

Trial ID:

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If section not complete state reason: _____

Resident's Initials:

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Completed by (initials):

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Date completed:

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ELECTRIC:

ELECTric Tibial nerve stimulation to Reduce Incontinence in Care homes

18 Week CRF

To be completed by the Regional Research Assistant

Please return to Trial Office on completion

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If section not complete state reason: _____

1. Outcome measures

Please record the following outcome measures from information provided on the bladder diary and data from the 24 hour pad weigh.

1.1. Use the 24 hour bladder diary to record the following:

	Number	Comments (from bladder diary)
Visits to toilet - 24 hours (1 day)		
Voids in toilet - 24 hours (1 day)		
Pads used – 24 hours (1 day)		
Soiled pads included - 24 hour (1 day) collection		

1.2. Record the dry pad weight based on the number and size of pads used during the 24 hour pad collection period & ENTER ONTO THE TRIAL DATABASE

Size & make of pad used (use separate row for each size used)	Number	Dry weight in grams (weigh a dry, unused pad of same make/size)

1.3. Record the total wet pad weight of pads collected in the 24hr pad collection (weigh bag containing all pads) & ENTER ONTO THE TRIAL DATABASE

Total weight:

_____g

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Once dry and wet pad weights are entered onto the trial database, the database will calculate the volume of urine leaked and level of incontinence (Q1.4 and Q1.5). Please record the results given on the database in the box below:

1.4. Calculate the volume of urine leaked during 24 hour pad collection:

(Minus)

Total wet pad weight - Total dry pad weight = Total volume of urine leaked

_____g - _____g = _____g

1.5. Level of urinary incontinence (tick one based on 24 pad weight test calculation)

Mild (0-200ml/24hr)

Moderate (200-400ml/24hr)

Severe (400+ml/24hr)

1.6. Please record three measurements of Post Void Residual Urine Volume (PVRU) obtained. Take all measurements at the same time i.e. after the resident has voided:

1st measurement _____ ml

2nd measurement _____ ml

3rd measurement _____ ml

Date PVRU measurements complete

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1.7. Use the 3 measurements in 1.6 to calculate the average PVRU (divide the total of all measurements by 3):

Average PVRU: _____ ml

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If section not complete state reason: _____

1.8. If average PVRU >300ml as calculated in 1.7 repeat measurements the following day or ASAP and record below:

1st measurement _____ ml

2nd measurement _____ ml

3rd measurement _____ ml

Date repeat PVRU measurements complete

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1.9. Use the 3 measurements in 1.8 to calculate the average PVRU (divide the total of all measurements by 3):

Average PVRU: _____ ml

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2. Resource use questionnaire

2.1. Medication prescribed for incontinence

Name of medication (generic name preferred)	Dose per day	Ongoing medication? (Y/N)	If No, indicate how many days medication prescribed

2.2. Appointments with health service staff for incontinence problems (in past 6 weeks)

Health Service staff	Number of appointments	In care home (Y/N)
GP		
Practice Nurse		
District Nurse		
Physiotherapist		
Occupational Therapist		
Continence Service		

2.3. Is assistance required from care home staff to attend toilet? Yes /No _____

i. If yes, please indicate how many staff are required per visit : _____

ii. If yes, please indicate how many visits (on average) are required per day: _____

(see bladder diary)

Trial ID:

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If section not complete state reason: _____

2.4. Has any special equipment been provided as a result of participant incontinence (eg. Sheets, hoist, commode) DO NOT INCLUDE ABSORBENT PADS

Item	Used on a daily basis?

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3. Patient Perception of Bladder Condition (P-PBC)

IF THE RESIDENT HAS CAPACITY/LUCID MOMENTS, ASK THEM THE FOLLOWING QUESTION AND RECORD THEIR ANSWER. IF THEY DON'T HAVE CAPACITY TO ANSWER THIS QUESTION RECORD IN TOP RIGHT CORNER OF THIS PAGE

**3.1. Which of the following statements describes your bladder condition best at the moment?
Please mark "X" in one box only.**

- My bladder condition does not cause me any problems at all.
- My bladder condition causes me some very minor problems.
- My bladder condition causes me some minor problems.
- My bladder condition causes me (some) moderate problems.
- My bladder condition causes me severe problems.
- My bladder condition causes me many severe problems.

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4. Family/ carer Perception of Bladder Condition (FC-PBC)

FOR ALL RESIDENTS PLEASE ASK A FAMILY MEMBER OR REGULAR VISITOR OF THE RESIDENT WHO HAS CONSENTED TO ANSWER THE FOLLOWING QUESTION AND RECORD THEIR ANSWER BELOW

4.1. Which of the following statements do you think best describes your relative/friend's bladder condition at the moment? Please mark "X" in one box only.

- Their bladder condition does not cause them any problems at all.
- Their bladder condition causes them some very minor problems.
- Their bladder condition causes them some minor problems.
- Their bladder condition causes them (some) moderate problems.
- Their bladder condition causes them severe problems.
- Their bladder condition causes them many severe problems.

- Relative / carer not aware of bladder condition
- Relative / carer not willing to answer 4.1 (perception of bladder condition)

**4.2. Name of person answering question 4.1: _____
and relationship to resident**

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5. Staff Perception of Bladder Control (S-PBC)

FOR ALL RESIDENTS PLEASE ASK A MEMBER OF STAFF INVOLVED IN THEIR CARE WHO HAS CONSENTED TO ANSWER THE FOLLOWING QUESTION AND RECORD THEIR ANSWER BELOW

5.1. Which of the following statements do you think best describes the resident's bladder condition at the moment? Please mark "X" in one box only.

- Their bladder condition does not cause them any problems at all.
- Their bladder condition causes them some very minor problems.
- Their bladder condition causes them some minor problems.
- Their bladder condition causes them (some) moderate problems.
- Their bladder condition causes them severe problems.
- Their bladder condition causes them many severe problems.

5.2. Name & role of person answering question 5.1: _____

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If section not complete state reason: _____

6. Minnesota Toileting Skills Questionnaire – Resident (MTSQ-R)

IF THE RESIDENT HAS CAPACITY/LUCID MOMENTS, ASK THEM THE FOLLOWING QUESTION AND RECORD THEIR ANSWER. IF THEY DON'T HAVE CAPACITY TO ANSWER THIS QUESTION RECORD IN TOP RIGHT CORNER OF THIS PAGE

6.1. Please consider each of the five scenarios in the table below and rate how difficult you find them to do using the following scale:

Response options: 0 = none, 1 = a little, 2= some, 3= quite a lot, and 4 = cannot do

How much difficulty do you have...	Response (0-4)
putting on and taking off long trousers (including managing fasteners)?	
walking through your home to get to the toilet in time?	
sitting down on and standing up from the toilet?	
reaching to the side to grab toilet paper?	
reaching your bottom to wipe with toilet paper?	

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If section not complete state reason: _____

7. Minnesota Toileting Skills Questionnaire – Staff (MTSQ-S)

FOR ALL RESIDENTS PLEASE ASK A MEMBER OF STAFF INVOLVED IN THEIR CARE WHO HAS CONSENTED TO ANSWER THE FOLLOWING QUESTION AND RECORD THEIR ANSWER BELOW

7.1. Please consider each of the five scenarios in the table below and rate how difficult you think the resident finds them to do using the following scale:

Response options: 0 = none, 1 = a little, 2= some, 3= quite a lot, and 4 = cannot do

How much difficulty do you have...	Response (0-4)
putting on and taking off long trousers (including managing fasteners)?	
walking through your home to get to the toilet in time?	
sitting down on and standing up from the toilet?	
reaching to the side to grab toilet paper?	
reaching your bottom to wipe with toilet paper?	

7.2. Name & role of person answering question 7.1: _____

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8. DEMQOL – resident

IF THE RESIDENT HAS CAPACITY, ASK THEM THE FOLLOWING QUESTION AND RECORD THEIR ANSWER. IF THEY DON'T HAVE CAPACITY TO ANSWER THESE QUESTIONS RECORD IN TOP RIGHT CORNER OF THIS PAGE.

Read each of the following questions (in bold) verbatim and show the respondent the response card.

Say ***“I would like to ask you about your life. There are no right or wrong answers. Just give the answer that best describes how you have felt in the last week. Don't worry if some questions appear not to apply to you. We have to ask the same questions of everybody. Before we start we'll do a practise question; that's one that doesn't count.”*** (Show the response card and ask respondent to say or point to the answer) ***“In the last week, how much have you enjoyed watching television?”***

a lot

quite a bit

a little

not at all

Follow up with a prompt question: **Why is that? or Tell me a bit more about that.**

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For all of the questions I'm going to ask you, I want you to think about the last week.

8.1. First I'm going to ask about your feelings. In the last week, have you felt.....

	A lot	Quite a bit	A little	Not at all
i. cheerful?*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ii. worried or anxious?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iii. that you are enjoying life?*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iv. frustrated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
v. confident?*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
vi. full of energy?*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
vii. sad?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
viii. lonely?*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ix. distressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
x. lively?*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
xi. irritable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
xii. fed up?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
xiii. that there are things that you wanted to do but couldn't?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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8.2. Next, I'm going to ask you about your memory. In the last week, how worried have you been about.....

	A lot	Quite a bit	A little	Not at all
i. forgetting things that happened recently?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ii. forgetting who people are?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iii. forgetting what day it is?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iv. your thoughts being muddled?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
v. difficulty making decisions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
vi. poor concentration?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8.3. Now, I'm going to ask you about your everyday life. In the last week, how worried have you been about.....

	A lot	Quite a bit	A little	Not at all
i. not having enough company?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ii. how you get on with people close to you?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iii. getting the affection that you want?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iv. people not listening to you?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
v. making yourself understood?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
vi. getting help when you need it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
vii. getting to the toilet in time?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
viii. how you feel in yourself?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ix. your overall health?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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8.4. We've already talked about lots of things: your feelings, memory and everyday life. Thinking about all of these things in the last week, how would you rate.....

i. your quality of life overall? **Very good** **Good** **Fair** **Poor**

** items that need to be reversed before scoring

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9. DEMQOL PROXY- carer/staff

FOR ALL RESIDENTS PLEASE ASK A FAMILY MEMBER OF MEMBER OF STAFF WHO HAS CONSENTED INVOLVED IN THEIR CARE TO ANSWER THE FOLLOWING QUESTIONS AND RECORD THEIR ANSWERS BELOW

Read each of the following questions (in bold) verbatim and show the respondent the response card.

Say ***"I would like to ask you about _____ (your relative's) life, as you are the person who knows him/her best. There are no right or wrong answers. Just give the answer that best describes how _____ (your relative) has felt in the last week. If possible try and give the answer that you think _____ (your relative) would give. Don't worry if some questions appear not to apply to _____ (your relative). We have to ask the same questions of everybody. Before we start we'll do a practise question; that's one that doesn't count."*** (Show the response card and ask respondent to say or point to the answer). ***"In the last week how much has _____ (your relative) enjoyed watching television?"***

a lot quite a bit a little not at all

Follow up with a prompt question: **Why is that?** or **Tell me a bit more about that.**

9.1. **What is the name of the proxy answering questions for the DEMQOL**

Proxy? _____

9.2. **What is the relationship of the person named in 9.1 to the**

resident? _____

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For all of the questions I'm going to ask you, I want you to think about the last week.

9.3. First I'm going to ask you about _____ (*your relative's*) feelings. In the last week, would you say that _____ (*your relative*) has felt .

	A lot	Quite a bit	A little	Not at all
i. cheerful?***	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ii. worried or anxious?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iii. frustrated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iv. full of energy?***	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
v. sad?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
vi. content?***	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
vii. distressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
viii. lively?***	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ix. irritable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
x. fed up?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
xi. that he/she has things to look forward to?***	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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9.4. Next, I'm going to ask you about _____ (*your relative's*) memory. In the last week, how worried would you say _____ (*your relative*) has been about.

	A lot	Quite a bit	A little	Not at all
i. his/her memory in general?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ii. forgetting things that happened a long time ago?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iii. forgetting things that happened recently?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iv. forgetting people's names?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
v. forgetting where he/she is?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
vi. forgetting what day it is?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
vii. his/her thoughts being muddled?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
viii. difficulty making decisions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ix. making him/herself understood?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9.5. Now, I'm going to ask about _____ (*your relative's*) everyday life. In the last week, how worried would you say _____ (*your relative*) has been about.

	A lot	Quite a bit	A little	Not at all
i. keeping him/herself clean (eg washing and bathing)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ii. keeping him/herself looking nice?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iii. getting what he/she wants from the shops?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
iv. using money to pay for things?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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v. looking after his/her finances?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
vi. things taking longer than they used to?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
vii. getting in touch with people?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
viii. not having enough company?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ix. not being able to help other people?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
x. not playing a useful part in things?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
xi. his/her physical health?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9.6. We've already talked about lots of things: _____ (your relative's) feelings, memory and everyday life. Thinking about all of these things in the last week, how would you say _____ (your relative) would rate:

	Very good	Good	Fair	Poor
i. his/her quality of life overall?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

** items that need to be reversed before scoring

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10. 18 week CRF Checklist

Please tick the boxes below to confirm that you have entered all the required data for this CRF before returning it to the trial office. If any section is not completed, please indicate why using in the space on the top right hand corner of each page:

1. Number of pads from 24hr pad collection
- Weight of 24 hour used pad collection
- 3 measurements of PVRU
2. Resource use questionnaire
3. PPBC
4. FCPBC
5. SPBC
6. MTSQ-R
7. MTSQ-S
8. DEMQOL
9. DEMQOL Proxy