

## Table of Contents

|   |    |
|---|----|
| Cuillin NanoLogger – System Summary .....                           | 3  |
| Cuillin NanoLogger - Specifications.....                            | 4  |
| Cuillin NanoLogger System Configurations.....                       | 5  |
| Cuillin as Desktop System with Computer .....                       | 5  |
| Cuillin System in Carrier Case.....                                 | 5  |
| Cuillin as Cart Based System .....                                  | 6  |
| Cuillin Accessories .....   | 6  |
| Gaeltec Investigation Application – Specification.....              | 7  |
| Computer Requirements.....  | 7  |
| Data Manager – Functionality.....                                   | 7  |
| Recording Modes .....   | 7  |
| Stationary Recording Protocols.....                                 | 7  |
| Anorectal.....  | 7  |
| Oesophageal.....  | 8  |
| Urology.....  | 8  |
| Ambulatory Studies.....   | 8  |
| Recording Mode Event Markers .....                                  | 8  |
| Traces etc .....  | 8  |
| Review, Analysis and Reporting .....                                | 9  |
| Event Marking .....   | 9  |
| Analysis and Reports.....   | 9  |
| Anorectal.....  | 9  |
| Oesophageal.....  | 9  |
| Urology.....  | 9  |
| Gaeltec Investigation Application .....                             | 10 |
| Data Manager .....  | 10 |
| Oesophageal Studies.....  | 11 |
| Oesophageal Study – Review - Full Study .....                       | 11 |
| Oesophageal Study - Review - Selected Zoomed Area .....             | 11 |
| Oesophageal Study - Review with Colour Contour Mapping.....         | 12 |
| Oesophageal Study - Ambulatory Study Review.....                    | 12 |
| Oesophageal – Ambulatory Study Review – Zoomed over pH Reflux ..... | 13 |
| Performing a Real-time Study – Study initialisation .....           | 14 |

Ano Rectal Studies .....15

    Real-time study in Progress (Rectal) .....15

    Rectal Study 1 - Study Review .....16

    Rectal Study 1 - Full Rectal Summary Report.....16

    Rectal Study 2 - Study Review .....17

    Rectal Study 2 – Full Rectal Report .....17

    Rectal Study 2 – Full Rectal Report – Sample Printout .....18

    Rectal Study 2 – Ano Rectal Manometry Summary Report .....19

    Rectal Study 2 – Ano Rectal Manometry Summary Report – Sample Printout .....20

Biofeedback.....21

    Biofeedback - Study Initialisation from Data Manager .....21

    Biofeedback - Study Protocol selection .....21

    Biofeedback – Recording of Study / Training Session - Recording .....22

    Biofeedback - Session / Study - Review .....22

    Biofeedback – Multiple Session / Study Review for comparison Studies .....23

Urology.....24

    Urology – Ambulatory Study Review .....24

    Urology – Ambulatory Study Review – Zoomed of Urine Flow Episode .....24

    Urology – Ambulatory Study Review – Report for Urine Flow Episode.....25

## Cuillin NanoLogger – System Summary

- Device Description:** The Cuillin NanoLogger is a multi-discipline recorder, used for the recording of non-vital physiological parameters such as esophageal pressures, urological pressures, pH etc. for up to 24 hours. The Cuillin NanoLogger can be used as both an ambulatory and static recorder. The user may plug in one or more Gaeltec pressure transducers or compatible sensors from other manufacturers. The recorded data is transferred to a computer for review and analysis – appropriate to the particular application – using the Gaeltec PC based Investigator™ software.
- Intended Use:** The Cuillin NanoLogger is intended primarily to record and store data to enable review and analysis of pressure and other various auxiliary (non-vital) physiological signals, in the field of, but not limited to: -
- Gastroenterology, the gastrointestinal tract (pharynx, esophagus, stomach, duodenum, Sphincter of Oddi, small bowel, colon and anorectal area including the rectum), and biofeedback training.
  - Urogynecology, the urinary track and pelvic floor.
- And when used in combination with other clinical data, may be used to: -
- Assist in the diagnosis and evaluation of gastrointestinal and swallowing disorders.
  - Assist in the diagnosis and evaluation of various urological disorders.
- Designated catheters and accessories are required for measurement in each specific area.

*The Cuillin NanoLogger is available in 2, 4, 5, 6, 8 and 9 channel versions.*

*It will be possible to cascade two 9 Channel Cuillin NanoLoggers together, to facilitate an 18 channel system.*

## Cuillin NanoLogger - Specifications

### Electrical Performance

|                       |   |
|-----------------------|---|
| Input channels:       | 2, 4, 5, 6, 8 or 9  |
| Sampling rate:        | 10 to 50Hz selectable (default 10 samples/s)                    |
| Recording duration:   | 24 hours  |
| Recording resolution: | 16 bits   |
| Ambulatory recording: | ambulatory or simultaneous real-time/ambulatory option          |
| Recording medium:     | direct to SD memory card or                                     |
| Real-time recording:  | over wireless link or patient isolated USB cable to host PC     |
| Data encryption:      | 128bit AES  |
| Recording download:   | via patient isolated USB cable                                  |
| Power source:         | Rechargeable Lithium-Ion battery                                |
| Battery charging:     | via patient isolated USB cable                                  |
| PC software:          | Gaeltec Investigator – compatible with Windows 7, 8, 8.1 and 10 |
| Dimensions:           | 3.54 x 5.11 x 1" (90 x 130 x 25mm)                              |
| Weight:               | 9.348 oz. (265g)  |

### Front Panel Indicators

#### Main Indicators

|                          |            |
|--------------------------|------------|
| Record indicator:        | Orange LED |
| Wireless indicator:      | Blue LED   |
| Power up/down indicator: | Green LED  |

#### Battery Status Indicators

|                              |            |
|------------------------------|------------|
| Charging active indicator:   | Orange LED |
| Charging complete indicator: | Green LED  |

### Installation

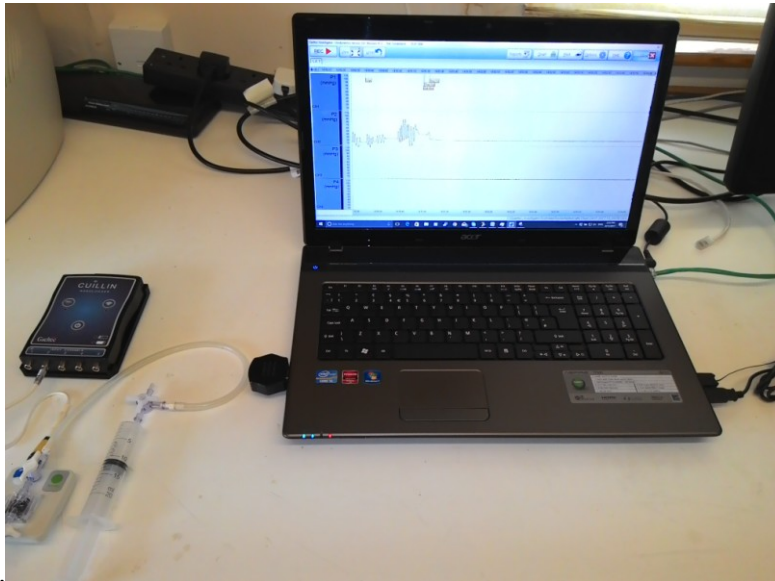
Installation is performed from a single Setup.exe file.

## Host PC Minimum Requirements

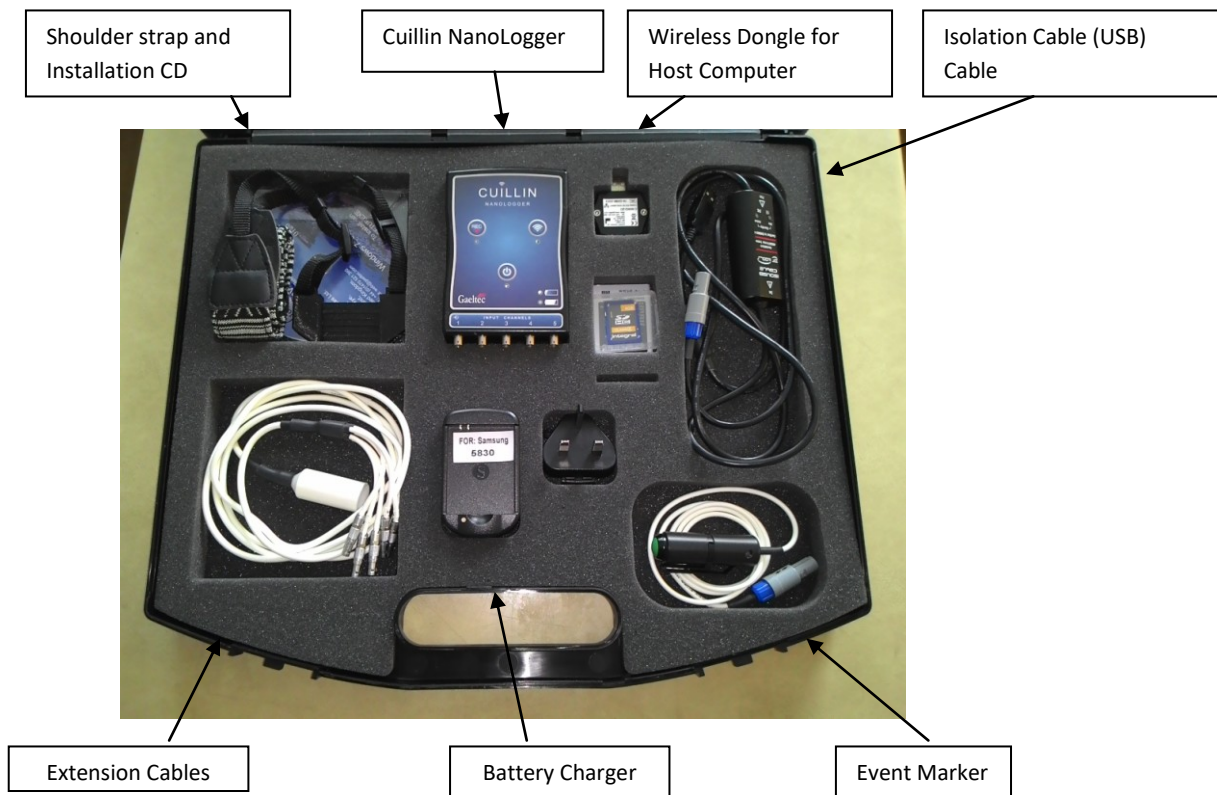
|                  |   |
|------------------|---|
| Processor        | Intel i3 or better  |
| RAM              | 4GB minimum   |
| Hard Disk        | 500GB minimum   |
| Display          | 1366*768 or 1920*1080 recommended                                 |
| USB Ports        | At least 2 free USB ports (USB1 / USB2 or USB3)                   |
| Card Reader      | SD Card Reader, if direct data download from memory card requires |
| Operating System | MS Windows 7, 8, 8.1 or 10  |

## Cuillin NanoLogger System Configurations

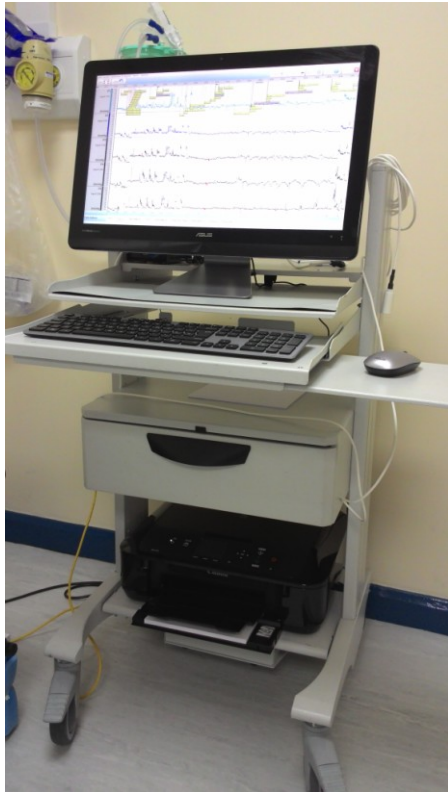
### *Cuillin as Desktop System with Computer*



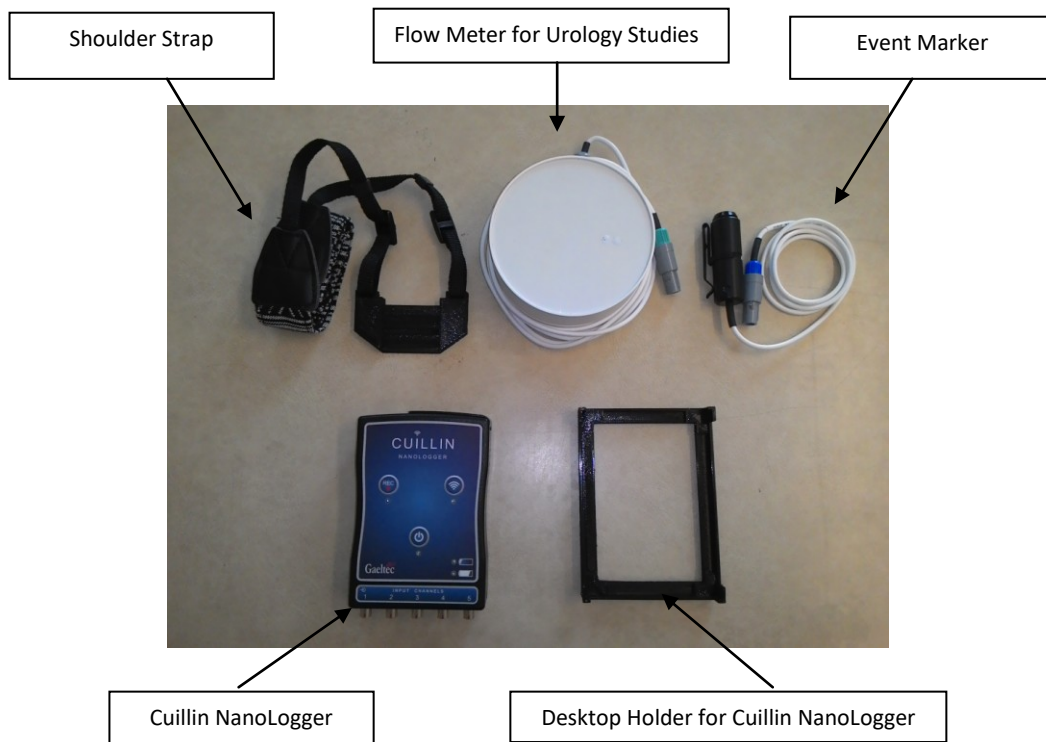
### *Cuillin System in Carrier Case*



***Cuillin as Cart Based System***



***Cuillin Accessories***





## Gaeltec Investigation Application – Specification

### ***Computer Requirements***

- Intel i3 processor, I5 or i7 recommended
- Minimum 4Gbytes RAM,
- 500Gbytes hard disk. SSD recommended.
- 2 free USB ports (USB2 / USB3)
- Full HD monitor (1920 \* 1080)

### ***Data Manager – Functionality***

- Study Recording
- Study Archiving
- Add / Edit / Delete selected study
- Add / Edit / Delete selected Patient
- Sort patient by surname up / down (A to Z or Z to A)
- Filter patients / studies by study type (Oesophageal, Anorectal, urology etc)
- Filter patients by gender.
- Fast patient located (by surname)

### ***Recording Modes***

- Stationary Real-time Studies
- Ambulatory Studies
- Combined Stationary / Ambulatory study.

### ***Stationary Recording Protocols***

#### **Anorectal**

- Station pull through
- Rapid pull through
- R.A.I.R
- Endurance Squeeze
- Balloon expulsion
- Sensory
- User Defined protocols
- Biofeedback Training

## **Oesophageal**

- Station pull through
- Rapid Pull Through
- Oesophageal Body

## **Urology**

- Free Flow
- Flow Cystometry
- Fill Cystometry
- Static UPP
- Stress UPP

## **Ambulatory Studies**

- 24hour plus recording duration
- Real-time viewing of active ambulatory study by wireless link to the host computer
- Combined real-time / ambulatory study recording mode

## **Recording Mode Event Markers**

- Default event markers specific to study type
- User definable Event Markers
- Free Text Event Marker

## **Traces etc**

- User selectable individual trace scales
- User defined channel zeroing
- User defined trace colours, thickness etc.
- User defined trace scroll speed



## ***Review, Analysis and Reporting***

- Dynamic trace scrolling
- Dynamic trace zooming
- Dynamic traces scaling

### Event Marking

- Fixed default events - Add / delete / edit / drag
- User defined events - Add / delete / edit / drag

### Analysis and Reports

#### Anorectal

- Station pull through
- R.A.I.R
- Sensory
- Balloon expulsion
- etc

Summary report of the individual reports present.

#### Oesophageal

- Station pull through
- Individual Swallows
- Lower Oesophageal Sphincter Relaxation
- Lower Oesophageal Sphincter
- etc

Summary report of the individual reports present.

#### Urology

- Free Flow
- Flow cystometry
- Fill Cystometry
- Pressure Flow
- Static UPP
- Stress UPP
- etc.

Summary report of the individual reports present.

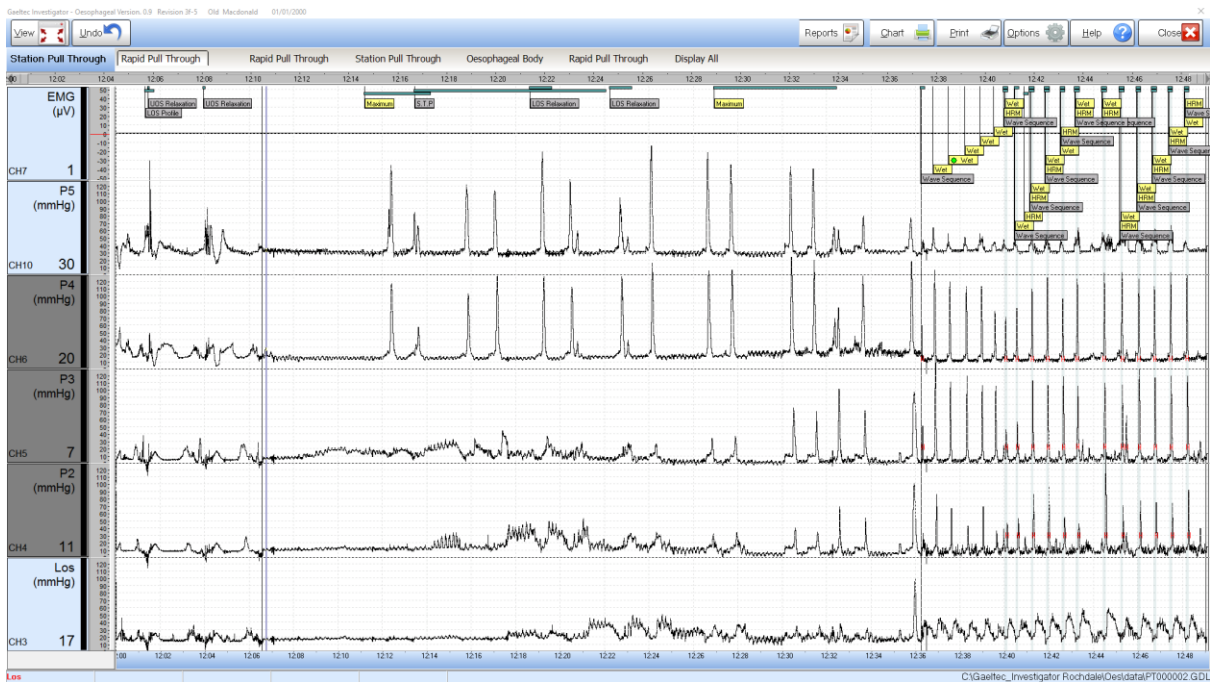
# Gaeltec Investigation Application

## Data Manager

The screenshot shows the 'Gaeltec Investigator - Data Manager' application window. At the top, there are menu options: Options, Uro, Oes, ARM, BioFeedback, Maintenance, Help, and Close. Below the menu is a patient list grid with columns A through Z and 'All'. A callout box labeled 'Patient List' points to this grid. The grid displays several patient cards, including one for 'Macdonald, Old' with details: PAT ID 1234, DOB 10/10/1955, GENDER M, and STUDIES FLOW (m), URO (m), OES (m), ANO (m). A callout box labeled 'Study Applications' points to the 'ARM' menu item. Below the grid is a 'Patient Details' editor with fields for Surname (Macdonald), First Name (Old), Patient ID, Date of Birth (01/01/1996), Age (21), Gender (M), Address, City, County, Post Code, Referring Doctor (NO), and Condition (leaking). A callout box labeled 'Patient Details Editor' points to the Age field. To the right of the patient details is a 'Study Details' editor with fields for Date (01/01/2000), Time (12:00), Department (Test 1), Doctor (Sr. J. Lane), and Clinician. A callout box labeled 'Study Details Editor' points to the Date field. Above the study details is a 'Study List for selected' callout box pointing to a small window showing 'Oes' with Date 01/01/2000 and Time 12:00. The bottom of the window shows 'Patient Count : 11' and 'Studies Count : 36'.

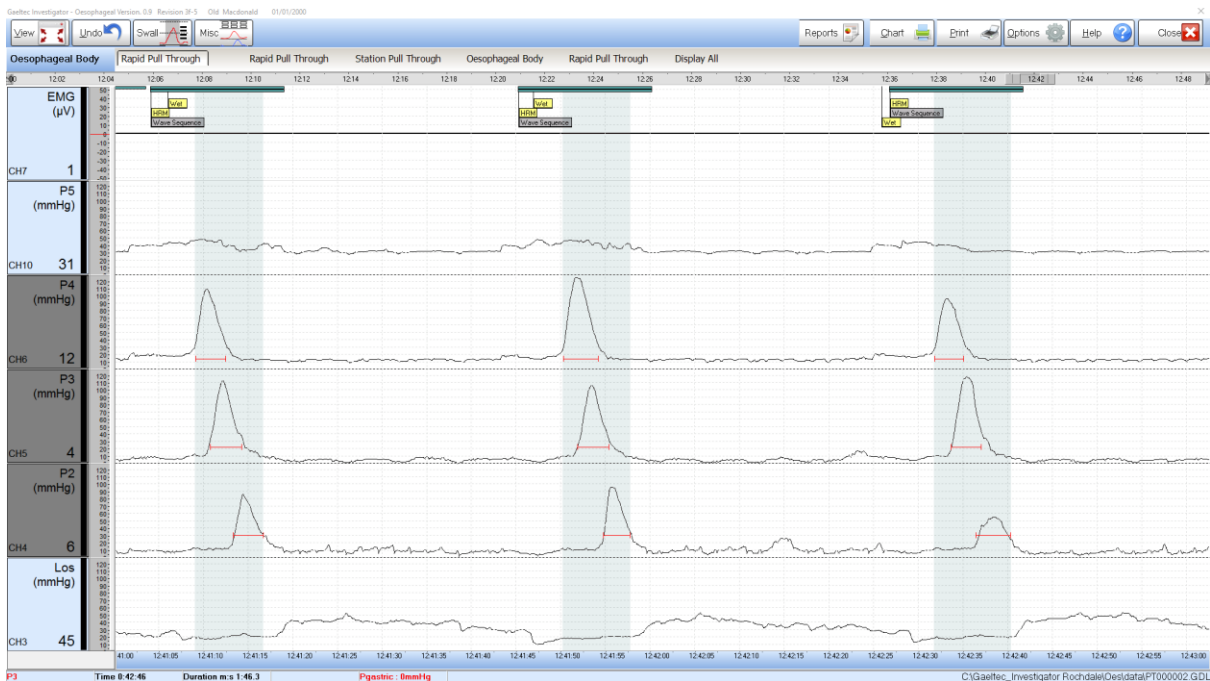
# Oesophageal Studies

## Oesophageal Study - Review - Full Study



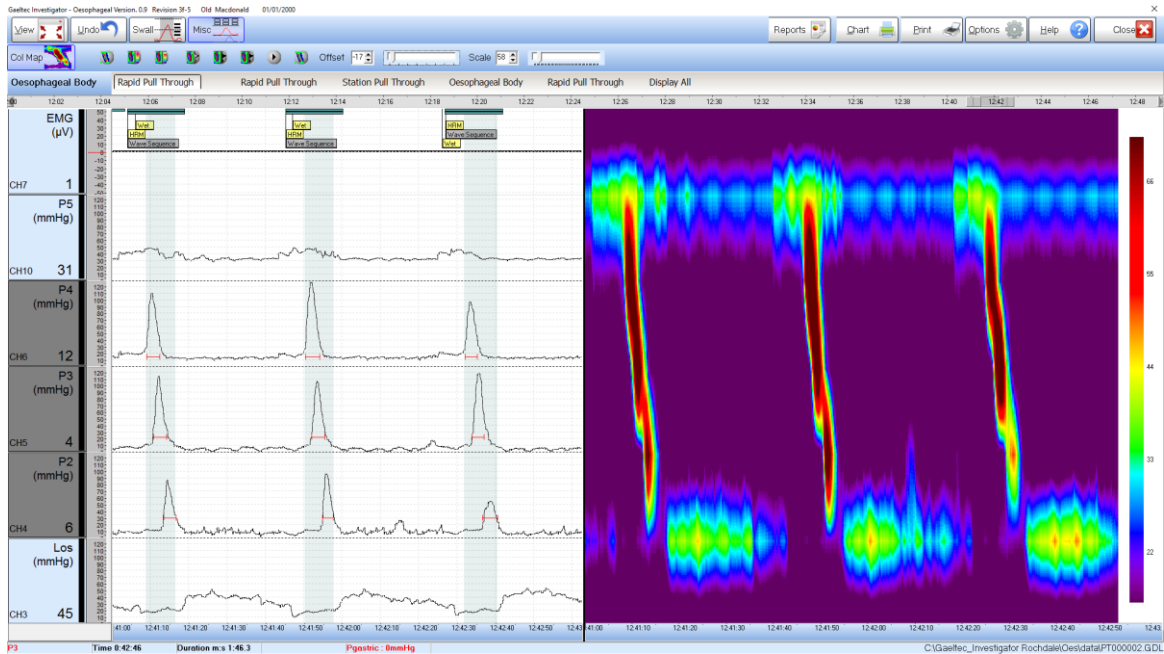
## Oesophageal Study - Review - Selected Zoomed Area

Zoomed on three swallows

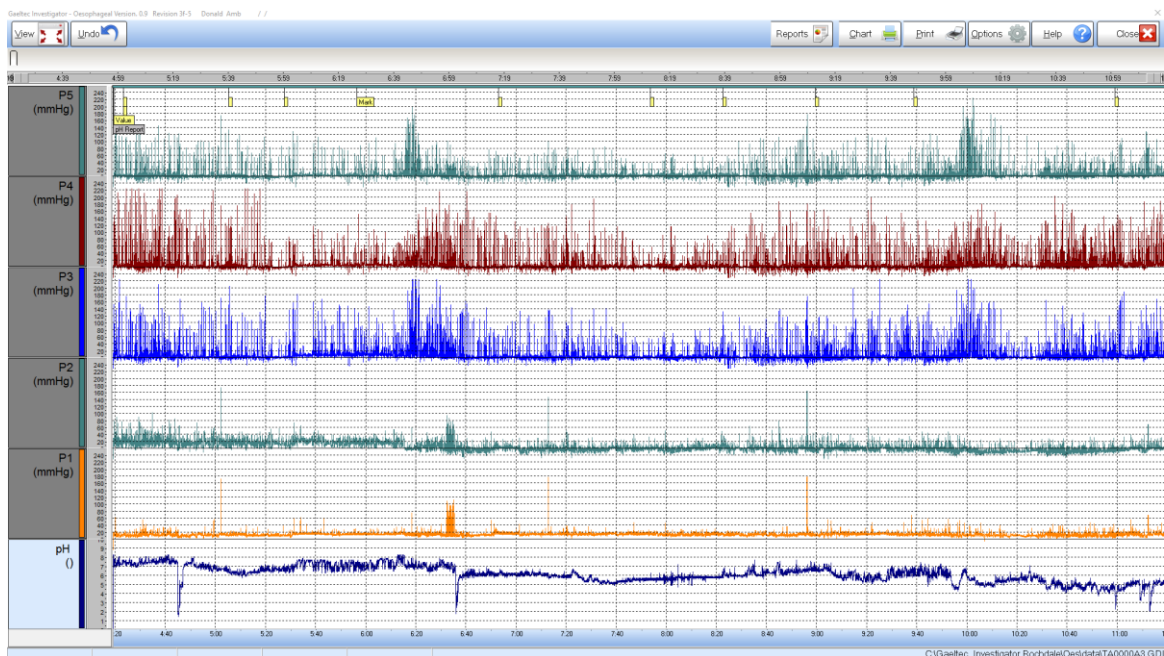


## Oesophageal Study - Review with Colour Contour Mapping

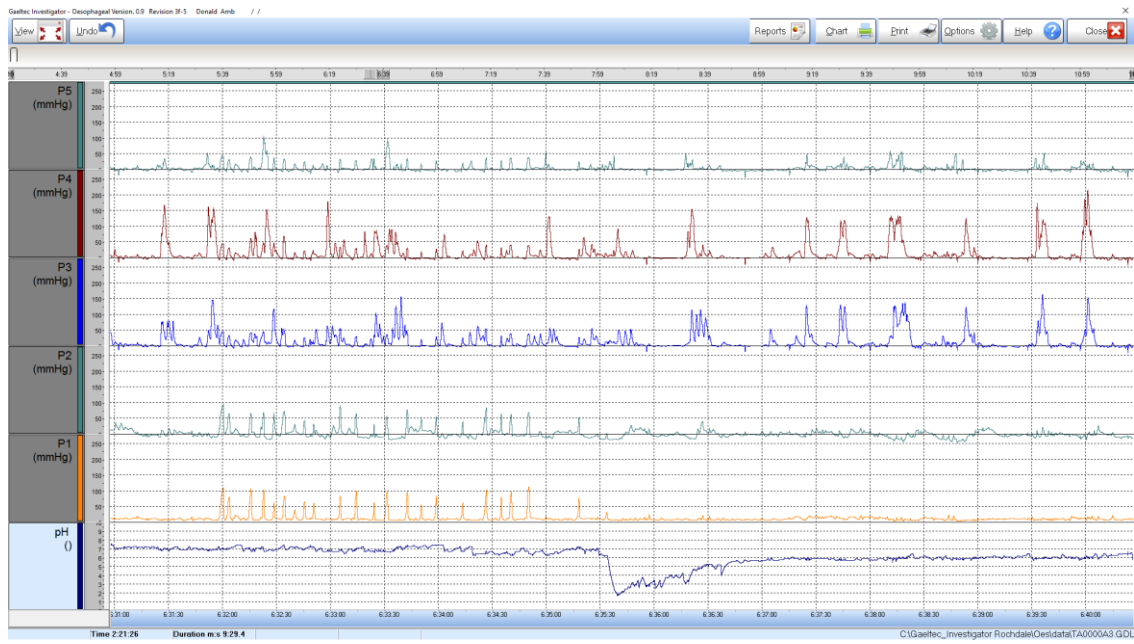
Zoomed on three swallows – With Colour Mapping Turned on



## Oesophageal Study - Ambulatory Study Review



### Oesophageal – Ambulatory Study Review – Zoomed over pH Reflux



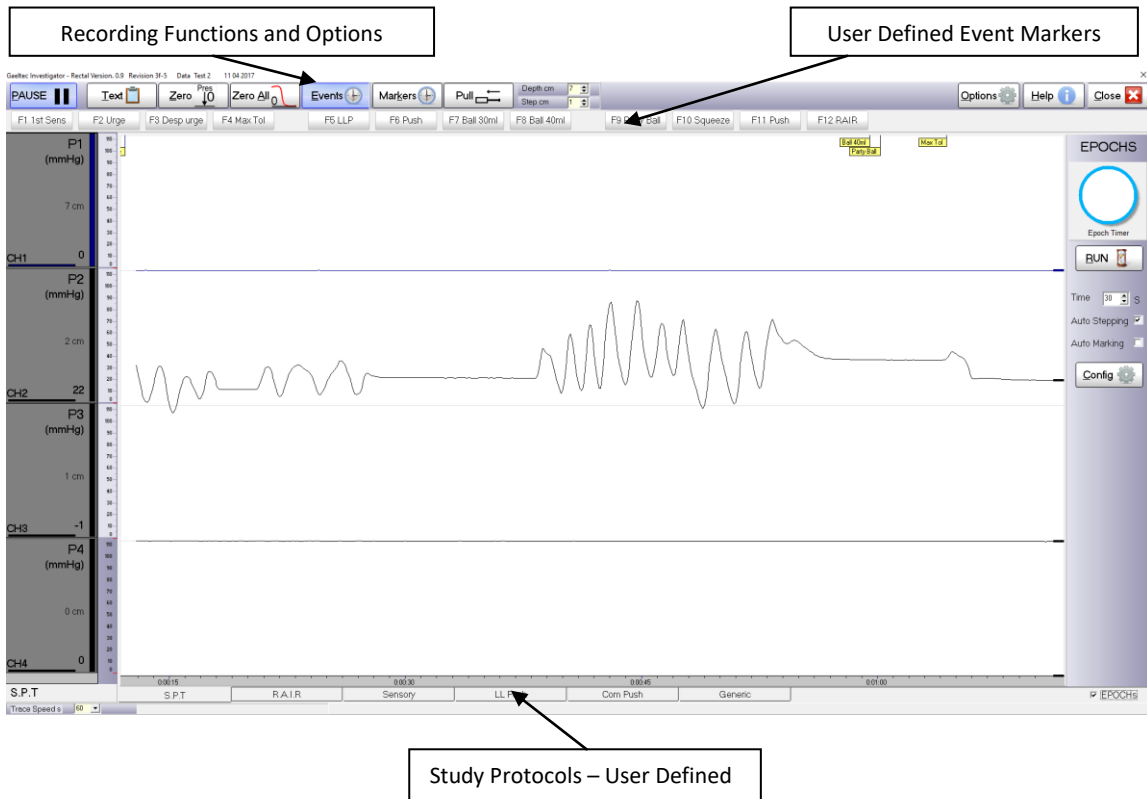
### Performing a Real-time Study – Study initialisation

Cuillin NanoLogger connectivity and Status Bar

Ambulatory and Stationary Study modes and options selected from the Study Mode Dialogue

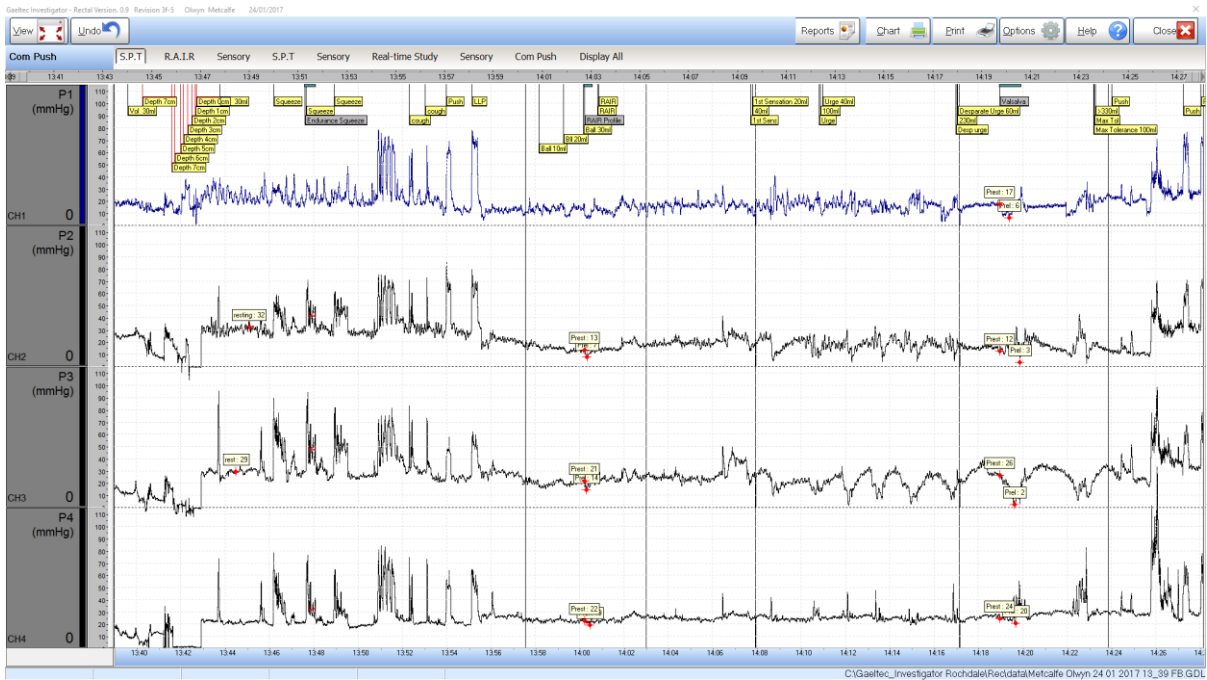
## Ano Rectal Studies

### Real-time study in Progress (Rectal)

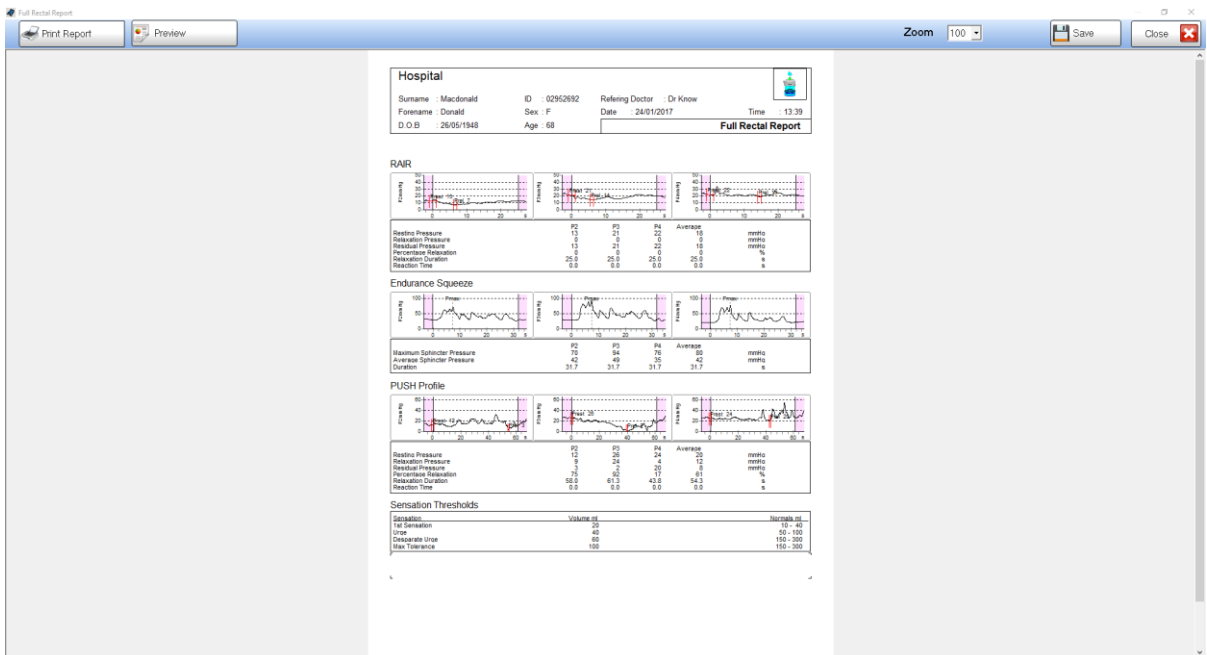




### Rectal Study 1 - Study Review



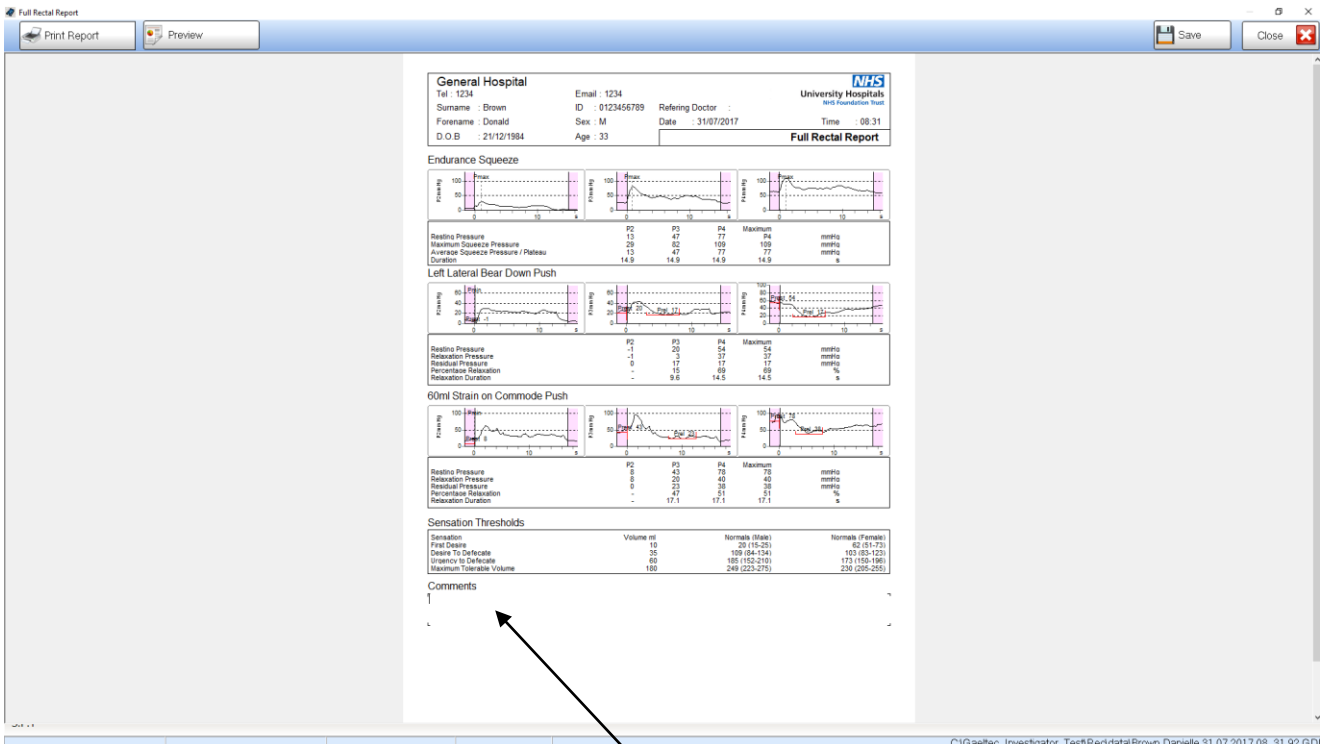
### Rectal Study 1 - Full Rectal Summary Report



## Rectal Study 2 - Study Review



## Rectal Study 2 – Full Rectal Report

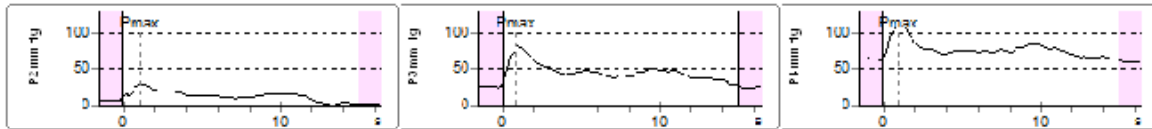


Text comments can be added and edited in this text box.

Rectal Study 2 – Full Rectal Report – Sample Printout

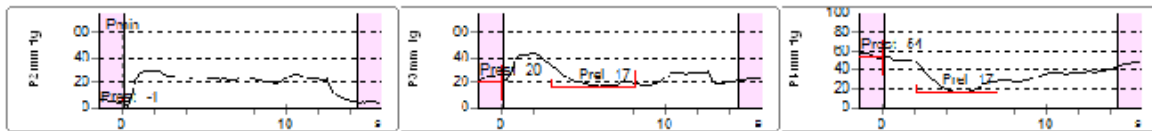
|                    |                 |   |              |
|--------------------|-----------------|---|--------------|
| General Hospital   |                 |   |              |
| Tel : 1234         | Email : 1234    | <b>University Hospitals</b><br>NHS Foundation Trust |              |
| Surname : Brown    | ID : 0123456789 | Referring Doctor :                                  | Time : 08:31 |
| Forename : Donald  | Sex : M         | Date : 31/07/2017                                   |              |
| D.O.B : 21/12/1984 | Age : 33        | <b>Full Rectal Report</b>                           |              |

Endurance Squeeze



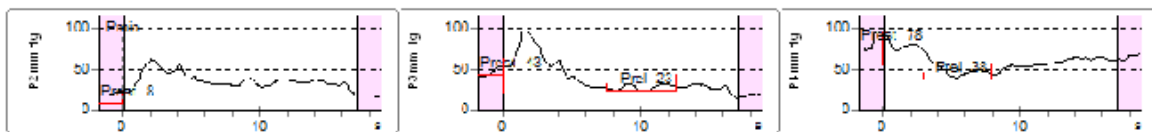
|                                    |      |      |      |         |      |
|------------------------------------|------|------|------|---------|------|
| Resting Pressure                   | P2   | P3   | P4   | Maximum |      |
| Maximum Squeeze Pressure           | 13   | 47   | 77   | P4      | mmHg |
| Average Squeeze Pressure / Plateau | 29   | 82   | 109  | 109     | mmHg |
| Duration                           | 13   | 47   | 77   | 77      | mmHg |
|                                    | 14.9 | 14.9 | 14.9 | 14.9    | s    |

Left Lateral Bear Down Push



|                       |    |     |      |         |      |
|-----------------------|----|-----|------|---------|------|
| Resting Pressure      | P2 | P3  | P4   | Maximum |      |
| Relaxation Pressure   | -1 | 20  | 54   | 54      | mmHg |
| Residual Pressure     | -1 | 3   | 37   | 37      | mmHg |
| Percentage Relaxation | 0  | 17  | 17   | 17      | %    |
| Relaxation Duration   | -  | 15  | 89   | 89      | s    |
|                       | -  | 9.6 | 14.5 | 14.5    |      |

60ml Strain on Commode Push



|                       |    |      |      |         |      |
|-----------------------|----|------|------|---------|------|
| Resting Pressure      | P2 | P3   | P4   | Maximum |      |
| Relaxation Pressure   | 8  | 43   | 78   | 78      | mmHg |
| Residual Pressure     | 8  | 20   | 40   | 40      | mmHg |
| Percentage Relaxation | 0  | 23   | 38   | 38      | %    |
| Relaxation Duration   | -  | 47   | 51   | 51      | s    |
|                       | -  | 17.1 | 17.1 | 17.1    |      |

Sensation Thresholds

|                          |           |                |                  |
|--------------------------|-----------|----------------|------------------|
| Sensation                | Volume ml | Normals (Male) | Normals (Female) |
| First Desire             | 10        | 20 (15-25)     | 62 (51-73)       |
| Desire To Defecate       | 35        | 109 (84-134)   | 103 (83-123)     |
| Urgency to Defecate      | 60        | 185 (152-210)  | 173 (150-198)    |
| Maximum Tolerable Volume | 180       | 249 (223-275)  | 230 (205-255)    |

Comments

## Rectal Study 2 – Ano Rectal Manometry Summary Report

Patient History Notes can be added and edited in this text box.

**General Hospital**  
 Tel : 1234      Email : 1234      Referring Doctor :  
 Surname : Brown      ID : 0123456789      Forename : Donald      Sex : M      Date : 31/07/2017      Time : 08:31  
 D.O.B : 21/12/1984      Age : 33

**ANO-RECTAL MANOMETRY REPORT**

Clinical History : Patients clinical notes go here

| Station Pull Through                                 | Male      | Female                      |
|--|-----------|-----------------------------|
| 100% Length  | 2.8 cm    | 3.4                         |
| Maximum Resting Pressure                             | 72 mmHg   | 73 (64-80) 65 (56-74)       |
| Endurance Squeeze                                    |           |                             |
| Maximum Squeeze Pressure                             | 109 mmHg  | 193 (175-211) 143 (124-162) |
| Relax Pressure                                       | 77 mmHg   |                             |
| Maximum Duration of Squeeze                          | 14.9 secs |                             |
| Cough / Party Balloon Response                       |           |                             |
| Rectal Pressure during Party Balloon Inflation       | 25 mmHg   | 68 (51-81) 62 (51-73)       |
| Anal Pressure during Party Balloon Inflation         | 60 mmHg   | 154 (136-170) 106 (89-123)  |
| Rectal Pressure during Cough                         | 0 mmHg    |                             |
| Anal Pressure during Cough                           | 0 mmHg    |                             |
| Rectal Sensory Study                                 |           |                             |
| First Sensation                                      | 10 ml     | 20 (15-25) 62 (51-73)       |
| Desire to Defecate                                   | 35 ml     | 109 (84-134) 163 (83-123)   |
| Urgency to Defecate                                  | 60 ml     | 185 (152-210) 173 (150-196) |
| Maximum Tolerable Volume                             | 180 ml    | 249 (223-275) 230 (205-255) |
| Rectal Anal Inhibitory Reflex (RAIR)                 |           |                             |
| Inhibitory Reflex induced at                         | 10 ml     | 1 (0-13) 13 (10-18)         |
| Balloon defecation 50cc (seconds)                    | 0 secs    | 60 (5-156) 57 (2-122)       |
| Bear Down Response                                   |           |                             |
| Left Lateral Bear down - Anal Pressure (Residual)    | 17 mmHg   | Type 4 Anismus              |
| Left Lateral Bear down - Anal Pressure (Relaxation)  | 69 %      |                             |
| Left Lateral Bear down - Rectal Pressure (Peak)      | 29 mmHg   |                             |
| Left Lateral Bear down - Defecation Index [DI]       | 1.7       |                             |
| 60mls Strain on Commode - Anal Pressure (Residual)   | 23 mmHg   | Type 4 Anismus              |
| 60mls Strain on Commode - Anal Pressure (Relaxation) | 51 %      |                             |
| 60mls Strain on Commode - Rectal Pressure (Peak)     | 83 mmHg   |                             |
| Left Lateral Bear down - Defecation Index [DI]       | 2.7       |                             |

Impression : Study impression and interpretation notes go here

Management Plan : Patient management plan and notes go here

SIGNED Name: \_\_\_\_\_ SIGNED Name: \_\_\_\_\_

Study notes and impression information can be added and edited in this text box

Patient management plan and notes can be added and edited in this text box

**Rectal Study 2 – Ano Rectal Manometry Summary Report – Sample Printout**

|                         |                 |   |              |
|-------------------------|-----------------|---|--------------|
| <b>General Hospital</b> |                 |   |              |
| Tel : 1234              | Email : 1234    | <b>University Hospitals</b><br>NHS Foundation Trust |              |
| Surname : Brown         | ID : 0123456789 | Referring Doctor :                                  |              |
| Forename : Donald       | Sex : M         | Date : 31/07/2017                                   | Time : 08:31 |
| D.O.B : 21/12/1984      | Age : 33        | <b>ANO-RECTAL MANOMETRY REPORT</b>                  |              |

Clinical History :

| Station Pull Through                                 |      |      | Male          | Female         |
|--|------|------|---------------|----------------|
| HPZ Length   | 2.0  | cm   | 3-4           | 3-4            |
| Maximum Resting Pressure                             | 72   | mmHg | 73 (64-80)    | 65 (56-74)     |
| <b>Endurance Squeeze</b>                             |      |      |               |                |
|  |      |      | Male          | Female         |
| Maximum Squeeze Pressure                             | 109  | mmHg | 193 (175-211) | 143 (124-162)  |
| Plateau Pressure                                     | 77   | mmHg |               |                |
| Maximum Duration of Squeeze                          | 14.9 | secs |               |                |
| <b>Cough / Party Balloon Response</b>                |      |      |               |                |
|  |      |      | Male          | Female         |
| Rectal Pressure during Party Balloon inflation       | 25   | mmHg | 66 (51-81)    | 62 (51-73)     |
| Anal Pressure during Party Balloon inflation         | 60   | mmHg | 154 (138-170) | 106 (89-123)   |
| Rectal Pressure during Cough                         | 0    | mmHg |               |                |
| Anal Pressure during Cough                           | 0    | mmHg |               |                |
| <b>Rectal Sensory Study</b>                          |      |      |               |                |
|  |      |      | Male          | Female         |
| First Sensation                                      | 10   | ml   | 20 (15-25)    | 62 (51-73)     |
| Desire to Defecate                                   | 35   | ml   | 109 (84-134)  | 103 (83-123)   |
| Urgency to Defecate                                  | 60   | ml   | 185 (152-210) | 173 (150-196)  |
| Maximum Tolerable Volume                             | 180  | ml   | 249 (223-275) | 230 (205-255)  |
| <b>Rectal Anal Inhibitory Reflex (RAR)</b>           |      |      |               |                |
|  |      |      | Male          | Female         |
| Inhibitory Reflex induced at                         | 10   | ml   | 1 (9-13)      | 13 (10-16)     |
| Balloon defecation 50cc (seconds):                   | 0    | secs | 60 (0-156)    | 57 (2-122)     |
| <b>Bear Down Response</b>                            |      |      |               |                |
|  |      |      |               |                |
| Left Lateral Bear down - Anal Pressure [Residual]    | 17   | mmHg |               | Type 4 Anismus |
| Left Lateral Bear down - Anal Pressure [Relaxation]  | 69   | %    |               |                |
| Left Lateral Bear down - Rectal Pressure [Peak]      | 29   | mmHg |               |                |
| Left Lateral Bear down - Defecation Index [DI]       | 1.7  |      |               |                |
| 60mls Strain on Commode - Anal Pressure [Residual]   | 23   | mmHg |               | Type 4 Anismus |
| 60mls Strain on Commode - Anal Pressure [Relaxation] | 51   | %    |               |                |
| 60mls Strain on Commode - Rectal Pressure [Peak]     | 63   | mmHg |               |                |
| Left Lateral Bear down - Defecation Index [DI]       | 2.7  |      |               |                |

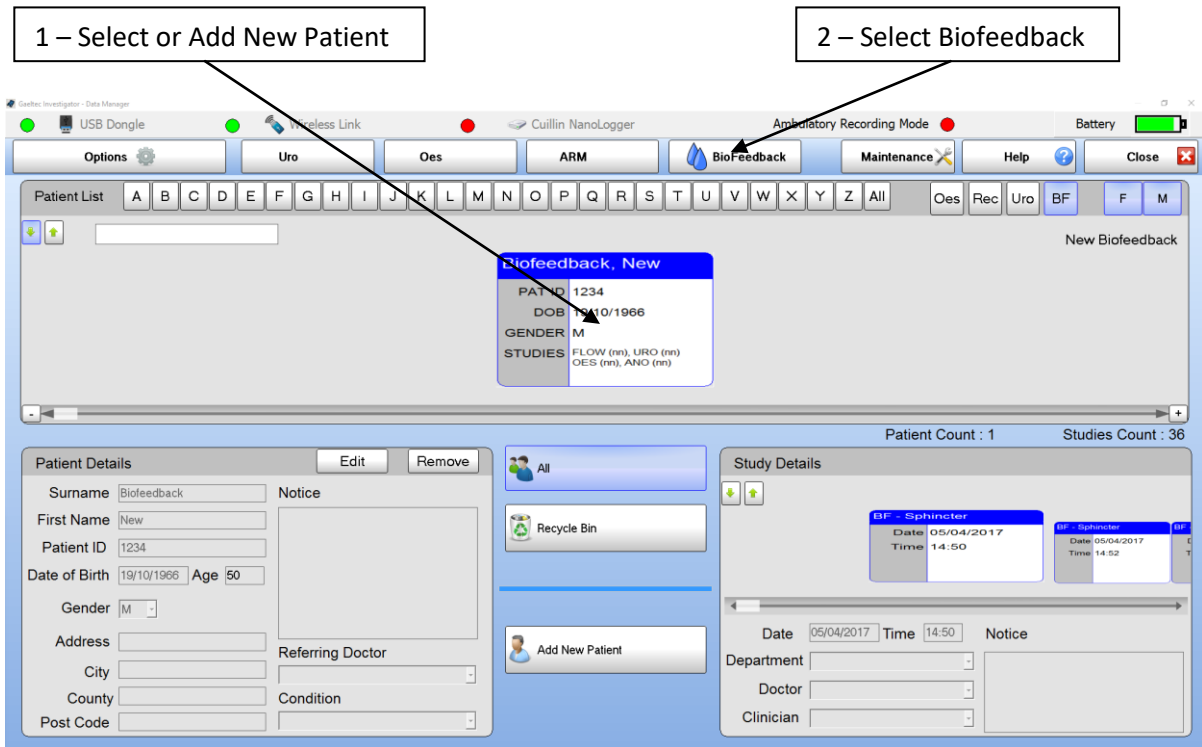
Impression :

Management Plan :

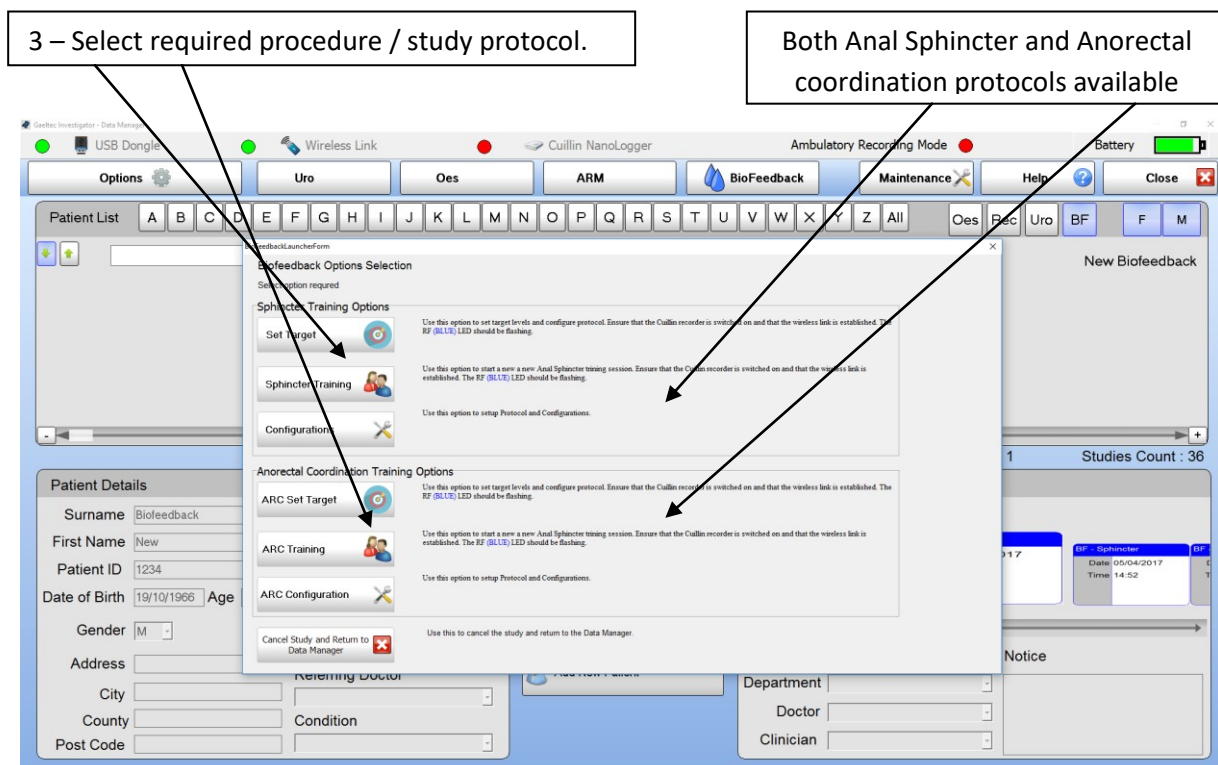
SIGNED: Name: \_\_\_\_\_ SIGNED: Name: \_\_\_\_\_  
 (Lead Doctor) \_\_\_\_\_ (GI Physiologist)

## Biofeedback

### Biofeedback - Study Initialisation from Data Manager



### Biofeedback - Study Protocol selection



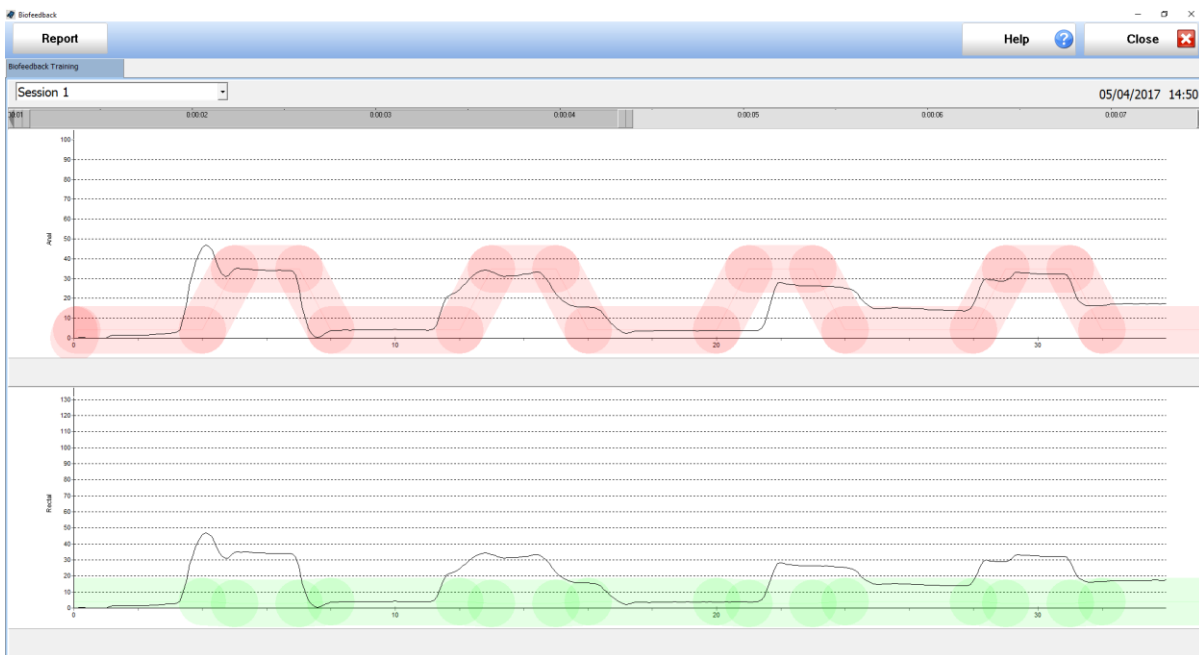


### Biofeedback - Recording of Study / Training Session - Recording

The Patient is asked to keep the Ball(s) within the lightly shaded lanes by squeezing and relaxing the anal sphincter. The lanes are specified/configured prior to the Study / Training session.



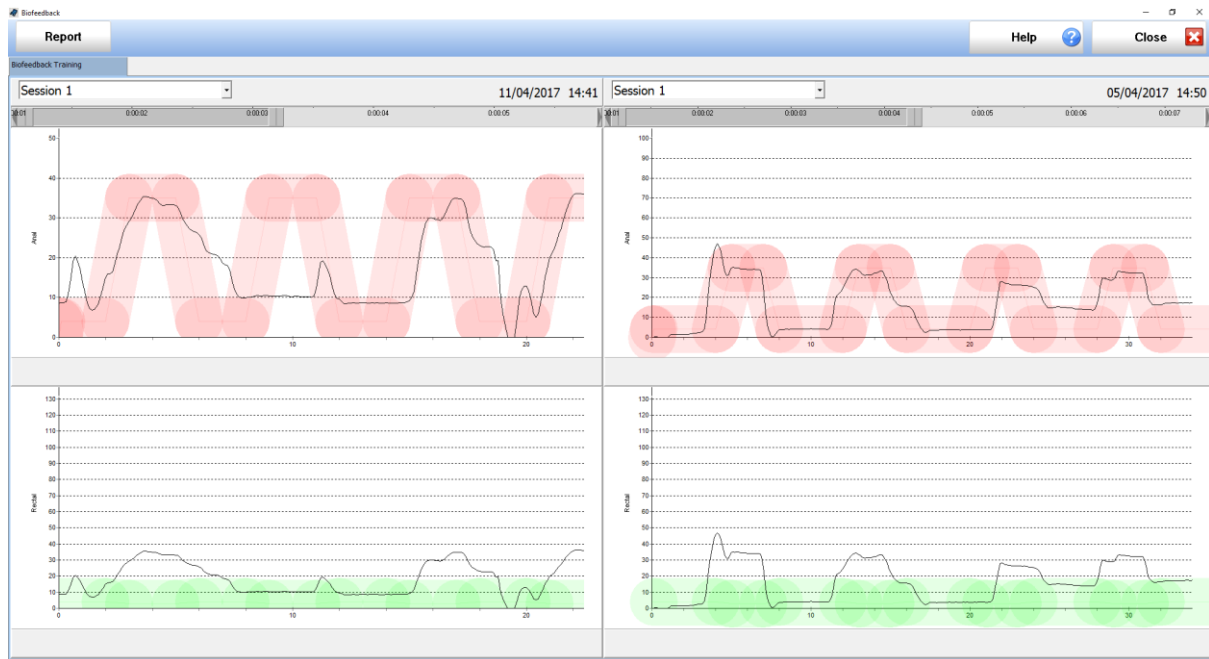
### Biofeedback - Session / Study - Review





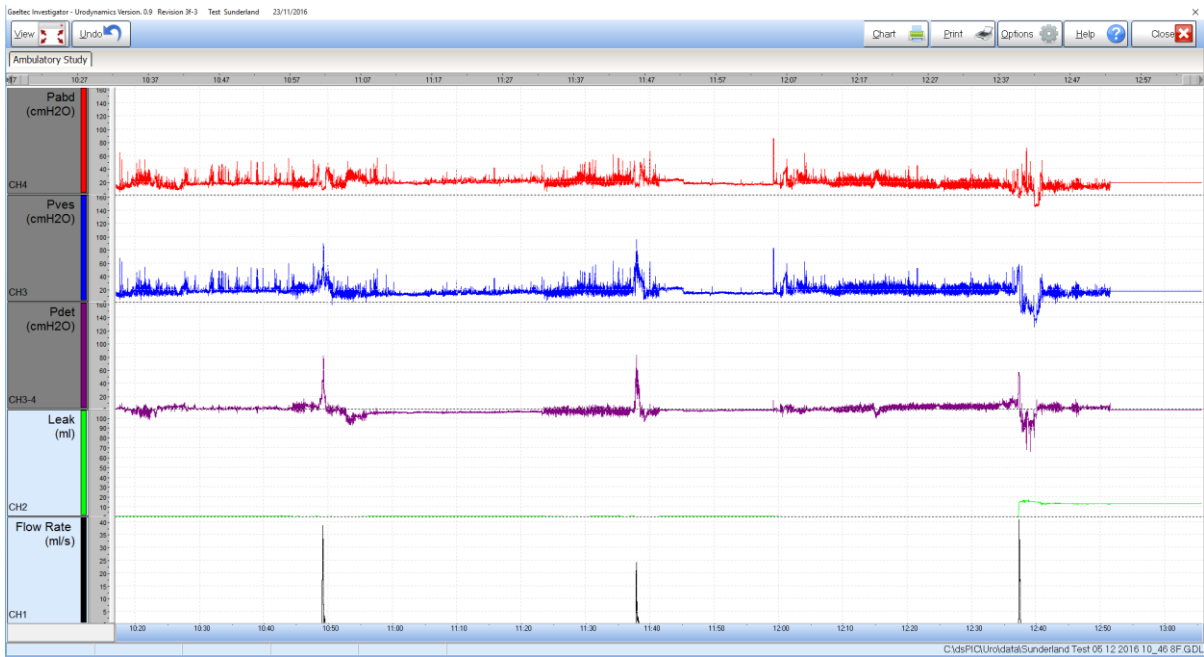
### Biofeedback – Multiple Session / Study Review for comparison Studies

For a selected patient, two studies / training session recorded on separate dates can be reviewed side by side for comparison.



# Urology

## Urology – Ambulatory Study Review



## Urology – Ambulatory Study Review – Zoomed of Urine Flow Episode



**Urology – Ambulatory Study Review – Report for Urine Flow Episode**

