



PARAMEDIC – Prehospital Randomised Assessment of a Mechanical Compression Device in Cardiac Arrest

Region:

TNO:

12 Month Follow Up Assessment

**For assistance with completing this booklet please contact the
PARAMEDIC team on: [REDACTED] or [REDACTED]**

Please read the instructions in this booklet carefully



**Warwick
Medical School**
CLINICAL TRIALS UNIT

**POCKET FOR SELF
ADDRESSED
ENVELOPES**

WRITING SHIELD

WRITING SHIELD

Instructions for entering data in this booklet

Write legibly in **black** or **blue** ink using a ball-point pen

When completing the forms please insert the writing shield behind the **pink** copy of the form to avoid marking consecutive pages.

Please enter the Region & TNO at the top of every page. The TNO is a unique, computer generated ID number for each

participant and will be given to you by the Trial Coordinating Centre.

Please ensure that ALL questions are answered as instructed

Where there are boxes put a cross in the relevant box to indicate your response

Where you are required to write a response please write legibly in BLOCK CAPITALS

Enter only one response for each item (unless otherwise specified)

Corrections

If corrections to data entered on the form are needed, draw a single line through the incorrect entry (do not obscure the original entry) and write the correct data next to the erroneous data, initial and date.

Corrections must be dated and initialled by the person making the change

Please DO NOT cover the original data by any method

Please DO NOT erase incorrect responses

Please DO NOT use correction fluid

Please DO NOT make corrections by overwriting an entry

If data are missing, this should be explained on the relevant form, for example by means of the statement “not done”, “unknown”

After each visit (at 3 months and at 12 months) please:

- ◆ Remove all top copy forms for the given time-point (**WHITE**)
- ◆ Return these to the PARAMEDIC office using a large freepost envelope
- ◆ File duplicate copies (**pink**) at site as per local guidelines

Informed consent

Please ensure that the correct consent form / agreement form is also completed and send to Warwick Clinical Trials Unit (separate to the questionnaires), site should keep a copy, copy should be sent to patient for their records.

12 month assessment checklist

Please tick only one box per questionnaire.

Ideally all questionnaires should be completed by patient (self-administered).

If administered by researcher (for example, because the patient has poor eye sight, is illiterate or is unable to write because of any physical handicap), the questions should be read aloud exactly as they appear on the questionnaires and the patient's exact answer used. Do not prompt patient or answer on their behalf.

If patient representative responds on patient's behalf, tick Proxy Assessment. If administered over the phone or by post then tick relevant box.

Region:

TNO:

To be completed by researcher conducting patient assessment.

Please place a cross in the appropriate box

Date of 12 Month Assessment

--	--

Day

--	--

Month

--	--	--	--

Year

YES	NO
<input type="checkbox"/>	<input type="checkbox"/>

Was consent received at 3 month assessment?

If No:

<input type="checkbox"/>	<input type="checkbox"/>
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Has patient willingly given written informed consent?

If No:

<input type="checkbox"/>	<input type="checkbox"/>
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Has a patient representative willingly given written informed agreement?

<input type="checkbox"/>	<input type="checkbox"/>
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Has Form 07 been completed (consultee information)?

12 month assessment checklist

	Self Administered	Administered by researcher	Proxy assessment	Administered over phone	Completed by Post
EQ5D					
SF-12					
HADS					
PTSD					
12 month Health Economics					
MMSE					

Has researcher remained blinded? Yes No

If No, when did unblinding occur? _____

Name of person conducting 12 month assessment (please print): _____

Signature of person conducting 12 month assessment: _____

3month checklist

The remaining forms are to be filled in by the participant with help from the researcher if needed, following completion of the consent process.

Questionnaire Instructions for Participants

- ◆ Please insert the writing shield behind the **PINK** copy of **each** form to avoid marking consecutive pages.
 - ◆ Please read these instructions before completing the questionnaires.
 - ◆ Please follow the instructions for each section carefully.
 - ◆ Please answer **ALL** the questions. Although it may seem that the questions are asked more than once, it is still important that you answer every one.
 - ◆ Please only enter one response for each item (unless otherwise specified).
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- ◆ Please use a **BLACK** or **BLUE** pen. Please do not use a pencil.
 - ◆ Please check that you have completed all sections.
 - ◆ If you make a mistake draw a single line through the incorrect entry, initial and date and add correct answer next to the incorrect entry.
 - ◆ Please **DO NOT** use correction fluid

Region:

TNO:

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

- I have no problems in walking about
- I have some problems in walking about
- I am confined to bed

Self-Care

- I have no problems with self-care
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

Usual Activities (e.g. work, study, housework, family or leisure activities)

- I have no problems with performing my usual activities
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

Pain/Discomfort

- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

Anxiety/Depression

- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed

Region:

TNO:

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

**Your own
health state
today**

