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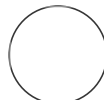
Fecobionics Test in Subjects with Fecal Incontinence

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We use this protocol and it's working

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ABSTRACT

It is the protocol of Fecobionics test in normal subjects. Briefly, the device will be inserted into participants' rectum and several motions (cough, squeeze, straining) will be done. After the motions, the bag will be inflated, and the participant may have different sensations during inflation. If the device falls out before the completion of the test, it will be re-inserted gently. Data will be recorded and shown in real time. Each participant will be tested up to 4 times at following dates: The day before percutaneous nerve evaluation (PNE) (pre-PNE), one day after PNE (day 1), seven days after PNE (day 7), and thirty days after sacral nerve stimulation (SNS) treatment (day 30 post-SNS).

- 1 Make sure the participant is diagnosed as fecal incontinence and eligible to do the study. Make sure he/she understands the study and has signed the informed consent form.

- 2 Ask the subject to empty bladder and rectum before the test.
- 3 Participant changes clothes and lies on left side.
- 4 Calibrate the Fecobionics device and make sure the transmission signal is good.
- 5 Fully lubricate Fecobionics device. Insert device gently into rectum, following a finger examination.
- 6 Participant moves to commode, in sitting position. Wait up to 5 mins until pressure data is stable.
- 7 Ask the participant to cough twice, with 15-30 seconds in between.
- 8 Ask the participant to squeeze three times, 5 seconds for each time, and 15-30 seconds in between.
- 9 Ask the participant to do a long squeeze that lasts 30 seconds.

- 10** Ask the participant to do a straining (contract both abdominal and anal muscles) that lasts 20 seconds.
- 11** Inflate the balloon with warm saline. Ask the participant to report sensations.
- 12** Stop inflating when the participant feels urge, or the maximum volume (100ml) is reached.
- 13** Detach the filling tube and give the participant privacy to defecate. If the participant cannot defecate Fecobionics in 3 minutes, withdraw it manually by pulling the thread attached to the device.
- 14** Test complete. Save data and clean up.