

OF CONTENTS **FABLE**

- Functional Mobility and Gait Assessment Form
- Components
- Clinical Gait Evaluation Diagram
- Sizing Guidelines
- Standard Configuration
- Donning Instructions
- Fitting Instructions
- Cleaning and Care
- Return & Refunds
- Clinician FAQ

NewGait FUNCTIONAL MOBILITY & GAIT ASSESSMENT FORM

Name	Diagnosis

TUG TEST SCORE

Time taken to rise from a chair, walk 3 meters, turn around, walk back and sit down.

DATE	TIME

SINGLE LEG BALANCE

Lift one leg while maintaining level hips and shoulders. Hold the balance position. Record the best of 3 attempts.

DATE	RIGHT LEG	LEFT LEG

10 METER WALK TEST

The patient walks 10 meters and the time is measured for the intermediate 6 meters to allow for 2 meters of acceleration and 2 meters of deceleration.

DATE	ASSISTIVE DEVICE USED	TIME/SPEED NO NEWGAIT	STEP LENGTH NO NEWGAIT	TIME/SPEED WITH NEWGAIT	STEP LENGTH WITH NEWGAIT

Speed: 6m / Recorded Time Step Length: 600cm / # of Steps

DYNAMIC GAIT INDEX (DGI)

Instructions and scoring information on a separate sheet. A score of less than 19 is predictive of fall risk.

Name	

FUNCTIONAL MOBILITY & GAIT ASSESSMENT FORM

FALLS EFFICACY SCALE (FES) SCORE

On a scale from 1 to 10, with 1 being very confident and 10 being not confident at all, how confident are you in performing the following activities without falling?

ACTIVITY	DATE	DATE	DATE
Bathe/shower			
Get dressed			
Prepare a meal			
Get in/out of bed			
Answer the door			

WALKING WHILE TALKING

Instruct the patient to ambulate 20 feet, turn around, and return (40 feet total). Additionally, instruct the patient to recite the alphabet aloud (simple), or recite the alternate letters of the alphabet (complex). The time to complete the walking distance is the score. 19 seconds or longer fr simple is indicative of fall risk. 33 seconds or longer for complex is indicative of fall risk.

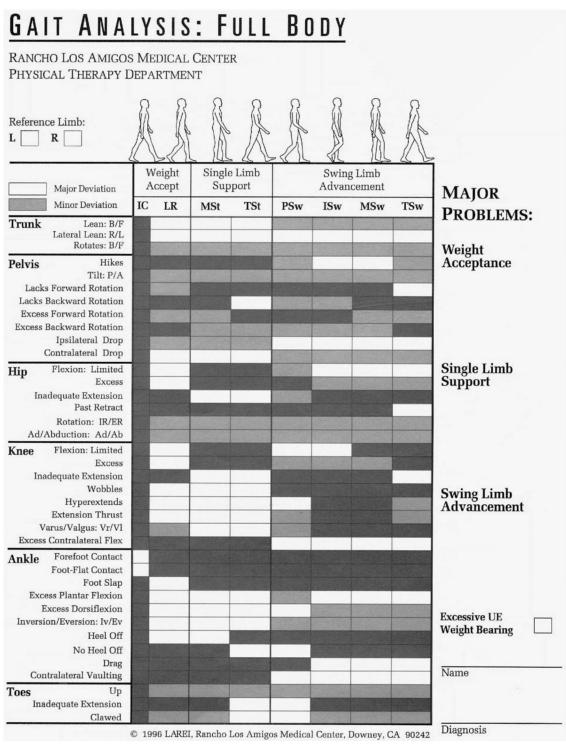
TESTS TO ASSESS FALL RISK

DATE	SIT TO STAND (# OF REPS IN 30 SEC.)	FES	WALKING WHILE TALKING (TIME)	DGI

NewGait FUNCTIONAL MOBILITY & GAIT ASSESSMENT FORM

Name	Diagnosis

RANCHO LOS AMIGOS OBSERVATIONAL GAIT ANALYSIS



3

NewGait DYNAMIC GAIT INDEX

Name	Diagnosis

The Dynamic Gait Index was developed to assess the likelihood of falling in older adults. It is composed of 8 gait tests with each being scored on a four point scale ranging from 0-3. "0" indicates the lowest level of function and "3" the highest level of function. The highest score possible is 24. A score less than 19 is predictive of fall risk.

1. Gait Level Surface

Walk at normal pace for 20'.

0 -Severe Impairment:

Cannot walk 20' without assistance, severe gait deviations or imbalance.

1 -Moderate Impairment:

Walks 20' slow speed, abnormal gait pattern, evidence for imbalance.

2 -Mild Impairment:

Walks 20' uses assistive devices, slower sped, mild gait deviations.

3 -Normal:

Walks 20' no assistive devices, good speed, no evidence for imbalance, normal gait pattern.

2. Change in Gait Speed

Walk at normal pace for 5', then instruct to "go," and walk fast for 5', instruct to "slow," and walk slowly for 5'.

0 -Severe Impairment:

Cannot change speeds or loses balance and has to reach for wall or be caught.

1 -Moderate Impairment:

Makes only minor adjustments to walking speed, or accomplishes a change in speed with significant gait deviations.

2 -Mild Impairment:

Is able to change to change speed but demonstrates mild gait deviations, or unable to achieve a significant change in velocity.

3 -Normal:

www.thenewgait.com

Able to smoothly change walking speed without gait deviations or loss of balance.

3. Gait with Horizontal Head Turns

Walk at normal pace. Then instruct to "look right," keep walking straight, but turn your head right. Then instruct to, "look left," keep walking straight and turn your head left. Then instruct to "look straight," keep walking straight and return your head center.

0 -Severe Impairment:

Performs task with severe disruption of gait, ie., staggers off path loses balance, stops, reaches for wall.

1 -Moderate Impairment:

Performs head turns with moderate change in gait velocity, slows down, staggers but recovers, can continue to walk.

2 -Mild Impairment:

Performs head turns smoothly with slight change in gait velocity.

3 -Normal:

Performs head turns smoothly with no change in gait.

4. Gait with Vertical Head Turns

Walk at normal pace. Then instruct to "look up," keep walking straight, but lift your chin up. Then instruct to "look straight," keep walking straight but return your head to center.

0 -Severe Impairment:

Performs task with severe disruption of gait, ie., staggers off path loses balance, stops, reaches for wall.

1 -Moderate Impairment:

Performs head turns with moderate change in gait velocity, slows down, staggers but recovers, can continue to walk.

2 -Mild Impairment:

Performs head turns smoothly with slight change in gait velocity.

3 -Normal:

Performs head turns smoothly with no change in gait.

Name

DYNAMIC GAIT INDEX

5. Gait and Pivot Turn

Walk at normal pace, then instruct to "turn and stop," turn as quickly as you can to face the opposite direction and stop.

0-Severe Impairment:

Cannot turn safely, requires assistance to turn and stop.

1 -Moderate Impairment:

Turns slowly, requires several small steps to catch balance.

2 -Mild Impairment:

Pivot turns safely in more than 3 seconds and stops with no loss of balance.

3 -Normal:

Pivot turns safely within 3 seconds and stops quickly with no loss of balance.

6. Step Over Obstacles

Walk at a normal speed, step over the box, not around it, and keep walking.

0-Severe Impairment:

Cannot perform without assistance.

1 -Moderate Impairment:

Is able to step over the box but must stop first.

2 -Mild Impairment:

Is able to step over the box, but must slow down.

3 -Normal:

Is able to step over the box without changing gait speed.

7. Step Around Obstacles

Walk at a normal speed. When you come to the first cone 6' away, walk around the right side. When you come to the next cone 6' past the first, walk around the left side.

0-Severe Impairment:

Unable to avoid the cones, walks into one or both cones, or requires physical assistance.

1 -Moderate Impairment:

Is able to avoid the cones, but must significantly slow speed.

2 -Mild Impairment:

Is able to avoid the cones, but must slightly slow and adjust steps.

3 -Normal:

Is able to walk around the cones safely without changing gait speed.

8. Steps

Walk up the stairs as you would at home, i.e., using the railing if necessary. At the top, turn around and walk down.

0 -Severe Impairment:

Cannot perform safely.

1 -Moderate Impairment:

Must place both feet on each step, and must use rail.

2 -Mild Impairment:

Alternating feet, but must use rail.

3 -Normal:

Alternating feet, no need to use the rail.

TOTAL SCORE:	/24
--------------	-----

NewGait GAIT ASSESSMENT FORM NORMATIVE DATA

NORMATIVE DATA TUG TEST			
AGE GROUP	TIME (SECONDS)		
40 - 49	7.1		
50 - 59	7.5		
60 - 69	8.1		
70 - 79	9.2		
80 - 89	11.3		

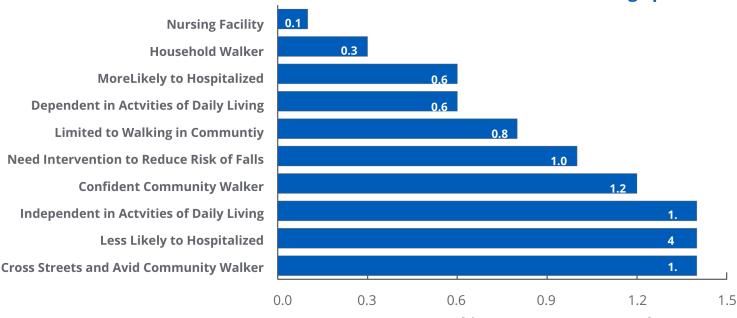
NORMATIVE DATA SINGLE LEG BALANCE TEST

*Greater than 14 seconds associated with high fall risk

AGE GROUP	TIME (SECONDS)
40 - 49	41.9
50 - 59	41.2
60 - 69	32.1
70 - 79	21.5
80 - 89	9.4

NORMATIVE DATA 10 METER WALK TEST			
STEP LENGTH	SPEED	STEP WIDTH	
70 - 82 cm	1.4 m/sec	Fist Width	







NewGait GAIT ASSESSMENT FORM **NORMATIVE DATA**

NORMATIVE DATA SIT TO STAND			
AGE GROUP	# OF REPS		
60 - 69	15		
70 - 79	12		
80 - 89	10		
90 - 99	9		

NORMATIVE DATA DYNAMIC GAIT INDEX

A score less than 19 is predictive of fall risk.

NORMATIVE DATA WALKING WHILE TALKING		
SIMPLE	COMPLEX	
20 seconds or longer is indicative of fall risk	33 seconds or longer is indicative of fall risk	

NORMATIVE DATA AND SCALE **FES SCORE**

LOW	MODERATE	HIGH
7 - 21	22 - 42	43 - 70

AGE GROUP	FES SCORE
40 - 49	10
50 - 59	15
60 - 69	21
70 - 79	30
80 - 89	43

COMPONENTS



Shoulder Harness

Sizing options: S, M, L

Used to provide trunk support and/or keep the waist belt in place



Elastic Tubing

Resistance options: yellow (light), red (medium), green (heavy)

Provides resistance or assistance



Waist Belt

Sizing options: S, M, L, XL

Provides a supportive structure for elastic tubing placement above or below



V-Anchor

Sizing options: one size fits all

Alternative to a D-ring anchor. Used in conjunction with calf limb strap to provide dorsiflexion assist.



Limb Strap

Sizing options: XS, S, M, L

Provides proprioceptive pressure and attachment for elastic tubing



Shoe Anchor

Sizing options: one size fits all

Used for dorsiflexion assist configuration. Provides a more secure anchor point for elastic tubing placement on the shoe



D-Ring Anchor

Sizing options: one size fits all

Slides on waist belt or limb straps to provide additional attachment points for the elastic tubing



Extender

Sizing options: M, L

Provides additional length for waist belt or shoulder harness if needed.



Plantar Flexion Anchor

Sizing options: one size fits all

Used for plantar flexion assistance. It is placed in the shoe, under the sole.



Blue Loops

Sizing options: one size fits all

Quick option for dorsiflexion or plantar flexion assistance. It is a clinical product only, not suitable for long term home use.

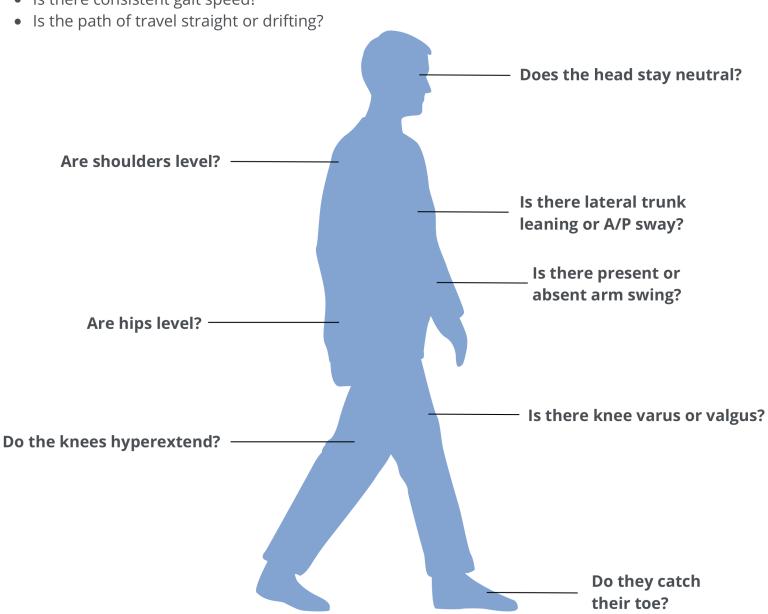




CLINICAL GAIT EVALUATION QUICK REFERENCE DIAGRAM

Consider the following:

- Is there consistent step length?
- Is there consistent step width?
- Is there consistent gait speed?







NewGait Sizing Guidelines

LEG STRAP SIZING

Leg size is measured on the lower part of the thigh, 1 inch above the knee. Or on the upper part of the calf, 1 inch below the knee.



Size	XS	S	M	L
Leg size	9-11	11-13	13-16	16-19
(inches)				

WAIST BELT SIZING



Waist measurement is taken where a belt would fit, just above the hips. *Order an extender if waist size is above 57 inches.

Size	S	M	L	XL
waist size	24-30	30-36	36-42	42-51
(inches)				•

*please note due to continued product improvements your components may look slightly different from those depicted in this manual



SHOULDER HARNESS SIZING

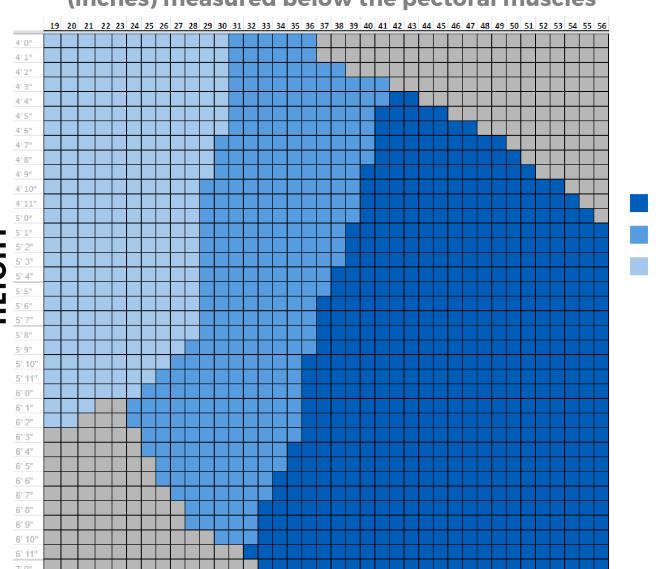


To properly size the shoulder harness a user must know their height and chest size. Chest size is measured just below the pectoral muscles across the sternum and around the torso. With these two figures locate your size using the table below.

S corresponds to small, M corresponds to medium, and L corresponds to large.

CHEST SIZE

(inches) measured below the pectoral muscles



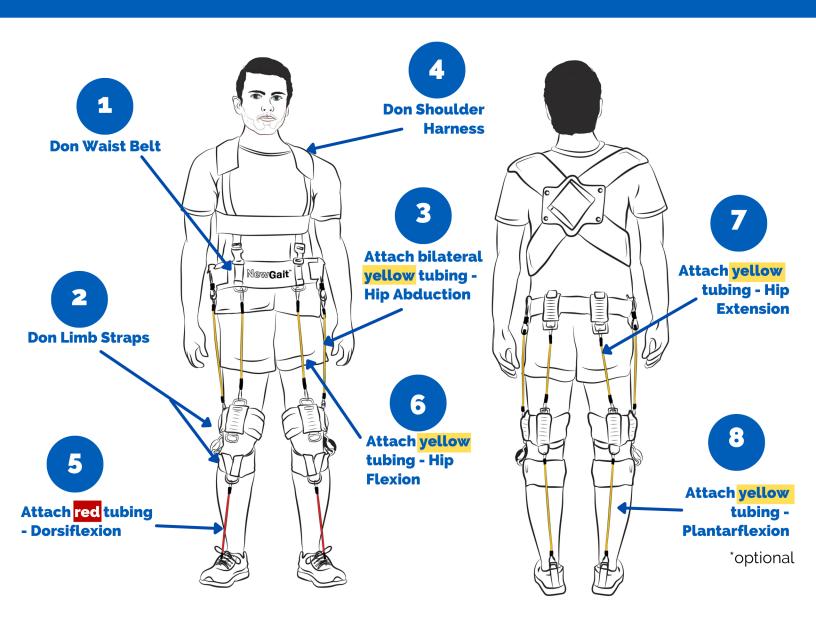


LARGE

MEDIUM

SMALL

Standard Configuration





Individualize unit based on comfort and gait quality.

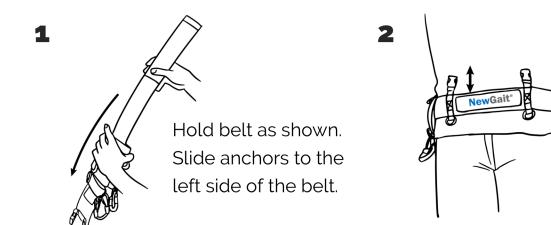
Options are to change elastic tubing strength, angle, remove it if needed. Some individuals find they move better without the use of both dorsiflexion and plantarflexion and may prefer one over the other.



Document Best Fit for reapplication of the NewGait system at future visits. Take photos and video to refer back to later

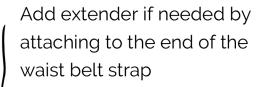
Donning Instructions

A. Waist Belt



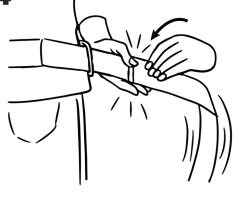
Thread strap through rectangular metal loop and close as shown.

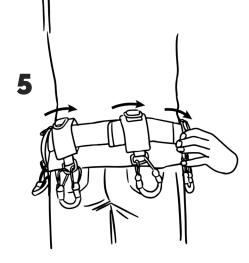
2



Align and center

the logo.





Slide Double D-ring Anchors into symmetrical spacing for hip abduction at trunk midline and posterior over gluteal musculature.

B. Limb Straps | Above Knee

Outside lateral side

1 Hold Right limb strap set as indicated by the white connector.

Identify superior patella (knee cap) with finger tips and align strap.

White connector - right side Black connector - left side

Place hook side (scratchy side) at medial (inside) of knee.



2

Loop material (soft part of "hook and loop")

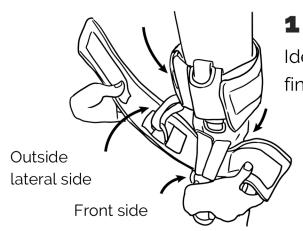


3

Wrap limb strap clockwise behind knee to close.

Position D-ring anchors with one positioned above the patella, one at the midline of the thigh, and one at the posterior thigh.

Limb Straps | Below Knee



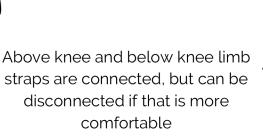
Identify inferior patella (knee cap) with fingertip and align strap.

2

Place hook (hook side) at medial (inside) of knee.



Wrap limb strap clockwise behind knee to close.





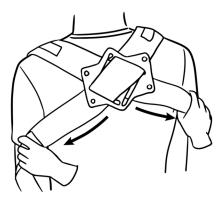
4

Position the sewn-on metal ring at mid leg and the V Anchor at the front of the shin.

Repeat limb strap application using a set of limb straps with a black connector for the Left lower extremity.

NOTE: These above and below knee straps will wrap counterclockwise.

C. Shoulder Harness



1

Place the Shoulder harness keeper over the head to lie between the shoulder blades.

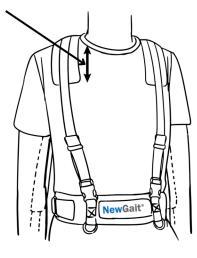


clip in and adjust length if needed

2

Clip the black fasteners into the white portion of the waist belt.

2 inches below collarbone



3

Adjust the fabric portion of the shoulder harness to lie approx. 2 inches below the collar bone.

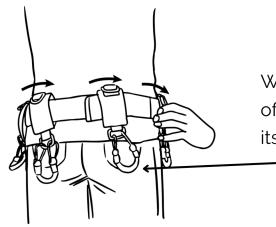


4

Ask the person to stand tall and gently draw the ends of the shoulder harness toward the front of the body to close under the breast line

NOTE: The closure can be above the breast line, depending on body shape. Readjust the shoulder harness keeper between the shoulder blade area.

Doffing Tips



When doffing your unit unhook one end of the elastic tubing and rehook it to itself

Remove limb straps and reclose hook and loop to hang and avoid catching hook and loop on other items.

Remove shoulder harness and close hook and loop to hang.

Remove the waist belt, be sure to take a moment to slide anchors to the left side of the belt. This will expose the most medial or central edge of the belt webbing to release the belt. Reclose belt.

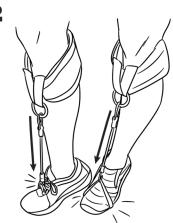
Fitting Instructions

1



Add yellow hip abduction tubing, then take several steps

2



add red dorsiflexion assistance tubing, then take several steps

Use 3 shoe laces nearest the toes OR a shoe anchor

Home Use

Use 3 shoe laces nearest the toes OR shoe loop

Clinic Use

3

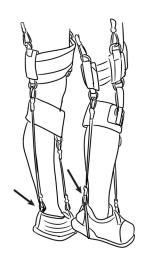


Attach bilateral yellow hip flexion. Walk several steps and assess comfort and gait.

4



Attach bilateral yellow hip extension. Walk several steps and assess comfort and gait.



Attach bilateral yellow plantarflexion assist. Walk several steps and assess comfort and gait

6 Individualize unit based on comfort and gait quality.
Options are to change elastic tubing strength, angle, remove it if needed, and other useful tips are included. Some individuals find they move better without the use of both dorsiflexion and plantarflexion and may prefer one over the other.

7



Document Best Fit for reapplication of the NewGait system at future visits. Take photos and video to refer back to later

LIMB STRAP CONFIGURATION

You may notice two pairs of limb straps fastened together using a hook and loop strap. These are there to prevent either limb straps from sliding up or down.

The Right side has the White hook and loop strap
The Left side has the Black hook and loop strap

Left Side

Above Knee Limb Strap

Right Side



Below Knee Limb Strap

Cleaning, disinfection and care instructions

Cleaning instructions

- Wash by hand using cold water and gentle detergent
- Dip the component into soapy cold water, then rinse in clean water
- Fasten all Velcro straps prior to washing to maintain the life of the Velcro
- Hang to dry, or pat dry with a towel with gentle pressure to transfer moisture

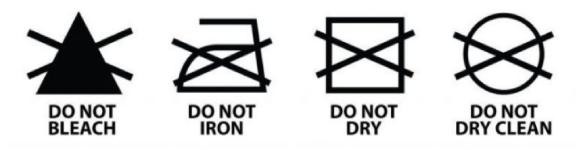


Disinfection protocol

- Spray the nylon webbing and neoprene components with 3%-6% pre-diluted standard hydrogen peroxide
 - Hydrogen peroxide breaks down to water, so it will not ruin clothing
- Purchase approved disinfecting products rather than diluting other products to avoid issues with chemical breakdown and storing of chemicals
- Allow the components to air dry before the next patient uses it
- Wash the components more thoroughly on a weekly basis
- Approved products for disinfection and general cleaning can be found at The Centers for Disease Control and Prevention website

Care tips

- Keep Velcro fastened so the coarse Velcro does not come into contact with the nylon or neoprene components to avoid material degradation
- Do not wash the elastic bands
- Do not expose any component to chlorinated or salt water
- Do not expose any component to direct heat (such as a dryer, iron, or direct sunlight)
- Do not rub any component against abrasive materials or surfaces
- Do not bleach any of the components





Returns & Refunds

At MQT Innovations, Inc. we hold customer satisfaction in very high regard. That is why we allow a 30-day refund policy. The item you wish to return must be in the same condition that you received it. It must be in the original packaging and needs to have the receipt or proof of purchase. Upon receiving your returned item and following its inspection, we will immediately notify you of the status of your refund.

If your return is approved, we will initiate a refund to your credit card (or original payment method). You will be responsible for paying for your shipping costs for returning your item and a 15% restocking fee. If you have any questions about returning your item to us, please contact us. If you find a manufacturing defect with your purchase, you have 12 months to contact us via sales@thenewgait.com to be eligible for a product exchange. Please note that the elastic bands are not covered under this 12-month policy, will wear over time, and may break if overstretched or abrased. However, when used and stored appropriately, the elastic bands can be expected to last 12 - 18 months.





Safety Notice

PLEASE NOTE

NewGait is like any other fitness equipment. It can cause injury if used improperly. If injury occurs while in use, stop immediately and consult your physician. Follow these steps to ensure safe use.



- The clinician must use proper judgement to provide a safe environment for the patient.
- The patient must have the ability to stand and initiate gait on their own to have success with the NewGait.
- When first equipping the NewGait, provide extra support as the patient will not expect the assistance and compression sensation with the first few steps.
- If the patient feels any discomfort, please discontinue using the device and reassess the placement of components.
- Caution: This product contains natural rubber latex which may cause allergic reactions.
- Do not use the NewGait with healing or unstable fracture sites, do not place the bands over healing incisions, deep vein thrombosis (blood clots), or leg edema.



Billing tips & tricks

During treatment sessions, physical therapists bill timed treatment codes, known as CPT codes, to denote services rendered to healthcare payers. The most commonly billed codes used by physical therapists using the NewGait are neuromuscular re-education, therapeutic activities, and gait training. Below is a description of each code, and an example of using the NewGait with that treatment code.

Neuromuscular Re-education: 97112

- Activities that facilitate re-education of movement, balance, coordination, kinesthetic sense, posture, or proprioception
- Example: using the NewGait device to facilitate muscle contraction at specific joints during standing dynamic balance activities

Therapeutic Activities: 97530

- Dynamic activities that improve functional performance, such as bed mobility, transfer training, stair negotiation, car transfers, sit-to-stand training, and activity mechanics training (such as squatting mechanics)
- Example: using the NewGait during stair training to facilitate hip flexion for foot clearance during the ascension of the step

Gait Training: 97116

- Activities that address specific gait impairments, performing training with an assistive device, practicing turns, working with modified weight-bearing status during gait
- Note: this code must be used to improve the biomechanics of gait. Using this code for engaging a patient in a walking program to improve cardiovascular endurance is not considered gait training
- Example: using the NewGait with a patient with foot drop, training them on the use of a single-point cane using a step-through gait pattern



Commonly asked questions

How did the Speedmaker become the NewGait?

A therapist in Michigan had a spinal cord injured patient with gait instability. The bands and versatility of the Speedmaker components improved the patient's hip flexion and dorsiflexion, which improved gait quality and stability. The therapist began to further manipulate the elastic tubing and strap placements and a variety of conditions began to benefit from the New Gait.

Who can use the NewGait?

The New Gait has been used on individuals with MS, ataxia, connective tissue disorder, post-surgical joint replacement, spinal cord injury, back/hip/knee/ankle pain, varying gait abnormalities, post-stroke, with prosthetics gait training, upper extremity impairment, and Parkinson's.

What are the precautions for patient use?

The clinician must use proper judgment to provide a safe environment to decrease the risk of falls.

What are the indications for patient use?

The patient must have the ability to stand and initiate gait with or without an assistive device.



NewGait



MEDICAL DEVICE



Caution: This device contains natural rubber latex which may cause allergic reactions.

INTENDED USE

- The device is intended to use for drop foot.
- The device is intended to align body structures for functional improvement.

INDICATIONS FOR USE

- Drop foot
- The device is intended to support adults with gait dysfunctions
- No known contraindications

CONTRAINDICATIONS

- Unhealed fracture sites
- Significant limb edema
- DVT
- Unhealed incisions
- Allergies to latex or neoprene

WARNINGS AND CAUTIONS

- Never wear the device directly on an open wound.
- Care should be taken not to overtighten the device.
- Patients with already compromised blood circulation in their extremities, like those with diabetes, or peripheral vascular
 disease, need to be extra careful and are advised to consult with a healthcare professional before using the device. If you
 experience pain, swelling, sensation changes, or if your extremity shows signs of insufficient blood flow (turns blue, white,
 or cold) while using this device, discontinue the use immediately and consult with a healthcare professional.
- Osteoporosis
- Implanted devices (ex: bladder stimulator or colostomy bag)

GENERAL SAFETY INSTRUCTIONS

Read these instructions carefully before use. Keep them for future reference. Any serious incident in relation to the device must be reported to the manufacturer and relevant authorities.

- The patient should stop using the device and contact a healthcare professional:
- If there is a change or loss in device functionality or if the device shows signs of damage or wear hindering its normal function
- If any pain, skin irritation, or unusual reaction occurs with the use of the device.
- The device is for a single patient multiple uses.



Media and Talent Release

NewGait
MQT Innovations, Inc.
info@thenewgait.com
www.thenewgait.com

MEDIA TYPE



Press Release including, but not limited to:

- Local media, newspaper, television, radio
- Regional and national media, newspaper, television, radio
- Internet, website and social media sites

I consent to the recording and broadcast of my image, voice and likeness without time limit, so as long as the broadcast is in good taste and is not obscene or indecent. My name, image, voice and likeness may be used in advertising and promotional material.



Photograph including, but not limited to:

- Local media, newspaper, television, radio
- Regional and national media, newspaper, television, radio
- Print advertisement, flyer, brochure or display
- Internet, website and social media sites.

I consent to photograph of my image and likeness without time limit, so as long as the broadcast is in good taste and is not obscene or indecent. My name, image and likeness may be used in advertising and promotional material.



Video including, but not limited to:

- Local media, newspaper, television, radio
- Regional and national media, newspaper, television, radio
- Internet, website and social media sites

I consent to the recording and broadcast of my image, voice and likeness without time limit, so as long as the broadcast is in good taste and is not obscene or indecent. My name, image, voice and likeness may be used in advertising and promotional material.

CONSENT



I represent that I am 18 years of age or older and have the right to enter into this agreement.



I am under the age of 18 years. My parent or legal guardian has consented to my execution of this consent.

TERMS

In giving this consent, I release MQT Innovations, Inc. and their agents from any liability for any violation of any personal or property rights which materials I might have a connection with. I understand that I am not being paid or reimbursed for participating in this media.

I hereby grant my unconditional permission and consent to MQT Innovations, Inc. its consultants, members, agents, employees, or representatives to use, reuse and/or publish photographic, audio, and/or video graphic or media materials, digital or otherwise, that depict me, my image, and/or my likeness in its website, other official printed publications or video productions, without payment to me.

I acknowledge MQT Innovations, Inc.'s right to crop the photographs or treat the photographic images at their discretion and hereby waive my right to review or approve such photograph, video, sound recording, or likeness prior to its use.

This permission and consent extend to all actions and purposes of MQT Innovations, Inc., including research, social media, website content, public promotional videos, commercials, or other purposes. I hereby release MQT Innovations, Inc., its agents, employees, or representatives from any liability and from any and all claims or causes of action which I may otherwise pursue in respect of, or arising from the reproduction of the photos, videos, images or likenesses as set forth above.

Printed Name:				
Signature:			Date:	
Address:	City:	State:	Zip:	
Phone Num	ıber / Email Address); 		

We are currently looking for more stories like yours to spread the message that hope can be restored! If you would like to be featured on our monthly newsletter, please check the box and someone will contact you in a few days.