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Stroll®

Navigait Instructions For Use (IFU)



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EXCLUSIVELY FOR CLINICAL INVESTIGATION

Welcome

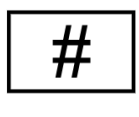
Strolll® Navigait engages patients in therapeutic exercises in a way that feels immersive and exciting; all from the comfort of their own home and at a time that's convenient for them, guided by the expertise of their healthcare professional.

In this instruction manual, we will guide you through the basics of using our software, from turning on and wearing the device to operating the Strolll® Navigait app and starting your first session. We've designed this manual to be user-friendly, easy to understand, and comprehensive, so that you can make the most of your experience.

We hope that this instruction manual serves as a helpful resource for you as you embark on your journey with our software. Let's get started!

Instructions For Use (IFU)

The instructions for use describe the proper use of Strolll® Navigait Health IT software.

Field		Detail
Manufacturer		Strolll Limited, 2A Staffordshire Place, Tipping Street, Stafford, England, ST16 2LP
Customer Service		Tel: +44 20 4558 4295 or +1 440 201 4074 Email: customerservice@strolll.co Web: https://www.strolll.co/
Country of Manufacture		Made in Great Britain
Software covered by this IFU		Strolll Navigait
		Strolll-NAVIGAIT-0001-ML2 — Strolll Navigait C1 (STD): Magic Leap 2, Software version v1.n.n
Basic UDI-DI		5065012458Navigait8U
EMDN Code		Z12069092 — Various physiotherapy and rehabilitation instruments: medical device software disease exercise software

Field		Detail	
EU Authorised Representative	EU REP	Sotas Europe Limited, 51 Bracken Road, Sandyford, Dublin, D18 CV48, Ireland	
Regulatory Status	MD	Exclusively for clinical investigation	

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Important Safety Information

Intended Use

The Navigait software platform is software as a medical device intended for adult patients with Parkinson's disease who experience freezing of gait (FoG). The device uses machine learning to automatically detect the user's motor state in real time and delivers personalised cues via augmented reality glasses to help reduce the number and duration of FoG episodes, and to improve or modify gait, facilitating improvement in walking continuity.

Cueing parameters are adapted by the software to the individual user and their environment based on the detected motor state. The device is for use under the prescription and supervision of a qualified healthcare professional and is intended to complement, not substitute for, pharmacological treatment, physiotherapy or routine clinical assessment.

Navigait is not intended for use in diagnosis, prognosis or monitoring of Parkinson's disease progression.

It is not intended for patients with uncontrolled or photosensitive epilepsy, severe cognitive impairment that prevents understanding of or response to visual cues, severe visual impairment that prevents perception of AR display content, or persons with total immobility.

Intended Population

Strolll® Navigait is designed for adult patients aged 18 years and above with a confirmed Parkinson's disease diagnosis. It is suitable for individuals who are able to walk independently or with minimal assistance.

Indications For Use

Strolll® Navigait is indicated for the management of Freezing of Gait (FoG) in adult patients with a confirmed Parkinson's disease diagnosis, as an adjunct to standard pharmacological treatment and physiotherapy/rehabilitation care.

Intended Users

Strolll® Navigait is intended to be used by licensed healthcare professionals, including a qualified physiotherapist or neurological rehabilitation specialist, prescribing physician, specialist nurse, or occupational therapist, for supervised therapy sessions in clinical settings.

It may also be prescribed for independent home-based rehabilitation when use is managed and monitored by a qualified healthcare professional.



Keep Out of Reach of Children

AR glasses are not a toy — keep out of reach of small children. Strolll Navigait is intended for adults aged 18 and older.



Volume

Frequent or extended exposure to loud noises when using the headset can cause temporary or permanent hearing loss. Start the volume at a low level and increase it until you can comfortably hear the sound.



Obstructions

Mixed reality glasses may distract you from, and partially obstruct, your view of the real world.



Environment

Strolll AR glasses are recommended for indoor use only, in the range 10–30°C. Avoid direct sunlight.



Virtual Objects

Remember that some objects you see in your mixed reality environment do not exist in the real environment. Do not attempt to sit on them or use them for support.



Comfort

Some people may experience nausea, disorientation, headache, fatigue, eye strain, or dry eyes when using AR glasses. Take regular breaks (a 10–15 minute break per hour) and stop and rest if needed. If symptoms are severe or persist, stop using the device and contact your healthcare professional.



Fit

Before using your AR glasses, ensure the glasses rest comfortably around your head and there is no discomfort.

Patient Profile

The patient's cognitive health shall be considered by the therapist in charge.

The patient should have adequate visual fields to be able to see the images using prescription spectacles, or may need to use prescription inserts to get the best experience.

The patient should be risk-assessed by their healthcare professional before participating in a prescribed training or rehabilitation regime to ensure suitability.



Contraindications

This device is not to be used if you experience the following conditions: photosensitive epilepsy, seizure disorder, severe cognitive impairment, severe vestibular disorder, insufficient visual acuity, or if you are a paediatric patient (under 18 years).

Healthcare Professionals

The healthcare professional should assess the patient's suitability for using this device prior to prescription. The healthcare professional should be trained and competent in the use of this device, and should be trained in the safe use of Strolll Navigait prior to training a lay user.

Residual Risks & Side Effects

Strolll is not aware of any undesirable residual risks or side effects associated with the use of this device. However, potential risks may include dizziness, balance disturbances, and eye strain or fatigue, which should be monitored by healthcare professionals.

Intended Use Environment

Strolll Navigait is intended for use in physiotherapy departments, private neurological rehabilitation clinics, outpatient clinics, and home settings.



Hallucinations

The device may increase susceptibility to hallucinations due to flashing or moving lights and images. Discuss this with your healthcare professional before using the device.



Photosensitive Seizures

Some people may experience a seizure, loss of awareness, or other conditions causing loss of consciousness due to flashing or moving lights or images. If you have a history of seizures, consult your healthcare professional before using the device.



Implantables

The augmented reality glasses contain magnets or electronic components that emit radio waves, which may impede the operation of implanted medical devices. Discuss this with your healthcare professional before using the device.

Device Description

Strolll Navigait is a software medical device intended to reduce the number and duration of freezing of gait (FoG) episodes in adult patients with Parkinson's disease. It uses machine learning to automatically detect the user's motor state in real time, interpreting the user's head position relative to their environment, and delivers personalised visual cues to help the user overcome or reduce the duration of freezing episodes and improve their walking.

Strolll® Navigait comes pre-installed on your augmented reality hardware device.

Expected Clinical Benefits

Strolll® Navigait provides assistive augmented-reality (AR) cueing to help reduce freezing of gait and to improve gait in people with Parkinson's disease. Existing clinical evidence with head-mounted cueing devices, like AR glasses, shows that the following clinical benefits may be expected when using Navigait:

- Navigait effectively modifies gait with AR cues (e.g. inducing changes in step length, walking speed and cadence relative to one's own gait pattern), as there is evidence that AR cues are equally effective for modulating gait as real-world cues in people with Parkinson's disease (Hoogendoorn et al. 2024a).
- Navigait may help to reduce the number of FOG episodes, as AR cues have been shown to reduce the number of FOG episodes — i.e. FOG prevention (Baugher et al. 2025b).
- Navigait may help to reduce the duration of FOG episodes, as there is evidence that AR cues reduce FOG durations when activated during FOG episodes — FOG alleviation (Baugher et al. 2025b). With Navigait, AR cues are presented automatically when FOG is detected.
- Navigait fulfils the needs of the intended users by incorporating recommended advances in AR cues and AR glasses (Baugher et al. 2025a), with prior evidence showing that Parkinson's disease patients are receptive to AR cueing (Baugher et al. 2025b), making AR FOG therapy with Navigait feasible for real-world use.

Supported Augmented Reality (AR) Devices

Strolll® Navigait software is available on Magic Leap 2 augmented reality glasses.

Wearable augmented reality glasses use sensors, cameras, and other advanced technologies to track the user's movements and position, and then overlay relevant digital content (holograms) onto the real-world view via see-through lenses.

In this section, we'll explain the important aspects of the supported devices, such as how to wear them correctly and key operations like turning the device on and off.



Instructions

Read the [Magic Leap safety guide](#) in addition to the Strolll Navigait IFU.



Damage

Do not use the Magic Leap device if it has been damaged.



Skin Irritation

If your skin becomes irritated, stop using the AR glasses.



Fit

Before using your AR glasses, ensure the glasses rest comfortably around your head and there is no discomfort. Consult the instruction guidance for correct fitment of the glasses.



Movement

Rapid movement or turning may lead to dizziness, motion sickness, or disorientation. Stop and rest if needed.

How To Operate Your Magic Leap 2

Fitting Your Magic Leap

The user should ensure correct fitting of the Magic Leap AR glasses prior to starting the application. If needed for patients with impaired visual fields, slot in the prescription lens inserts.



Cables

Cables pose a potential tripping hazard or could become entangled — ensure they are secure.

Magic Leap 2 Device Apparatus



1. Start with your headset facing away from you and open the headset like a pair of headphones by pulling apart the back band until it fits over your head. Be careful not to over-expand the back band.



2. Unlike a pair of glasses, the headset is not meant to sit directly on your ears. For the best experience, rest the front of the headset on the bridge of your nose, with the sidearms angled slightly above your ears.



3. Make sure the cable is free and not tangled up in the back of the headset. Secure the headset by pushing the back band together with both hands.



4. Secure the compute pack using the shoulder strap. Clip the shoulder strap hooks to the compute pack slots. Wear the strap over your shoulder, just like a messenger bag, and adjust the strap length for optimal positioning and comfort.

Turning the Glasses On and Off



Once you've fitted the glasses on your head, hold down the button on the compute pack for a 3-second count. You should see LED lights appear on the compute pack to indicate the device has turned on. The same action — holding the button for 3 seconds — turns the device off.

Turning the Controller On and Off

If you have been given a controller with your device, pick it up and hold down the home button on the hand control until the LED light at the base of the controller turns on. To turn the controller off, hold down the home button until the LED light at the base turns off.

Control	Function
Power Button	Hold down for 3 seconds to turn the device On/Off
Volume Control	Adjusts headset volume
LED Indicator	Shows device power status

How To Operate Strolll® Navigait



Environment

Use only in a safe space that is appropriate for your activities. Avoid trip hazards, stairs, low ceilings, and fragile or valuable items that could be damaged.



Lighting

Avoid direct sunlight. Dark colours, mirrors, and glass surfaces can affect the visibility of cues.

Getting Started

When you turn on the device, you will see the Magic Leap main menu. Select the "Navigait" app from the list. You may need to scroll the menu to find it.

Controls

The app will open and you will see the Controls menu, where you can choose your control scheme. This determines how you interact with the menus in the Navigait app.

It is recommended to use the controller. If you do not have access to a Magic Leap controller, you can use the hand controls. On this menu, you can use either the controller or your hands.

Controller

To press a button with the controller, point the controller at the button. You will see a beam extending from the end of the controller that shows you what you're pointing at. Buttons will change colour when you point at them. Squeeze the trigger on the back of the controller to press the button.

To drag a menu with the controller, point the controller at the drag symbol in the top-left corner of a menu. Press and hold the trigger — the menu will follow where your controller is pointing until you release the trigger.

Hands

To press a button with your hands, point your index finger (either hand) at the button and stick your thumb out sideways. You will see a beam extending from the end of your finger that shows you what you're pointing at. Buttons will change colour when you point at them. To press the button, touch your thumb to your index finger; once pressed, stick your thumb out sideways again.

To drag a menu with your hands, point your index finger at the drag symbol in the top-left corner of a menu. Touch your thumb to your index finger and keep it there — the menu will follow your finger until you stick your thumb out sideways again.

User Calibration

After you have selected a control scheme, you will see the Calibration menu. It is important that your calibration is accurate so that the motor state system can make correct predictions.

1. Enter your normal walking speed. Use the +/- buttons to increase or decrease the value. Speed is measured in metres per second. A normal walking pace for a healthy user is roughly 5 kilometres per hour, which is about 1.38 m/s.
2. Enter your upright standing height. Use the +/- buttons to increase or decrease the value. Height is measured in metres.
3. Stand up straight and press the "Set Standing Level" button. Once you have set your standing level, the "Set Sitting Level" button will appear. You can press "Set Standing Level" again if you need to change the height.
4. Find a chair and sit down, then press the "Set Sitting Level" button. You can move the menu if you need to bring it to the chair with you. Once set, the "Confirm" button will appear. You can press "Set Sitting Level" again if you need to change the height.

Once your calibration is set correctly, press the "Confirm" button and select "Yes".

Settings

- **Cue Height:** how tall the cues are, in metres.
- **Cue Thickness:** how deep the cues are, in metres.
- **Cue Spacing:** the minimum distance between cues, in metres. Your height is used to set a recommended spacing.

There is a setting called Cueing Level, which can be set to Low, Medium, or High. At a high level, this means more cues will appear. Low means cues will only appear when the system thinks you really need them; high means cues will appear everywhere.

More specifically, the Cueing Level drives the following settings:

- **Freezing Threshold:** how confident the freezing prediction must be to consider your movements as freezing. A higher value means the system is less likely to predict freezing. It ranges between 0 (always freezing) and 1 (never freezing).
- **Time to Show Radial Cue After Freezing:** how long you are freezing for before the radial cue appears, in seconds.
- **Show Radial If Standing:** if you are standing and not freezing, should the radial cue appear?
- **Time to Show Radial Cue After Standing:** if you are standing and not freezing, how long until the radial cue is shown, in seconds.
- **Cold Spots Only:** should line cues appear everywhere, or just close to cold spots? Cold spots are detected doorways and narrow passages. If Cold Spots Only is enabled, line cues only appear within 1.5 metres of doorways, or where the available width is less than 0.75 metres.

The predefined cueing levels apply the following values:

Setting	Low	Medium	High
Freezing Threshold	0.3	0.2	0.1
Time to Show Radial Cue After Freezing (s)	3	0 (Immediately)	0 (Immediately)
Show Radial If Standing	False	True	True
Time to Show Radial Cue After Standing (s)	n/a (Not shown)	5	2
Cold Spots Only	True	False	False

If a predefined cueing level does not suit you, you can adjust these values individually. Next to the Cueing Level is the "Customise" button — this opens the Cueing Level Settings menu, from which you can adjust any of these settings.

Ready to Begin

Once you have confirmed your settings, the app will load — please be patient during this time. It takes approximately 15 seconds.

Once the app has loaded, the Ready menu will appear. When you want to begin seeing cueing and recording data, press the "Begin" button.

Cueing

Cues will begin appearing on the floor, according to your current motor state and settings. When you are sat down, no cues will appear.

- When you are stood still and not freezing, the radial cue will show if settings permit: "Show Radial If Standing" must be true, and cues will appear after the "Time to Show Radial Cue After Standing" delay.
- When you are freezing, the radial cue will show after the "Time to Show Radial Cue After Freezing" delay.
- When you are walking, line cues will appear in front of you. Lines will only appear near doorways and narrow passages if Cold Spots Only is enabled.

If No Cues Appear

There might be a few reasons why no cues appear. Try these solutions in order:

- Look at the floor for a few seconds — the app needs a clear view of the floor to know where to place cues.
- Make sure your room is well lit. Open curtains and switch on overhead lights; the app cannot detect the environment in low light.
- Ensure your calibration is correct — the device only places cues when it detects you standing. If your calibration is wrong, it might think you're sitting and therefore not place any cues.
- Changing floor levels (up or down stairs or slopes) after starting the app is not currently supported.
- Ensure your settings are as desired. If you expect radial cues while standing still, make sure "Show Radial If Standing" is enabled and that you have been standing longer than "Time to Show Radial Cue After Standing".
- If you expect line cues whenever you walk, make sure Cold Spots Only is disabled. If enabled, cues will only appear around doors and narrow passageways — look carefully at each door for a few seconds so the app can scan them.
- If the Camera Error warning is showing on the home screen, the app was unable to initialise the cameras. Restart the device (not just the app).
- Restart the app — there may be an error preventing it from working properly.
- Restart the device — there may be an error with the device or its sensors that can be fixed by a restart.

Main Menu

There are the following controls on the main menu:

1. Show/Hide Motor State: shows or hides the motor state UI that follows the user.
2. Show/Hide Cues: shows or hides the cues. Cues will still be placed even if they are hidden.
3. Show/Hide Current Calibration: shows a screen displaying the current settings and calibration.
4. Show/Hide Console: shows a debugging console.

There is also the Save & Quit button. It is important that you use this button to quit the app, otherwise your session will not be saved.



Important

Do not use the hand controls to bring up the Magic Leap main menu — the session will not save.

Storage & Maintenance

Maintenance Information — Cleaning Your Augmented Reality Device

- To remove any build-up of loose dirt or dust, gently wipe the lens with a dry, lint-free microfiber cloth.
- To sanitise the device, use alcohol or antibacterial "sani" wipes on the surface of the AR glasses.
- Never submerge any device in water to clean it.

UVisan Cabinet

If you have purchased a UVisan cabinet with your devices, simply place your AR headset into the UVisan cabinet to disinfect, charge, and store it.

Storage and Disposal

Store the headset in the case provided. Dispose of it in accordance with the headset manufacturer's safety guide (WEEE).



Decommissioning

- Personal details are not stored on the AR glasses.
- Follow the cleaning instructions above.
- Return the device to Strolll in accordance with your agreement.

Troubleshooting

If you experience any technical difficulties, please contact us at support@strolll.co or call UK +44 20 4558 4295. You may also contact your prescribing healthcare professional.

For the latest information, please visit www.strolll.co. For the latest version of the instructions for use, contact customerservice@strolll.co or scan the QR code on the AR glasses label.

Known Issues

- Occasionally, furniture, windows, or decorative patterns are identified as doors. Cues will be placed around them as if they were cold spots.
- Challenging environmental conditions such as low lighting, shadows, or reflective surfaces can sometimes introduce depth-estimation noise. This may affect the position of cues.
- Small, thin, or partially occluded obstacles may not be detected.

Error Messages

Code	Description
ERR-001	Depth camera unavailable — informs the user that the depth camera cannot be accessed and to attempt recovery.

Technical Description



Headset

Read the Magic Leap safety guide in addition to the Strolll Navigait IFU (see "[Essential Documents & Legal Resources](#)" on the Magic Leap website).

The Strolll® Navigait application is pre-installed for use with Magic Leap 2 AR glasses.

In the event of a security failure where the application is modified, the application will not run. In this situation, the user should contact their prescribing healthcare professional or Strolll directly on cyberit@strolll.co

Performance Characteristics

- Display refresh rate: 15 Hz.
- Real-time is defined as producing predictions of the user's motor state (including freezing of gait) with an end-to-end detection-to-cue latency of less than 0.5 second.

Maintenance Restrictions

Software updates will be performed by Strolll personnel.



Environment

Strolll AR glasses are recommended for indoor use only, in the range 10–30°C. Avoid direct sunlight.



Keep Out of Reach of Children

AR glasses are not a toy — keep out of reach of small children. Strolll Navigait is intended for adults aged 18 and older.

Regulatory Symbols Used in Labelling and Directions for Use

For further information about the Strolll Navigait Health Software application, refer to the settings screen within the application. An electronic copy of the directions for use can be obtained by scanning the QR code on the AR glasses label.

Any serious incident that has occurred in relation to the device should be reported to Strolll and the competent authority of the member state in which the user is established.

Symbol	Meaning
	Warning: indicates a hazard that could cause severe personal injury, death, or substantial property damage if ignored.
	Caution: indicates that caution is necessary when operating the device, or that the current situation needs operator awareness or action to avoid undesirable consequences (minor injury or property damage if ignored).
	Manufacturer: indicates the medical device manufacturer.
	EU REP: authorised representative in the European Community / European Union. Importer: Any natural or legal person established within the Union that places the device on the Union market.
	REF (Catalogue Number): indicates the manufacturer's catalogue number so the medical device can be identified.
	UDI: indicates a carrier that contains Unique Device Identifier information.
	MD (Medical Device): indicates the item is a medical device.

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Therapy must be determined by the prescribing Healthcare Practitioner. Before using Strolll® Navigait, please read these Directions for Use and retain them for future reference.

Please note that the information provided in this document is intended to get you up and running. Strolll will not accept responsibility for any damage or injury arising from improper use. The information in this document is subject to change without notice. This document is believed to be complete and accurate at the time of publication.