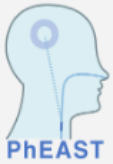
Device Deficiency

Record ID _____

*Phagenesis Ltd, who manufacture the Phagenyx® PES system, indemnify their equipment.



Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial (PhEAST)

UK ISRCTN 98886991
UK IRAS306761
UK CPMS 50913
WHO UTN U1111-1273-9942

Device deficiency form v1.2

▶ Please check consent form obtained.

Section A: Participant details

A1. Center name : _____

A2. Participant ID : _____

A3. Participant initials : _____

Section B: Device deficiency Phagenyx® is CE marked

B1. Date and time of device deficiency

_____
(Date & time (DD-MM-YYYY HH:MM:SS))

B2. Timing of deficiency

◯ Before starting patient treatment, i.e. before first PES treatment
◯ During patient treatment, i.e. between first and last PES treatments
◯ After treatment, i.e. after last PES treatment
◯ Unknown

B3. Device component

◯ Base station ◯ Catheter

B4a. Were there any equipment/device problems?	◯ None ◯ Cable could not connect to basestation ◯ Cable could not connect to catheter ◯ Cable broke/snapped ◯ Catheter broke ◯ Base station screen not working ◯ Base station software freezes ◯ Safety button used to stop PES ◯ Device calculated stimulation differs from calculation by more than 2mA ◯ Other (Choose one answer)
B4b. If "Other", please give a short description of the problem.	_____
B4c. Was there an associated:	☐ ADE ☐ SADE ☐ UADE ☐ USADE
B5. Please provide as much information as possible on the equipment failure/problem. This may be shared with the manufacturer so no identifying information please.	_____ (This may be shared with the manufacturer so no identifying information please.)

□□ Photo of deffective device, catheter or basestation

B6. You may upload an image of the device, catheter or basestation showing the problem.	(□□ Photo (but no faces, name badges or identifiers please).)
B7. Description of event	_____
B8a. Deficiency related to	◯ Labeling ◯ Quality ◯ Durability ◯ Reliability ◯ Perfromance ◯ Safety ◯ Other (Choose one answer)
B8b. If "Other", please explain the deficiency	_____
B9. Deficiency associated with an (serious) adverse event? If yes, please also complete a SAE form even if after 7 days post-randomisation.	◯ Yes ◯ No (If yes, please also complete a SAE form)
B10. Device component(s) returned, or intention to return, to manufacturer (Phagenesis)?	◯ Yes ◯ No
B11. Safety button used to stop PES (Urgent safety measure)	◯ Yes ◯ No

Section C: Catheter and device details.

C1. Catheter Lot number

_____
(([pes_catheter_lotno_1]) ([pes_catheter_lot_no_2])
([pes_catheter_lot_no_3]) ([pes_catheter_lot_no_4])
([pes_catheter_lot_no_5]) ([pes_catheter_lotno_2]))

C2. Base station serial number

_____
(([pes_basestation_serialno_1])
([pes_basestation_serialno_2]))

Section D: Assessor information.

D1. Please enter your name

_____

D2a. What is your professional role?

◯ Doctor
◯ Research coordinator
◯ Nurse, clinical
◯ Research nurse
◯ Physiotherapist
◯ Occupation therapist
◯ Speech & Language therapist
◯ Other
(Choose one answer)

D2b. If "Other", please specify your role

_____

D3. Does your role involve working on stroke wards?

◯ Yes ◯ No

D4. Please enter your name if you did not collect the information

_____

D5. Please sign the form

_____
(✍ Signature)

⚠ Please Sign the form.

Comments and full explanation for missing data

Are any values missing due to tests not done (or measures not taken), or because data are unknown and every effort has been made to find the data - i.e. 'Not done' / 'Not known'?

◯ Yes
◯ No

If any values are missing, please provide a full explanation □□ Comments