

Wheelchairs powered by

SOFTWHEEL

Introducing the NEW

SOFTWHEEL 3



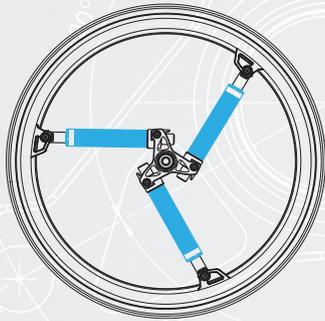


SoftWheel's innovative
in-wheel suspension technology
can help reduce pain and
provide a more comfortable ride



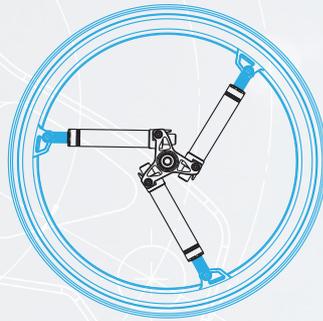
For more info visit www.softwheel.technology

Patented In-Wheel Suspension System



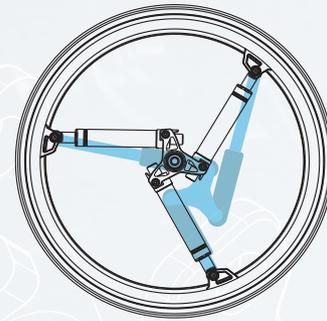
In-Wheel Suspension

3 suspension arms are built inside the wheel and compress to absorb shocks



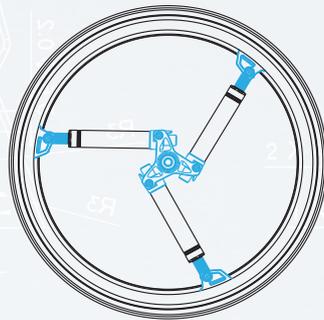
Rigid Rim

Wheel rim is always rigid & strong, while the suspension arms & hub compress to provide shock absorption



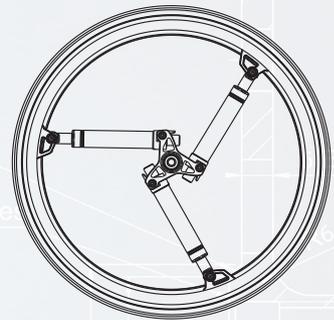
Automatic Actuation

Suspension arms automatically compress when encountering an obstacle or rough terrain, and remain rigid & strong over flat surfaces



360° Suspension

Arms are set equidistant around a central hub to provide shock absorption - no matter the angle of impact



Rapid Shock Reset

Suspension arms immediately reset and return the wheelchair – and rider, to a level ride

R1 All around
Both sides

2.4° Both Sides
45° Both Sides

+0.1
54 0

Both Sides

+ 0.010
Ø28 -0.021

DIMENSION AFTER COATING
SEE NOTE 3.5

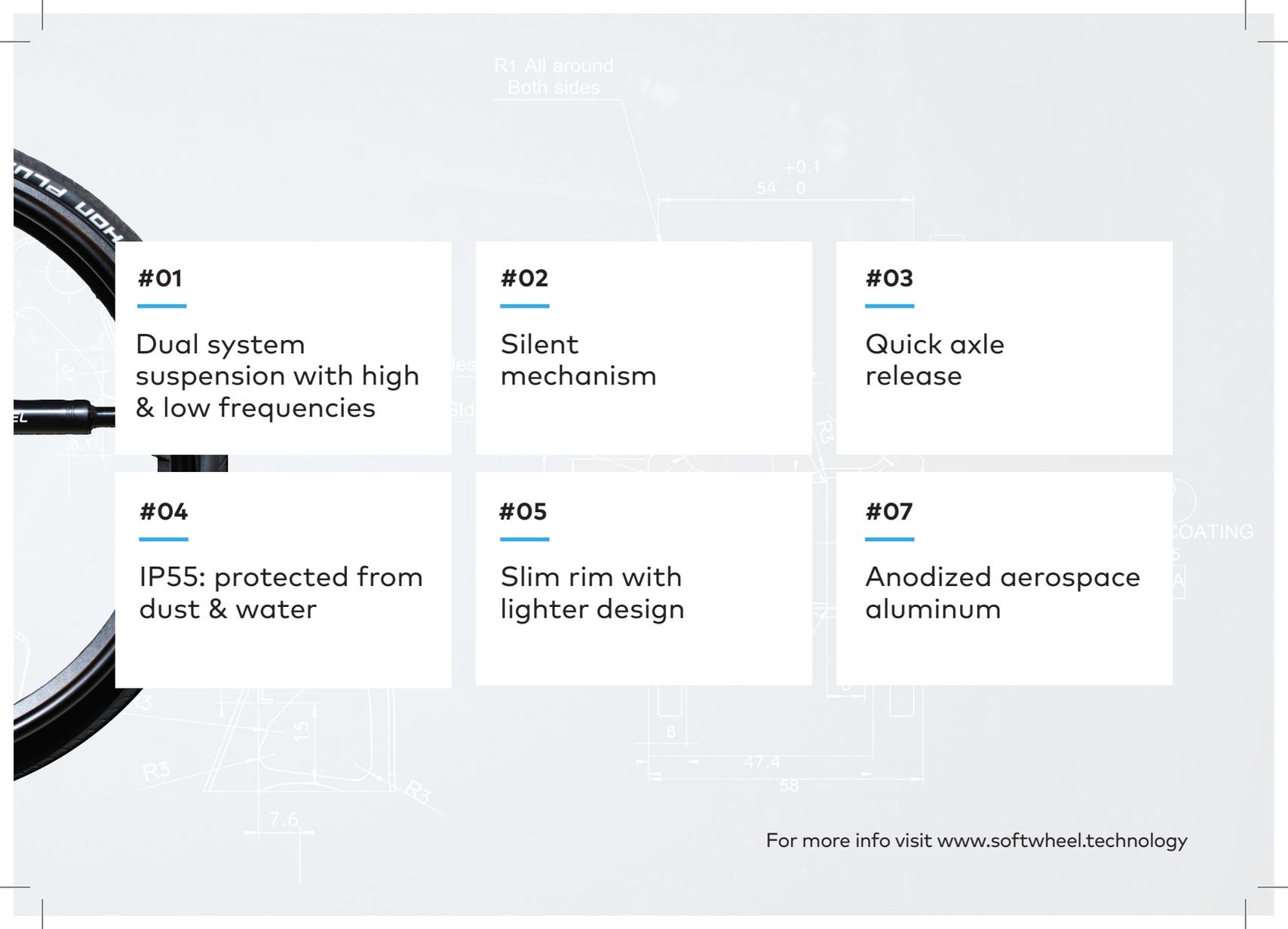
Ø 0.05 A

1.7 X 30°

SoftWheel Features

SOFTWHEEL





R1 All around
Both sides

+0.1
54 0

#01

Dual system suspension with high & low frequencies

#02

Silent mechanism

#03

Quick axle release

#04

IP55: protected from dust & water

#05

Slim rim with lighter design

#07

Anodized aerospace aluminum

Shock Absorption That Actuates Only When You Need It

The wheel rim always remains rigid, while the suspension arms & hub shift to provide shock absorption only when needed – when encountering an obstacle or rough terrain.

This leads to a smoother, more efficient ride over all types of terrain.



SOFTWHEEL





R1 All around
Both sides

+0.1
54 0

SOFTWHEEL

Sides

5 Both Sides

X45° Both Sides

C

+ 0.010
Ø28 -0.021
DIMENSION AFTER COATING
SEE NOTE 3,5

Ø 0.05 A

Ø40 (X2)
Ø36 (X2)

R0.3 (X2)

1.7 X 30°

R3

R3

7.6

15

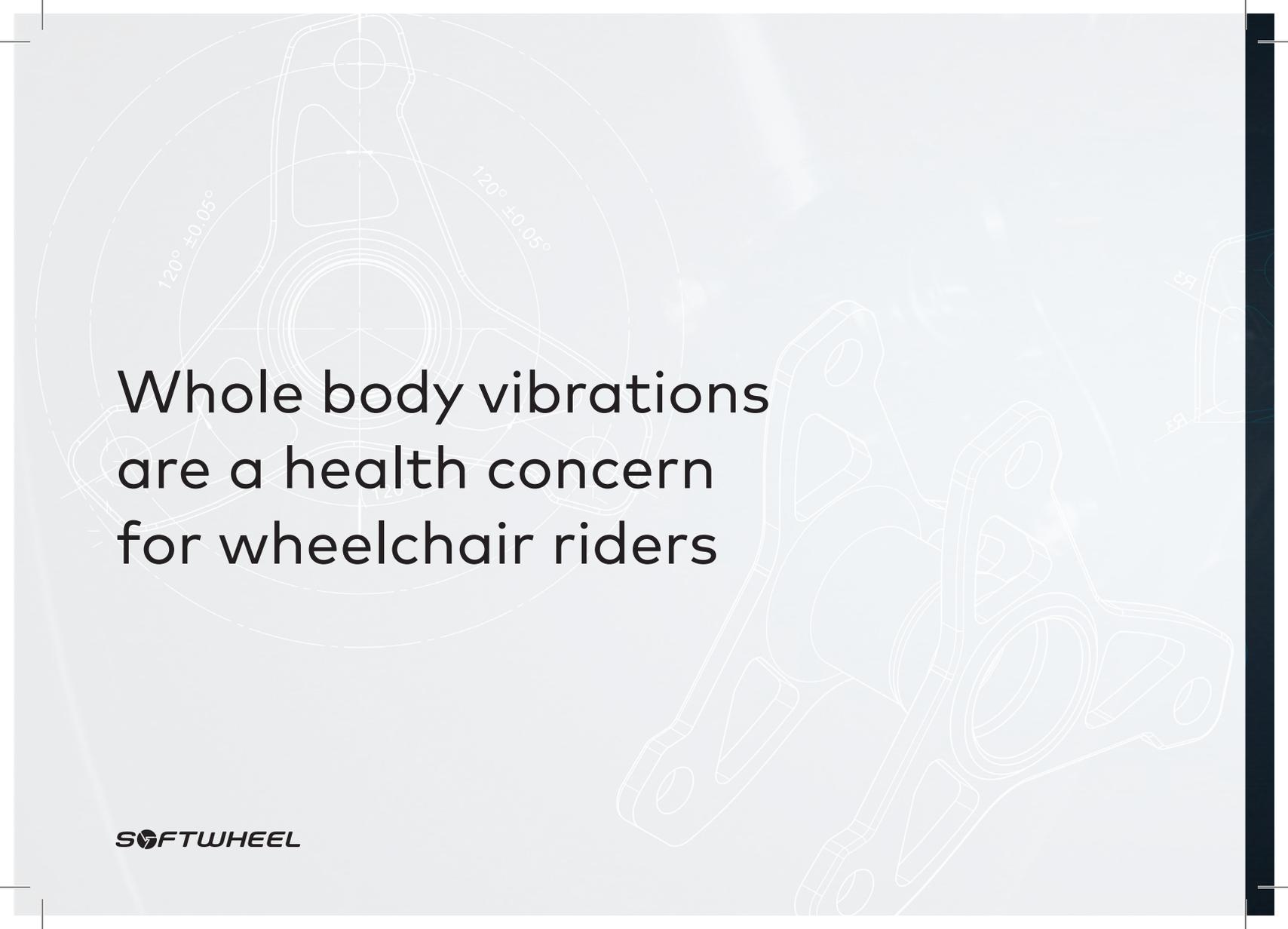
8

47,4

58

9.6

For more info visit www.softwheel.technology



Whole body vibrations
are a health concern
for wheelchair riders

01

Long-term exposure to vibrations has been demonstrated to have a negative impact on people's **health & comfort**

02

Clinical studies have shown that wheelchair riders are **exposed to vibrations that exceed the recommended exposure limits**

03

Health risks associated with vibrations for wheelchair riders include **lower back pain**, effects on the **spine**, and muscle **fatigue**

References:

"Health risks of vibration exposure to wheelchair users in the community," Garcia-Mendez Y, Pearlman J, Boninger ML, Cooper RA; *The Journal of Spinal Cord Medicine* 2013 Jul; 36(4):365-375

"Analysis of vibrations induced during wheelchair propulsion," VanSickle DP, Cooper RA, Boninger ML, DiGiovine CP; *Journal of Rehabilitation Research and Development* 2001 Jul-Aug; 38 (4):409-421



120° ±0.05°
120° ±0.05°
120°

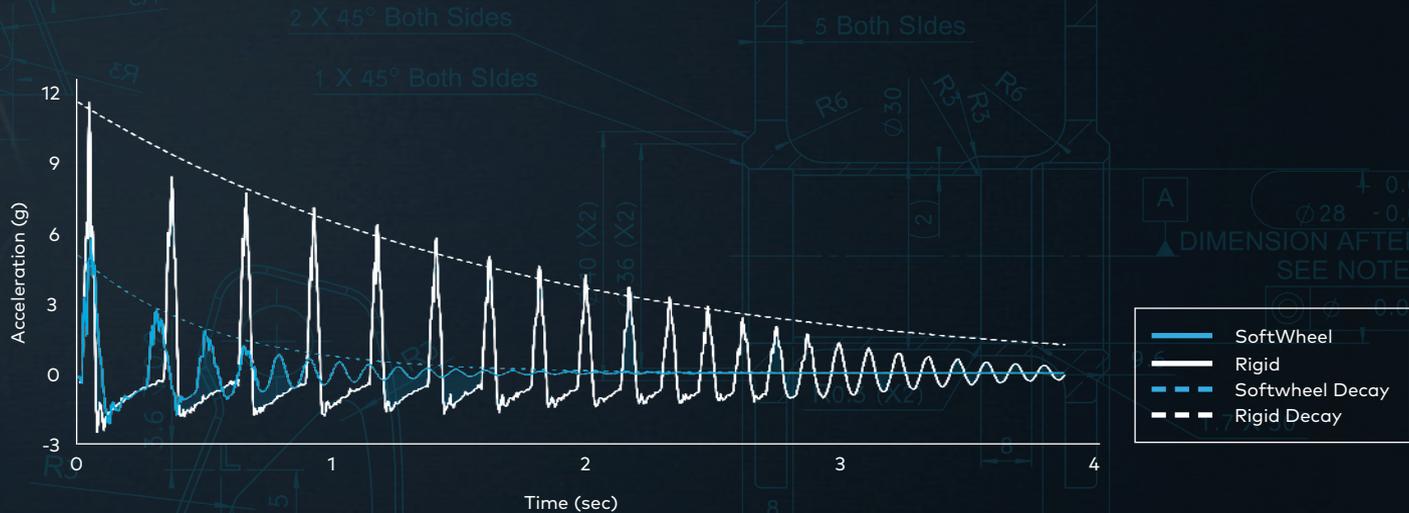
SoftWheel Reduces Vibrations

SOFTWHEEL

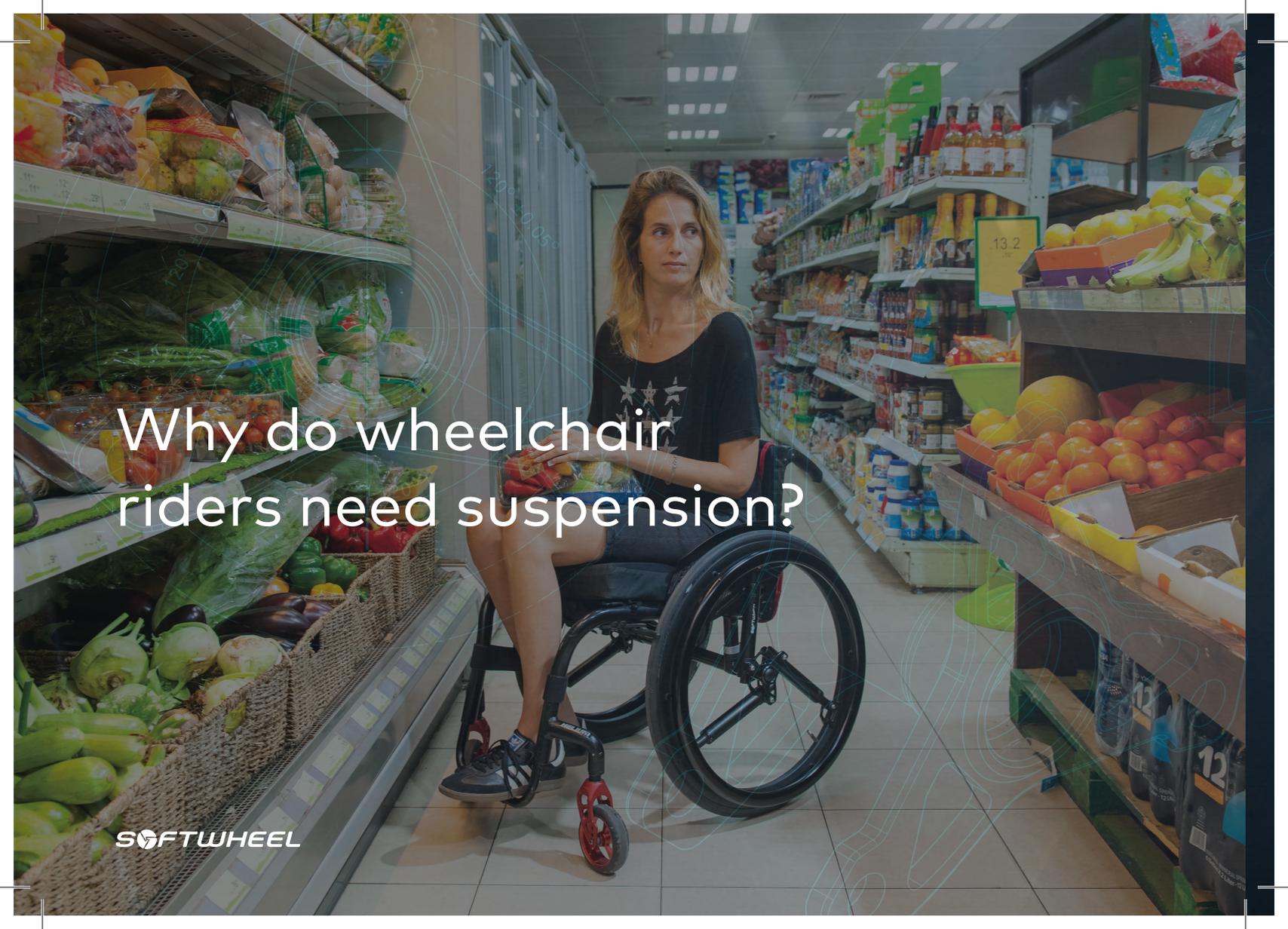
The innovative suspension & damping technology disperses the impact energy, thereby shortening the **impact duration** and **shock magnitude** transferred to the rider

Fewer vibrations are therefore transmitted to the rider, leading to a smoother, more comfortable ride

SoftWheels are more **energy efficient**, helping to maintain forward momentum, which can reduce fatigue



Drop Test from 15 cm (standard curb height)
SoftWheel vs. Standard Rigid Wheel: Acceleration Over Time

A woman with long blonde hair is sitting in a black wheelchair in a grocery store aisle. She is holding a bag of produce. The wheelchair has a small red front wheel. The aisle is filled with shelves of various goods, including fresh produce like tomatoes, eggplants, and green beans on the left, and packaged goods on the right. A price tag with the number '13.2' is visible on the right. The image is overlaid with faint blue technical diagrams, including circles and lines, with labels like '120° ± 0.05°' and '120° ± 0.05°'.

Why do wheelchair riders need suspension?

SOFTWHEEL

HEALTH



Can help reduce **back & neck pain**, and decrease **fatigue** at the end of the day

SAFETY



Keeps the rider **steady** while going over bumps and remains **stable & rigid** over flat terrain

COMFORT



Absorbs shock & vibrations on all types of terrain, providing **maximum cushioning**

A group of four people, two men and two women, are sitting on a wooden deck. They are all using wheelchairs. A large, fluffy dog is lying on the deck in front of them. The background shows a building with a door and windows. The scene is outdoors and appears to be a social gathering.

SoftWheel meets the daily needs of wheelchair riders

 **SOFTWHEEL**

Can provide riders with:

#01

Less Pain

1 X 45° Both Sides

#02

Greater Comfort

#03

Increased Independence

#04

Better Outdoor Mobility

R1 All around
Both sides

+0.1
54 0

+ 0.010
Ø28 -0.021

DIMENSION AFTER COATING

SEE NOTE 3.5

⊙ Ø 0.05 A

1.7 X 30°



Clinical research shows
SoftWheel helps improve
health, safety, and comfort

SOFTWHEEL

"In general, I hardly felt vibrations while riding"



"I feel very secure while riding the wheelchair"



"I feel it was easy & comfortable to propel on uneven terrain"



Source: Clinical Trial 2017, Emek Medical Center

For more info visit www.softwheel.technology

The background features a technical drawing of a wheel hub in a light blue line-art style. The drawing shows a central hub with three spokes. Key dimensions are labeled: '120° ±0.05°' for the angles between the spokes, and '50.75' for a radial dimension. The overall background is a dark blue gradient.

Softwheel makes a real
difference in people's lives

SOFTWHEEL

R1 All around
Both sides

+0.1
54 0



"I had **immediate relief** from **lower back pain** after switching to SoftWheels"

Kimberly



"For me, **SoftWheels** are **freedom**"

David



"Since I've started using SoftWheels, I **don't feel any pain**"

Nataly

For more info visit www.softwheel.technology

Review my
Wheelchair

9.5

AMAZING

"A Significant Ride Improvement"

"Soft-roading is a breeze, moving over rougher ground without any significant sudden jolts..."

It reduces the impact transferred from frame to spine...

SoftWheels offer a working professional a significant ride improvement."

Review My Wheelchair
April 2018

SOFTWHEEL





"A Softer Ride"

"A pretty impressive feat of engineering...

the ride did become noticeably softer. All the bumps, cracks and drops on my daily pushing routes were noticeable smoothed...

By switching wheels, my chair felt like it had built-in suspension."

New Mobility
November 2018



For more info visit www.softwheel.technology

Certifications



The information you provided has been recorded against the reference number shown at the top of this letter, which we ask you to quote in all future correspondence and communications.

Please inform us of any changes to:

- the company information
- additional generic groups of devices (add individual products within an existing generic group)
- discontinuation of a generic group of devices.

Please use FD2, the Registration form, to tell us about any of these changes.

Thank you for registering the following generic groups of devices:

Class / Devices:
Wheelchairs (Non-Powered) And Accessories

Custom Made Devices:
None

Products Covered By Article 12:
None

Confidentiality

Please note that in accordance with Directive 2007/47/EC as of 21st March 2010 information on the registration of persons responsible for placing devices on the market will no longer be treated as confidential and the Competent Authority will provide third parties with information on the name and address of manufacturers and authorised representatives and their devices that have been registered. However the names of individuals, their telephone numbers and email addresses will remain confidential unless you have chosen to trade using personal details. This change only applies to medical devices and does not affect In Vitro Diagnostic device registration, which remain confidentially under Article 19 of the In Vitro Diagnostic Directive 98/79/EC.

If your company name or that of a manufacturer that you represent is based on an individual's personal name it will be published unless you inform the MHRA that you would like the company name to remain confidential.

Likewise, if your company address or that of a manufacturer that you represent is the personal home address of an individual it will be published unless you inform the MHRA that you would like the company address to remain confidential.

Should you have any queries regarding your registration, please do not hesitate to contact us.

Yours sincerely



Sean Williams
Regulatory Affairs Officer
Tel: 0203 880 7325
Email: sean.williams@mhra.gov.uk

GD/Reg Vies 3 Sep 2008

CE Certificate

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Ave., W066 Room 2621
Silver Spring, Maryland 20993-0002

April 7, 2015

Dear Sir or Madam,

The U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) received registration and listing information identifying you as the Official Correspondent for the medical device facility listed below. Please keep this confirmation email and any attachments for your records.

Establishment Name SOFTWHEEL LTD.
Establishment Address 24 RAOUL WALLENBERG
TEL AVIV, TEL-AVIV 6971920
ISRAEL

PI/PCH Details :	
PI#	50138289
PCN	15263489

If you have any questions or need assistance, please e-mail CDRH Registration and Listing at reglist@cdrh.fda.gov, or call (301) 796-7400, Monday through Friday, between 8:00 am and 5:00 pm ET.
CDRH Registration and Listing Office

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File: TR 71310340.doc
Reg. No: 71310340
Page(s): 1
Page 1 of 1

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Germany

FDA – Class 1



Technical Report No. 71310340
Revision: 0
dated 2017-08-19

Client: SoftWheel Ltd.
Raul Wallenberg St. 24
IL-6971920-Tel Aviv

Manufacturing plant: SoftWheel Ltd.
Raul Wallenberg St. 24
IL-6971920-Tel Aviv

Test object: Drive wheel with hand rim for manual wheelchairs
Type: Accroball A
max. load: 145 kg (wheelchair with patient)

Test specification: EN 12183:2014, section 7.2
- ISO 7176-8:1998, section 5.4, 10.4 and 10.5

Purpose of examination: Testing according to the test specifications.

Test result: The test results show that the presented product is in compliance with the specified requirements.

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TUVP

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TÜV SÜD



R15 Ground
Both Sides

+0.1
0

C

5 Both Sides

20
Tol R6

0.010

0.024

DIMENSION AFTER COATING

SEE NOTE 3.5

0.05 A

50°

For more info visit www.softwheel.technology

For maximum performance,
SoftWheel is available in 4 stages,
customized to a rider's weight

Stage	Weight (kg)	Weight (lbs.)
A	up to 50 kg	up to 110 lbs.
B	50 - 70 kg	110 - 155 lbs.
C	70 - 90 kg	155 - 200 lbs.
D	90 - 136 kg	200 - 300 lbs.

Size: 24" & 25"

Hub: AL 6061 T6; high precision CNC

Rim: AL 6061 T6

Bearing diameter: U.S. or
European standard

Load limit: 136 kg (300 lbs.)

Wheel weight: 1.8 kg (4 lbs.)

Drum Brake: Optional



For more info visit www.softwheel.technology

100.0.0.11

$120^\circ \pm 0.05^\circ$

$120^\circ \pm 0.05^\circ$

120°

SOFTWHEEL

Wheel Reinvented

www.softwheel.technology

You can find us on:

