

User-Centered Research on Wearable Product Experience

Information about the Study

Thank you for participating this study. This document provides you with information about why the research is being done and what will be involved. Please take some time to read through this information sheet carefully and ask questions if anything is unclear or if you would like more information.

This study is part of the master Integrated Product Design student Yuxiang Wang's graduation project (study number: 4744314) at Delft University of Technology, which is supervised by Prof. Kaspar Jasen, and Ir. Iemkje Ruiter and Liselotte Stolk from the company Praxa Sense.

Purpose of the study

The goal of the study is to gather user insights (e.g. needs of convenience, hygiene etc.) by interviewing people to help design a wearable heart rhythm monitor.

What will happen if I decide to take part?

I will ask you several questions about your experience with wearable objects, during which written notes and audio recording may be done to help me document the interview. If you agree to take part, I will provide you with full instructions. You will also be given the opportunity to ask any questions. You may ask questions at any time if you do not understand anything.

What will happen to my information?

The study complies with the Human Research Ethics requirements from TU Delft. All information provided will be captured by hand written notes and electronically (audio recording or taking photographs) and stored on a password protected computer. It will be destroyed after any publication arising from the work, in accordance with the university data storage policy. Your name (i.e. signature on consent form) will be kept separate from your questionnaire responses. Consent forms will be stored in a locked filing cabinet for the duration mentioned above. The information that I collect during this project will be used to inform my design. Your name will not be used in association with the data.

Will my taking part in this study be kept confidential?

Yes. Only my supervisors and I have the access to the raw materials (audio recordings or photographs). If I need to present in public your image will be blurred out.

Free to withdraw

You can withdraw from the study at any time without having to provide a reason. If you do withdraw, any information that you have collected will be destroyed and will not be included in the study. You also do not have to answer any particular question.

Who is organizing and funding the research?

This research is being conducted as a master's student thesis project at Delft University of Technology, the Netherlands.

Who do I contact if I have questions or require further information?

If you have any questions, please feel free to contact:

Student: **Yuxiang Wang:** y.wang-64@student.tudelft.nl
+31 (0) 618242822

Supervisors: **Prof. Kaspar Jansen:** K.M.B.Jansen@tudelft.nl
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1. What objects are you wearing? What did you wear before? How often and how long do you wear them? What do you like/dislike about the product? Are they comfortable or not during daily activities/sports? How many shirts do you have? How often do you change them? How do you wash them? How many shirts do you need? Show pics of patch and bodyplus

watches, bangles, rings, gloves, glasses, masks or any other sports accessories.

band-aids, cast

(ask for **weight, size, materials**)

Objects	Positive	Negative

2. What 2nd hand product did you buy (with direct contact with your skin)?

Objects	Positive	Negative

To what extent can you accept used wearables from others? (patch/band/shirt)

3. How do you like your phone? Do you use WiFi/Bluetooth/Mobile data often? Case? What other smart product do you use? Did you look at the manuals?

4. What functions do you want on a wearable device?

Delft University of Technology
ETHICS REVIEW CHECKLIST FOR HUMAN RESEARCH
(Version 01.02.2019)

This checklist should be completed for every research study that involves human participants and should be submitted before potential participants are approached to take part in your research study.

In this checklist we will ask for additional information if need be. Please attach this as an Annex to the application.

Please upload the documents (go to [this page](#) for instructions).

Thank you and please check our [website](#) for guidelines, forms, best practices, meeting dates of the HREC, etc.

I. Basic Data

Project title:	Design a wearable device to detect Atrial Fibrillation
Name(s) of researcher(s):	Yuxiang Wang
Research period (planning)	April to September 2019
E-mail contact person	y.wang-64@student.tudelft.nl
Faculty/Dept.	
Position researcher(s):¹	IPD master student
Name of supervisor (if applicable):	Kaspar Jansen (chair), Iemkje Ruiten (mentor)
Role of supervisor (if applicable):	

II. A) Summary Research

(Please very briefly (100-200 words) summarise your research, stating the question for the research, who will participate, the number of participants to be tested and the methods/devices to be used. Please avoid jargon and abbreviations).

This study is part of the master IPD student Yuxiang Wang's graduation project (study number: 4744314) at TU Delft. The goal of the study is to gather user insights (e.g. needs of convenience, hygiene etc.) by interviewing people to help design a wearable Atrial Fibrillation diagnosis device. 5-10 People aged from 50-75 yrs will be interviewed by the researcher Yuxiang Wang alone. Notes will be taken during the interview and audio will be recorded if the participant signs an informed consent form.

B) Risk assessment

Please indicate if you expect any potential risks for the participants as a result of your research and, if so, how you will try to minimize these.

Please take into consideration any personal data you may gather and privacy issues.

The audio recording of the interview may contain personal information of the participants. To minimize the risk, consent of recording the interview must be obtained from the participants by signature before the interview takes place. During the project, all data will be stored on a computer with password protection

¹ For example: student, PhD, post-doc

and only the researcher and the supervisors can access the data. All raw data of the interview including the recoding will be destroyed after the project.

III. Checklist

Question	Yes	No
1. Does the study involve participants who are particularly vulnerable or unable to give informed consent? (e.g., children, people with learning difficulties, patients, people receiving counselling, people living in care or nursing homes, people recruited through self-help groups).		x
2. Are the participants, outside the context of the research, in a dependent or subordinate position to the investigator (such as own children or own students)? ²		x
3. Will it be necessary for participants to take part in the study without their knowledge and consent at the time? (e.g., covert observation of people in non-public places).		x
4. Will the study involve actively deceiving the participants? (For example, will participants be deliberately falsely informed, will information be withheld from them or will they be misled in such a way that they are likely to object or show unease when debriefed about the study).		x
5. Personal data <ul style="list-style-type: none"> Will the study involve discussion or collection of confidential (sensitive) personal data? (e.g., BSN number, location, sexual activity, drug use, mental health)? <p>If 'yes': Did the data steward approve your data management plan? Please upload proof.</p>		x
6. Will drugs, placebos, or other substances (e.g., drinks, foods, food or drink constituents, dietary supplements) be administered to the study participants?		x
7. Will blood or tissue samples be obtained from participants?		x
8. Is pain or more than mild discomfort likely to result from the study?		x
9. Does the study risk causing psychological stress or anxiety or other harm or negative consequences beyond that normally encountered by the participants in their life outside research?		x
10. Will financial inducement (other than reasonable expenses and compensation for time) be offered to participants?		x
Important: if you answered 'yes' to any of the questions mentioned above, please submit a full application to HREC (see: website for forms or examples).		
11. Will the experiment collect and store videos, pictures, or other identifiable data of human subjects? ³	x	

² **Important note concerning questions 1 and 2.** Some intended studies involve research subjects who are particularly vulnerable or unable to give informed consent. Research involving participants who are in a dependent or unequal relationship with the researcher or research supervisor (e.g., the researcher's or research supervisor's students or staff) may also be regarded as a vulnerable group. If your study involves such participants, it is essential that you safeguard against possible adverse consequences of this situation (e.g., allowing a student's failure to complete their participation to your satisfaction to affect your evaluation of their coursework). This can be achieved by ensuring that participants remain anonymous to the individuals concerned (e.g., you do not seek names of students taking part in your study). If such safeguards are in place, or the research does not involve other potentially vulnerable groups or individuals unable to give informed consent, it is appropriate to check the NO box for questions 1 and 2. Please describe corresponding safeguards in the summary field.

³ Note: you have to ensure that collected data is safeguarded physically and will not be accessible to anyone outside the study. Furthermore, the data has to be de-identified if possible and has to be destroyed after a

Question	Yes	No
<p>If "yes", please fill in Annex 1 and make you sure you follow all requirements of the applicable data protection legislation. In addition, please provide proof by sending us a copy of the informed consent form.</p>		
<p>12. Will the experiment involve the use of devices that are not 'CE' certified?</p> <p><i>Only, if 'yes': continue with the following questions:</i></p>		x
<p>➤ Was the device built in-house?</p>		
<p>➤ Was it inspected by a safety expert at TU Delft? <i>(Please provide device report, see: HREC website)</i></p>		
<p>➤ If it was not built in house and not CE-certified, was it inspected by some other, qualified authority in safety and approved? <i>(Please provide records of the inspection).</i></p>		
<p>13. Has or will this research be submitted to a research ethics committee other than this one? <i>(if so, please provide details and a copy of the approval or submission).</i></p>		x

IV. Enclosures (tick if applicable)

- Full proposal (if 'yes' to any of the questions 1 until 10)
- Informed consent form (if 'yes' to question 11)
- Device report (if 'yes' to question 12)
- Approval other HREC-committee (if 'yes' to question 13)
- Any other information which might be relevant for decision making by HREC
- Data management plan approved by a data steward (if yes to question 5B)

V. Signature(s)

Signature(s) of researcher(s)
 Date: 20/05/2019

Signature (or upload Electronic Consent) research supervisor (if applicable)
 Date:

Appendix 1: Privacy and data protection

Please fill this in if you have answered 'yes' to question 11 in the checklist

- a. Will the participants have access to their own data? If no, please explain.
Yes, they can access their own data and decide on the data to be collected. For the interview, audio recording will be done to help the researcher analyse the notes taken during the meeting. Possible pictures of products will be taken to offer examples for the study but none of them involve any identifiable information. All data mentioned above will only be collected after the participant signs a informed consent form, which is provided for this project.

- b. Will covert methods be used? (*e.g. participants are filmed without them knowing*)

- c. Will any human tissue and/or biological samples be collected? (*e.g. urine*)

Research with General Practitioner on Atrial Fibrillation

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Purpose of the study

The goal of the study is to gather insights on the products they love and to find opportunities to offer the GP useful information they need (for AFib patients).

What will happen if I decide to take part?

I will ask you several questions about your experience with wearable objects, during which written notes and audio recording may be done to help me document the interview. If you agree to take part, I will provide you with full instructions. You will also be given the opportunity to ask any questions. You may ask questions at any time if you do not understand anything.

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Interview Plan with GP

Goal

1. Find opportunities to offer the GP useful information they need (for AFib patients).
2. Get insights on the products they love to use

Process

1. Brief introduction of myself, graduation project
2. Explain the purpose of the interview
3. Interview conversation
4. Offer a small gift

Questions

1. Do you check ECG from patients? And how? What does ECG help with?
2. Do you hand out devices/equipment to patients? What do you like/dislike about them? How is the product cleaned?
3. What kind of devices would you buy? What are the factors to consider? How did you know about them?
4. What do you do you want to improve in your work flow as a GP?
5. What do you usually ask (what information do you need) from patients?
6. Among these, what kind of information are difficult to get? And what kind of information are prone to be less accurate?

Nr.	Datum & Tijd	Syst.	MAP	Diast.	HR	PD	RPP	Commentaar
1	26-6-2019 15:32	153	112	89	55	64	8415	Handmatige meting
2	26-6-2019 15:57	144	111	93	71	51	10224	
3	26-6-2019 16:25	156	111	94	71	62	11076	
4	26-6-2019 17:00	160	120	102	65	58	10400	
5	26-6-2019 17:27	139	108	87	51	52	7089	
6	26-6-2019 17:52	127	99	82	51	45	6477	
7	26-6-2019 18:24	142	111	88	54	54	7668	
8	26-6-2019 19:00	153	119	101	71	52	10863	
9	26-6-2019 19:29	139	113	94	63	45	8757	
10	26-6-2019 20:03	165	122	93	71	72	11715	
11	26-6-2019 20:30	141	104	87	60	54	8460	
12	26-6-2019 21:02	150	104	81	58	69	8700	
13	26-6-2019 21:37	151	111	87	55	64	8305	
14	26-6-2019 22:05	175	126	97	57	78	9975	
15	26-6-2019 22:36	161	111	92	61	69	9821	
16	27-6-2019 0:05	135	101	81	55	54	7425	
17	27-6-2019 1:02	130	96	76	49	54	6370	
18	27-6-2019 2:06	114	89	73	47	41	5358	
19	27-6-2019 3:02	127	93	71	55	56	6985	
20	27-6-2019 4:05	125	93	70	49	55	6125	
21	27-6-2019 5:09	120	91	73	46	47	5520	
22	27-6-2019 6:15	115	86	67	45	48	5175	
23	27-6-2019 7:18	124	95	77	46	47	5704	
24	27-6-2019 8:19	135	105	85	50	50	6750	
25	27-6-2019 8:49	147	113	92	67	55	9849	
26	27-6-2019 9:22	149	107	88	54	61	8046	
27	27-6-2019 9:50	159	120	96	59	63	9381	
Gebeurtenis	27-6-2019 10:22							Foutieve meting (nr. 2)
28	27-6-2019 10:57	151	116	93	55	58	8305	
29	27-6-2019 11:23	157	111	90	70	67	10990	
30	27-6-2019 11:48	159	122	102	73	57	11607	
31	27-6-2019 12:17	177	131	103	60	74	10620	
32	27-6-2019 12:50	151	108	86	60	65	9060	
33	27-6-2019 13:23	139	106	83	57	56	7923	
34	27-6-2019 13:58	154	117	91	63	63	9702	

Algemeen:	Totaal:	Wakend:	Slapend:
Aantal metingen	34	26	8
% geslaagd	97%	96%	100%
Totale tijd	22:26:00	14:12:00	08:14:00
Gemiddelde	145 / 87 mmHg	151 / 91 mmHg	124 / 74 mmHg
SD	15,9 / 9,6 mmHg	11,6 / 6,2 mmHg	7,2 / 4,4 mmHg
Polsdruk	57,6 mmHg	59,9 mmHg	50,3 mmHg

Systolisch:			
Aantal metingen	21 (62%) >= 140	21 (81%) >= 140	4 (50%) >= 125
Maximum	177 mmHg op 12:17	177 mmHg op 12:17	135 mmHg op 0:05
Minimum	114 mmHg op 2:06	127 mmHg op 17:52	114 mmHg op 2:06

Diastolisch:			
Aantal metingen	15 (44%) >= 90	15 (58%) >= 90	1 (13%) >= 80
Maximum	103 mmHg op 12:17	103 mmHg op 12:17	81 mmHg op 0:05
Minimum	67 mmHg op 6:15	81 mmHg op 21:02	67 mmHg op 6:15

Hartfrequentie:			
Gemiddelde	58 spm	61 spm	49 spm
SD	8,2 spm	7,1 spm	4,0 spm
Maximum	73 spm op 11:48	73 spm op 11:48	55 spm op 0:05
Minimum	45 spm op 6:15	50 spm op 8:19	45 spm op 6:15

Wakend/slappend daling, vroege ochtend:

Daling:	18,2% / 19,6% (Dipper)
Ochtendgemiddelde:	141,0 / 88,5 mmHg

Interview with AFib Patient

Interviewee: Herman Ravae

Interviewer: Yuxiang

Location: YesDelft

Date and time: 13:00, 10th July

Goal

1. Get familiar with the AFib diagnosis procedure from patient's point of view
2. Find opportunities to offer patients better diagnosis product experience

Process

1. Brief introduction of myself, graduation project
2. Explain the purpose of the interview
3. Give information sheet. Sign informed consent form
4. Interview conversation
5. Offer a small gift

Questions

1. **When** and **how** did you find out that you had AFib?
2. How did you feel when you were having an AFib episode? And what was your emotion at the moment?
3. Age? Sports?
4. Who did you turn to at the beginning?
5. What was the diagnosis procedure?
 - a. What were you asked about?
 - b. What were you told to do?
 - c. **What devices were used in/off hospital/practice?**
 - d. **How did you feel about it? Like/dislike? Interference with daily activities?**
6. What do you like / dislike when it comes to the whole diagnosis journey?

User test of Vibration as the Interaction Method

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Purpose of the study

The goal of the study is to explore the perception of vibration as an interaction method for a heart rhythm monitoring device.

What will happen if I decide to take part?

You will be wearing a small vibration motor on the sternum to experience the vibration and offer me feedback. You may ask questions at any time if you do not understand anything.

What will happen to my information?

The study complies with the Human Research Ethics requirements from TU Delft. All information provided will be captured by hand written notes and electronically (audio recording or taking photographs) and stored on a password protected computer. It will be destroyed after any publication arising from the work, in accordance with the university data storage policy. Your name (i.e. signature on consent form) will be kept separate from your questionnaire responses. Consent forms will be stored in a locked filing cabinet for the duration mentioned above. The information that I collect during this project will be used to improve my design. Your name will not be used in association with the data.

Will my taking part in this study be kept confidential?

Yes. Only my supervisors and I have the access to the raw materials (audio recordings or photographs). If I need to present in public your face will be blurred out.

Free to withdraw

You can withdraw from the study at any time without having to provide a reason. If you do withdraw, any information that has been collected will be destroyed and will not be included in the study. You also do not have to answer any particular question.

Who is organizing and funding the research?

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Research of Vibration as the Interaction Method

Informed Consent Form

This form is part of the master Integrated Product Design student Yuxiang Wang's graduation project (study number: 4744314) at Delft University of Technology.

This document asks for your consent to participate in the study and permission for audio recording and possible photographs. Please take some time to read through this information sheet carefully and ask questions if anything is unclear or if you would like more information.

- I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
- I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason.
- I understand that my information will be used by the researcher to support the development of their design. I understand that my data will be anonymized.
- I understand that my conversation will be recorded, and photographs may be taken. The data will be securely stored.
 1. I am happy for my interview to be audio recorded:
YES/NO (delete as applicable)
 2. I am happy for photos of me taken to be used for the project:
YES/NO (delete as applicable)

Name of Participant

Date

Signature

Researcher to complete

Participant ID: _____

Vibration Perception Test

Experiment goal

1. The success of correct perception is more important than the pleasantness of the vibration in this case, so the test should start with the maximum intensity of the given ERM and whether participants can sense and distinguish among the three designed vibrations in various situations should be tested.
2. The activity of people doing may influence the perception of the intensity of the vibration, which may lead to different intensity for different situations.
3. Whether people feel the vibration pleasant or not.

Experiment setup

1. Test whether participants can feel and distinguish among the three different vibrations when they are sitting quietly, walking, distracted and when they can't hear the vibration
2. Given a same vibration, let participants compare the intensity while they are sitting and doing daily physical activities.
3. Get a score for pleasantness of the vibration while sitting calmly.

Experiment results

1. Vibration perception

Condition \ Vibration	Seated quietly	Auditory interference	Distracted	Walking	Walking + Auditory interference
Single (0.6s)	✓	✓	✓	✓	✓
Two quick ones (0.3s)	✓	✓	✓	✓	✓
Single long (2s)	✓ (3x longer)	✓	✓	✓	✓

Handwritten notes: cooking, making pancakes. → go by upstairs.

2. Activity influence (simple daily activities)

	Sitting quietly	Activity
Perceived Intensity	=	=

3. Comfort test

Vibration Intensity	1	2	3	4
Comfort score (1-10)	9	8-9	8-9	6-7

Handwritten note: not likely to feel it while activity.

Handwritten note: more irritating like a slight electric

Participant ID: 1

Date: 29/08/2019

Handwritten comment: ① like constant monitoring of body vitals.

Handwritten comment: ② more vitals: BP, HR, Sugar -? → PPG (value).

Vibration Perception Test

Experiment goal

1. The success of correct perception is more important than the pleasantness of the vibration in this case, so the test should start with the maximum intensity of the given ERM and whether participants can sense and distinguish among the three designed vibrations in various situations should be tested.
2. The activity of people doing may influence the perception of the intensity of the vibration, which may lead to different intensity for different situations.
3. Whether people feel the vibration pleasant or not.

Experiment setup

1. Test whether participants can feel and distinguish among the three different vibrations when they are sitting quietly, walking, distracted and when they can't hear the vibration
2. Given a same vibration, let participants compare the intensity while they are sitting and doing daily physical activities.
3. Get a score for pleasantness of the vibration while sitting calmly.

Experiment results

1. Vibration perception

Condition \ Vibration	Seated quietly	Auditory interference	Distracted	Walking	Walking + Auditory interference
Single (0.6s)	✓	✓	✓	2X	✓ ✓
Two quick ones (0.3s)	✓	✓	✓	✓	✓ ✗
Single long (2s)	✓	✓	✓	✓	✓ ✓

explain. Report. talking,

2. Activity influence (simple daily activities)

	Sitting quietly	Activity
Perceived Intensity	<i>weaker.</i>	<i>stronger.</i>

3. Comfort test

Vibration Intensity	1	2	3	4
Comfort score (1-10)	<i>5-9</i>	<i>8-7</i>	<i>5</i>	<i>3-2</i>

stairs = 6-7 same

Participant ID: 2

Date: ~~28/08/2019~~
29/08/2019

Vibration Perception Test

Experiment goal

1. The success of correct perception is more important than the pleasantness of the vibration in this case, so the test should start with the maximum intensity of the given ERM and whether participants can sense and distinguish among the three designed vibrations in various situations should be tested.
2. The activity of people doing may influence the perception of the intensity of the vibration, which may lead to different intensity for different situations.
3. Whether people feel the vibration pleasant or not.

Experiment setup

1. Test whether participants can feel and distinguish among the three different vibrations when they are sitting quietly, walking, distracted and when they can't hear the vibration
2. Given a same vibration, let participants compare the intensity while they are sitting and doing daily physical activities.
3. Get a score for pleasantness of the vibration while sitting calmly.

Experiment results

1. Vibration perception

Condition \ Vibration	Seated quietly	Auditory interference	Distracted	Walking	Walking + Auditory interference
Single (0.6s)	✓	✓	2x	✓	✓
Two quick ones (0.3s)	✓	✓	✓	✓	✓
Single long (2s)	✓	✓	✓	✓	✓

still too long.
↓
make it shorter.

talked
felt weaker

more concentration with audio
↓
easy to concentrate on senses.

2. Activity influence (simple daily activities)

	Sitting quietly	Activity
Perceived Intensity	stronger ↑ (shorter duration)	weaker.

3. Comfort test

Vibration Intensity	1	2	3	4
Comfort score (1-10)	1	3	6	7

too weak.
don't like them!
like firm interaction also with people.

Participant ID: 3

Date: 29/08/2019



Preliminary PRODUCT CLINICAL DATA SUMMARY

Product Numbers 2477 aka MSX 6931B

3M Double-Coated TPE Tape with Silicone Adhesive and Acrylate Adhesives

Product Number 2477P aka MSX 6932B

**3M Double-Coated TPE Tape with Silicone Adhesive and Acrylate Adhesives on Premium Liner
Effective: December 2011**

A similar adhesive (next to the clear liner), used in product numbers 2477 and 2477P, in conjunction with a *different* liner, has been subjected to the following safety evaluations:

***In Vitro* Cytotoxicity**

The test was to determine the potential for cytotoxicity based on the requirements of International Organization for Standardization (ISO 10993-5): Biological Evaluation of Medical Devices- Part 5: Tests for *In Vitro* Cytotoxicity. Triplicate wells were dosed with a 1cm x 1cm portion of the test article. Triplicate wells were dosed with a 1 cm length of high density polyethylene as a negative control. Triplicate wells were dosed with a similar portion of latex as a positive control. Each was placed on an Agarose surface directly overlaying a sub-confluent monolayer of L-929 mouse fibroblast cells. After incubating at 37 degrees C in the presence of 5% CO₂ for 24 hours, the cultures were examined macroscopically and microscopically for any abnormal cell morphology and cell lysis. The test article showed no evidence of causing mild cell lysis or toxicity. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity). 3M Study 05-012205

Primary Skin Irritation

The test article was evaluated for primary skin irritation in accordance with the guidelines of ISO 10993 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. Two 25mm x 25mm sections of the test article and control article were topically applied to the skin of each of three rabbits and left in place for 24 hours. The sites were graded for erythema and edema at 1, 24, 48, and 72 hours after removal of the single sample application. There was very slight erythema and no edema observed on the skin of the animals. The Primary Irritation Index for the test article was calculated to be 0.1. The response of the test article was categorized as negligible. 3M Study 05-012155

Guinea Pig Sensitization

The test article was evaluated for the potential to elicit delayed dermal contact sensitization in the guinea pig based on the requirements of ISO 10993-10, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization. The test article was extracted in 0.9% sodium chloride USP and sesame oil, NF. Each extract was intradermally injected and occlusively patched to ten test guinea pigs (per extract). The extraction vehicle was similarly injected and occlusively patched to five control guinea pigs (per vehicle). Following a recovery period, the ten test and five control animals received a challenge patch of the appropriate test and vehicle control. All sites were observed for evidence of dermal reactions at 24 and 48 hours after patch removal. The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article extracts and test article were not considered to be sensitizers in the guinea pig maximization test. 3M Study 05-012153

Preliminary PRODUCT CLINICAL DATA SUMMARY

Product Numbers 2477 aka MSX 6931B

3M Double-Coated TPE Tape with Silicone Adhesive and Acrylate Adhesives

Product Number 2477P aka MSX 6932B

3M Double-Coated TPE Tape with Silicone Adhesive and Acrylate Adhesives on Premium Liner

Effective: December 2011

Page 2/2

In addition, a 200+ human study using this adhesive has shown the following results:

Repeated Insult Patch Test (Draize) in Humans

Protocol reference: Draize: Appraisal of the Safety of Chemicals in Food, Drugs and Cosmetics (1965). Published by the Editorial Committee of the Association of Food and Drug Officials of the United States. 3M Study 05-012167

Results: Does not indicate potential for dermal irritation or allergic contact sensitization.

The use of the term "hypoallergenic" has come to indicate a product that is non-sensitizing to the general public. The hypoallergenic claim for this product is supported by clinical evaluation using the repeated insult patch test in humans, commonly known as the Draize test. This protocol involves repeated application of samples on 200 healthy volunteers for a 2- to 3-week induction period, followed by a 2-week rest period and a challenge application. To be termed hypoallergenic, 3M Medical Specialties products are required to show no evidence of sensitization potential under these test conditions.

It is the responsibility of our customers to determine the final suitability of our products for their application.



Technical Information Sheet

3M™ Medical Specialty Tape

Product Number #2477P [formerly MSX-6932B]

Double-coated “2-in-One” Medical Silicone/Acrylic Tape

Effective Date: August 2013

Supersedes all previous information sheets

Product Description:

3M #2477P is double-coated Differential Silicone/Gentle acrylic adhesive tape designed for medical & retail lamination applications. The tape is supplied on a flexible TPE carrier with a paper release liner on the gentle acrylic adhesive side of the tape. The 3M proprietary Silicone adhesive side is protected by a premium 3M Fluoropolymer-release PP film liner.

Features and Benefits:

- Two Adhesive Systems/2 Release Liners
- Gentle acrylic adhesive for device attachment
- 3M proprietary silicone adhesive for skin contact
- No Natural Rubber Latex
- Medical and Retail Device Applications
- EtO Sterilization Compatible Only

Composition:

Tape caliper, no liner	7.2 mils [0.18 mm] Silicone/Acrylic “2-in-One” DC TPE Tape
Carrier	1.5 mil [0.04mm] translucent Thermoplastic Elastomeric [TPE] Film
Adhesives	4 mil [0.10 mm] 3M Medical Grade Gentle Silicone adhesive
	1.7 mil [0.04mm] Gentle Acrylic, developed for medical/surgical use
Release Liners	3.5 mil [0.09mm] Clear Polypropylene Film, one side fluoropolymer ctd
	60 lb. Bleached Kraft paper, silicone release one side [3.3 mil/0.08 mm]

Typical Properties¹:

Adhesion to Stainless Steel, Si Side	3.5 oz/inch [85 gms/25.4 mm]
180° Peel Acr Side	32 oz/inch width [0.9 kg/25.4 mm width]
Liner Release, Preliminary, Si Side	9 gm/inch width [9 gm/25 mm width]
180° Peel Acr Side	10 gm/inch width [10 gm/25 mm width]
Moisture Vapor Transmission Rate [MVTR] upright cup	~400 gms/sq.m/24 hrs

¹ Properties listed based on very limited data and subject to change.

Roll Description: Tape supplied on 6-inch [15.24 cm] diameter cores.

Length, Maximum	200 yards [183 meters]
Width, Maximum	23.75 inches [60.3 cm]

Recommended Storage Conditions:

Product as supplied in original packaging will maintain stated test properties for a period of two [2] years when stored at temperatures of 50-80°F (10-27°C) and a relative humidity between 40-60 percent.

Note: Product should be stored in the original packaging out of direct sunlight or high-intensity indoor lighting.

Please see reverse side for important product, safety and warranty information.

Product and Safety Information: User is solely responsible for determining the suitability of 3M samples and products for the intended use including any necessary safety or toxicity assessment. 3M will provide Material Safety Data Sheets and results of toxicity testing upon request. In every case before using any product in full scale production users should conduct their own tests to determine to their own satisfaction whether the product is of acceptable quality and is suitable for their particular purposes under their own operating conditions.

Notice: Nothing contained herein shall be construed to imply the nonexistence of any relevant patents or to constitute a permission, inducement or recommendations to practice any invention covered by any patent, without authority from the owners of this patent.

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Limitation of Remedies: If products are proven not to meet 3M's specifications, the sole and exclusive remedy available and 3M's only obligation shall be, at 3M's option, to replace such quantity of Products which are proven out of specification or to refund the purchase price paid for Products.

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PRODUCT CLINICAL DATA SUMMARY

Product Number 1509

3M™ DC Polyethylene Medical Tape

Effective: April 2017

Page 1 of 2

The adhesive used on this tape, as part of a different construction, has been subjected to the following safety evaluations:

In Vitro Cytotoxicity

The test was to determine the potential for cytotoxicity based on the requirements of International Organization for Standardization (ISO 10993-5): Biological Evaluation of Medical Devices- Part 5: Tests for *In Vitro* Cytotoxicity. Triplicate wells were dosed with a 1cm x 1cm portion of the test article. Triplicate wells were dosed with a 1 cm length of high density polyethylene as a negative control. Triplicate wells were dosed with a similar portion of latex as a positive control. Each was placed on an Agarose surface directly overlaying a sub-confluent monolayer of L-929 mouse fibroblast cells. After incubating at 37 degrees C in the presence of 5% CO₂ for 24 hours, the cultures were examined macroscopically and microscopically for any abnormal cell morphology and cell lysis.

The test article showed no evidence of causing any cell lysis or toxicity. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

MEM Elution

An additional *in vitro* study was conducted to evaluate for potential cytotoxic effects following the guidelines of International Organization for Standardization 10993-5: Biological Evaluation of Medical Devices, Part 5: Tests for *In Vitro* Cytotoxicity. A single preparation of the test article was extracted in single strength Minimum Essential Medium at 37 degrees C for 24 hours. The negative control, reagent control and positive control were similarly prepared. Triplicate monolayers of L-929 mouse fibroblast cells were dosed with each extract and incubated at 37 degrees C in the presence of 5% CO₂ for 48 hours. Following incubation, the monolayers were examined microscopically for abnormal cell morphology and cellular degeneration. The test article extract showed no evidence of causing cell lysis or toxicity. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

Primary Skin Irritation

The test article was evaluated for primary skin irritation in accordance with the guidelines of ISO 10993 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. Two approximate 25mm x 25mm sections of the test article and control article were topically applied to the skin of each of three rabbits and left in place for 24 hours. The sites were graded for erythema and edema at 1, 24, 48, and 72 hours after removal of the single sample application. There was very slight to well defined erythema and no edema observed on the skin of the animals. The Primary Irritation Index for the test article was calculated to be 0.4. The response of the test article was categorized as negligible.

PRODUCT CLINICAL DATA SUMMARY

Product Number 1509

3M™ DC Polyethylene Medical Tape

Effective: April 2017

Page 2 of 2

Guinea Pig Sensitization

The test article was evaluated for the potential to elicit delayed dermal contact sensitization in the guinea pig based on the requirements of ISO 10993-10, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. The test article was occlusively patched to the intact skin of ten animals for 6-8 hours, three times a week over a 3 week period. The control article was similarly patched to 5 animals. Following a 2-week recovery period, the ten test and five control animals were occlusively patched with the test and control article. All sites were observed for evidence of dermal reactions at 24 and 48 hours after patch removal. The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig. 3M Study O11342 (all)

It is the responsibility of our customers to determine final suitability of our products for their application. Final testing of a converted device made with this material is the responsibility of the customer.



Technical Information Sheet
Product Number 1509
3M™ Double Coated Medical Tape

Effective: June 2013
Supersedes all previous specifications

Features and Benefits:

- Hypoallergenic pressure sensitive adhesive
- EtO & Gamma compatible
- Clear film
- Heavy weight release liner
- Easy to apply
- Adheres to a wide range of substrates

Composition:

Tape caliper w/o liner	4.9 mil (0.12 mm) Double Coated Polyethylene Tape
Carrier	3 mil (0.08 mm) Transparent Polyethylene Film
Adhesive	Tackified Acrylic designed for medical/surgical use
Release Liner	80 lb. Bleached Kraft paper, silicone release coated both sides (4.5 mil/0.10 mm)

Typical Properties⁺:

180° Peel Adhesion to Stainless Steel	53 ounces/inch width (1.5 Kg/25 mm) (14.7 N/25 mm)
Liner Release	14 gm/inch width (14 gm/25 mm)

⁺3M test methods are available upon request.

Roll Description: Tape supplied on 3 inch (76 mm) diameter cores.

Length	600 yards (548 m) ± 2% Maximum
Width	48 inch (122 cm) ± 1/32 in (1.0 mm) Maximum

Splices: Splices on the tape are intended for continuous processing.

Roll Width	Maximum Number of Splices per Roll
≤ 8 inch (20 cm)	2 per 100 yd (91 m)
	3 per 200 yd (183 m)
	6 per 600 yd (548 m)

Information on the splice frequency in roll widths greater than 8 inch (20 cm) is available upon request.

Packaging and Recommended Storage

Product as supplied in original packaging will maintain stated properties for a period of two years from date stamped on shipping container when stored at temperatures of 50-80°F (10-27°C) and a relative humidity between 40-60 percent.

Please see reverse side for important product, safety and warranty information.

Product and Safety Information: User is solely responsible for determining the suitability of 3M samples and products for the intended use including any necessary safety or toxicity assessment. 3M will provide Material Safety Data Sheets and results of toxicity testing upon request. In every case before using any product in full scale production users should conduct their own tests to determine to their own satisfaction whether the product is of acceptable quality and is suitable for their particular purposes under their own operating conditions.

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PRODUCT CLINICAL DATA SUMMARY
NO. 1522
3M™ Double Coated Medical Tape
Effective: March 2017
Page 1 of 2

The adhesive used on No 1522, as part of a different construction, has been subjected to the following safety evaluations:

***In Vitro* Cytotoxicity**

The test was to determine the potential for cytotoxicity based on the requirements of International Organization for Standardization (ISO 10993-5): Biological Evaluation of Medical Devices- Part 5: Tests for *In Vitro* Cytotoxicity. Triplicate wells were dosed with a 1cm x 1cm portion of the test article. Triplicate wells were dosed with a 1 cm length of high density polyethylene as a negative control. Triplicate wells were dosed with a similar portion of latex as a positive control. Each was placed on an Agarose surface directly overlaying a sub-confluent monolayer of L-929 mouse fibroblast cells. After incubating at 37 degrees C in the presence of 5% CO₂ for 24 hours, the cultures were examined macroscopically and microscopically for any abnormal cell morphology and cell lysis. The test article showed no evidence of causing any cell lysis or toxicity. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

MEM Elution

An additional *in vitro* study was conducted to evaluate for potential cytotoxic effects following the guidelines of International Organization for Standardization 10993-5: Biological Evaluation of Medical Devices, Part 5: Tests for *In Vitro* Cytotoxicity. A single preparation of the test article was extracted in single strength Minimum Essential Medium at 37 degrees C for 24 hours. The negative control, reagent control and positive control were similarly prepared. Triplicate monolayers of L-929 mouse fibroblast cells were dosed with each extract and incubated at 37 degrees C in the presence of 5% CO₂ for 48 hours. Following incubation, the monolayers were examined microscopically for abnormal cell morphology and cellular degeneration. The test article extract showed no evidence of causing cell lysis or toxicity. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

Primary Skin Irritation

The test article was evaluated for primary skin irritation in accordance with the guidelines of ISO 10993 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. Two approximate 25mm x 25mm sections of the test article and control article were topically applied to the skin of each of three rabbits and left in place for 24 hours. The sites were graded for erythema and edema at 1, 24, 48, and 72 hours after removal of the single sample application. There was very slight to well-defined erythema and no edema observed on the skin of the animals. The Primary Irritation Index for the test article was calculated to be 0.8. The response of the test article was categorized as slight.

PRODUCT CLINICAL DATA SUMMARY
NO. 1522
3M™ Double Coated Medical Tape
Effective: March 2017
Page 2 of 2

Guinea Pig Sensitization

The test article was evaluated for the potential to elicit delayed dermal contact sensitization in the guinea pig based on the requirements of ISO 10993, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. The test article was occlusively patched to the intact skin of ten animals for 6-8 hours, three times a week over a 3 week period. The control article was similarly patched to 5 animals. Following a 2-week recovery period, the ten test and five control animals were occlusively patched with the test and control article. All sites were observed for evidence of dermal reactions at 24 and 48 hours after patch removal. The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig. 3M Study # 05-011343 (all)

It is the responsibility of our customers to determine final suitability of our products for their application. Final testing of a converted device made with this material is the responsibility of the customer.



Technical Information Sheet
Product Number #1522
3M™ Double Coated Medical Tape
 Effective: July 2013
 Supersedes all previous specifications

Features and Benefits:

- Hypoallergenic pressure sensitive adhesive
- EtO & Gamma Sterilization Compatible
- Clear Film Carrier
- Heavy weight release liner for diecutting
- Easy to Apply
- Adheres to a wide range of substrates

Composition:

Tape caliper, no liner	6.3 mil (0.16 mm) Double Coated Polyethylene Tape
Carrier	3 mil (0.08 mm) Transparent Polyethylene Film
Adhesive	Acrylate designed for medical/surgical use
Release Liner	80 lb. Bleached Kraft paper, silicone release both sides (4.5 mil/0.11mm)

Typical Properties⁺:

180° Peel Adhesion to Stainless Steel, Face [Open] side	28 oz/inch width (800 gm/25mm)
Liner Release	9 gm/inch width (9 gm/25 mm)

+ Properties listed based on very limited data and subject to change. Methods available upon request.

Roll Description: Tape supplied on 3 inch (76 mm) diameter cores.

Length	550 yards (503 m) ± 2% Maximum
Width	48 inch (122 cm) ± 1/32 in (1.0 mm)

Number of Splices: Splices on the tape are intended for continuous processing.

Roll Width	Maximum Number of Splices per Roll
≤ 8 inch (20 cm)	2 per 100 yd (91 m)
	3 per 200 yd (183 m)
	6 per 550 yd (503 m)

Information on the splice frequency in roll widths greater than 8 inch (20 cm) is available upon request.

Packaging and Recommended Storage

Product as supplied in original packaging will maintain stated properties for a period of three (3) years from date stamped on shipping container when stored at temperatures of 50-80°F (10-27°C) and a relative humidity of 40-60 percent.

Please see reverse side for important product, safety and warranty information.

Product and Safety Information: User is solely responsible for determining the suitability of 3M samples and products for the intended use including any necessary safety or toxicity assessment. 3M will provide Material Safety Data Sheets and results of toxicity testing upon request. In every case before using any product in full scale production users should conduct their own tests to determine to their own satisfaction whether the product is of acceptable quality and is suitable for their particular purposes under their own operating conditions.

Notice: Nothing contained herein shall be construed to imply the nonexistence of any relevant patents or to constitute a permission, inducement or recommendations to practice any invention covered by any patent, without authority from the owners of this patent.

Warranty Information

All statements, technical information and recommendations herein are based on tests 3M believes to be reliable, but the accuracy or completeness thereof is not guaranteed. 3M warrants only that products will meet 3M's specifications at the time of shipment to the customer. 3M does not offer any other warranty and does not warrant the performance, safety or such other characteristics of Products in combination with other materials. 3M specifically DOES NOT warrant Products for any intended or unintended uses (whether or not foreseeable); for compatibility or suitability with other components or compatibility with any methods of manufacture or conversion. The foregoing warranty is made in lieu of all other warranties, expressed or implied, including the implied warranties of merchantability, fitness for a particular purpose and freedom from non-infringement.

Limitation of Remedies: If products are proven not to meet 3M's specifications, the sole and exclusive remedy available and 3M's only obligation shall be, at 3M's option, to replace such quantity of Products which are proven out of specification or to refund the purchase price paid for Products.

Limitations of Liabilities: The remedies provided herein are exclusive remedies against 3M for any alleged or actual nonconformance to specifications or defect or other failure in products or for 3M's performance of its supply obligations. Under no circumstances is 3M liable for any direct, indirect, incidental, special or consequential damages (including lost profits) in any way related to the product under any theory of law including, but not limited to, negligence and strict liability.

Ordering Information

Call us at Customer Service to place an order: 800-742-1994 (U.S.). Visit our website: www.3M.com/medicalspecialties for product and services information, news about conferences we will be attending, new product highlights or to make a direct inquiry.

To have a sales representative contact you, to request samples or clinical and safety summaries, please contact us at 3M HELPLINE 800-228-3957 (U.S.) or for international inquiries, please contact your local country representative. Our 3M Medical Specialties subsidiary contacts are listed below.

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3M

3M Medical Specialties

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St. Paul, MN 55144-1000 USA
Tel.: 800 228-3957



Covidien Adult Electrodes

OTHER ELECTRODES



Medi-Trace™ 200

Code: 31050522
Description: Round, stud, general monitoring electrode, 35mm
Special features: Packed in perforated strips



Medi-Trace™ 133

Code: 31439725
Description: Round, stud, general monitoring electrode, 30mm
Special features: Smaller version of Medi-Trace™ 200, smaller and packed in strips of 3

Alternative electrode:

Medi-Trace 100 (31118733)

As 31439725, Smaller version of Medi-Trace™ 200, smaller and packed in strips of 5



Medi-Trace™ 530

Code: 31013926
Description: Round, stud, general monitoring electrode, 45mm
Special features: Pack of 30 loose electrodes

KENDALL™ ECG FOAM ELECTRODES WET GEL



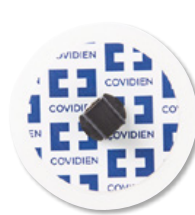
H34LG

Code: 31.1345.21
Description: Round, stud, stress electrode, 50x45mm



H135LG

Code: 31.1413.21
Description: Round, stud, diagnostic stress electrode, 40mm



H1354LG

Code: 31.1414.21
Description: Round, banana adaptor diagnostic & stress electrode, 40mm



H66LG

Code: 31.1663.21
Description: Round, stud, diagnostic stress electrode, 55mm
Also available with a banana adaptor, code 31.1664.21

HOLTER MONITOR DIARY



American Heart Association.

While you are being monitored by a Holter monitor, it's important to keep an accurate diary of your activities and symptoms during the test. If you feel symptoms such as chest pain, shortness of breath, uneven heartbeats or dizziness, note in your diary the time of day they began and what you were doing. Your diary will be compared to the changes in your ECG recorded by the Holter monitor.

Remember that your doctor needs a complete picture of your activities. If in doubt, write it down. Use the following diary to record all of your daily activities:

- **Time of day** – Write the time of day for every activity or symptom that you write in the diary.
- **Your activities** – Sitting, walking, strenuous exercise, eating, sexual activity, taking medications, etc.
- **Your symptoms** – Chest pain, back pain, dizziness, nausea, other pain – whether or not you feel they are important.

DATE	TIME	ACTIVITY	SYMPTOMS

Sticker User Test Result



1. ECG at the practice

+ Easier at the practice

"It's easier when the ECG is done at the practice itself."

- Difficult to read, adds to the workload

"I am not sure that some GPs have the skill to read ECGs, and some GPs send every ECG to the hospital to be taken by the cardiologist."

"Sometimes it's not easy to read. Sometimes you see ECGs, difficult to analyse"

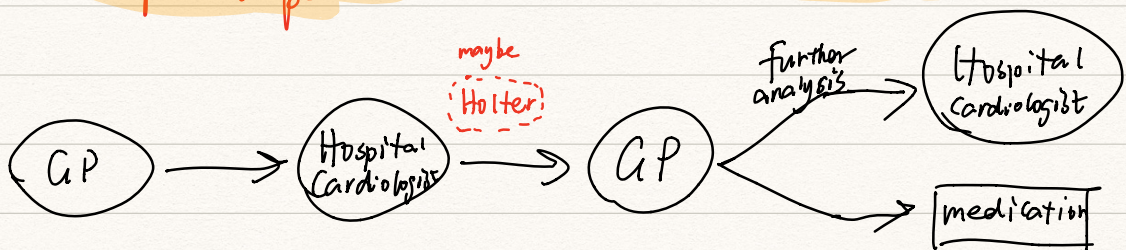
o GPs receive feedbacks from the cardiologist

"Simple things like fibrillation, ischemia of the heart, other obvious abnormalities

"We are not equipped, we don't have the knowledge to read a holter"

• Interested in Yes/No diagnosis, complex P.Q.R.S.T things. "we don't like these kind of remarks, because we are not cardiologist and we don't know what to do with them"

Keep it simple! could be this... could be that... TOO MUCH!



Loss of time: multiple processes, all appointment needed

2. Information to GPT

① What are they feeling? (pain on the chest)

② In what kind of situation the complaints happen (sporting? active? doing nothing?)

③ Heart problems with family members

④ Meds they use

* ⑤ NICE guidelines

⑥ How long is the symptom existing

⑦ 2-month diary/agenda (what, when, how long last? How much pain)


3. 24H BP register [Get more info online, 20 min MAX]

① Computers gives conclusions

5yrs ago, at least 10 yrs in the market

② Re-assure the patient in a short time

③ Can trust it: "It's a calculator, it's very simple"

④ "What the patient doing at that time sometimes it's helpful". 

⑤ People worry when they take BP at practice → higher pressure.

⑥ Ease of use is *. Sometimes it squeeze the arm, which is uncomfortable

⑦ satisfaction of the device is very important.

4. Financial insights.

① G.P purchase, get refund from insurance company. (€1500)

€20 refund
use

Purchasing Decision

If it helps

in daily routine of helping people

not to give patient meds. in times when he in the past would have given medication.

Financial sustainable

Other insights

① We comfort the patients saying "your Holter is OK, there's no real reasons for you to worry, so wait and see"

3M™ Electrically Conductive Adhesive Transfer Tape 9703

Product Description

3M™ Electrically Conductive Adhesive Transfer Tape (ECATT) 9703 is a pressure sensitive adhesive (PSA) transfer tape with anisotropic electrical conductivity. The PSA matrix is filled with conductive particles which allow interconnection between substrates through the adhesive thickness (the “Z-axis”) but are spaced far enough apart for the product to be electrically insulating in the plane of the adhesive. The PSA tack properties and lack of any thermal curing make 3M ECATT 9703 easy to use in assembly operations.

3M ECATT 9703 electrically connects and mechanically bonds medium pitch flexible circuits with other flexible circuits (flex), rigid printed circuit boards (PCB) or LCD screens. 3M ECATT 9703 is electrically conductive and offers good adhesion to common PCB substrates such as copper, gold, FR-4 epoxy, DuPont™ Kapton™ polyimide and polyester films. Stable electrical performance in any flexible circuit interconnection application may require mechanical reinforcement (clamping).

3M ECATT 9703 also electrically connects and mechanically bonds EMI/RFI shield and gaskets to metal frames and enclosures. The low contact resistance and tape construction result in good EMI performance. 3M ECATT 9703 can be applied as die cut parts or in roll form and has good adhesion to common EMI/RFI substrates such as aluminum, stainless steel, and smooth gasket materials.

Product Construction

Property	Value
Adhesive Type	Filled Acrylic Pressure Sensitive
Release Liner	Silicone Treated Polycoated Kraft Paper
Approximate Thickness	
Adhesive	2 mil (50 µm)
Liner	4 mil (100 µm)

3M™ Electrically Conductive Adhesive Transfer Tape 9703

Typical Physical Properties and Performance Characteristics

Note: The following technical information and data should be considered representative or typical only and should not be used for specification purposes.

Adhesive Properties:

Peel Adhesion to Stainless Steel:

Tested in accordance with a modified ASTM D3330 test method, 12 ipm peel rate, 1 in. width, 2 mil PET backing, 180 degree)

Dwell Time @ Room Temperature
23°C

1 Hour
29 oz./in. (3.2 N/cm)

24 Hours
32 oz./in. (3.5 N/cm)

Note: Peel values will often be higher than noted above when using a non-PET backing. Different backing types effect the backing modulus, thickness and stiffness and these differences directly effect the peel test result value. As an example, a 2 mil aluminum backing will change the test value of the peel adhesion as the peel back angle at the interface will change due to the backing stiffness. A 2 mil aluminum backing would generally increase the peel values.

Temperature Performance¹

Application Use Temperatures:

-40 to +85°C in a properly designed end use application. See Note 1.

Application Storage Temperatures:

See “Shelf Life and Storage” comments. End user needs to qualify converted material for a broader storage environmental range.

See also the Application section of this document

Outgassing:

(NASA SP-R-0022 or ASTM E595)

125°C, 24 hrs, 2 × 10⁻⁶ Torr vacuum

Total Mass Loss (TML)

0.7%

Collected Volatile Condensable Materials (CVCM)

0.01%

Electrical Properties:

Insulation Resistance ^{2,3}	3.4 × 10 ¹⁴ ohms/square (estimated based on 3M™ Electrically Conductive Adhesive Transfer Tape 9703)
Contact Resistance ¹	< 0.3 ohms (3M Test Method, Gold PI Flex onto Gold PCB, RT Initial R, 6 mm ²)
Minimum Gap ⁴	15 mil (0.4 mm)
Minimum Overlap Area ⁵	5000 mil ² (3.2 mm ²)
Apparent Thermal Conductivity ⁶	0.16-0.20 W/mK

1. The final assembly must be tested to verify that the 3M™ Electrically Conductive Adhesive Transfer Tape 9703 can achieve the desired performance in the assembly’s end use application environmental conditions (temperature, humidity, temperature cycling, shock, application assembly design, assembly variation, etc.). 3M ECATT 9703 may achieve the -40 to +85°C temperature range (or broader temperature range excursions) in an end use application if the final assembly design is designed so that the conductive particles remain in sufficient mechanical contact between surfaces to achieve the desired contact resistance. Some type of mechanical bond line compression design as determined by the end use customer (clip, clamp, screw, compressed foam, etc.) that will apply a constant minimum pressure across the bond line may be required to meet the desired end use environmental ranges and contact resistance specification. The temperature use range is dictated by two primary items: Temperature performance of the acrylic adhesive (generally in the range of -40°C to about 95°C depending on other environmental conditions) as it supports the conductive particles in the adhesive/ particle matrix and the potential movement of the conductive fillers in the adhesive system in an end use application design. Items contributing to the performance of the Tape 9703 for resistance level performance include, but are not limited to: assembled bond line force (constant force present across the bond line after assembly and over the life of the product), types of substrates bonding, surface features in bonded area, environmental conditions, (temperature, humidity, CTE, shock, environmental cycling, etc.), assembly surfaces and 3M ECATT 9703 compatibility, 3M ECATT 9703 filler and assembly surfaces galvanic potential compatibility, etc. (See section on mechanical clamping for added information).

2. Tested in accordance with ASTM D-257 test method.

3. Estimate based on 3M™ Electrically Conductive Adhesive Transfer Tape 9703 test data.

4. Minimum free space between adjacent conductors suggested to ensure electrical isolation. Customers may qualify finer pitch performance in their applications.

5. Minimum recommended conductor overlap area (pad area) in the interconnection of individual circuit lines to ensure Z-Axis conductio.

6. Tested in accordance with a modified ASTM D5470 thermal test method.

3M™ Electrically Conductive Adhesive Transfer Tape 9703

Available Sizes

Slit Tape Width 0.25 to 0.5 inch (6.9 to 13 mm)	Standard Length 36 yds. (32.9 m)	Maximum Length 36 yds. (32.9 m)
0.5 to 12 inch* (13 to 354 mm)	36 yds. (32.9 m)	108 yds. (98.8 m)
Normal Slitting Tolerance	0.03125 in. (0.8 mm)	

*Contact your 3M Technical Service Engineer for rolls wider than 12 inches.

Application Techniques

Bonding

- To obtain maximum adhesion, the bonding surfaces must be clean and dry.
- Pressure must be applied to the bond line after assembly to wet the substrates with 3M™ Electrically Conductive Adhesive Transfer Tape (ECATT) 9703 and to engage the conductive particles with the substrates to make electrical connection. Mechanical pressure (roller, metal bar) or finger pressure at 15 psi (0.10 Mpa) or greater is suggested. Heat may be applied simultaneously to improve wetting and final bond strength.
- 3M ECATT 9703 should be applied between 60°F - 158°F (15°C - 70°C). Tape application below 50°F (10°C) is not recommended because the adhesive will be too firm to wet the surface of the substrate, resulting in low adhesion.
- Adhesion builds with time, up to 24 hours may be required to reach final adhesion values.

Mechanical Clamping

To assure electrical resistance stability of 3M ECATT 9703 in any flexible circuit interconnection application, a mechanical clamp or other compressive force (i.e. foam strip held in compression over bond area.) should be considered in the design of the application. Any stress inherent in the assembly design (i.e. tensile, shear, cleavage) or temperature excursions (encountered through normal product use) applied to the bond area could result in an electrical open in the bonded circuit over time when no clamp or mechanism for maintaining a constant compressive forces is used. A well designed mechanical clamp will reduce the environmental stress on the bond line and improve the electrical reliability of the bond. In addition, the temperature operating range for the adhesive can be improved with a properly designed mechanical clamping system to ensure the conducting particles in the 3M ECATT 9703 maintain electrical contact. Several types of mechanical clamps have been used successfully including foam strips attached to lids or cases and screw-attached plastic clamps. Contact your 3M Technical Service Engineer for further information about mechanical clamping.

3M™ Electrically Conductive Adhesive Transfer Tape 9703

Application Techniques (continued)

Temperature Performance

The electrical performance of 3M™ Electrically Conductive Adhesive Transfer Tape (ECATT) 9703 is more sensitive to temperature than the peel performance. 3M ECATT 9703 is not recommended for high or low temperature excursions where the electrical performance might be compromised, even if holding power is not affected. The user is responsible for the temperature performance qualification of 3M ECATT 9703 in their design. Contact your 3M Technical Service Representative for further information about the temperature performance of 3M ECATT 9703.

Rework

Mechanically separate the parts using torque for rigid parts and peel for flexible ones. Remove the adhesive by rubbing it off with a Scotch-Brite® Hand Pad, clean up the site and apply new adhesive. The force needed to separate the parts and/or remove the adhesive can be reduced by softening the adhesive by heating 158°F - 212°F (70°C - 100°C) or using solvents.*

***Note:** When using solvents, be sure to follow the manufacturer's precautions and directions for use when handling such materials.

General Information

3M ECATT 9703 is part of a family of anisotropic (Z-Axis) conductive tapes and thermoset films. For applications where mechanical clamping is not desired, or where improved electrical, thermal and mechanical performance is required, these alternative products should be considered.

Application Ideas

3M™ Electrically Conductive Adhesive Transfer Tape (ECATT) 9703 is ideal for interconnection of flexible circuits with other flexible circuits (flex), rigid printed circuit boards (PCB) or LCD screens. Applications include polyester flex circuit splicing, keyboard manufacturing, LCD assembly and many others. 3M ECATT 9703 is also ideal for EMI/RFI shield and gasket attachment applications. Applications include EMI shields for displays and gasket attachment to EMI/RFI cabinets and enclosures.

3M™ Electrically Conductive Adhesive Transfer Tape 9703

Certificate of Analysis (COA):

The 3M Certificate of Analysis (COA) for this product is established when the product becomes commercially available from 3M. The Technical Data Sheet (TDS) technical information, test methods and data should be considered representative or typical only and should not be used for specification purposes. The Technical Data Sheet (TDS) information is based on a limited set of test results and do not reflect the COA specification limits. Final product specifications and associated manufacturing facility testing methods used for the commercialized product are outlined in the products Certificate of Analysis (COA) that is provided upon request or with the products shipment.

The COA contains the 3M specifications and test methods for the products performance limits that the product will be supplied against. The 3M product is supplied to 3M COA test specifications and the COA test methods. Inquire with 3M for the COA for this product.

Storage and Shelf Life

The shelf life of 3M™ Electrically Conductive Adhesive Transfer Tape 9703 is 24 months from the shipment date from the manufacturing location when stored in original packaging at 21°C (70°F) and 50% relative humidity.

Safety Data Sheet: Consult Safety Data Sheet before use.

Regulatory: For regulatory information about this product, contact your 3M representative.

Technical Information: The technical information, recommendations and other statements contained in this document are based upon tests or experience that 3M believes are reliable, but the accuracy or completeness of such information is not guaranteed.

Product Use: Many factors beyond 3M's control and uniquely within user's knowledge and control can affect the use and performance of a 3M product in a particular application. Given the variety of factors that can affect the use and performance of a 3M product, user is solely responsible for evaluating the 3M product and determining whether it is fit for a particular purpose and suitable for user's method of application.

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Limitation of Liability: Except where prohibited by law, 3M will not be liable for any loss or damage arising from the 3M product, whether direct, indirect, special, incidental or consequential, regardless of the legal theory asserted, including warranty, contract, negligence or strict liability.



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