UROREPORT METHODOLOGY

BASIC REQUIREMENTS FOR AUTOMATIC ANALYSIS:

The following sections described the waveform requirements for automatic identification of a Urodynamic test phase. If a test phase type can not be determined by appropriate user entered event comments or primary waveform patterns the user will be prompted with a small on-screen 'Transfer Data' window to select a phase (fill or void) and the data points then manually selected on the waveforms.

FILL PHASE:

Within the user highlighted selection of data:

- Void volume baseline must be stable for 2-3 seconds at a level not exceeding 5ml.
- Fill volume total must exceed 20ml.

The report software will not automatically analyse data outside of these criteria.

VOID PHASE:

Within the user highlighted selection of data:

- Flow rate baseline must be stable for 2-3 seconds at a level not exceeding 3 mlsec⁻¹.
- Voided flowrate must exceed 5 mlsec⁻¹.

The report software will not automatically analyse data outside of these criteria.

BASIC REQUIREMENT OF RAW DATA (MANUAL ANALYSIS)

Urethral Full Phase:

Within the waveform inspection area:

- Filled volume must equal or exceed 50ml.
- Maximum Pura pressure# must exceed 20cmH₂0.
- Start for Fill must be 100ml or less.

Urethral Empty Phase:

Within the highlighted selection of data:

- Vesical volume should be less than 50mL.
- Maximum Pura pressure# must be greater than 20cmH₂0.
- Start for Fill must be 100ml or less.

Note: # refer below for an explanation on how these points are determined.

AUTOMATIC ANALYSIS CRITERIAW

This section provides a description of all the data points accepted by the automated UroReport software.

FILL PHASE

Point Definitions:

Start of fill "Fill started, bladder commences filling"

First desire "Patient indicates first sensation of bladder filling"

Normal desire "Patient indicates normal desire to void"

Urgency "Patient indicates fear of leakage with further filling"
Pain "Patient indicates pain at current bladder volume"
End of fill "Fill stopped, bladder at maximum tolerated volume"

First leak "First leakage detected"

Incontinence leak "Sustained leakage occurred"

Derived Data Points:

Time -

First desire = Event time - Start of fill. Time(secs)
Normal desire = Event time - Start of fill. Time(secs)
Urgency = Event time - Start of fill. Time(secs)
Pain = Event time - Start of fill. Time(secs)
Total fill time = End of fill time-Start of fill.Time(secs)

<u>Fill rate</u> = (End of fill Vol. - Start of fill Vol.) / (End of fill Time - Start

of fill Time) (ml/min)

<u>Compliance</u> = (End of fill Vol. - Start of fill Vol.) / (End of fill Pdet - Start

of fill Pdet) (ml/cmH₂O)

Volumes Derived:

Vesical capacity = Vol. Fill (end of fill) - Vol fill (start of fill) (ml)

First desire = Vfill @ event (ml)
Normal desire = Vfill @ event (ml)
Urgency = Vfill @ event (ml)
End of fill = Vfill @ event (ml)

Comment Fields:

Fill Medium comment field indicating the fluid medium entered in the filling phase.

Fill Method comment field indicating the filling method (gravity, pumped, other).

Urge, Stress, Incontinence, Instability clinical determination selectable as report comment.

Detected Event Comment Data Points:

Predefined user entered comments, added to the recording will be sought and used for analysis during a fill phase. At each comment location three measurements are taken (Pressure, Time and Volume) or calculated by the software:

Event Comments:

'Search for' Event Comments list:

Normal Desire First Desire Strong Desire Urgency Pain End of fill End of fill First Leak

Incontinence Leak Told to Void

Algorithms for Determining Data Points:

The following data points and the method for their determination: Start of fill:

Defined as the first point in the fill volume waveform from the commencement of the user (mouse/cursor) selection of the Filling Phase.

End of Fill:

Defined as the last point in the fill volume before the end of the user (mouse/cursor) selection of the Filling Phase.

VOID PHASE

Point Definitions:

Told to void "Instruction by operator for patient to void"

Premict_Pressure "Resting values when patient relaxed prior to urine

flow"

Pdet rise "First indication of detrusor pressure rise"
Start of void "Commencement of sustained urine flow"
Max void flow "Max. recorded void flow rate in void phase"

Max Pabd "Max. recorded Pabd in void phase"

Max Pves "Max. Pves in void phase"

End of void "Termination of sustained urine flow- should be zero"

Time Derived Variables:

Void Time= End of QVoid.Time - Start of QvoidTime(secs)Time to Qmax= Qvoid max.Time - Start of Qvoid .Time(secs)Opening Time= Pdet rise.Time - Qvoid start.Time(secs)Hesitancy= Start Of Void Time - Told To Void TimeTime(secs)

Pressure Derived Variables:

Max Detrusor Pressure

= Pdet (during Qvoid)max - Pdet (pre-micturition) (cmH₂O)

Max Vesical Pressure

= Pves (during Qvoid)max - Pves (pre-micturition) (cmH₂O)

Flow Derived Variables:

Max Flow Rate = Qvoid max - Qvoid zero baseline (ml/sec)

Average Flow Rate = Vvoid/void.Time (ml/sec)

Pdet@ Qvoid Max = Pdet @ Qvoid max - Pdet pre-micturition (cmH₂O) = Pves@ Qvoid max - Pves pre-micturition (cmH₂O) = Pabd@ Qvoid max - Pabd pre-micturition (cmH₂O)

Volume Derived Variables:

Voided Volume = Vvoid(end of void) - Vvoid(start of void) (ml)

Detected Event Comment data points:

Predefined user entered comments, added to the recording will are sought and used for analysis during a fill phase. For each event comment located three measurements are taken (Pressure, Time and Volume) or a calculation performed.

Algorithms for determining data points:

The following data points and the methods for their determination are discussed: For correct location of these points, ten samples of steady state data must be acquired either side of a candidate measurement point.

Start Of Void:

Defined as the first point in the fill volume waveform from the commencement of the user (mouse/cursor) selection of the Voiding Phase.

End Of Void:

Defined as the last point in the fill volume waveform before the end of the user (mouse/cursor) selection of the Voiding Phase.

Premicturition Pressure:

• Defined as the earliest stable baseline point of the selected area.

Maximum Pabd:

Defined as the first maxima within the selected time where the pressure range must be equal to or greater than 10 cmH₂O and the maximum pressure determined must be equal to or greater than 10 cmH₂O.

Pdet Rise:

Defined as the first point in the rise in the detrusor pressure waveform, within the selected time, where the pressure range is greater than or equal to 10 cmH₂O and the time between the start of void and the start of pressure rise is greater than or equal to 0 sec.

The rise point in the detrusor pressure waveform is that which exceeds a threshold defined by the equation:

threshold := Pdet.min+ ((Pdet.max - Pdet.min) * 10%)

and is determined by seeking the first minima prior to the threshold within the selected time.

Maximum Pves:

Defined as the first maxima within the selected time where the pressure range must be greater than or equal to $10~\rm cmH_2O$ and the maximum pressure determined must be greater than or equal to $10~\rm cmH_2O$.

URETHRAL PHASES

Point Definitions:

Start_Pves "Resting Vesicular pressure prior to start of profile measurement"

Pura_Rise "First indication of a rise in urethral pressure"
Max_Pura "The maximum urethral pressure obtained"

Pura_Fall "Urethral pressure falls to starting (resting) value"

Zero_Pura "Lowest urethral pressure value after fall"

Pres_Tx_Ref 'Reference value of Pura. prior to stress (cough) change"

Pres_Tx_Max "Maximum Pura. during stress (cough)"

Time Derived Variables:

Functional Urethral Length (Withdrawal Catheter) = (Pura fall to rest.Time - Pura rise above Pves.Time)/withdrawal speed,mm/sec (mm)

Total Urethral Length = Pura fall to Pamd.Time - Pura rise.Time / withdrawal speed mm/sec (mm)

Pressure Derived Variables:

 $\label{eq:max-pressure} \begin{aligned} \text{Max Urethral Closing Pressure} &= \text{Pura}(\text{during UPP}) \text{max} - \text{Pves}(\text{during UPP}) \text{max} \\ (\text{cmH}_2\text{O}) \end{aligned}$

Pressure Transmission Ratio = (Pura (cough) max - Pura transmission ref / Pura (cough) max)*100 (%)

Algorithms for determining data points:

The following data points and the methods for their determination are discussed: For correct location of these points, ten samples of steady state data must be acquired either side of a candidate measurement point.

Maximum Pura:

Defined as the first maxima within the selected time where the pressure range must be 10 cmH₂O or greater. The maximum pressure determined must exceed 10 cmH₂O.

Start Pves:

Defined as the earliest pressure, greater than or equal to 0 cmH₂O, in the selected area.

UROVOLUME CALCULATION

Trigger Level:

Defined as the threshold above which the integrator will start and/or stop integrating flow data.

Post Acquisition Timer:

Defined as the time in seconds for which the software will integrate data once Qvoid is less than the Trigger Level. A flow signal exceeding the trigger level but fall outside of the post acquisition timer period will not be added into the total volume integration.

Algorithm for determining data points:

The volume trace is determined by the integrated data for which Qvoid is greater than or equal to the user entered Trigger Level. Once Qvoid is less than the Trigger Level then Qvoid will continue to be integrate for the duration of the Post Acquisition Time. If Qvoid exceeds the Trigger Level during the post acquisition time limit then the total post acquisition time is reset and integration will continue until Qvoid is again less than the Trigger Level.

NS02381A 31/3/02