

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**

12 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. 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

**2.1. 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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If section not complete state reason: _____

3. 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

3.1. 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 3.1 (perception of bladder condition)

3.2. Name of person answering question 3.1: _____
and relationship to resident _____

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4. 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

4.1. 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.

4.2. Name & role of person answering question 4.1: _____

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If section not complete state reason: _____

5. 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

5.1. 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: _____

6. 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

6.1. 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?	

6.2. Name & role of person answering question 6.1: _____

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7. 12 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. PPBC
3. FCPBC
4. SPBC
5. MTSQ-R
6. MTSQ-S