Designing compression garments with integrated sensors for enhanced monitoring & treatment

Appendix

Delft University of Technology
June 2023

Master Thesis
Faculty of Industrial Design Engineering
Master Integrated Product Design
Medisign specialisation

Author
Hidde Hijlkema
5400376

Supervisory Team
Prof. dr. Ir. Jansen, K.M.B. (TU Delft)
MA. Wang, T. (TU Delft)
Dr. van Rijn, M.J.E. (Erasmus MC, Rotterdam)

Content

Project Brief

DESIGN FOR our future

TU Delft

IDE Master Graduation

Project team, Procedural checks and personal Project brief

This document contains the agreements made between student and supervisory team about the student's IDE Master Graduation Project. This document can also include the involvement of an external organisation, however, it does not cover any legal employment relationship that the student and the client (might) agree upon. Next to that, this document facilitates the required procedural checks. In this document:

- The student defines the team, what he/she is going to do/deliver and how that will come about.
- SSC E&SA (Shared Service Center, Education & Student Affairs) reports on the student's registration and study progress.
- IDE's Board of Examiners confirms if the student is allowed to start the Graduation Project.

USE ADOBE ACROBAT READER TO OPEN, EDIT AND SAVE THIS DOCUMENT

Download again and reopen in case you tried other software, such as Preview (Mac) or a webbrowser.

STUDENT DATA & MASTER PROGRAMME

Save this form according the format "IDE Master Graduation Project Brief_familyname_firstname_studentnumber_dd-mm-yyyy".
Complete all blue parts of the form and include the approved Project Brief in your Graduation Report as Appendix 1 !

family name	Hijlkema
initials	HJF
given name	Hidde
student number	5400376
street & no.	
zipcode & city	
country	
phone	
email	

Your master programme (only select the options that apply to you):

IDE master(s):	★ IPD ○ DfI ○ SPD
2nd non-IDE master:	
individual programme:	- - (give date of approval)
honours programme:	○ Honours Programme Master
specialisation / annotation:	★ Medisign
	○ Tech. in Sustainable Design
	○ Entrepeneurship

SUPERVISORY TEAM **

Fill in the required data for the supervisory team members. Please check the instructions on the right !

** chair	Kaspar Jansen	dept. / section:	SDE, EM
** mentor	Tingting Wang	dept. / section:	HCD, AED
2nd mentor	Marie Josee van Rijn		
	organisation: Erasmus MC		
	city: Rotterdam	country:	Netherlands

comments (optional): Marie Josee van Rijn is a vascular surgeon-epidemiologist

Chair should request the IDE Board of Examiners for approval of a non-IDE mentor, including a motivation letter and c.v..

Second mentor only applies in case the assignment is hosted by an external organisation.

Ensure a heterogeneous team. In case you wish to include two team members from the same section, please explain why.

introduction (continued): space for images

image / figure 1: Compression stockings for edema (source: https://huidtherapie-dewildt.nl/steunkousen-aanmeten/)

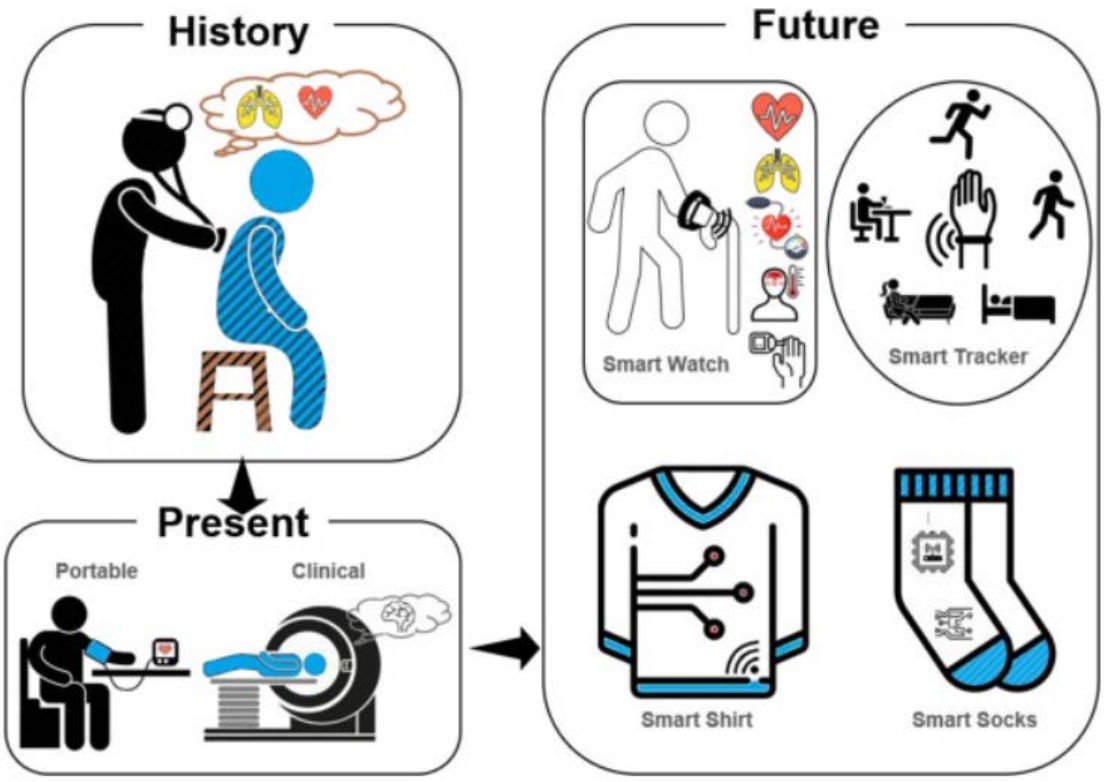


image / figure 2: Healthcare development (source: https://doi.org/10.1016/B978-0-12-820777-2.00006-6)

PROBLEM DEFINITION **

Limit and define the scope and solution space of your project to one that is manageable within one Master Graduation Project of 30 EC (= 20 full time weeks or 100 working days) and clearly indicate what issue(s) should be addressed in this project.

The healthcare system is developing into an advanced digitally supported system with the potential to monitor patients 24/7 at every location. Yet, not every area within the healthcare system is developing. Compression therapy, which is used for a lot of medical complications, barely developed at all.

Currently, adherence to compression therapy is low and district nurses are put under a lot of pressure to deal with the high demands for home care. Supporting elderly with their compression therapy also requires a lot of physical heavy work.

Therefore, this project introduces a weft-knitted linear stretch sensor for compression therapy. Throughout the project, applications for the sensor, and acceptance of monitoring are researched. This will be done in 4 phases; analysis, concept, embodiment, and user testing.

In the end, the finalized solution(s) support both patient and healthcare provider with a more advanced and personalized healthcare.

ASSIGNMENT **

State in 2 or 3 sentences what you are going to research, design, create and / or generate, that will solve (part of) the issue(s) pointed out in "problem definition". Then illustrate this assignment by indicating what kind of solution you expect and / or aim to deliver, for instance: a product, a product-service combination, a strategy illustrated through product or product-service combination ideas, ... In case of a Specialisation and/or Annotation, make sure the assignment reflects this/these.

Design and test an innovative compression stocking (with a modern look) with integrated flexible sensors. Beside applying the right amount of compression they can track user activity and measure their level of fitness. This information is directly linked back to the user (and vascular surgeon) in an understandable way. The state-of-the-art sensor stocking will motivate users to exercise through positive feedback and is an improvement in patient experience.

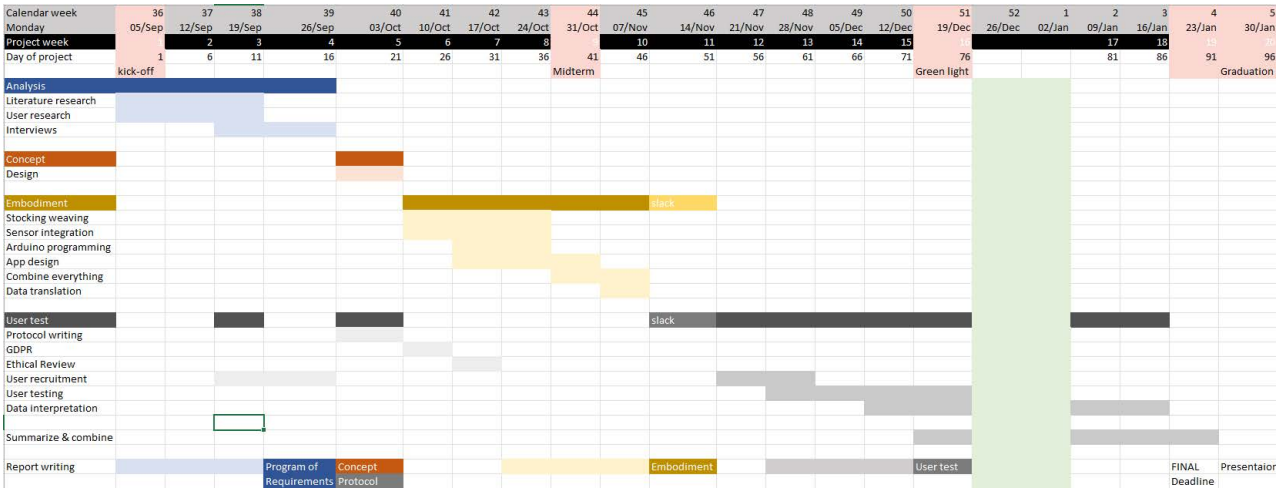
Initials & Name HJF Hijlkema Student number 5400376

Title of Project Smart Stockings

PLANNING AND APPROACH **

Include a Gantt Chart (replace the example below - more examples can be found in Manual 2) that shows the different phases of your project, deliverables you have in mind, meetings, and how you plan to spend your time. Please note that all activities should fit within the given net time of 30 EC = 20 full time weeks or 100 working days, and your planning should include a kick-off meeting, mid-term meeting, green light meeting and graduation ceremony. Illustrate your Gantt Chart by, for instance, explaining your approach, and please indicate periods of part-time activities and/or periods of not spending time on your graduation project, if any, for instance because of holidays or parallel activities.

start date 7 - 9 - 2022 1 - 2 - 2023 end date



Initials & Name HJF Hijlkema Student number 5400376

Title of Project Smart Stockings

MOTIVATION AND PERSONAL AMBITIONS

Explain why you set up this project, what competences you want to prove and learn. For example: acquired competences from your MSc programme, the elective semester, extra-curricular activities (etc.) and point out the competences you have yet developed. Optionally, describe which personal learning ambitions you explicitly want to address in this project, on top of the learning objectives of the Graduation Project, such as: in depth knowledge a on specific subject, broadening your competences or experimenting with a specific tool and/or methodology, ... Stick to no more than five ambitions.

With this project I want the outside world to understand what type of designer I am. I want to graduate as a healthcare designer with a focus on human/patient empowerment.

This project should show that I am able to emphasize with my users and design with a user/patient centred design approach. By taking their needs into account I am able to help them, yet not end up with a stigmatizing or excluding design. Therefore, I want the technology in the stockings to be integrated in such a way that it is part of the design but does not completely look like a technological product (e.g. that I end up like an exoskeleton stocking).

After this project, I am able to write code and deal with technology through a hands-on approach. Even though dealing with such integrated sensors is something I have not yet worked with I do not back down from the unknown and embrace challenges. This is combined with writing code and creating a medium in which I can inform users about their health stats.

As products are becoming smarter, we are collecting more and more data. Through this project I want to show that I am able to understand (my) generated data and also that I am able to translate this into an understandable manner for users that have no prior knowledge about it. This might mean converting, cleaning, and/or displaying data in different manners than it is collected. The collected data should empower the user and support healthy lifestyles rather than confuse, bore, or scare the user.

Lastly, because I am dyslectic I always experienced report writing as extremely difficult. This project I want to finish with a clearly written report which strongly displays my process and that resonates my enthusiasm for the project.

FINAL COMMENTS

In case your project brief needs final comments, please add any information you think is relevant.

Initials & Name HJF Hijlkema Student number 5400376

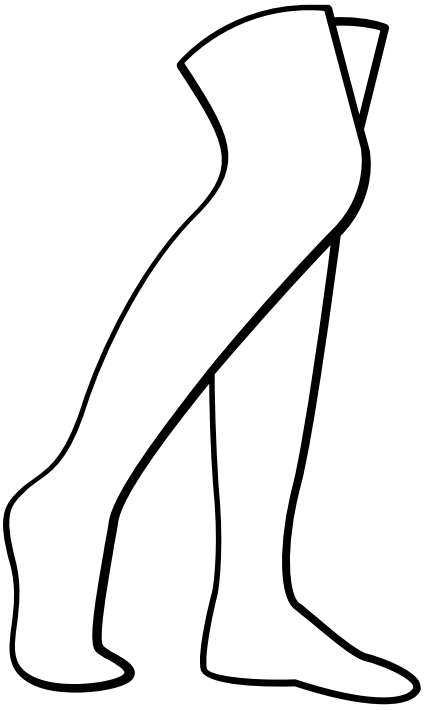
Title of Project Smart Stockings

Recruitment flyer

Help jij mee met steunkousen innoveren?

Draag je steunkousen, of zou je ze eigenlijk moeten dragen, maar vind je het maar niks? Dan kom ik graag met je in gesprek!

Terwijl alles om ons heen slimmer wordt zijn steunkousen vrijwel niet veranderd. Dat moet anders!



Voor mijn afstudeerproject aan de TU Delft werk ik samen met jouw vaatchirurg van het Erasmus MC. We willen steunkousen veranderen tot slimme producten die jij graag wilt aandoen!

Daarom ben ik super benieuwd naar jouw mening over steunkousen en hoe ze verbeterd kunnen worden. Ik nodig je graag uit voor een interview, dit kan zowel fysiek als online, wat voor jou het beste uit komt!

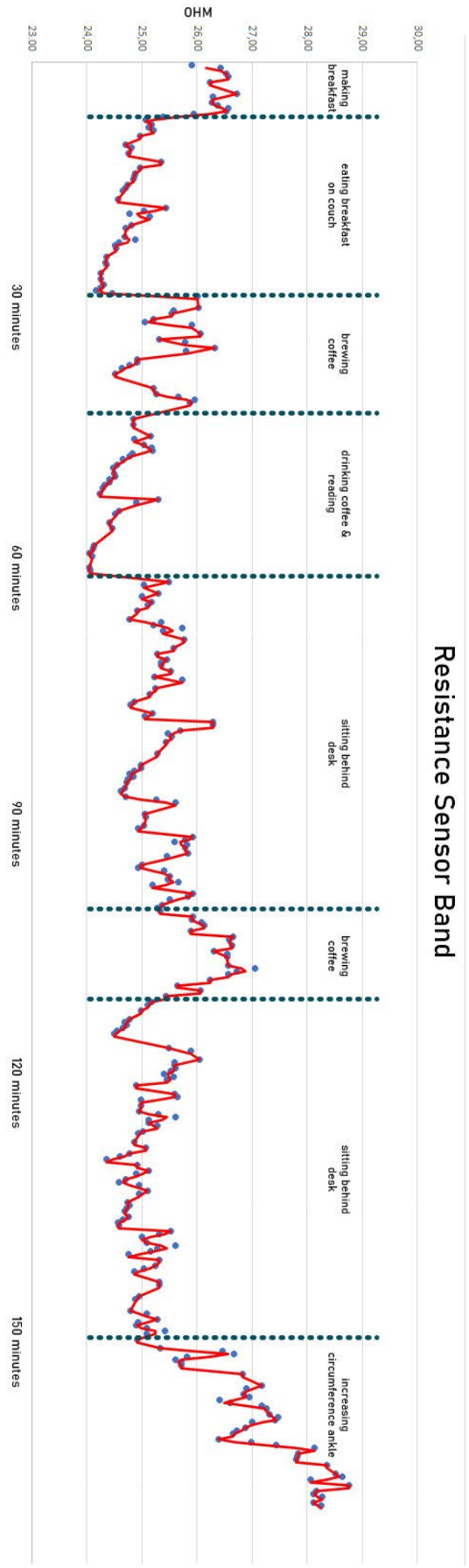
Als je een mailtje stuurt naar: ... of je mailadres via de **QR code** achter laat, dan neem ik contact met je op en gaan we samen de eerste stappen naar jouw toekomstige steunkousen maken!

Ik ben Hidde en doe de master Industrieel Ontwerpen. Via design help ik mensen gezonder te worden en nog meer te kunnen genieten van hun leven. Het liefst ontwerp ik samen met de toekomstige gebruikers van mijn producten.

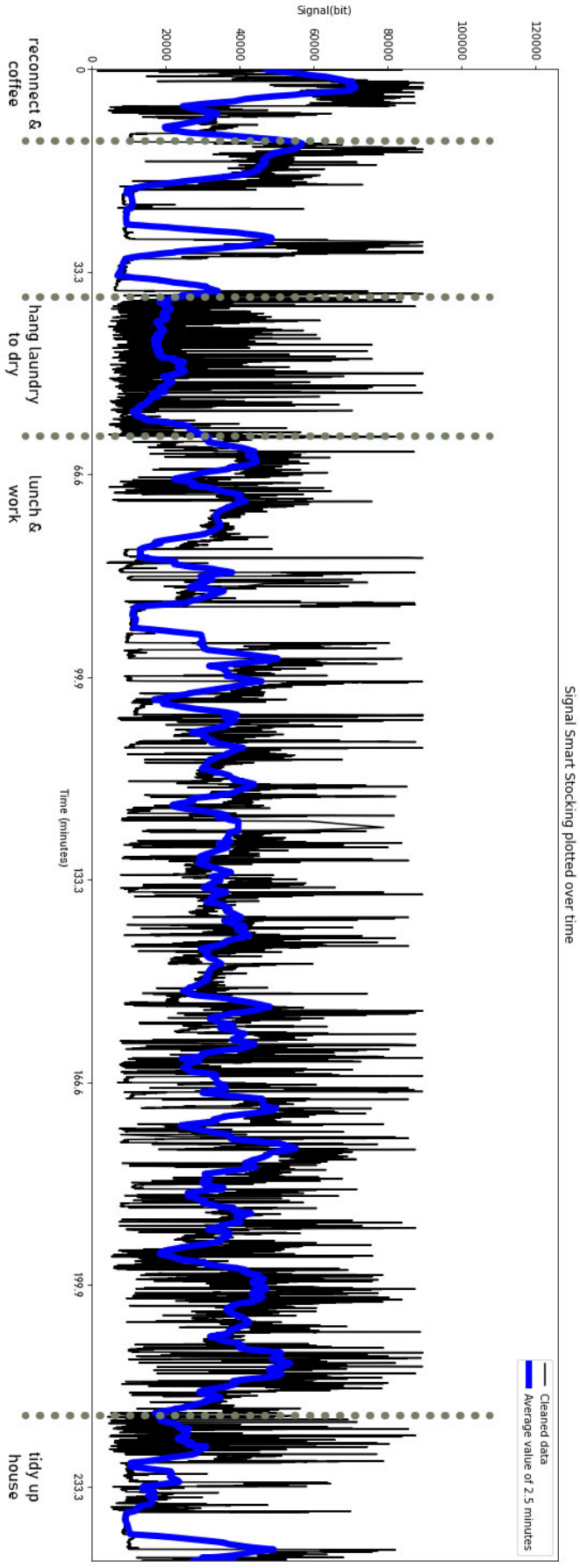
TU Delft

Erasmus MC
Universitair Medisch Centrum Rotterdam

Enlarged results wear test 8.1.1



Enlarged results user test 9.3.1



Handout user test

GEBRUIKERS TEST
SLIMME STEUNKOUSEN DRAGEN

STAPPENPLAN

Allereerst ontzettend leuk dat je wilt helpen door mee te doen aan deze gebruikerstest. Dankzij jouw hulp ontwikkel ik nieuwe waardevolle inzichten voor mijn afstudeerproject en aankomende projecten die dit project zullen doorzetten.

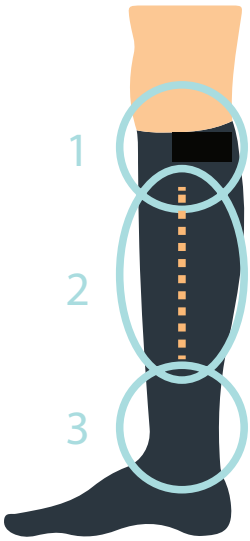
De gebruikerstest bestaat uit verschillende onderdelen. Deelname aan deze test is op vrijwillige basis en kan elk moment (zonder verklaring) onderbroken en gestopt worden. De stappen zijn:

1. Product verkennen
2. Product aandoen
3. Telefoon verbinden
4. Dagboek introduceren
5. Feedback op app interface
6. Dragen
7. Feedback op dragen en ervaringen

PRODUCT VERKENNEN

De slimme kous bestaat uit verschillende elementen. Deze worden nu uitgelegd.

De kous bestaat uit een sensor die druk meet door middel van een weerstand verandering (FSR sensor), een verbindingstuk over de lengte van de kous, een batterij en een microcontroller. De batterij en microcontroller zitten in dezelfde hoes en zijn het enige dat los is van de kous, deze zitten in het ‘zakje’ boven aan de kous.



1. Zakje voor batterij en microcontroller
2. Verbinding van sensor tot zakje
3. Sensor

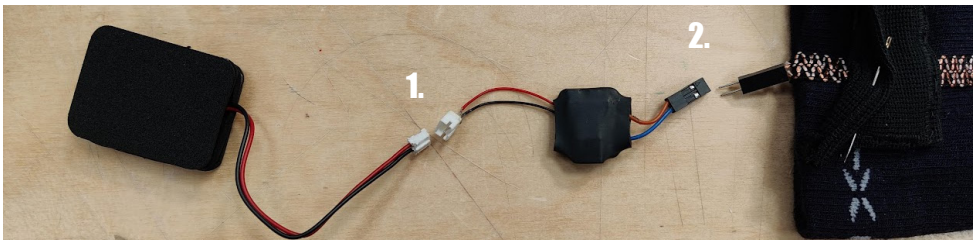
Wanneer je de onderdelen begrijpt, mag je de kous aantrekken en doorgaan naar het verbinden met de telefoon.

VERBINDEN MET TELEFOON

Nadat de kous aan is gedaan gaan we verbinden met de telefoon om data te verzamelen.

Het stappenplan om de slimme kous met de telefoon te verbinden is als volgt:

1. Batterij aan microcontroller zetten door de zwart/rode kabels uit de batterijhoes op elkaar aan te sluiten door de witte sluitingen te verbinden. Let er op dat de sluiting maar op een manier dicht kan.
2. Microcontroller aan kous verbinden door de zigzaggende draden met zwarte sluiting van de kous met de oranjeblauwe draden van de microcontroller te verbinden (de zwarte sluitingen).
3. Telefoon verbinden door naar de volgende website te gaan: https://adriek.github.io/ble-app/BluetoothCollector2023.html (of scan de QR code)
4. Klik op connect en verbindt met het gevonden apparaat (Circuitpython)
5. Probeer verbinding te houden door niet verder dan 20 meter tussen telefoon en slimme kous te hebben.
6. Dragen voor een onbepaalde tijd en hou dagboekje bij.
7. Afsluitend ga naar de webpagina en druk op ‘get ready to save’, klik vervolgens op save. Stuur dit bestand door naar: …



TU Delft Erasmus MC Universitair Medisch Centrum Rotterdam

DAGBOEK

Om de verzamelde data beter te begrijpen word je gevraagd een overzicht te geven van je activiteiten tijdens het dragen. Hoe meer detail, hoe meer inzicht.

Tijdstip van verbinden: .....

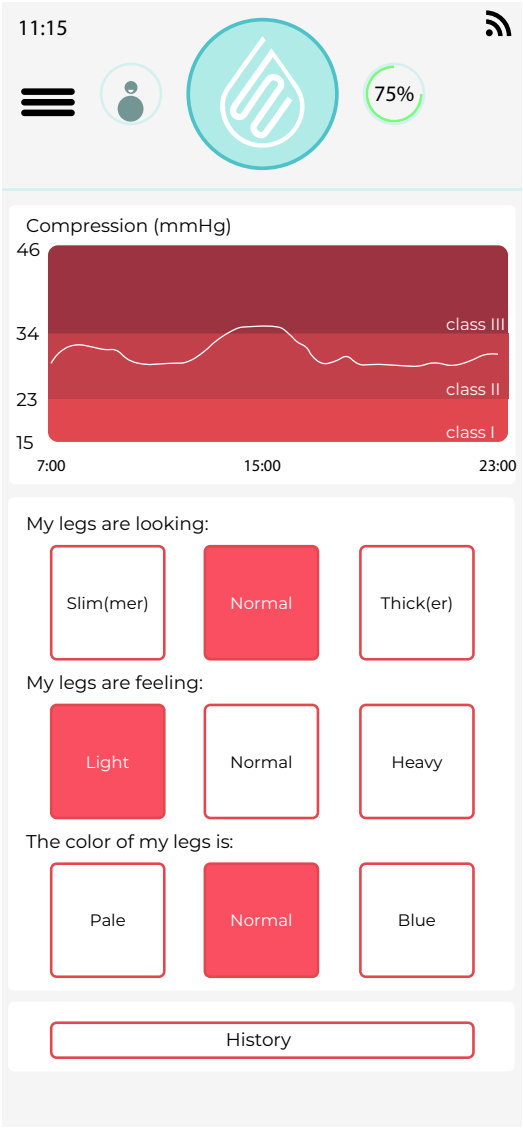
Planning of events (met voorbeeld):

7:45	*opstaan & aankleden*
8:00	*ontbijt maken & eten*
9:00	*van ontbijt naar werk racen (fiets)*

APP DESIGN

De data verzamel pagina is een functioneel prototype. Een app voorstel staat hieronder. Kan je hier feedback op geven?

Alle feedback is gewaardeerd, maar denk bijvoorbeeld aan:
Wat vind je duidelijk? Wat mis je? Wat zou je graag extra willen?



FEEDBACK KOUS

Alle gedachten die er tijdens het dragen zijn opgekomen kan je hier opschrijven.

Alle feedback is gewaardeerd, maar denk bijvoorbeeld aan:
Hoe voelde je tijdens je kous dragen? Wat wil je anders? Wat moet zo blijven? Wat zou je graag extra willen? Is de verbinding tijdens het dragen weg gevallen?

FSR factsheet

INTERLINK ELECTRONICS
Sensor Technologies

FSR® 400 Series Data Sheet

Force Sensing Resistors®

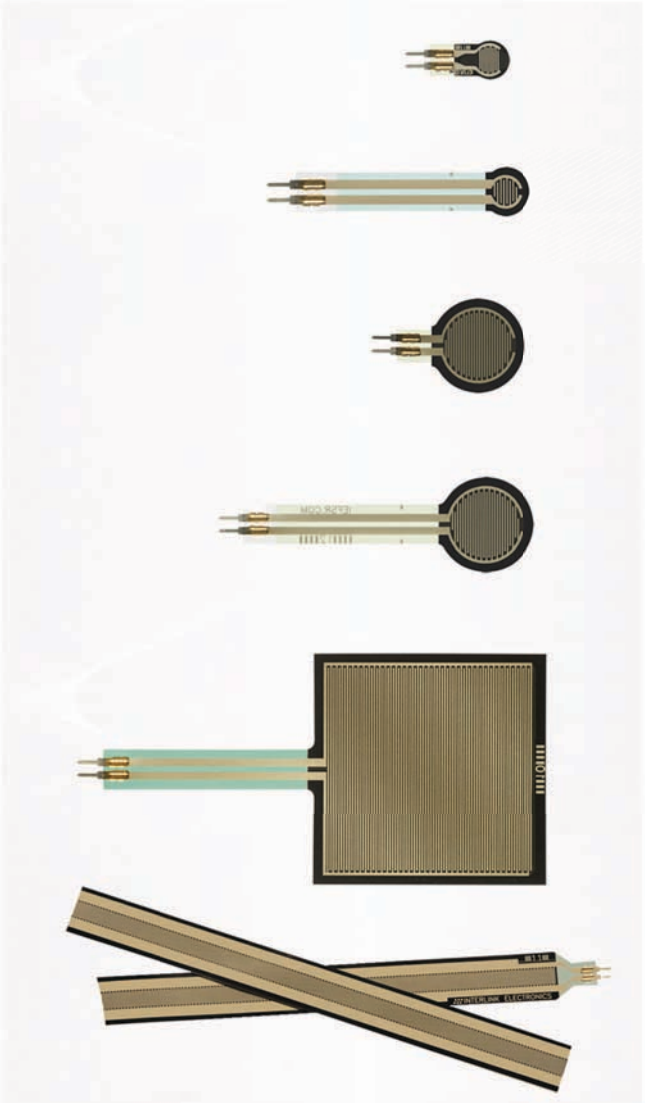
Features and Benefits

- Actuation Force as los w as 0.2N and sensitivity range to 20N
- Cost Effective
- Ultra Thin
- Robust; up to 10M actuations
- Simple and easy to integrate

Description

Interlink Electronics FSR® 400 series is part of the single zone Force Sensing Resistor® family. Force Sensing Resistors®, or FSR®s, are robust polymer thick film (PTF) devices that exhibit a decrease in resistance with increase in force applied to the surface of the sensor. This force sensitivity is optimized for use in human touch control of electronics devices such as automotive electronics, medical systems, industrial, and robotics applications.

The 400 series sensors come in six different models with four different connecting options.



FSR® 400 Short
5mm Circle x 20mm

FSR® 400
5mm Circle x 38mm

FSR® 402 Short
13mm Circle x 25mm

FSR® 402
13mm Circle x 56mm

FSR® 406
38mm Square x 83mm

FSR® 408
10mm x 622mm strip

P/N: 94-00027 Rev. E

Embrace the Power of Sensor Technologies

Device Characteristics

Actuation Force*	~0.2N min
Force Sensitivity Range*	~0.2N – 20N
Force Resolution	Continuous (analog)
Force Repeatability Single Part	+/- 2%
Force Repeatability Part to Part	+/- 6% (Single Batch)
Non-Actuated Resistance	>10 Mohms
Hysteresis	+10% Average (RF+ - RF-)/RF+
Device Rise Time	< 3 Microseconds
Long Term Drift	
1kg load, 35 days	< 5% log10(time)
Operating Temperature Performance	
Cold: -40ºC after 1 hour	-5% average resistance change
Hot: +85ºC after 1 hour	-15% average resistance change
Hot Humid: +85ºC 95RH after 1 hour	+10% average resistance change
Storage Temperature Performance	
Cold: -25ºC after 120 hours	-10% average resistance change
Hot: +85ºC after 120 hours	-%5 average resistance change
Hot Humid: +85ºC 95RH after 240 hours	+30% average resistance change
Tap Durability	
Tested to 10 Million actuations, 1kg, 4Hz	-10% average resistance change
Standing Load Durability	
2.5kg for 24 hours	-5% average resistance change
EMI	Generates no EMI
ESD	Not ESD Sensitive
UL	All materials UL grade 94 V-1 or better
RoHS	Compliant

Specifications are derived from measurements taken at 1000 grams, and are given as (one standard deviation/mean), unless otherwise noted.
*Typical value. Force dependent on actuation interface, mechanics, and measurement electronics.

Connector Options

Bare Tail

Female Tin Contacts
PN: TE 2-487406-4

Female Tin Contacts with 2 Pin Housing
PN: TE 2-487406-4
PN: TE 2-487378-1

Solder Tabs
PN: TE 1-88997-2

Other Available Part Numbers:
Hardware Development Kit, PN 54-76247

Application Information

For specific application needs please contact Interlink Electronics support team. An Integration Guide and Hardware Development Kit (HDK) are also available. FSR®s are two-wire devices with a resistance that depends on applied force. Below is a force vs. resistance graph that illustrates a typical FSR® response characteristic. Please note that the graph values are reference only and actual values are dependent upon actuation system mechanics and sensor geometry.

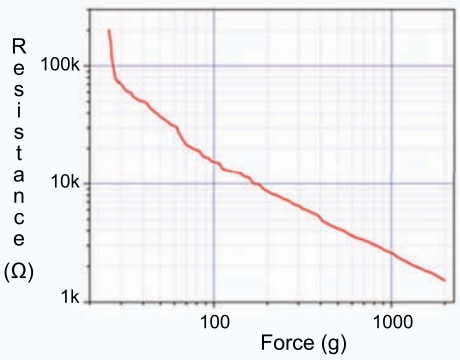
For simple force-to-voltage conversion, the FSR® device is tied to a measuring resistor in a voltage divider (see figure below) and the output is described by the following equation.

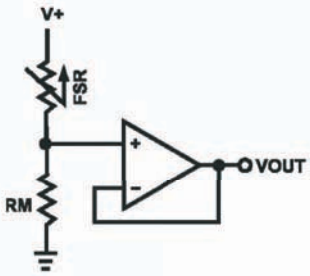
$$V_{OUT} = \frac{R_M V +}{(R_M + R_{FSR})}$$

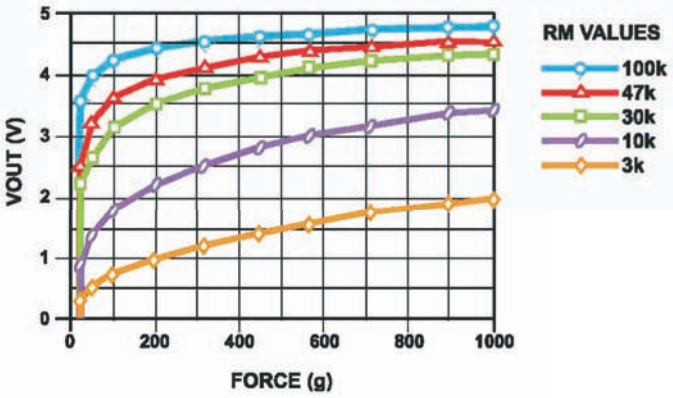
In the shown configuration, the output voltage increases with increasing force. If RFSR and RM are swapped, the output swing will decrease with increasing force. The measuring resistor, RM, is chose to maximize the desired force sensitivity range and to limit current. Depending on the impedance requirements of the measuring circuit, the voltage divider could be followed by an op-amp.

A family of force vs. VOUT curves is shown on the graph below for a standard FSR® in a voltage divider configuration with various RM resistors. A V+ of 5V was used for these examples. Please note that the graph values are for reference only and will vary between different sensors and applications.

Refer to the FSR ® Integration Guide for more integration methods and techniques.







INTERLINK ELECTRONICS
Sensor Technologies

FSR® Model 400

Force Sensing Resistor®

Model 400:

Active Area: Ø5.08mm

Nominal Thickness: 0.30mm

Switch Travel: 0.05mm

Available Part Numbers:

PN: 34-00007 Model 400

- No contacts or solder tabs

PN: 34-00011 Model 400

- with female contacts

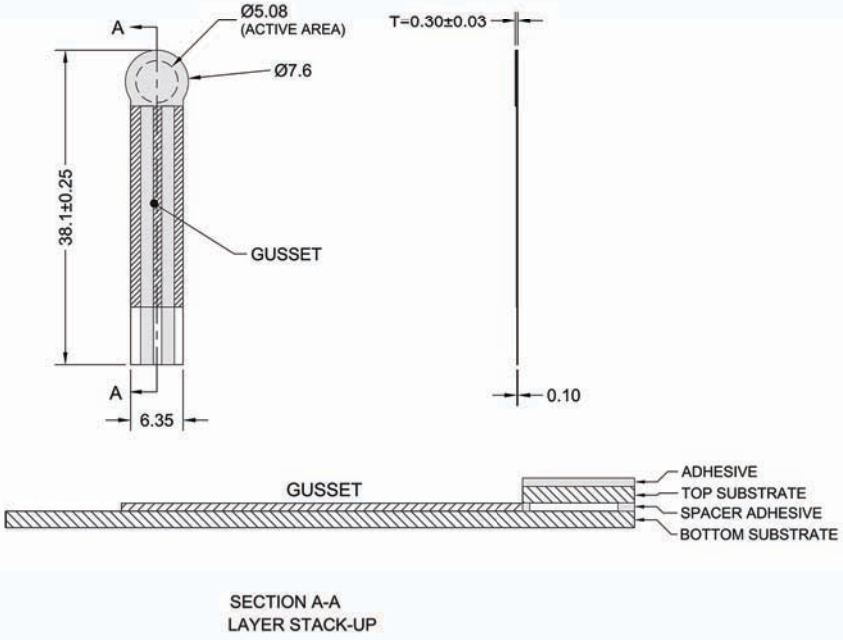
PN: 34-44001 Model 400

- with female contacts and housing

PN: 30-49649 Model 400

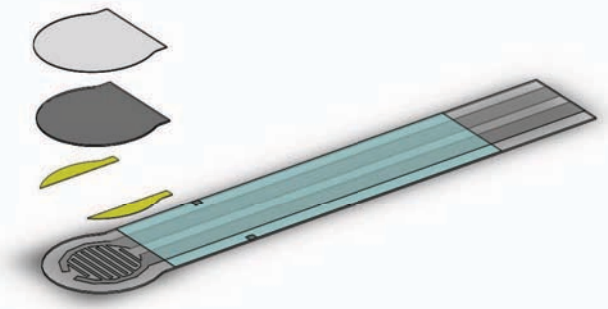
- with solder tabs

Sensor Mechanical Data



SECTION A-A
LAYER STACK-UP

Exploded View



For more information consult the Integration Guide found on our website: www.interlinkelectronics.com/support

INTERLINK ELECTRONICS
Sensor Technologies

FSR® Model 400 Short Tail

Force Sensing Resistor®

Model 400 Short Tail:

Active Area: Ø5.62mm

Normal Thickness: 0.30mm

Switch Travel: 0.05mm

Available Part Numbers:

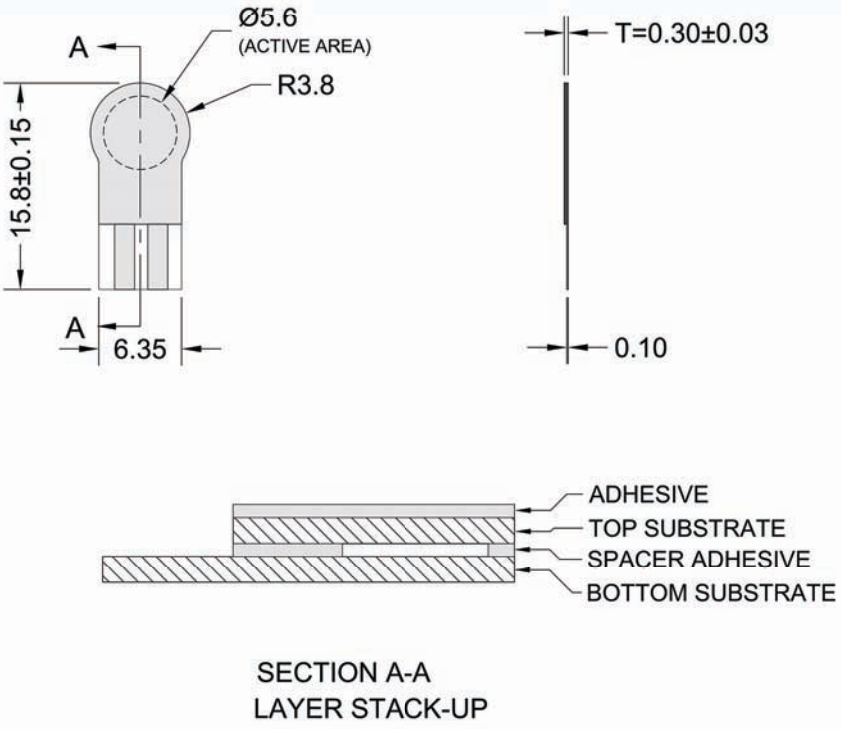
PN: 34-47021 Model 400 Short Tail
- No contacts or solder tabs

PN: 34-00005 Model 400 Short Tail
- with female contacts

PN: 34-00006 Model 400 Short Tail
- with female contacts and housing

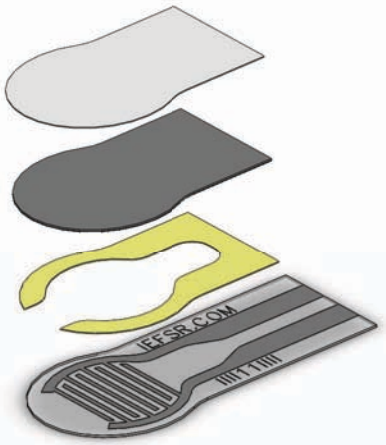
PN: 34-00004 Model 400 Short Tail
- with solder tabs

Sensor Mechanical Data



SECTION A-A
LAYER STACK-UP

Exploded View



For more information consult the Integration Guide found on our website: www.interlinkelectronics.com/support

INTERLINK ELECTRONICS
Sensor Technologies

FSR® Model 402

Force Sensing Resistor®

Model 402:

Active Area: Ø14.68mm

Nominal Thickness: 0.46mm

Switch Travel: 0.15mm

Available Part Numbers:

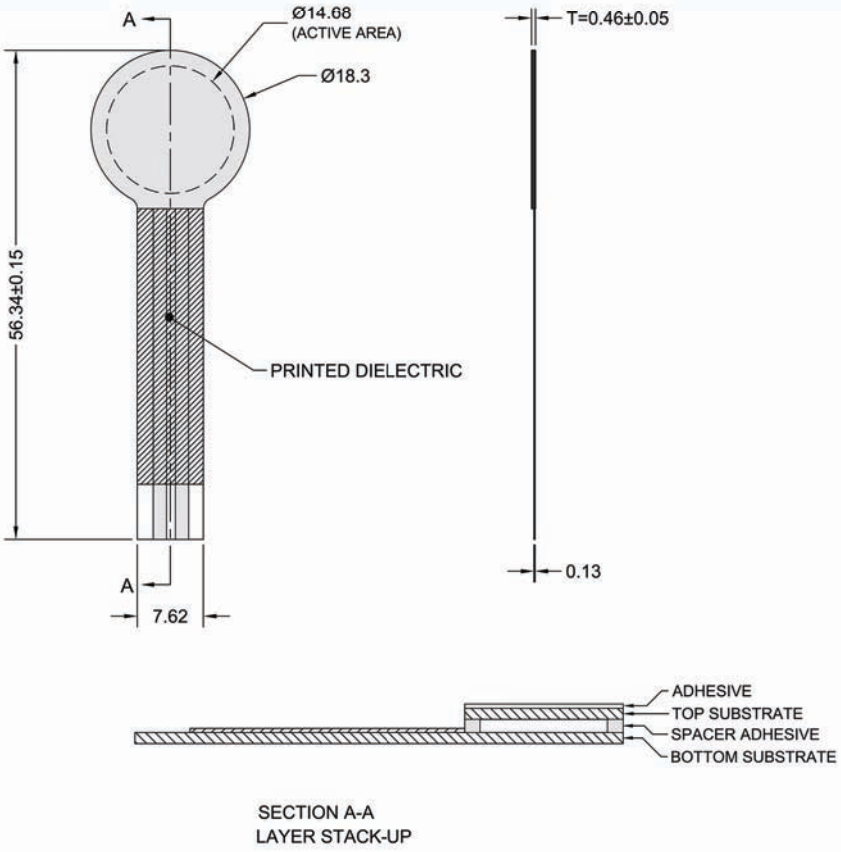
PN: 44-29103 Model 402
- No contacts or solder tabs

PN: 34-00012 Model 402
- with female contacts

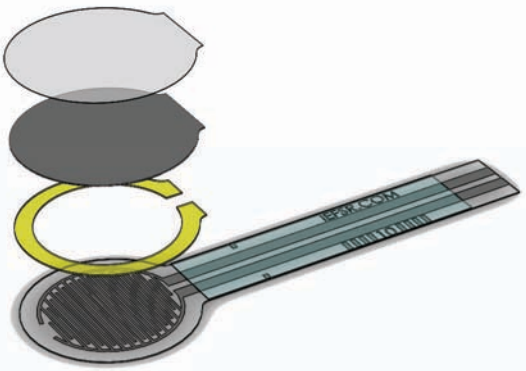
PN: 34-00001 Model 402
- with female contacts and housing

PN: 30-81794 Model 402
- with solder tabs

Sensor Mechanical Data



Exploded View



For more information consult the Integration Guide found on our website: www.interlinkelectronics.com/support

INTERLINK ELECTRONICS
Sensor Technologies

FSR® Model 402 Short Tail

Force Sensing Resistor®

Model 402 Short Tail:

Active Area: Ø12.70mm

Normal Thickness: 0.46mm

Switch Travel: 0.15mm

Available Part Numbers:

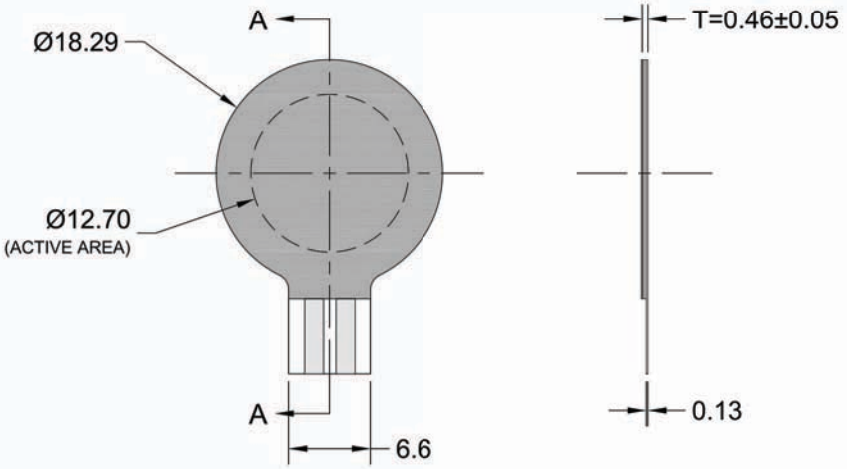
PN: 34-00016 Model 402 Short Tail
- No contacts or solder tabs

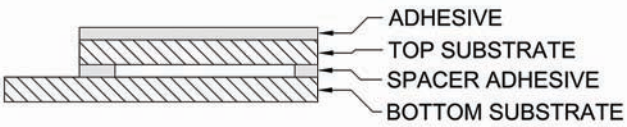
PN: 34-00017 Model 402 Short Tail
- with female contacts

PN: 34-00018 Model 402 Short Tail
- with female contacts and housing

PN: 34-00015 Model 402 Short Tail
- with solder tabs

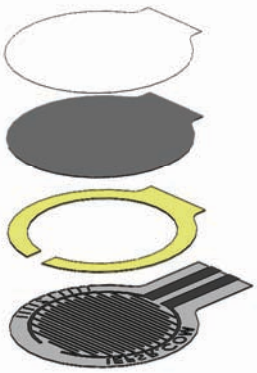
Sensor Mechanical Data





SECTION A-A
LAYER STACK-UP

Exploded View



For more information consult the Integration Guide found on our website: www.interlinkelectronics.com/support

INTERLINK ELECTRONICS
Sensor Technologies

FSR® Model 406

Force Sensing Resistor®

Model 406:

Active Area: 39.6mm x 39.6mm

Nominal Thickness: 0.46mm

Switch Travel: 0.15mm

Available Part Numbers:

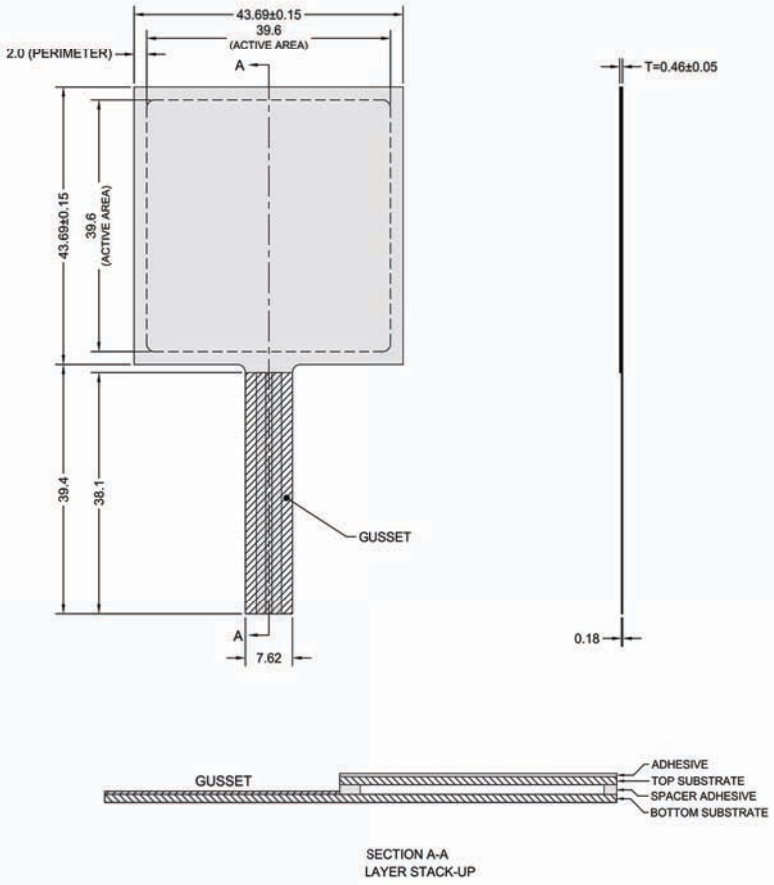
PN: 34-00009 Model 406
- No contacts or solder tabs

PN: 34-00013 Model 406
- with female contacts

PN: 34-61152 Model 406
- with female contacts and housing

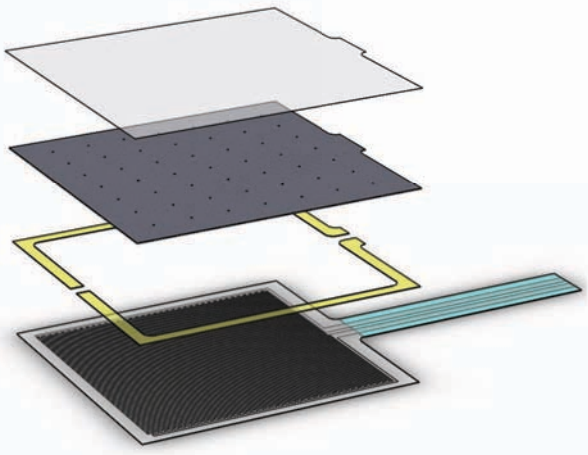
PN: 30-73258 Model 406
- with solder tabs

Sensor Mechanical Data



SECTION A-A
LAYER STACK-UP

Exploded View



For more information consult the Integration Guide found on our website: www.interlinkelectronics.com/support

INTERLINK ELECTRONICS
Sensor Technologies

FSR® Model 408

Force Sensing Resistor®

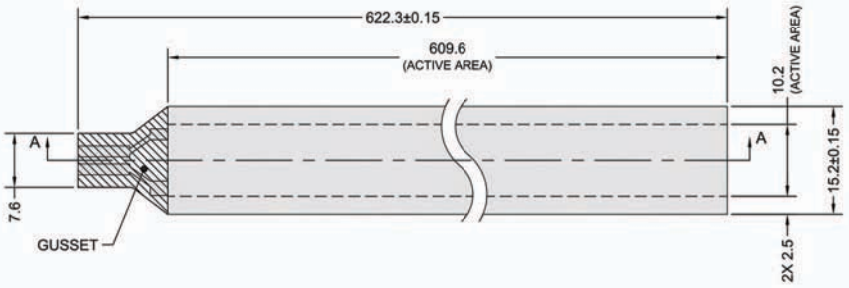
Model 408:

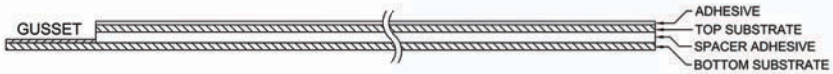
Active Area: 609.6mm x 10.2mm

Nominal Thickness: 0.41mm

Switch Travel: 0.15mm

Sensor Mechanical Data





SECTION A-A
LAYER STACK-UP

Available Part Numbers:

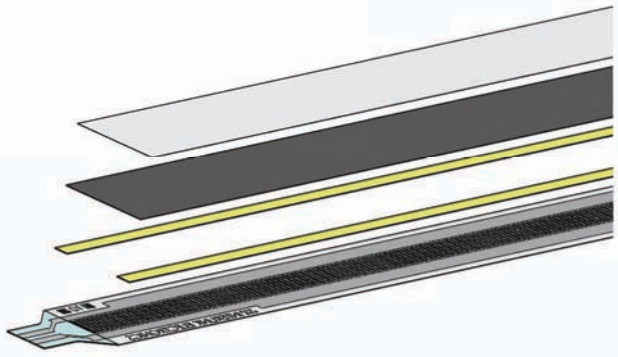
PN: 34-00010 Model 408
- No contacts or solder tabs

PN: 34-75319 Model 408
- with female contacts

PN: 34-23845 Model 408
- with female contacts and housing

PN: 30-61710 Model 408
- with solder tabs

Exploded View



Contact Us

United States
Corporate Office
Interlink Electronics, Inc.
546 Flynn Road
Camarillo, CA 93012, USA
Phone: +1-805-484-8855
Fax: +1-805-484-9457
www.interlinkelectronics.com
Sales and Support:
sales@interlinkelectronics.com

Japan
Japan Sales Office
Phone: +81-45-263-6500
Fax: +81-45-263-6501
www.interlinkelec.co.jp

(unfiltered) List of requirements

Unfiltered requirement list

No.	Requirement	Contributing factor	Need
1	Functionality	Sensor	Product needs to measure the compression and is capable of detecting low pressures ranging from 0 - 50 mmHg
2		Sensor	Product should measure (at least) on the ankle, where the MCS is expected to exert the highest amount of compression
3		Sensor	Is embedded into the stockings
4		Sensor	Is not noticeable when wearing (based on physical feeling)
5		Microcontroller	Compatible with sensor
6		Microcontroller	Collect data through sensor
7		Microcontroller	Have a power input
8		Microcontroller	Data to user output
9		Microcontroller	Small, lightweight & removable
etc.		Microcontroller	BLE enabled
		Material	Don’t cause skin irritation
		Communication	Connect to microcontroller
		Communication	Share measured data with user
		Communication	Share measured data with healthcare providers
		Communication	Visualise collected data

		Material	Don’t cause skin irritation
	Performance	Sensor	Provide rapid response to changes in compression levels, enabling real-time feedback
		Sensor	Withstand daily activities
		Sensor	Washing & waterproof
		Sensor	Stable and consistent results, so sensor can be calibrated
		Sensor	Minimal drift
		Sensor	Last until product is replaced (12 months)
		Microcontroller	Have enough processing power to handle real time
		Microcontroller	Waterproof
		Microcontroller	Ability to measure for the duration of at least one wearing cycle (waking up to sleeping)
		Embedding	No short circuits
		Embedding	Withstand daily activities
		Embedding	Stretch with the product
		Battery	Ability to power microcontroller for the duration of at least one wearing cycle (waking up to sleeping)
		Battery	Rechargeable
		Battery	Small, lightweight & removable
		Battery	Waterproof

		Storage	Store measured compression over an extended period of time
		Communication	The feedback should represent compression in mmHg
		Communication	Provide immediate feedback or monitoring of measurements
		Communication	Visualise measured compression over an extended period of time
		Communication	Warn user if compression is too high or too low
		Communication	Data should be calibrated to user dimensions
		Material	The compression should remain for 12 months (since MCS are yearly reimbursed)
	Usability	Microcontroller	Easy to connect with sensor
		Microcontroller	Easy to connect with communication
		Microcontroller	Easy to connect with battery
		Microcontroller	Subtle aesthetic
		Communication	Compatible with operating systems of user
		Communication	Feedback should be intuitive for users
		Communication	Users can customize the visualised data
		Aesthetic	Usable for all age groups (avoid small wires and include clear use cue)
		Aesthetic	Removable parts of stockings should be on the front or side of leg

		Aesthetic	Not only skin coloured but a wider range of product colours (possibly trend related)
		Packaging	Excites users to wear
	Reliability	Regulations	Product is a medical device and should comply with MDR class II devices
		Material	If the product fails to measure correctly, the primary function of exerting the intended compression should not be compromised
		Testing	The product must be tested on this list
		Privacy	Data of users should be anonymized and safely stored