

**510(k) Summary****DRAERD 510(k)****Summary of Safety and Effectiveness Information**

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| <b>Submitter's name</b>          | Synectics Medical AB<br>Renetiernas gata 12<br>S-116 28 Stockholm<br>Sweden   | Synectics Medical Inc<br>3850 Victoria Street North<br>Mail Stop V215<br>Shoreview, MN 55126 2978 |
|                                  | Contact: Anna Pettersson  | Contact: Keith Jung   |
| <b>Name of device</b>            | Urodynamic Analysis Module  |   |
| <b>Name of equivalent device</b> | PolyUro Polygram Software (DOS environment)<br>(included in 924383 - PolyUro)   |   |
| <b>Description of device</b>     | <p>The Urodynamic Analysis Module is identical, in function and types of analyses that can be performed, to the PolyUro Polygram Software (DOS). The main difference is that the PolyUro Polygram Software (DOS) is written for the DOS environment and the Urodynamic Analysis Module is written for the Windows environment. PolyUro Polygram Software (DOS) works in the DOS environment and the Urodynamic Analysis Module works in the Windows environment.</p> <p>The Polygram Software for Windows (K946322) was designed to record and handle/store physiological parameters. After a recording, the user is able to review the tracings on the computer screen and print the signal tracings or just parts of them. When reviewing the data on the computer screen, the user is able to mark certain segments and calculate certain parameters from the selected signal segments. These parameters include minimum and maximum values, length of selection.</p> <p>By adding the Urodynamic Analysis Module to the Polygram Software for Windows, the user can also have all the pressure, flow and volume data analyzed in terms of physiological properties, comparison with normal values, etc. The analyzed data can thereafter be viewed on screen or printed out on a separate paper.</p> <p>The analysis report includes sections such as patient demographics; interpretation and comment (for user to insert); procedure summary; Urodynamic tracing; analyses (as specified below); and physician signature section.</p> <p><u>Analyses:</u></p> <ul style="list-style-type: none"> <li>• <b>Uroflow analysis:</b> position, subjective grading, residual volume, numerical uroflow analysis, voided volume, bladder capacity, maximum flow (<math>Q_{max}</math>), average flow, voiding time, flow time, Time to maximum flow, volume at maximum flow, urethral conductance, flow index.</li> <li>• <b>Cystometry analysis:</b> position, infusion rate, infused volume, residual volume before procedure, maximum cystometric capacity, first sensation, compliance, detrusor activity, leakage during filling, catheter via, infusion stopped because, infusion time, diuresis, squeezing, sensation levels, leak point pressure analysis, pressure/infused volume graph.</li> <li>• <b>Pressure/flow voiding analysis:</b> position, subjective grading, residual volume, voided volume, vesical capacity, maximum flow rate (<math>Q_{max}</math>), average flow rate, voiding time, flow time, time to maximum flow, volume at maximum flow, vesical pressure at <math>Q_{max}</math>, detrusor pressure at <math>Q_{max}</math>, urethral</li> </ul> |   |

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292

minimum operating pressure, urethral resistance, pressure/flow graph, nomograms in the P/Q graph, filter in the P/Q loop, curve adaption in the P/Q loop, pressure minimal urethral opening (Pmuo).

- **Urethral pressure profile:** static UPP, Pucp graphs, maximum closing pressure, urethral functional length, closure area, pull speed, cough profiles, Pucp graphs, Pves amplitude, closure pressure, transmission factor, relative length, pull speed, transmission graph.

The analysis report can then serve as a tool for the physician's diagnosis and post treatment evaluation.

**Performance Testing**

The Urodynamic Analysis Module has been thoroughly tested during the development phase, that is, alpha testing in terms of integration testing has been performed and documented and beta testing in terms of hospital site testing has been done and documented.

It has been concluded that the alpha and beta testing has meet and passed the specified objectives and should therefore be released to the market.

**Statement of Intended use/indication for use**

The Urodynamic Analysis Module is a software program that has been designed to analyze pressure, volume and flow data recorded from the urological tract in pediatric and adult populations.

The Urodynamic Analysis Module includes the following analyses:  
Uroflow analysis, Cystometry analysis, Pressure/flow voiding analysis, Urethral Pressure Profile

The program is to be used on a personal computer analyzing patient data in the hospital environment under supervision of a trained physician. The analyzed data can be viewed on the computer screen or printed out on a separate paper.