

Life-Tech

UROLAB[®] SYSTEM V

FIVE URODYNAMIC
SYSTEMS, COMPLETELY
EXPANDABLE

ISO 9001
CERTIFIED

NOVUS OPUS PRIMUS JANUS MAXIMUS

UROFLOWMETRY

CYSTOMETRY

ELECTROMYOGRAPHY

PRESSURE-FLOW STUDY

URETHRAL PRESSURE PROFILOMETRY

URETHRAL CLOSURE PRESSURE

VALSALVA AND VESICAL
LEAK POINT PRESSURE TESTS

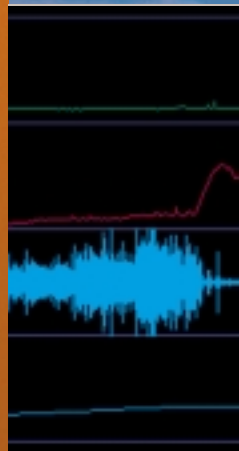
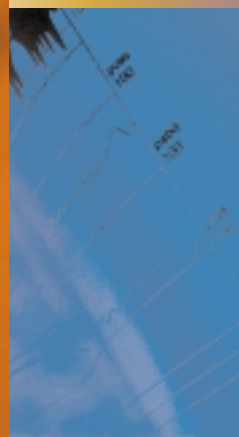
CAVERNOSOMETRY

GI MOTILITY

ANORECTAL MANOMETRY

PELVIC FLOOR RETRAINING

EVOKED POTENTIAL TESTING



WINDOWS-BASED URODYNAMIC SYSTEM

A compact, easily user customized and fully upgradeable system that is exceptionally easy to use yet provides advanced analysis and reporting capabilities. Fully integrated software eliminates the need to open and close multiple programs to perform different operations during a urodynamic study.

ADVANCED SYSTEM CAPABILITIES

- True 32-bit Windows® program
- Multiple networking options
- Three clinical database levels
- Automatic report and referral letter generation

SPECIAL OPERATING FEATURES

- Unique ability to customize system operation to meet the personal needs of individual clinicians
- Extensive selection of pre-labeled or user defined event marks
- Automatic or manual artifact recognition and removal
- Comprehensive data analysis and reporting
- Extensive choice of plots and nomograms

EASY TO USE

- Entire procedure can be performed with only three commands
- All operations can be under manual control or completely automated at the user's discretion

UPGRADABLE AND EXPANDABLE

- 3-12 recording channels
- Video Urodynamics (Urovision®)
- Cavernosometry
- GI Motility
- Anorectal Manometry
- Pelvic Floor Retraining
- Evoked Potential Testing



ADVANCED SYSTEM CAPABILITIES

True 32-bit operation with multiple external and internal networking options and wireless hand-held and voice control options.

TRUE 32-BIT OPERATION

- True 32-bit operation provides faster and more reliable image processing, data management and networking, and allows the use of long file names.



SYSTEM NETWORKING

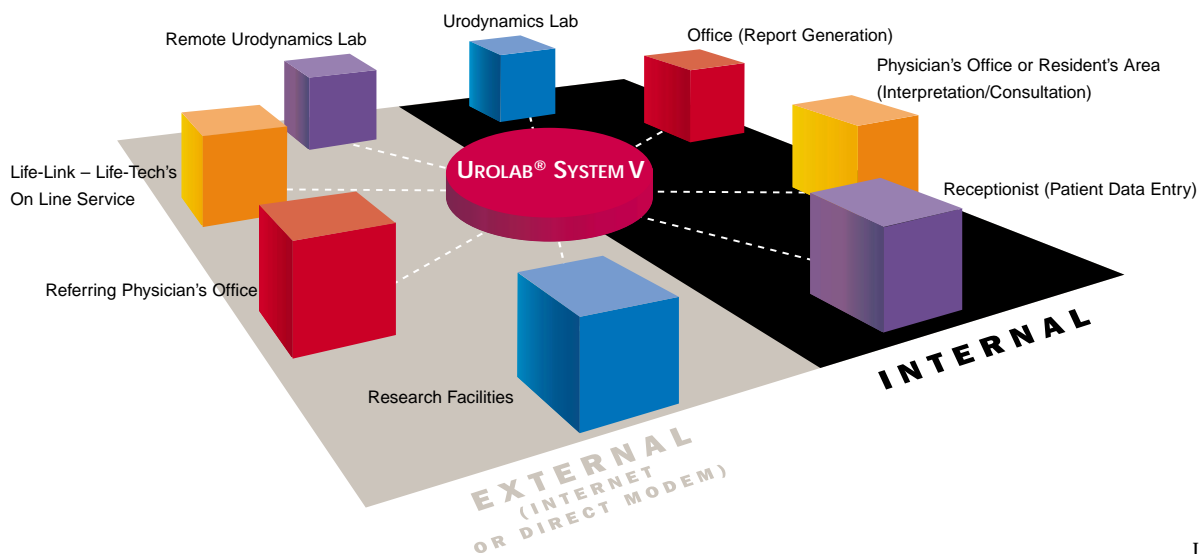
- Multiple networking options are available for locations where remote review, data input, and interface with a hospital information system are required.
- All patient and study data, as well as reports and referral letters, can be transmitted directly to any network location, thus facilitating a true paperless office.
- Life-Link allows Life-Tech's trained service technicians and clinical specialists to monitor and control the user's computer to identify problems, instruct the user, download problem files for analysis, install software upgrades and perform virus scans.

MULTIPLE CONTROL OPTIONS

- Wireless infrared remote control facilitates interaction with the patient during the procedure.
- Wireless voice control provides hands free operation during studies.
- Touch screen control allows operation of the system without a mouse.



NETWORK, LIFE-LINK, REMOTE SITE ANALYSIS



FULLY INTEGRATED CLINICAL DATABASE

Access®-based clinical database is integrated with Word®, Excel®, Query® and PowerPoint®. Files are available in multiple formats such as HTML, Bitmap, Jpeg, and Text.

PATIENT DATA WINDOW

Any entry into the database, including patient data, is completely optional and can be made at any time, either before or after the urodynamic study.

PATIENT STUDY WINDOW

All repeat patient studies are automatically filed in one location under a single patient identifier that is accessed from, a single patient file.

AUTOREAD DATA INPUT

Handwriting recognition input option achieves 98% accuracy and dramatically reduces keyboard entry time.

INTELLIGENT REFERRAL LETTER

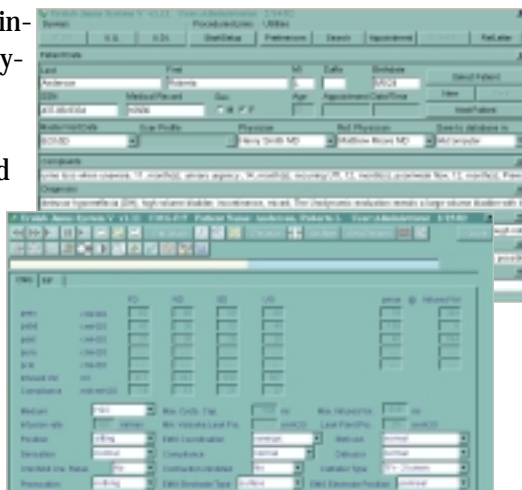
Data from both the clinical database and urodynamic analysis results are combined in an automatically produced referral letter. The Intelligent Referral Letter (Advanced and Galen database automatically adjusts grammar and format for omitted data fields.



THREE INTEGRATED DATABASE LEVELS

CAPABILITY	PATIENT MANAGEMENT DATABASE	ADVANCED MANAGEMENT DATABASE	GALEN COMPREHENSIVE CLINICAL DATABASE
Patient demographics	●	●	●
All patient studies filed under a single patient ID	●	●	●
Appointment scheduler	●	●	●
Automated referral letter	●	●	●
Export or import of patient procedure and data	●	●	●
30 day safety storage of all deletions	●	●	●
Intelligent referral letter		●	●
Advanced query/search engine		●	●
Advanced database report designer		●	●
Statistical analyzer		●	●
Incontinence Impact Questionnaire (IIQ)		●	●
Urogenital Distress Inventory (UDI)		●	●
International Prostate Symptom Survey (IPSS)		●	●
Customizable referral letter			●
Customizable data fields			●
Follow up notes/charting			●
Voiding diary and pad test			●
Comprehensive history, physical and laboratory results			●
AutoRead	○	○	○

○ = optional



Final output allows modification of all aspects of the letter.

UNIQUE CUSTOMIZATION AND OPERATING FEATURES

Operation can be personalized to meet diverse clinical requirements, including the needs of either multiple single clinicians or groups.

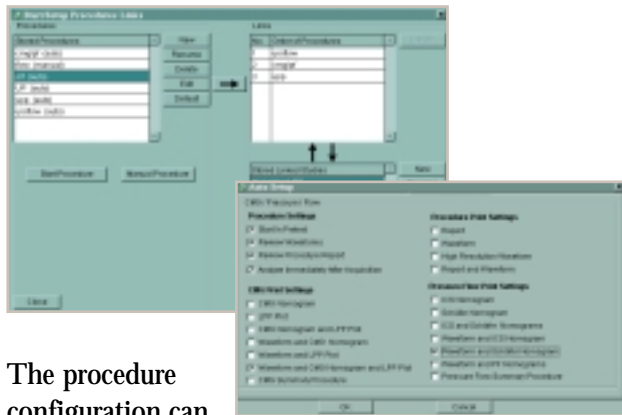


PROCEDURE AUTOMATION



User Preferences window allows a comprehensive selection of operating features.

Set Up Procedure window allows each clinician to select and store an unlimited number of personalized procedure configurations.



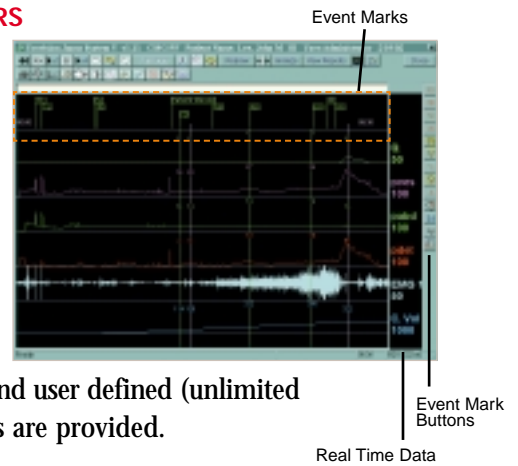
The procedure configuration can be further personalized from the Auto Setup window by setting up an automated sequence of all procedure steps, including analysis, and generation of reports and the referral letter. Multiple procedures can be linked, eliminating the need to establish a new file name or restart the study when starting a new procedure.

PRETEST AND STANDBY

Prior to beginning the study, or at any time during the study, all channels can be made to scroll across the monitor in real time without storage to allow adjustments under direct observation.

EVENT MARKERS

An unlimited number of event markers can be inserted at any time during either acquisition or post processing. Predefined ICS events, other common events and user defined (unlimited characters) events are provided.



REAL TIME SCROLLING

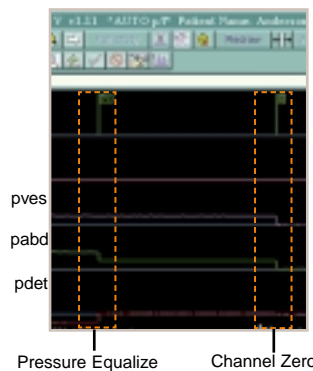
As data is acquired, the entire graph, including event markers, scrolls across the screen from right to left emulating a strip chart recorder.

WAVEFORM SCROLLBACK

Any part of the record that has passed from view can be scrolled back into view while without interrupting the display of real time numeric data.

PRESSURE EQUALIZE AND CHANNEL ZERO

At any time during the study abdominal or urethral pressure can be balanced to vesicle pressure with a single click. All channels are automatically zeroed at the beginning of the study. Any channel can be re-zeroed at any time during the study.

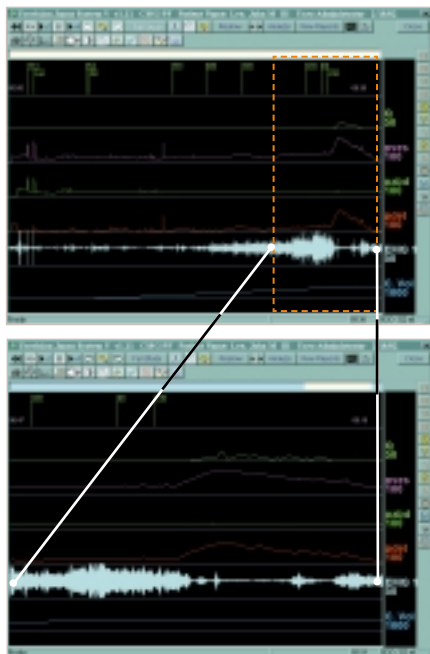




ADVANCED ANALYSIS AND REPORTING CAPABILITIES

Any record segment can be expanded to full screen. Artifacts can be manually or automatically removed, and any screen can be converted into a presentation slide.

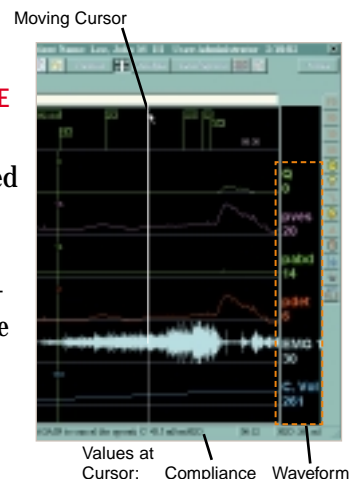
WAVEFORM ZOOM



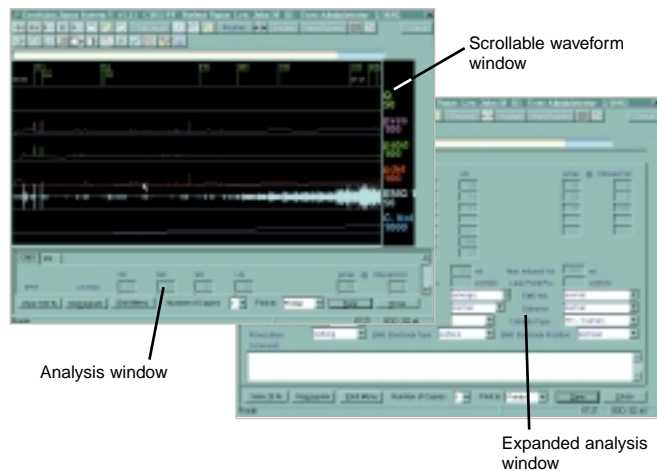
Selected channels from any study segment can be expanded easily, and the expanded segment can be moved anywhere in the study.

MOVING CURSOR WITH AUTOMATIC COMPLIANCE CALCULATIONS

A moving cursor can be placed anywhere on the waveform and moved to any location. Numeric values of each channel and calculated compliance at the cursor's location are displayed continuously.



AUTOMATED ANALYSIS

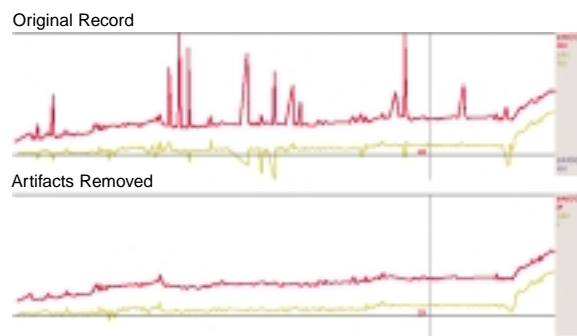


REAL TIME STUDY PLAYBACK

All, or any part, of the study can be reviewed in simulated real time at one or four times the original recording speed.

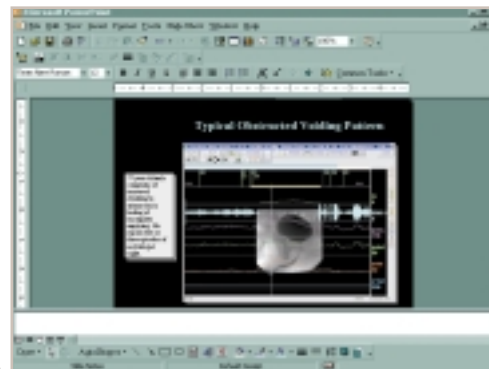
ARTIFACT RECOGNITION AND REMOVAL

Artifacts can be manually or automatically removed from the waveform.



SLIDE CAPTURE AND FILE STORAGE

With a single click, waveform screens can be stored as files for export to documents, PowerPoint®, or other slide- or image-processing programs. This capability includes video images.



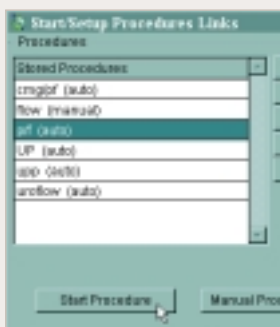
EXCEPTIONALLY EASY TO USE

Only three button clicks perform a study. Multiple nomogram, plot and report options are easily selected.

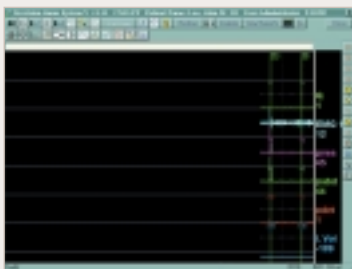
TESTING IS AS EASY AS 1, 2, 3

Perform a basic or advanced study with only three commands¹.

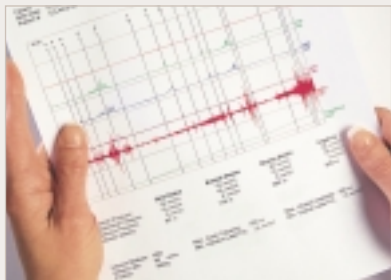
CLICK 1 Selects preprogrammed study.



CLICK 2 Starts preprogrammed study.



CLICK 3 Ends study, analyses the results and the report.



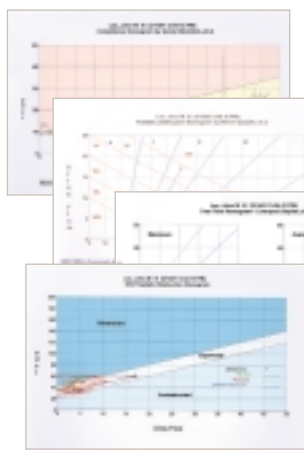
¹ Assumes patient data has been entered and excludes set marker commands during the Study.

FLEXIBLE CONTROL OPTIONS

Study automation is fully specifiable, from completely automatic to completely manual. Studies can be started, completed, analyzed, and printed before entering any patient data or ID numbers.

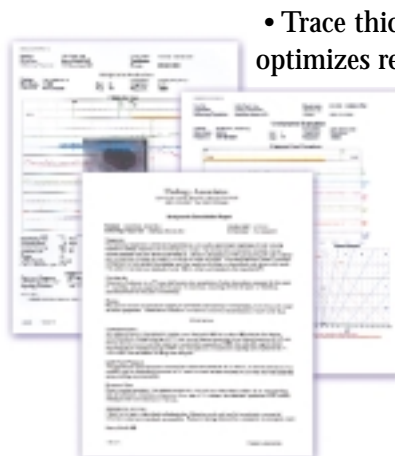
EXTENSIVE SELECTION OF NOMOGRAMS, PLOTS AND PRINTOUTS

Nomograms and plots allow quick comparison of results to internationally accepted standards of normalcy.

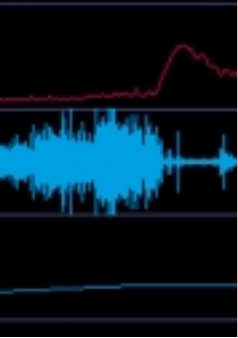


- Liverpool Uroflow Nomogram (Halen et al)
- Pressure/Flow Nomogram (Schäfer et al)
- ICS Pressure Flow Nomogram (Abrams-Griffiths)
- PQ Plot
- Descending Pressure Slope Calculation
- Ghoniem Compliance Plot
- Leak Point Pressure Plot
- Urethral Pressure
- Transmission Ratio Plot

Advanced Printout Capabilities include a wide selection of standard report formats.



- Trace thickness control optimizes readability
- Fast, high quality color printout
- ICS-standard nomenclature
- High resolution waveform printout
- Automatic referral letter generation



FULLY UPGRADEABLE AND EXPANDABLE

Purchase only what is needed now and expand later. Urolabs utilize the same basic system, hence are easily upgraded from the most basic urodynamic system to the most advanced video urodynamic system.



CAPABILITY	NOVUS	OPUS	PRIMUS	JANUS	MAXIMUS
Fully upgradeable to any level	●	●	●	●	●
Compatible with Urovision	●	●	●	●	●
3 to 12 recording channels	●	●	●	●	●
Up to 2 EMG channels with or without audio	●	●	●	●	●
Volume infused capability	●	●	●	●	●
Up to 8 direct and 2 derived pressures	●	●	●	●	●
Patient Management database (see page 3)	●	●	●	●	●
Basic printout capability	●	●	●	●	●
Unlimited real-time marker insertion and editing	●	●	●	●	●
Manual slide capture	●	●	●	●	●
Patient study export	●	●	●	●	●
Leak point pressure recording and analysis	●	●	●	●	●
Advanced leak point pressure analysis and report		●	●	●	●
Unlimited waveform zoom		●	●	●	●
Advanced printout capability		●	●	●	●
Unlimited post processing, marker insertion and editing		●	●	●	●
Re-analysis and editing of studies		●	●	●	●
Saved report editing		●	●	●	●
Patient and study import		●	●	●	●
Cut and paste studies		●	●	●	●
GI recording capability	○	●	●	●	●
Cavernosometry recording capability (see page 3)	○	●	●	●	●
Advanced patient database			●	●	●
Zoomed scroll of entire waveform			●	●	●
Unlimited, real-time user defined event marks			●	●	●
Acquisition scrollbar			●	●	●
Compliance calculation at any selected point			●	●	●
Automatic study protocol, analysis, and printout	●			●	●
Linked automatic study protocol				●	●
Artifact recognition and removal				●	●
Cough removal				●	●
Playback x1 and x4				●	●
Automatic slide capture				●	●
MS Word report writer	○	○	○	○	●
Galen comprehensive clinical database	○	○	○	○	●
Life-link real time modem service	○	○	○	○	●
Advanced hardware configuration	○	○	○	○	●
AutoRead input by handwriting recognition	○	○	○	○	○

○ = Optional

Novus. Fully automated. Inexpensive, yet provides the highest quality clinical records. Includes the Patient Management Database with patient demographics, automated referral letter and appointment scheduler.

Opus. Adds extensive post processing and re-analysis capability, including expanded viewing of any portion of the study waveform, event mark editing and advanced leak print pressure report.

Primus. Upgrades to the Advanced Management Database, which includes IPSS, IIQ and UDI questionnaires and Intelligent Referral Letter. Adds waveform scroll-back and insertion of user defined event markers at any time during acquisition.

Janus. Saves time by allowing automation or most complex urodynamic procedures. Also adds the ability to edit coughs and artifacts and the ability to automatically produce presentation slides.

Maximus. The most advanced urodynamic system available. Upgrades to maximum software and hardware configurations, and the Galen clinical database, which includes intelligent referral letter, voiding diary and pad test.

UROVISION® – ADDS FULLY INTEGRATED VIDEO URODYNAMICS TO ANY UROLAB SYSTEM

Provides exceptional image quality and advanced image processing and filing capabilities.

MULTIPLE IMAGE OPTIONS

Combines either a fluoroscopic or ultrasound image with the urodynamic waveform. Color endoscopic images also can be stored in the patient's file.

DIGITAL IMAGE STORAGE

Provides real time storage of the combined video image and the urodynamic waveform. Storage capacity is effectively limited only by patient fluoroscopy exposure time.

Although image compression is available, images are not automatically compressed, to allow subsequent review at the highest resolution.

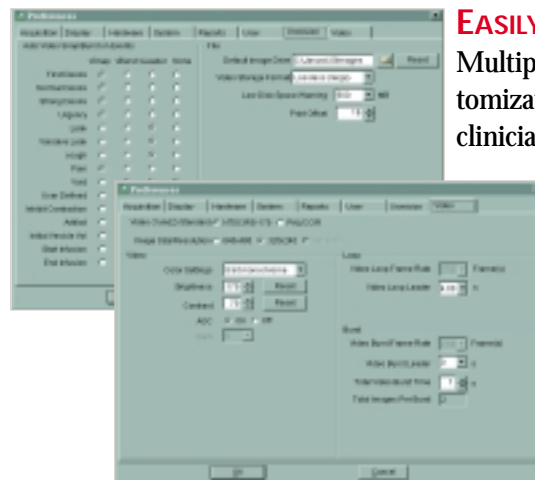
EASY TO USE

Image capture can be initiated by mouse, function key, wireless infrared remote control, wireless voice control, touch screen control or specified events.

SYSTEM CAPABILITIES

MODEL NUMBER	UV5-1	UV5-2	UV5-3	UV5-4	UV5-5	UV5-6
Video images and the urodynamic waveform are time linked together in a single window	●	●	●	●	●	●
Cursor selected images from anywhere in the study can be displayed	●	●	●	●	●	●
Zoom and scroll of images and waveform	●	●	●	●	●	●
Unlimited number of images	●	●	●	●	●	●
Video Loop (sequence of stored image snapshots)	●	●	●	●	●	●
Waveform/image split screen display of waveform and image	●	●	●	●	●	●
Image delete	●	●	●	●	●	●
Contrast adjustment	●	●	●	●	●	●
Image gallery		●	●	●	●	●
Image and waveform save to other than C drive		●	●	●	●	●
Image invert (b/w-w/b)		●	●	●	●	●
Video leader		●	●	●	●	●
Image edit (keep only selected)			●	●	●	●
Image pan			●	●	●	●
Image zoom			●	●	●	●
Select from image gallery			●	●	●	●
Monochrome histogram			●	●	●	●
Waveform/image overlay			●	●	●	●
Gallery zoom				●	●	●
Gallery image scroll				●	●	●
Slide capture				●	●	●
Continuous video loop				●	●	●
Video loop leader				●	●	●
Video storage compression				●	●	●
Video burst					●	●
Adjustable video burst length					●	●
Playback x 1 or x 4 of either study or study + images					●	●
Video snapshot with events					●	●
Video burst with events					●	●
Colorization						●
Color histogram						●
Gallery view frame editing						●
Frame rate adjustable video loop and video burst						●
Video burst leader						●
Video leader with events						●
Event gallery						●
User selected gallery						●

Pending release



EASILY CUSTOMIZED

Multiple preference selections allow customization to meet the needs of individual clinicians. Video image capture, storage, and processing can be completely pre-programmed. Video images can also be saved automatically whenever a pre-specified event mark is placed.

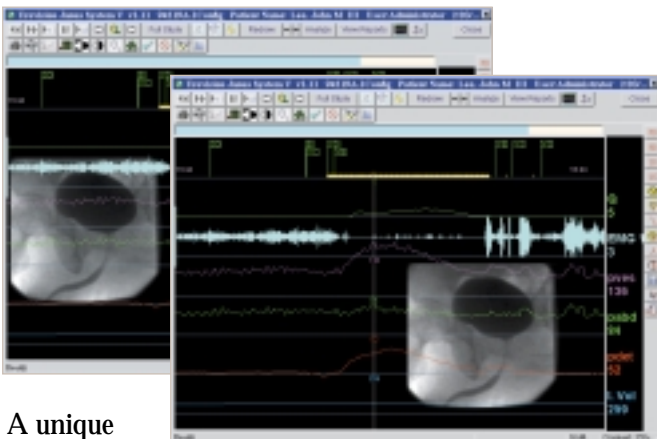
UNIQUE IMAGE ACQUISITION CAPABILITIES

Images can be positioned anywhere on the screen, and, with video leader, images occurring before the capture command can be captured. Dynamic time indexing allows the urodynamic record and video image to be displayed in a single window.

TIME-CORRELATED IMAGE ACQUISITION

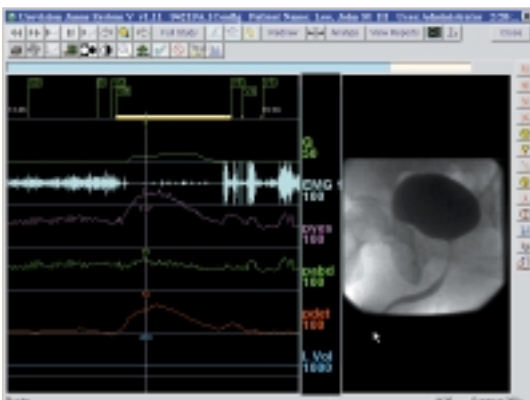
Urovision's unique dynamic time indexing algorithm time-correlates the video images and urodynamic record. This allows viewing of the urodynamic record and the video image in a single window.

VIDEO OVERLAY OR SPLIT



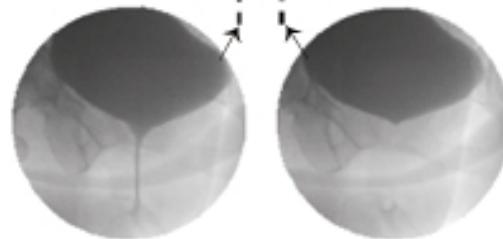
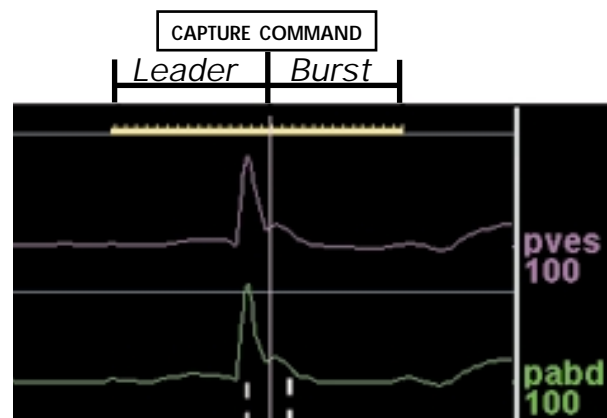
A unique "look through" video window overlays the video image and urodynamic record. The overlaid video image can be easily repositioned anywhere on the display and zoomed to any size.

Alternatively, the video and urodynamic windows can be displayed separately.



FLEXIBLE IMAGE CAPTURE OPTIONS

- **Video Loop.** Acquires images as user-selected sequential snapshots, or uniquely, as a continuous series. Can be started and stopped at will, thereby storing only the desired images.
- **Video Burst.** Captures images sequentially for a predetermined time period. (0-48 seconds).
- **Video Leader.** A unique Urovision feature allows capture of video images that occur before the capture command is given.



Cough with leak occurs before capture command.

Without leader, the first image captured after the command would be too late to show the leak.

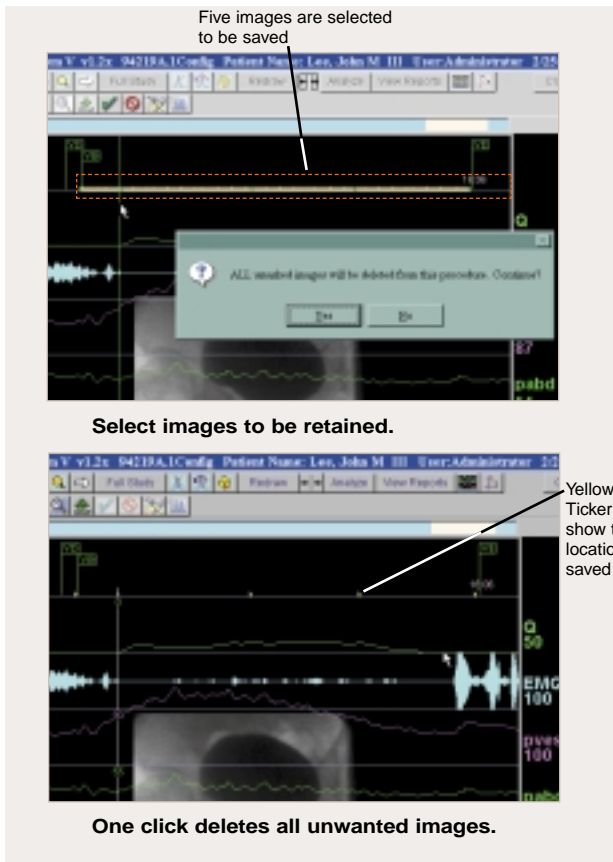
UNSURPASSED IMAGE PROCESSING AND EXPORT CAPABILITIES

Any acquired image can be saved or deleted; flexible image contrast setting allows image optimization; unique gallery presentation displays multiple sequential images.



TIME-CORRELATED TO INDIVIDUAL IMAGE EDITING

- Save or delete any selected image(s).

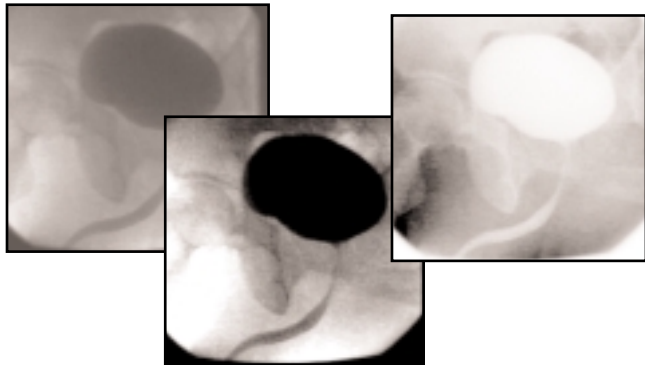


Many video urodynamic systems store images in AVI (digital movie) files, which do not allow editing of individual images. Urovision's dynamic time indexing algorithm overcomes this disadvantage by giving the user the ability to selectively delete or save individual images while retaining the images' time relationship to the urodynamic record.

- Create a time correlated fluoroscopic "moving picture". Dynamic time indexing also allows the user to create a "moving picture" of stored fluoroscopic images that is time-correlated with the urodynamic record.

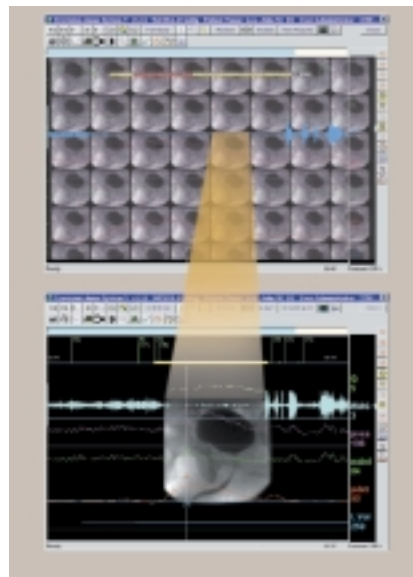
FLEXIBLE CONTROL OF IMAGE DISPLAY

- Contrast Adjustment



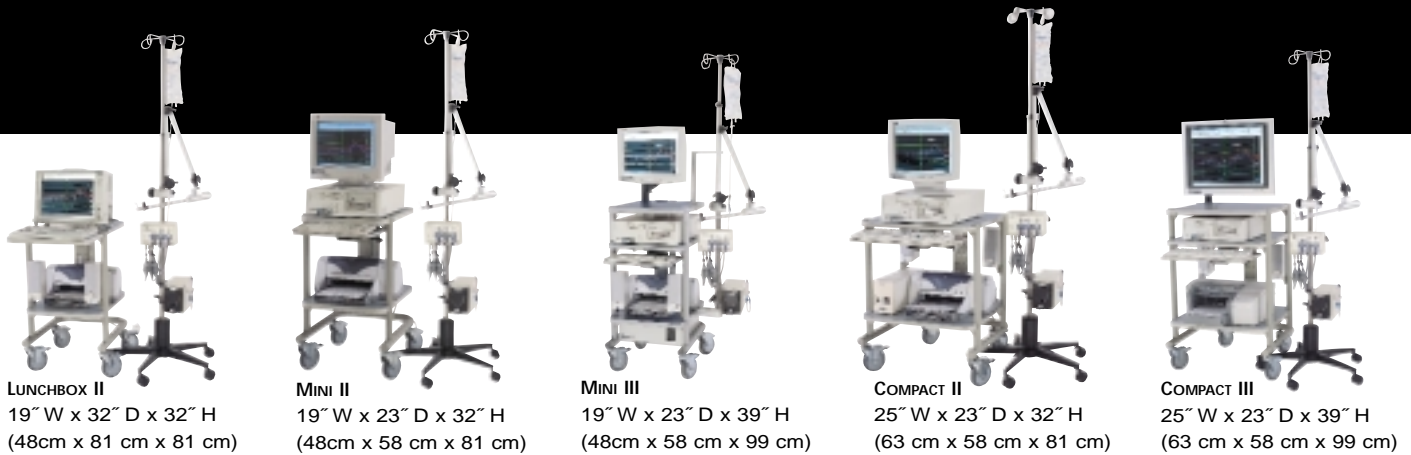
The user has complete control of the image contrast setting to optimize the image display. Reverse contrast is also available.

- Gallery Presentation. Up to 81 images preceding any selected point on the urodynamic record can be displayed in sequence. This presentation facilitates viewing the sequence of images preceding an incident of incontinence or obstructed voiding. Clicking on any gallery image displays only that image and marks its time location on the waveform display.



TROLLEY CONFIGURATIONS

Any Urolab or Urovision system can be mounted on any Trolley configuration.



LUNCHBOX II
19" W x 32" D x 32" H
(48cm x 81 cm x 81 cm)

MINI II
19" W x 23" D x 32" H
(48cm x 58 cm x 81 cm)

MINI III
19" W x 23" D x 39" H
(48cm x 58 cm x 99 cm)

COMPACT II
25" W x 23" D x 32" H
(63 cm x 58 cm x 81 cm)

COMPACT III
25" W x 23" D x 39" H
(63 cm x 58 cm x 99 cm)

Trolley Configurations: Include System V wiring raceway, keyboard caddy, and 4" (10.2 cm) or 5" (12.7 cm) locking castors.

Instrument Stand: Left (not shown) or right cart mounted, or five wheel stand-alone.

Computer Hardware: Custom configured computers provide an optimal real time acquisition environment. Only Pentium or higher Intel processors and the most reliable components are included in the computer hardware. High-resolution LCD displays or monitors are available as well as the latest HP Printers.

UROLAB SPECIFICATIONS

RECORDING CAPABILITY:	PRESSURE:	MAINTENANCE FLOW:	CERTIFICATIONS AND SUPPORT:
<p>12 Channels, 8 Direct, 4 Overlay (Upgradeable to 16 channels)</p> <p>Sample Rate: 50 samples/sec/channel</p> <p>UROFLOW 1 & 2 Includes: uroflow chair 20" W x 19.25" D x 31" H (51cm x 49cm x 79cm)</p> <p>Measuring Range: 0 to 100 ml/sec</p> <p>Display Scale: 0 to 25 ml/sec, 0 or 50 ml/sec</p> <p>UROFLOW VOLUME: Measuring Range: 0 to 2,000 ml</p> <p>Display Scale: 0 to 1,000 ml</p>	<p>Eight primary pressures, two derived pressures</p> <p>Pressure 1: pves, pabd, pura Cavernosometry, anorectal manometry or GI</p> <p>Pressure 2: pves, pabd, pura, pdet, pclo, Maintenance flow, or GI</p> <p>Pressure 3: pura, pclo or GI</p> <p>Pressures 4 - 8: GI</p> <p>Measuring Range: -40 to 400 cm H₂O or mm Hg</p> <p>Display Scale: 0 to 50, 0 to 100, 0 to 200 cm H₂O or mmHg</p>	<p>Measuring Range: 0-400 ml/min Display Scale: 0 to 100 ml/min, 0 to 200 ml/min</p> <p>ELECTROMYOGRAPHY: EMG 1 & 2: Direct or Integrated Optional: audio amplifier</p> <p>Measuring Range: 5,000 μV full scale</p> <p>Display Scale: (Striated) 25, 50, 100, 200, 500 μV/div</p> <p>Display Scale: (smooth) 0.2 Hz-33 Hz</p> <p>INFUSED VOLUME: Water, saline, contrast, CO₂</p> <p>Measuring Range: 0-2,000 ml</p> <p>Display Scale: 0 to 1,000 ml</p>	<p>Quality: ISO 9001/EN46001 FDA GMP</p> <p>Safety: IEC 601-1, En 60601-1, UL 2601-1</p> <p>CLINICAL SUPPORT: Tutorials, clinical workshops, clinical assistance, software updates and Life-Link, online modem support.</p> <p>SERVICE SUPPORT: 24 Hour technical support 7 days a week. Life-Link, online modem support.</p>

UROVISION SPECIFICATIONS

IMAGE INPUT:	IMAGE STORAGE:	VIDEO CAPTURE SETTINGS:	IMAGE SIZE:
<p>NTSC/RS-170/RS-330 PAL/CCIR. Composite or S-video format; 4:3 aspect ratio General purpose video: SVHS</p>	<p>Rate: 2.5 images/sec; upgradeable to 30 images/sec in NTSC format; 25 images/sec in PAL format. Convenient export to zip disc, CD, or DVD.</p>	<p>Leader: Presettable - 0 - 4 sec Burst: Presettable - 0 - 48 sec</p>	<p>UV5-1 and higher 320 x 240 or 380 x 288 UV5-2 and higher 466 x 432 (pending release) 480 x 360 or 466 x 432 UV5-4 and higher 640 x 480 and 756 x 576</p>



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Life-Tech International



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