled aquatic environments

NOTE

The IN-EXON® device is designed to assist rehabilitation activities by improving stability and controlled buoyancy. It does not actively move the user's limbs and shall not be considered a powered exoskeleton.

Chapter 4

Intended use

4.1 Intended Medical Purpose

IN-EXON® is a passive inflatable exoskeleton intended to support individuals with reduced mobility during aquatic rehabilitation, adapted aquatic activities, supervised water-based exercise, and assisted swimming.

The device provides controlled buoyancy and whole-body biomechanical support in aquatic environments. By partially reducing the effects of gravity, IN-EXON® promotes body stabilization, facilitates functional movement, and enables users to perform rehabilitation exercises, aquatic mobility tasks, and swimming activities that may be difficult or impossible to perform on land.

IN-EXON® is designed to support users in a wide range of aquatic environments, including rehabilitation facilities, swimming pools, and other calm bodies of water suitable for supervised activities. The device may be used for both therapeutic and adapted aquatic activities aimed at improving mobility, functional independence, and participation in water-based environments.

Depending on the user's functional abilities and the intended activity, the device shall be used under the supervision of a qualified healthcare professional, trained caregiver, or another competent person capable of providing immediate assistance when required.

IN-EXON® is not intended to replace certified life-saving flotation devices or independent mobility aids outside aquatic environments.

4.2 Therapeutic Applications

IN-EXON® is intended to support a broad range of aquatic rehabilitation programs and therapeutic activities aimed at improving functional mobility and promoting patient recovery.

Table 4.1: Typical therapeutic applications of the IN-EXON® device.

Application	**Description**
Aquatic Physiotherapy	Supports rehabilitation exercises performed in aquatic environments under professional supervision.
Neurological Rehabilitation	Assists patients with neurological disorders requiring motor rehabilitation in water.
Post-Traumatic Functional Recovery	Supports progressive recovery of functional mobility after traumatic events.
Balance and Postural Control Training	Promotes postural stability and balance through controlled buoyancy.
Lower-Limb Motor Re-education	Facilitates coordinated lower-limb movement during rehabilitation exercises.
Assisted Gait Simulation	Allows gait-related movement patterns to be practiced in a reduced-load aquatic environment.
Passive and Active-Assisted Mobilization	Supports joint mobilization and therapist-assisted movement exercises.
Muscle Strengthening Exercises	Enables progressive strengthening exercises with reduced gravitational loading.
Controlled Aquatic Exercise	Provides a stable environment for supervised therapeutic physical activity.
Assisted Swimming Activities	Facilitates supervised swimming exercises as part of rehabilitation or adapted aquatic activities.

The rehabilitation program shall always be defined and adapted by qualified healthcare professionals according to the patient's clinical condition and therapeutic objectives.

4.3 Zero-Gravity Rehabilitation Concept

The innovative therapeutic principle of IN-EXON® is based on the controlled reduction of gravitational loading through adjustable aquatic buoyancy.

Once properly fitted and inflated, the device creates a condition of partial body-weight unloading that allows users to perform movements with considerably lower mechanical stress than on land. This effect facilitates rehabilitation by reducing the forces acting on the musculoskeletal system while preserving natural movement patterns.

The Zero-Gravity Rehabilitation Concept enables healthcare professionals to progressively adapt rehabilitation exercises according to the patient's functional abilities while maintaining a safe and supportive environment.

Compared with conventional land-based rehabilitation, the reduction of gravitational loading may facilitate:

- Spinal decompression;
- Reduced joint loading;
- Improved postural alignment;
- Greater freedom of movement;
- Easier execution of complex motor tasks;
- Earlier functional rehabilitation after injury or neurological impairment;
- Internal organs repositioning;
- Circulation reactivation;
- Lung capacity enhancement;
- Reduced physical effort during therapeutic exercises.

By combining controlled buoyancy with the natural therapeutic properties of water, IN-EXON® provides a rehabilitation environment that supports both functional recovery and active patient participation.

Chapter 5

Operating instructions

5.1 Wearing the Device

1. Position the belt on your abdominal wall, ensuring it is properly centered.
2. Fasten the belt by securing the velcro firmly.
3. Adjust the fit so that the belt is fitted but comfortable.
4. Position and fasten the legs module.
5. Make sure the elastic straps are tight on the leg.
6. Place the whole upper section (junction between the front and back sections) on your head.
7. Attach it to the abdominal belt through velcros.
8. Connect the upper module with the legs module.
9. Secure all velcro parts and adjust the elastic straps for a firm fit.
10. Make sure the fit is secure but not too tight.

5.2 Inflation Procedure

1. Take the hand pump.
2. Connect it to the click valve on the front device.

3. Connect the second hand pump to the legs.

4. Inflate manually to a maximum pressure of 4 psi (or until optimal rigidity is reached).

5. Use the deflate button to release air and deflate the device.

5.3 Functional Check

Adjust the device and inflation so that you feel comfortable and have adequate buoyancy.

5.4 Functional Check and Rehabilitation Activities

1. Adjust the device and inflation so that you feel comfortable and have adequate buoyancy.

2. Perform rehabilitation activities following the therapist's instructions. Read 4.2 for more details.

5.5 Swimming Activity

Before entering the water, ensure that the IN-EXON device is correctly fitted and that all fastening systems are securely adjusted. Inflate the Upper Module to a pressure between 3 and 4 PSI to provide the structural rigidity required for adequate upper body support during swimming. Inflate the Leg Modules gradually until the desired buoyancy is achieved, ensuring that the resulting floating angle does not exceed 5° relative to the water surface (floating line). A progressive inflation approach is recommended, with the Leg Modules generally inflated to a lower pressure than the Upper Module. The optimal inflation pressure should be determined according to the user's body characteristics, functional abilities, and therapeutic objectives.

For improved comfort and swimming performance, the use of a Lycra swim shirt is recommended. The garment reduces friction between the device and the skin, facilitates shoulder and arm movement during the swimming stroke, and provides additional skin protection during prolonged use.

For front crawl (freestyle) swimming, the use of a swimming mask with a front-mounted snorkel is recommended, particularly for users who are unable to rotate the head sufficiently to breathe without compromising body alignment. The snorkel allows continuous breathing while maintaining a stable and symmetrical swimming position.

Initial swimming sessions should be performed progressively to allow the user to become familiar with the buoyancy characteristics and handling of the device. Users should gradually evaluate their ability to maintain balance, control body position, and perform swimming movements safely before attempting more advanced activities.

The first use of the device in water should always be carried out under the supervision of appropriately trained personnel. Continuous supervision by a qualified therapist, instructor, or other competent professional is strongly recommended until the user demonstrates safe and effective control of the device in the aquatic environment.

Chapter 6

Device care

6.1 Cleaning Procedure

Proper cleaning after each rehabilitation session is essential to maintain device performance, preserve material integrity, and reduce the risk of contamination. Always clean the device immediately after use, particularly following exposure to chlorinated or salt water. The following procedure is the recommended one:

- It is not necessary to completely deflate the device.
- Rinse all external surfaces with clean fresh water.
- Remove chlorine, salt, sand, or other residues.
- Clean using a soft cloth or sponge with mild neutral detergent.
- Rinse thoroughly.
- Dry completely before storage.

6.2 Routine Inspection

The device does not require scheduled mechanical maintenance.

However, periodic inspection shall be performed to verify the integrity of all pneumatic and structural components. before every use check:

Table 6.1: Pre-use inspection checklist.

Component	**Inspection Criteria**
Upper Body Module	Verify that the inflatable structure is free from punctures, cuts, excessive wear, or air leaks.
Adjustable Waist Belt	Ensure correct attachment, proper adjustment, and absence of visible damage or excessive wear.
Lower Leg Modules	Verify structural integrity and ensure that no cuts, punctures, or excessive deformation are present.
Inflation Valves	Check that all valves open, close, and seal correctly without air leakage.
Valve Connectors	Ensure secure connection between the inflation pump and the pneumatic system.
Quick Deflation Valves	Verify correct operation and complete air release when activated.
Adjustable Straps	Inspect straps for fraying, cuts, excessive wear, and proper adjustment.
Buckles and Fastening System	Ensure that all fastening elements lock securely and operate correctly.
External Surfaces	Inspect all external surfaces for dirt, abrasions, punctures, or other visible damage.

6.3 Storage

Store the device:

Table 6.2: Recommended storage conditions.

Parameter	Requirement
Storage Temperature	5–40 ℃
Humidity	Store in a dry environment.
Sunlight	Avoid prolonged exposure to direct sunlight.
Heat Sources	Keep away from heaters, flames and **hot surfaces**.
Sharp objects	Keep away from sharp objects.
Storage Condition	Store completely dry.
Folding	Do not bend the device excessively to avoid stress during bending.

WARNING

Strictly avoid prolonged exposure to **sunlight**. It can cause serious damage to the device.

6.4 Transport

Table 6.3: Transport recommendations.

Recommendation	Description
Folding	Do not bend the device excessively to avoid stress during bending.
Protect from puncture	Prevent contact with sharp or pointed objects.
Avoid compression	Do not place heavy objects on top of the device.
Environmental exposure	Avoid prolonged exposure to heat, sunlight or moisture during transport.

6.5 End-of-Life Disposal

At the end of its service life, dispose of the device according to local regulations applicable to plastic, textile, and polymeric materials.

Do not dispose of the device in the environment.

If required by local regulations, contact the manufacturer for information regarding proper disposal procedures.

Chapter 7

Technical Specifications

The technical specifications provided in this chapter define the operating limits and physical characteristics of the IN-EXON® device. Compliance with these specifications is essential to ensure safe operation, optimal rehabilitation performance, and preservation of the device throughout its expected service life.

The device shall only be used within the limits specified below.

7.1 General Specifications

Table 7.1: General technical specifications of the IN-EXON® device.

Parameter	**Specification**
Device Trade Name	IN-EXON®
Device Type	Inflatable exoskeleton for aquatic rehabilitation
Operating Principle	Passive pneumatic buoyancy assistance
Reusable	Yes
Power Supply	Not required
Inflation System	Manual air pump
Operating Environment	Controlled aquatic environments

7.2 Sizes and Physical Characteristics

Table 7.2: Physical characteristics.

Parameter	Specification
Device Weight	1.0–3.0 kg
Maximum User Weight	120 kg
Available models	XS, S, M, L, XL, XXL

NOTE

The IN-EXON® device features size adjustment via the belt; the user adjusts the width of the abdominal belt according to their waist size.

7.3 Materials

Table 7.3: Main construction materials.

Component	Material
Inflatable Chambers	Medical-grade TPU
Structural Elements	Reinforced technical polymers
External Covering	High-resistance synthetic fabric
Straps	High-strength woven textile
Buckles	Engineering polymer
Valves	Medical-grade polymer

Chapter 8

Manufacturer information

8.1 Manufacturer

Table 8.1: Manufacturer information.

Item	Information
Manufacturer	ASSURE Medical Equipment Co., Ltd.
Brand Name	IN-EXON®
Country	China
City	Zhenjiang, Jiangsu
Address	No. 297/799, Chuqiao Road
Website	www.in-exon.com

8.2 Distribution and Customer Assistance

The IN-EXON® device is distributed through authorized distributors and commercial partners.

The availability of user training, maintenance, technical assistance, and after-sales support may vary depending on the country or region.

For information regarding product availability, local support services, replacement parts, or warranty conditions, users should contact their authorized distributor or the manufacturer.

NOTICE

Only distributors and service providers authorized by the manufacturer are permitted to supply original replacement parts and approved accessories for the IN-EXON® device.

The use of non-approved components may compromise device safety, performance, and regulatory compliance.

8.3 Additional Information

The latest version of the Instructions for Use, product updates, safety notices, and additional documentation may be available through the In-exon's QR code furnished in the box.

Users are encouraged to verify that they are using the most recent version of this manual.

8.4 Trademarks and Copyright

IN-EXON® is a registered trademark of ASSURE Medical Equipment Co., Ltd. (hereinafter referred to as ASSURE) and its affiliated companies. All other product names, company names, trademarks, and registered trademarks mentioned in this manual are the property of their respective owners and are used for identification purposes only.

ASSURE Medical Equipment Co., Ltd. reserves the right to modify the design, specifications, documentation, and other information relating to the IN-EXON® device without prior notice, in order to improve product performance, safety, or regulatory compliance.