Urodynamic System

Operating Manual

Guangzhou Potent Medical Equipment Joint Stock Co., Ltd.

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Registration applicant: Guangzhou Potent Medical Equipment Joint Stock Inc. (after-sales service provider)

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Operating Manual for Urodynamic System

Chapter1 Product overview

1. Overview

Urodynamic System, classified as a kind of Class I BF type device, is essential for urodynamic testing commonly used in the contemporary urology surgery. Urodynamics determination with use of Urodynamic System and ensuing comprehensive analysis may help doctors make correct diagnosis by gaining first-hand information necessary to know to what extent that patients suffer the urinary tract dysfunction. Urodynamic System plays an important role in undergoing the clinical and scientific research in the urinary tract function and dysfunction diseases.

2. Characteristics

The analyzer is configured for easy operation as it has a well designed operation interface containing the operator-oriented menu in Chinese. Thus, it is easy to complete a number of testing, such as urinary flowrate determination, urethral pressure determination, bladder pressure determination in the period of filling and pressure-flowrate-myoelectricity simultaneous determination, etc. Such testing can help perform data analysis on urination disorder P-Q graph, AG graph, LPURR graph and URA graph. Patients' full records can be kept so as to obtain the printed Chinese graph information in a standard format, such as personal information, determination curve and test results, etc. Moreover, provide access to search, modification and deletion of medical records.

Resetting the variables already set in the system is possible at customized function. Therefore, regular calibration of pressure sensor, urinary flowrate determination device, hauling machine system and filling pump by means of instrument calibration in a selective manner can be performed.

Chapter2 Structure and function

1. Main structure

1) Analyzer structure

Ndly 11B series analyzer consists of operating system, control system and liquid circuit connection system.

Ndly 11B front view in Fig.I, Ndly 11B back view in Fig.II

Fig. I

Fig.II (EMG)

2) Analyzer specification as given below

Model		Ndly 11B
Composition structure	Operating system	Passage determination device
		Filling pump
		Pressure sensor
		EMG determination device
		Injection pump
		Hauling machine system
		Urinary flowrate determination device
	Control system	Control console
		Control system software
	Liquid circuit connection system	Liquid circuit tube, creep pressure tube, urodynamics tube, anorectal manometry tube
Performance indicators	Urinary flowrate	a) Range of determination of total urine volume: 0mL-1000mL, ±2% error b) Range of voiding time determination: 0s-240s, ±1% error c) Range of average urinary flowrate determination: 0mL/s-50mL/s,±5% error
	Range of pressure determination	Range of pressure: -50cmH20～200cmH20, ±3% error
	Hauling machine	a) Hauling length: ≥280mm b) Hauling velocity: 0.5mm/s, 1.0mm/s, 2.0mm/s and 4.0mm/s ±3% error
	Injection pump	Injection flowrate: 2mL/min～5mL/min (rise in a rate of 1mL/min.); ±3% error
	Filling pump	Range of filling flowrate setting: 2mL/min～10mL/min (rise in a rate of

		1mL/min.); 10mL/min～80mL/min (rise in a rate of 5mL/min.). Filling flowrate error: 0mL/min～50mL/min. ±3% error; >50mL/min ±5% error
	EMG measurement	a) Range of amplitude response: 20μV～1mV b) Electrode wire length: ≥180cm
	Analyzer function	a) To create medical records; b) To facilitate control and display of parametric measurement process; c) To perform auto analysis and report printing; d) To put patients records under custody; e) To provide the bladder pressure over-limit protection at a threshold setting of 150cmH2O.

※ The computer and printer as ancillary equipment of the Urodynamic System will be purchased by customers separately.

2. Product characteristics

1）Classification as protection against electric shock: Class I

2）Classification as an extent of protection against electric shock: BF type

3）Electromagnetic compatibility group: Group 1 Type A

4）Presence of inflammable anesthetizing gas mixed with air or inflammable anesthetizing gas mixed with oxygen or nitrous oxide not allowed

5）Mode of operation: continuous operation

6）Type BF applied part: Pves pipeline, Pura pipeline, Pabd pipeline,perfusion pump pipeline, infusion pump pipeline, EMG.

3. Operating principle

1) Pressure measurement principle

By taking into account the hydrodynamics principle, the measured bladder pressure, abdominal pressure and urethral pressure are transmitted to each pressure sensor via tube, in which pressure signals are converted to weak electrical signals. Then, these signals are sent to the amplification channel for amplification and further to the analog-digital converter (A/D) for generation of digital signals. These digital signals are subject to data acquisition, processing, display and printing in the computer.

2) Urinary flowrate measurement principle

As specified by the weighing principle, perform continuous measurement on the weight of the urine to obtain the urinary flowrate in the computer, followed by generation of a real-time urinary flowrate graph.

3) EMG measurement principle

It is commonly known that human tissue and organ activities may lead to potential variation. Thus, determination of potential variation may give us indirect indications conducive to understanding how well these tissues or organs function. As a result, it is possible to plot the muscle and neuromuscular junction activities.

4. Block diagram

Ndly 11B Urodynamic System consists of hardware system and software system, in which the hardware system is illustrated in Fig. III below.

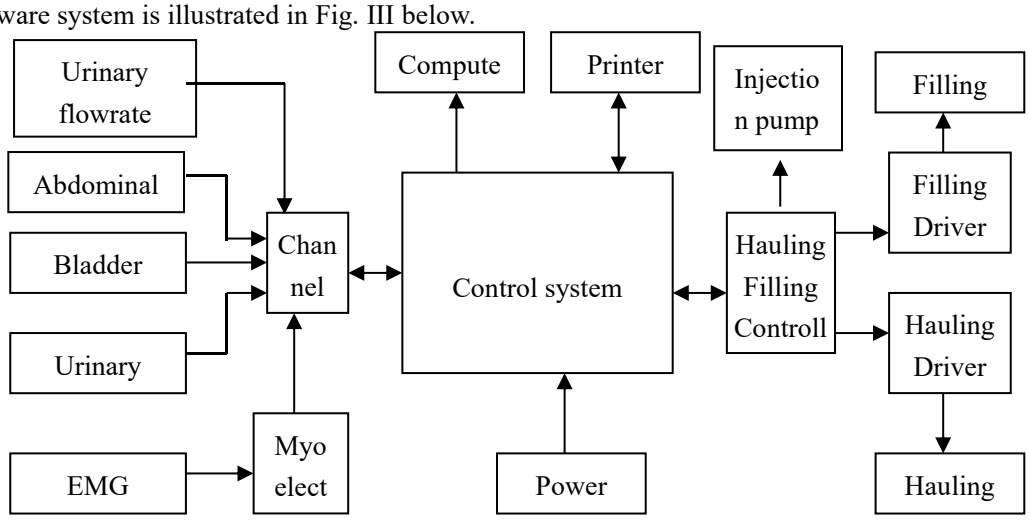


Fig. III Operating principle

The system is configured for computer-based control on operation of the filling pump and hauling device (filling flowrate, hauling velocity), followed by detection, amplification and processing of electrical signals on the bladder pressure, abdominal pressure, urethral pressure, urinary flowrate and myoelectricity in 3 pressure sensors, a weighing sensor and an EMG electrode separately. Then, proceed to analog-digital conversion via A/D card and real-time processing in the computer. Provide screen display of measurement results, and printed reports in a standard format.

Chapter3 Identification and symbol, abbreviation interpretation

S/N	Symbol	Location	Meaning		S/N	Symbol	Location	Meaning
1		On/Off button	Power Off		27	Pura	Product instructions and	Urethral pressure
2	|	On/Off button	Power On		28	VB	Product instructions and	Start micturition
3		Back panel of operating	BF application		29	MF	Product instructions and	Max. urinary flowrate
4		Back panel of control system	Protective earthing		30	VE	Product instructions and	Stop micturition

5		Back of operating system	Functional earthing		31	C1	Product instructions and	First cough
6	F2AL250V	Back of control system	Fuse		32	C2	Product instructions and	Second cough
7	输入 a.c.220V	Back of control system	220V socket plug		33	S1	Product instructions and	Abdomen in
8	信号连接口	Back panel of operating	Signal transmission cable for		34	PB	Product instructions and	Start plotting
9	系统电源座	Back panel of operating	Port of power cable for control		35	MU	Product instructions and	Max. urethral pressure
10	尿流率连接口	Back panel of control system,	Port of urinary flowrate		36	MC	Product instructions and	Max. urethral closure
11	膀胱压力通道	Back panel of operating	Port of bladder pressure		37	PE	Product instructions and	Stop plotting
12	直肠压力通道	Back panel of operating system	Port of rectal pressure sensor to test channel		38	P1	Product instructions and product software	Bladder neck pressure
13	尿道压力通道	Back panel of operating	Port of urethral pressure		39	P2	Product instructions and	Seminal hillock pressure
14	牵引机连接口	Back panel of host computer	Port of hauling device and		40	FD	Product instructions and	Initial micturition desire
15		Instructions requiring attention	Hazards, warnings and		41	SD	Product instructions and	Strong micturition desire
16	EMG	Product instructions and	Myoelectricity		42	UR	Product instructions and	Urgent micturition desire
17		Back of operating system	Nonionizing radiation		43	CC	Product instructions and	Max. bladder capacity
18	CMRR	Product instructions and product	Common mode rejection		44	MP	Product instructions and	Max. detrusor pressure

19	Div	Product instructions and product	Division		45	PQ	Product instructions and	Pressure/flowrate analysis
20	Volum	Product instructions and product	Urine volume		46	AG	Product instructions and	Pressure/flowrate analysis
21	Flow	Product instructions and product	Urinary flowrate		47	LPURR	Product instructions and	Linear passive urethral
22	Pdet	Product instructions and product	Detrusor pressure		48	URA	Product instructions and	Pressure/flowrate analysis
23	Pves	Product instructions and product	Bladder pressure		49	PuraDif	Product instructions and	Urethral closure pressure
24	Pabd	Product instructions and product	Abdominal pressure		50	25 KG	Upper platform of control	Maximum load
25		nameplate	Follow instructions for use		51		nameplate	Manufacturer
26		nameplate	Serial number		52		nameplate	Date of manufacture

Potent 普东医疗	Product	Urodynamic system			
Model	Ndly 11B	SN	xxxxxxxx		xxxx-xx-xx
Voltage	220V-230 Vac	Frequency	50/60Hz	Input Power	220VA
	Guangzhou Potent Medical Equipment Joint-Stock Co.,Ltd ADD: Room 5002-5003,A01 Building, Ping'an Technology Guigu Industrial Park,No.74 Chuangyu Road, Ningxi Street,Zengcheng District, Guangzhou, China				
	Follow instructions for use				

Urodynamic System nameplate

Potent 普东医疗	Product	Urodynamic console			
Model	Kzt 11B	SN	xxxxxxxx		xxxx-xx-xx
Voltage	220Vac	Frequency	50Hz	Input Power	220VA
	Guangzhou Potent Medical Equipment Joint-Stock Co.,Ltd ADD: Room 5002-5003,A01 Building, Ping'an Technology Guigu Industrial Park, No.74 Chuangyu Road, Ningxi Street,Zengcheng District, Guangzhou, China				
	Follow instructions for use				

Urodynamics control console nameplate

Indicators on Urodynamic Urocap:

Link state indicator(Green):

Indicator Status	Equipment status
blink	Already linked
solid	Searching for device

Potent 普东医疗		Product	Urodynamic Urocap		
Model	PT-JNQ	SN	xxxxxxxx		xxxx-xx-xx
Voltage	12V	Frequency	50Hz	Input Power	36VA
	Guangzhou Potent Medical Equipment Joint-Stock Co.,Ltd ADD: Room 5002-5003,A01 Building, Ping'an Technology Guigu Industrial Park, No.74 Chuangyu Road, Ningxi Street,Zengcheng District, Guangzhou, China				
	Follow instructions for use				

Urodynamics urocap nameplate

Back panel of control

Chapter4 Specification

1. Normal operating conditions

Ambient temp.: 5℃-40℃;

Relative humidity: 30-75%;

Atmospheric pressure: 86kPa～106kPa;

No intense electromagnetic interference at workplace;

No strong high-frequency interference with power supply system;

Proper mounting without dislocation and vibration during operation;

Power supply: ～220V-230V, 50Hz/60Hz

Rated input power: 220VA

Fuse rating: F3AL250V

Warning:The equipment can not be used in conjunction with oxygen rich environments.

Use environment:Intended application sites are institutions or units with healthcare capabilities,

including but not limited to: Hospital, emergency rooms, observation room etc.

2. Parameters

1) Urinary flow rate determination device

a) Range of determination of total urine volume: 0mL-1000mL, ±2% error

b) Range of voiding time determination: 0s-240s, ±1% error

c) Range of average urinary flow rate determination: 0mL/s-50mL/s, ±5% error

2) Pressure measurement

Pressure range: -50cmH20(-4.9kPa)～200cmH20(19.6kPa), ±3% error

3) Hauling machine

a) Hauling length: ≥280mm

b) Hauling velocity: 0.5mm/s, 1.0mm/s, 2.0mm/s and 4.0mm/s, ±3% error

4) Filling pump

Range of filling flowrate setting

2mL/min～10mL/min (rise in a rate of 1mL/min.); 0mL/min～50mL/min, ±3% error

10mL /min～80mL/min (rise in a rate of 5mL/min. >50mL/min ±5% error

5) Injection pump

Injection flowrate: 2mL/min～5mL/min (rise in a rate of 1mL/min.); ±3% error

6) EMG measurement

a) Range of amplitude response: 20μV～1mV

b) Electrode wire length: ≥180cm

7) Urodynamics urocap adaptor

a) input:100-240VAC,50/60Hz, 0.5A

b) Output:12V, 1.5A, 18W max

Chapter5 Indications and contraindications

1. Range of application

The Urodynamic System, model Ndly 11B, is a system which can provide doctors with printed graphs on determination of urinary flowrate, bladder pressure, abdominal pressure, urethral pressure and EMG for diagnosis purpose

2. Contraindications

Patients suffering the acute urinary tract infection and acute urethritis are not allowed to undergo urethral catheterization so as to prevent infection diffusion, septicemia and Urethral fever.

Patients not allowed to undergo urethral catheterization due to urethral stricture or other reasons, such as serious automatic hyperreflexia, are not subject to the cystometry examination.

Chapter6 Precautions

1.Put in place the protective earthing wire for ～220V/50Hz power socket to ensure the integrity of the analyzer in operation.

2. Make sure that the EMG-to-ground connection must be completed by means of the analyzer's EMG earthing wire prior to operation so as to protect the analyzer from interference during operation.

3. Carefully read the Chapter "Instrument installation" before wiring.

4. Only urology doctors are allowed to run the analyzer, who must proficiently operate the computer in addition to urodynamics knowledge and skill.

5. Doctors must be present at workplace during testing.

6. When the analyzer is put into clinical application for the first time or resumes operation after shutdown for an extended period, perform cleaning and disinfection of the filling channel and pressure sensor channel to protect patients from infection.

7.The key of operating system should be kept by well-trained serviceman.

8.Replacement of lithium batteries or fuel cells when incorrect replacement would result in an unacceptable risk.

9.The whole equipment is not serviced or maintained while in use with the patient.

10.The equipment supplied with an integral multiple socket-outlet provided.

11.There are two 18650 lithium batteries in the Urinary flowrate determination device. If you have any problems, please contact us.Unauthorized replacement of batteries poses a risk of equipment fire or explosion.

12.Warning: No modification of this equipment is allowed.

13.Computer and printer are connected to multiple socket-outlet which must meet the requirements of the applicable safety standards (e.g. IEC 62368 safety standards for information technology equipment). During using, the responsible user must make sure that ME system meet the requirements of the IEC 60601-1 ME equipment and systems standard.

14.Only computer, printer and the BF part of the equipment can be connected to the system.

15.Operator should not touch the shell of the equipment and the patient at the same time.

Chapter7 Acceptance and installation

1. Instrument installation

It is the responsibility of the manufacturer's representative or designated service provider for analyzer unpacking and installation, as well as field test and acceptance.

1) Unpacking acceptance

a) Precautions

(1) Check package integrity before unpacking;

(2) Put the crate at the front side up without upside down when it is unpacked.

b) Content of inspection

(a) Documents complete with shipment

① Documents complete with shipment One

② Packing list One

③ Certificate of conformity One

④ Warranty card One

(2) Wiring and accessories (see the packing list for details)

c) Spare parts (see the packing list for details)

2) Acceptance

a) Perform acceptance with the packing list attached to the shipment.

b) Run the analyzer as instructed in the manual, making sure that the analyzer operates as expected. If so, acceptance ends.

3) Electrical requirements

The analyzer is designed to operate at 220VA/50Hz without over 10% voltage variation. Utilize a single-phase 3-wire 220V (one wire to the protective earthing). The analyzer must operate at a voltage set by our or authorized technical staff to adapt to the user's power voltage. Moreover, confirm that the AC power supply system has been well earthed with adequate protective earthing wire in place.

4) Instrument installation

a) Always keep the analyzer dry and clean without exposure to humid environment and any load.

b) Make sure that the analyzer can easily be power down.

b) Make sure that the EMG-to-ground connection must be completed by means of the analyzer's EMG earthing wire prior to operation so as to protect the analyzer from interference during operation.

c) Carefully read the Chapter "Instrument installation" before wiring.

d) The auxiliary power sockets in the analyzer are sized at a level only suitable for use with the computer and printer rather than other devices.

5) Operation requirements

a) Only urology doctors are allowed to run the analyzer, who must proficiently operate the computer in addition to urodynamics knowhow and skill. Doctors must be present at workplace during testing.

When the analyzer is put into clinical application for the first time or resumes operation after shutdown for an extended period, perform cleaning and disinfection of the filling channel and pressure sensor channel to protect patients from infection.

2. Software installation

It is the responsibility of the manufacturer's representative or designated service provider for analyzer software installation, as well as field test and acceptance.

3. Liquid circuit connection

1) Ndly 11B filling pump liquid circuit connection

a) Put a bottle of 500mL filling solution at standby.

b) Obtain the filling tube and adaptor out of the accessory kit: a creep pressure tube, an infusion tube with buffer chamber and a 1400mm pressure transfer tube separately. Remove the nuts at the outer ends of the creep pressure tube to facilitate adaptation to the infusion tube and pressure transfer tube. Complete connection to the creep pressure tube by tightening the nuts, as illustrated in the right of Fig. IV.

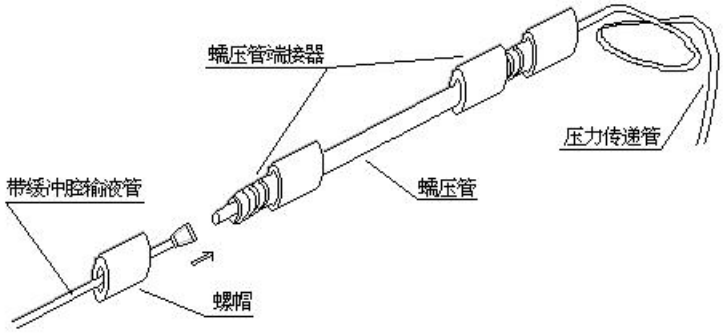


Fig. IV

c) Fit the assembled circuit onto the filling pump in a clockwise direction from the right to the left. This installation allows the creep pressure tube's right endface to fit against the pump casing and excess of the creep pressure tube to remain in the left (as illustrated in Fig. V).

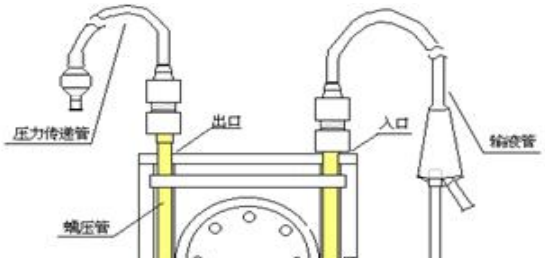


Fig. V

d) Insert the tip of infusion tube into the filling bottle. Attach the pressure transfer tube adaptor to the holder, and then put the bottle on the holder.

Note: Putting the filling bottle upside down is prohibited until the pump is closed or the pressure transfer tube outlet is positioned.

An individual holder is sized for 1kg load, and max. 5kg during operation.

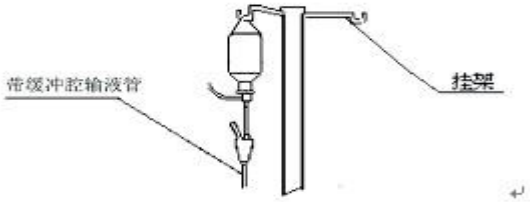


Fig. VI

2) Pressure transfer tube circuit connection

a) Obtain out of the accessory kit a sensor, a 20mL injector and a liquid circuit connection tube.

b) Put the liquid circuit connection tube into the water intake in the top of the sensor, as illustrated below (note: operation by force is prohibited to prevent sensor damage).

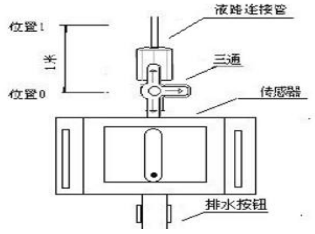


Fig. VII

c) Rotate the sensor-mounted rotary valve to a horizontal position to put the tee at a closing position (tee's On/Off status as illustrated below).

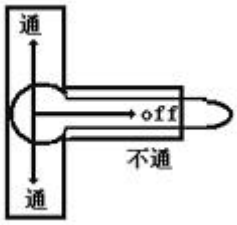


Fig. VIII

d) Attach the pressure transfer tube to the screwcap adaptor at the top of the sensor.

e) Complete assembly of other two liquid circuits by repeating the above a, b, c and d. Position the assembled sensor and pressure transfer tube on the jig fixture, as illustrated below.

Fig. IX

4. Manufacturer's standard configuration

The manufacturer’s standard configuration may provide preset parameters at the time of analyzer delivery, which are deemed as settings by default provided no change is made by users, as detailed below:

	Abbreviation	Unit	Parameter setting at delivery	Range of parameter setting
Pressure-flowrate-myoelectricity simultaneous determination	Urine volume (Volume)	mL/div	100	100 、200、500
	Urinary flowrate (Flow)	mL/s/div	10	1、2、5、10
	Detrusor pressure (Pdet)	cmH_2O/div	20	5、10、20、30、50
	Bladder pressure (Pves)	cmH_2O/div	20	5、10、20、30、50
	Abdominal pressure (Pabd)	cmH_2O/div	20	5、10、20、30、50
	Electromyography (EMG)	μV/div	50	1、2、5、10、20、50、100、200、500
	Horizontal scale	s/div	2	2、4、6、8、10、12、14、16、18、20、24、26、28、30
	Filling rate	mL/min	50	2、3、4、5、6、7、8、9、10、15、20、25、30、35、40、45、50、55、60、65、70、75、80
Bladder pressure determination in the filling period	Detrusor pressure (Pdet)	cmH_2O/div	20	5、10、20、30、50
	Bladder pressure (Pves)	cmH_2O/div	20	5、10、20、30、50
	Abdominal pressure (Pabd)	cmH_2O/div	20	5、10、20、30、50
	Horizontal scale	s/div	2	2、4、6、8、10、12、14、16、18、

				20、24、26、28、30
	Filling rate	mL/min	50	2、3、4、5、6、7、8、9、10、15、20、25、30、35、40、45、50、55、60、65、70、75、80
Urethral pressure determination	Urethral pressure (Pura)	cmH_2O/div	20	5、10、20、30、50
	Urethral closure pressure (PuraDif)	cmH_2O/div	20	5、10、20、30、50
	Bladder pressure (Pves)	cmH_2O/div	20	5、10、20、30、50
	Horizontal scale	s/div	2.0	2、4、6、8、10、12、14、16、18、20、24、26、28、30
	Filling rate	mL/min	2	2、3、4、5、6、7、8、9、10、15、20、25、30、35、40、45、50、55、60、65、70、75、80
	Hauling velocity	mm/s	2.0	0.5、1.0、2.0、4.0
Urinary flowrate	Urinary flowrate (Flow)	mL/s/div	10	1、2、5、10
	Horizontal scale	s/div	2	2、4、6、8、10、12、14、16、18、20、22、24、26、28、30

Note:

Users may not necessarily make change to the above manufacturer's standard configuration. Users may use the above parameters whenever deemed necessary to make change. The system may reset to the default settings when after reboot. Please refer to the Section below for more details on setting.

5. Instrument calibration

As the analyzer has been well calibrated before delivery, recommend to undergo calibration once a month. Integrity and accuracy of measurement results depend on how well the analyzer is calibrated. Thus, a password for calibration has been set to prevent confused data arising from unauthorized operation. The password is Ndly11AX.

Instrument calibration is necessary under one of the following circumstances:

① Uncertain about accuracy of measurement results even though the analyzer hardware, software, sensor and tubes demonstrate operation as expected;

② At the time of replacement of sensor, creep pressure tube, etc.;

③ Perform calibration when the creep pressure tube has been working for a period. Close all sub-windows, and click on "System calibration" with mouse to select any item requiring calibration:

1) Urinary flowrate channel calibration

Necessary appliances: 1000mL urine cup and 100mL graduated cylinder.

Select "Pressure channel and urinary flowrate calibration", and enter the password for access to the dialog box. Click on "Urinary flowrate calibration" with mouse to proceed to operation as instructed in the screen:

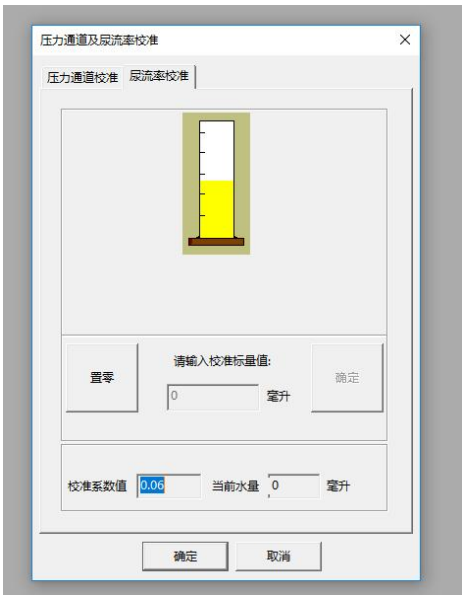


Fig. X

a) Drain the urine cup of the urinary flowrate sensor. About half a minute later, click to start with mouse, and the dialog box says that the system initialization is underway. A dialog box pops up after initialization is done. Then, charge with water the urine cup of the urinary flowrate sensor, and enter the quantity of charge in mL. About half a minute later, click to start with mouse. The system automatically completes calibration.

Proceed to the urinary flowrate determination for double check if necessary. Charge with water again to check whether the indicated water volume is the same as the quantity of charge. If not, re-calibrate.

b) Press on "OK" after calibration to return to the master control interface.

2) Pressure channel calibration

Necessary appliances: 3 200mm standard hooks (accessories complete with shipment).

Select “Pressure channel and urinary flowrate calibration”, and enter the password for access to the dialog box. Click on “Pressure channel calibration” with mouse to proceed to operation as instructed in the screen:

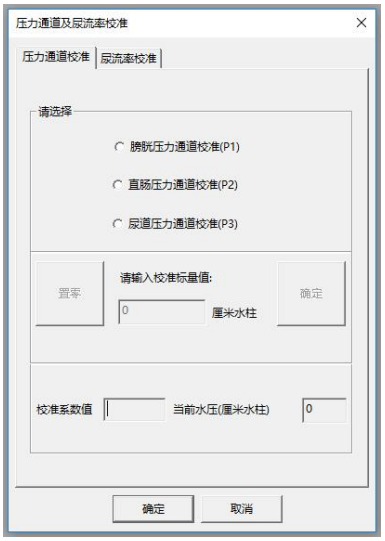


Fig. XI

a) Select a pressure channel requiring calibration. Attach the holder-mounted liquid bottle hose to the pressure sensor.

b) Attach the liquid bottle to the holder with use of 3 (or 2) hooks to keep the level in the liquid bottle to approach the sensor elevation. This elevation is set as a calibration zero. Click to start with mouse, and the dialog box says that the system initialization is underway. A dialog box pops up after initialization is done.

c) By removing the standard hooks, directly attach the liquid bottle to the holder and maintain the level unchanged. Enter the water column value in cm representing how far the liquid bottle moves up, as instructed in the screen, i.e. the length of standard hook being used (200mm). Click on Ok with mouse, and the instrument automatically completes calibration of this pressure channel. Proceed to simultaneous determination for double check if necessary. Move the liquid bottle up and down to check whether the changing water column in cm is the same as the indicated value. If not, re-calibrate.

d) Perform calibration of other two pressure channels with the above steps.

e) A store icon pops up after calibration. Click on the icon to store the data. Press on "OK" to return to the master control interface.

3) Filling pump calibration

Necessary appliance: 100mL graduated cylinder.

Select “Filling pump calibration”, and enter the password for access to the dialog box below. Click on “Filling pump calibration” with mouse to proceed to operation as instructed in the screen:

Fig. XII

a) Select the filling flowrate at 80mL/min., and start the filling pump for tube venting.

b) Select the total flowrate and filling flowrate to be calibrated.

c) Put the liquid bottle hose outlet into an empty graduated cylinder (no air allowed during filling). Start the filling pump.

d) When filling stops, enter in the “Actual filling volume” the liquid volume in the graduated cylinder in mL. Click on calibration so that the instrument automatically completes calibration. Drain the graduated cylinder for double check if necessary. Restart the filling pump for filling to check whether the actual filling volume is the same as the selected total flowrate. If not, re-calibrate.

e) Perform calibration of other filling flowrate with the above steps.

f) Click on "Exit" after calibration to return to the master control interface.

4) Hauling device calibration

Necessary appliance: 100mm ruler.

Select “Hauling device calibration”, and enter the password for access to the dialog box below. Proceed to operation as instructed in the screen:

Fig. XIII

a) Select the distance and hauling speed to be calibrated. Click on “Start” to start movement of the hauling head.

When the hauling head stops, figure out the distance of movement with the ruler, to be entered into the “Actual hauling length”. Click on “Calibration” so that the system automatically completes calibration of the selected speed. Reposition the hauling device for double check if necessary. Check whether the actual hauling distance is the same as the selected hauling distance. If not, re-calibrate.

c) Perform calibration of other hauling velocities with the above steps.

d) Click on "Exit" after calibration to return to the master control interface.

5) Injection pump calibration

a) Perform the injection pump calibration in the same steps as that for the filling pump. Perform calibration at 2mL/min, 3mL/min, 4mL/min and 5mL/min separately.

b) Click on "Exit" after calibration to return to the master control interface.

Chapter8 Operation method

1. Preparations

Keep in mind the following points before operation to assure proper operation of the analyzer:

a) Presence of air bubbles in the anorectal manometry tube may lead to negative abdominal pressure. Remove all air bubbles before use.

b) Request patients to remain calm and still from the zero clearing till testing completion. After reset to zero, the position of the anorectal manometry tube may be varied as a result of patients’ position change, leading to a position different from that at zero clearing, and consequently the abdominal pressure change. Thus, diagnosis accuracy may be challenged as a result of the ensuing detrusor pressure change. Under such circumstance, diagnosis may mainly depend on the bladder’s internal pressure.

c) Patients shall get relaxed to facilitate testing. The zero clearing accuracy may be challenged if the rectum repeatedly withdraws.

d) Patients shall relieve themselves without desire to defecate. Otherwise, the rectum may repeatedly withdraw, or the manometry tube is covered with feces, affecting testing accuracy. Moreover, the zero clearing accuracy may be challenged if patients have desire to defecate.

e) For simultaneous determination and bladder pressure filling determination, patients are generally told to cough, which may lead to the inhibited contraction so that the manometry tube is likely to relocate or slide out as cough continues, thus affecting testing results.

f) Testing results may be challenged if the manometry tube is not correctly positioned. Ask patients to cough. Typically, the abdominal pressure and bladder pressure curves move up simultaneously in the same amplitude while the detrusor pressure shows no variation or a lower negative biphasic with pretty small amplitude only. If the detrusor pressure also rises, and the bladder pressure rises much faster than the abdominal pressure, check whether related tubes are correctly connected and positioned.

g) For urethral pressure measurement, both the urethral pressure and urethral closure pressure are not placed at zero initially while the bladder pressure is at zero. Perform zero clearing again.

h) Carry out zero clearing to set a zero so as to start testing from this zero as benchmark. The rectum contraction or manometry tube relocation arising from any external influence may lead to change to the abdominal pressure. The detrusor pressure is obtained from calculation (detrusor pressure=bladder pressure – abdominal pressure) rather than direct determination.

i) User shall make replacement of any liquid circuit connection tube, manometry tube and creep pressure tube which are not disinfected or not working well as a result of age hardening before patient testing.

j) Use conduits which are disposal sterile products complying with national standards when the analyzer is used for patient testing.

k) Other devices which are rated to emit at a level complying with national standards are likely to interfere with normal operation of the analyzer.

l） The whole equipment shouldn’t serviced or maintained while in use with the patient.

m）The access covers of Urodynamic System are not allowed to be opened unless the analyzer stops running for over 30 seconds.

2. Operation steps

1) System overview

Ndly 11B operates with Windows-based operating system, featuring a friendly operation interface conducive to simple operation and adequate visualization. The analyzer is configured for mouse operation as instructed in the software system. The system provides access to an easily understood online operation guideline for the purpose of search during operation.

The system function and operation process are as illustrated below:

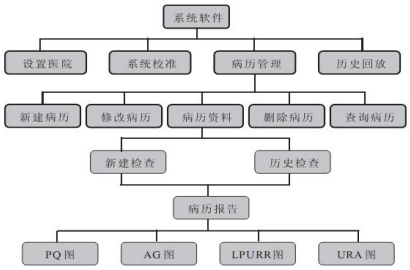


Fig. XIV

2) Hospital setting

Select “Hospital message” option in the menu bar “Hospital setting” [or click on the left mouse]. Fill out the dialog box being popped out. Close the dialog box by click on “Ok”. End the hospital setting. Click on “Cancel” button, meaning no hospital name is set.

3) System calibration

Select items requiring calibration in the menu bar to proceed to calibration. For more details, refer to Chapter IV Instrument calibration.

4) Medical records management

a) Create patients information:

Select “Establish medical records” option in the menu bar “Medical records operation” or tool bar. Fill out the dialog box being popped out. Close the dialog box by click on “Ok” to end establishment. Click on “Cancel” button to cancel establishment.

Fig. XV

Fig. XVI

Note: ensure every patient (first consultation or further consultation) to have unique basic information as redundant information is unnecessary.

b) Revise patients information:

Select with mouse any information requiring revision. Select "Revise medical records" option, and carry out revision in the popped dialog box.

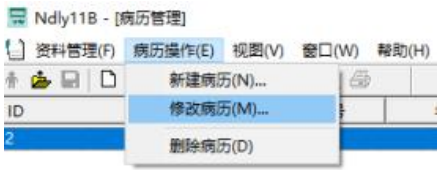


Fig. XVII

c) Delete information:

Select with mouse any information requiring deletion. Select "Delete medical records" option. Deleted information will not be restored any more.

d) View detailed information:

Select with mouse basic information of a patient. Select the “Historical records” option. Now, a new window containing all tests done for this patient will appear.

Fig. XVIII

e) Medical records

(1) Create new testing:

Select the “Create new test” option in the tool bar. Fill out the popped dialog box. Click on “Ok” button to close the dialog box to end establishment of new test. A “Establish new test” window will automatically appear. Click on “Cancel” button to cancel new test.

Fig. XIX

(2) Revision:

Select with mouse any information requiring revision. Select "Revise testing" option, and carry out revision in the popped dialog box.

(3) Delete

Select with mouse any information requiring deletion. Select "Delete testing" option. Deleted information will not be restored any more.

(4) View historical records

Select with mouse any testing information of a patient. Select the “Historical records” option in the menu bar “View”. A new window containing historical records on all tests done for this patient will automatically appear.

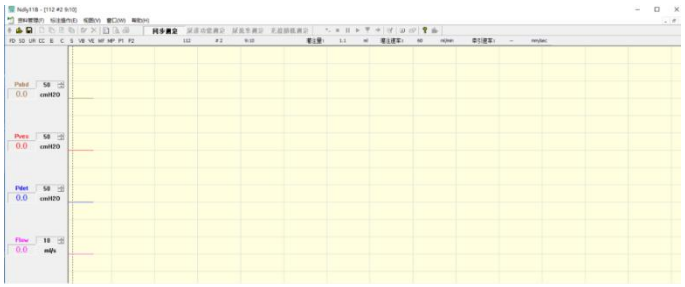


Fig. XX

(5) Report and printing:

Select with mouse any testing information of a patient. Select the “Records view” option in the menu bar “View”. A report window will automatically appear. Note: report view is as illustrated in Fig. XXII.

Fig. XXI

Fig. XXII (date)

f) Search information

(1) Go to the "Medical records management" interface. Select the "Condition search" option in the menu and a search dialog box pops up.

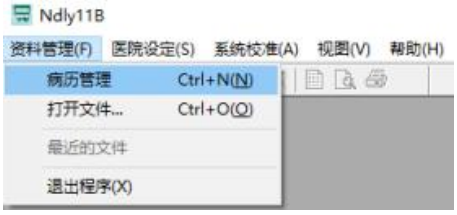


Fig. XXIII

Fig. XXIV

(2) Search is divided into "Classification search" and "Display all information".

① If “Display all information” is selected, directly proceed to click on “Ok” button. All information of all patients will appear.

② If “Classification search” is selected, proceed to complete “Search condition”. Max. 3 search conditions are available, including S/N of a column being selected and the content of the column (vary from different columns).

③ A new window containing search results will appear. The edition of search results is impossible.

Fig. XXV

3. Operation steps with Ndly 11B

The steps of determination in 4 urodynamics items are detailed in this Section. The same methods in establishment and management of patients medical records may apply to individual determination.

1) Simultaneous determination, i.e. pressure - flowrate - electromyography simultaneous determination

a) Required assemblies: pressure sensor P1 and P2, urinary flowrate determination device, filling pump, urodynamics tube, anorectal manometry tube, muscle electrode and leg electrode.

b) Patient preparation: Patient shall drain the bladder as much as possible, and lie on the bed in preparation for testing.

c) Preparations:

(1) Clean the skin of the anal week and knee parts, if the hair is strong, it should be clean up first.

(2) Place two electrodes(L/R) peri-anally at the 9 o’clock and 3 o’clock position,as close to the anal verge as possible.Place the third electrode(F) on a bony prominence(such as the knee) or on a fatty portion of the inner thigh.

(3) Attach the muscle electrode pad to the sphincter.

(4) Attach the EMG electrode cable into the electrode socket.

(5) Complete connection of pressure sensor and urinary flowrate determination device to the channel unit.

(6) Put the filling system in good condition by ensuring that the filling channel is working well.

(7) Remove air out of the pressure sensor and pressure transfer tube.

(8) Start the analyzer for calibration of pressure sensor, urinary flowrate sensor and filling pump (whenever necessary or not required).

(9) Connection of pressure measurement tube:

As instructed, attach the green port of urodynamics tube to the filling tube, and the red port to the bladder pressure sensor P1 (Pves);

Attach the anorectal manometry tube to the abdominal pressure sensor P2 (Pabd).

(10) Conduct the bladder and rectal intubation under the sterile condition:

Put the urodynamics tube into the patient's bladder to a depth until two test ports just penetrates into the bladder.

Deal with any possible urine with a small cup during operation. Figure out the remaining urine volume with a graduated cylinder, to be entered in the result page after determination.

Put the anorectal manometry tube into the patient's anus.

(11) Fix with ribbon the urodynamics tube, anorectal manometry tube and electrode lead onto the patient's leg to prevent dislocation of the inserted tubes

d) The simultaneous determination interface is as illustrated below, indicating the determination in steps below:

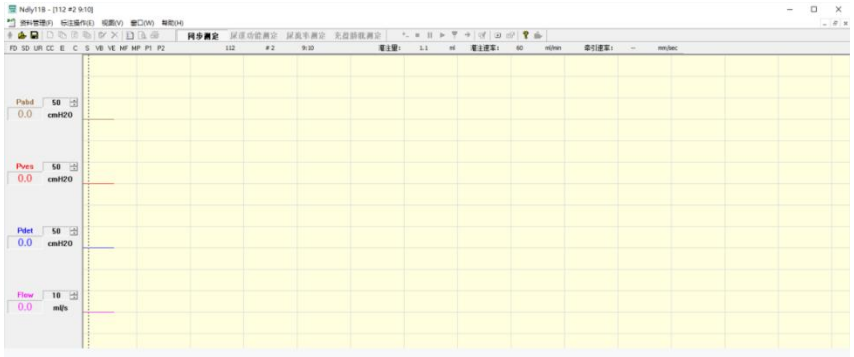


Fig. XXVI

(1) Setting of determined parameters

① Proportionality coefficient setting and default value

i.e. determination of display scale in the curve's longitudinal graphics, including

Urinary volume (Volum), default value = 100mL/div (milliliter per division)

Urinary flowrate (Flow), default value = 10mL/s/div (milliliter per second per division)

Bladder detrusor pressure (Pdet), default value = 20 cmH2O/div (centimeter water column per division)

Bladder pressure (Pves), default value = 20 cmH2O/div (centimeter water column per division)

Abdominal pressure (Pabd), default value = 20 cmH2O/div (centimeter water column per division)

Myoelectricity (EMG), default value = 50 μV/div (microvolt per division)

Typically, conduct determination at default values. Whenever necessary, vary the values by press on the arrow.

Fig. XXVII

② Filling rate setting and default value

Default value=50mL/min (milliliter per minute). Reset in steps below whenever necessary.

Fig. XXVIII

③ Horizontal scale sett and default value

i.e. determination time value represented by x-coordinate, default value=2s/div (second per division). Reset whenever necessary.

Fig. XXIX

(2) Select the "Zero clearing" option in the menu bar "Check operation". The system automatically performs zero calibration on 3 test channels except for EMG. Zero calibration ends about 8sec. later.

Fig. XXX

(3) Click on “Start” in the menu bar “Check operation” to start determination. Provide the real-time indication of determination curve in the screen and real-time indication of filling volume in the left top corner of the screen. Ask the patient if he/she has micturition desire across the determination. Click on “Initial micturition desire” – “Strong micturition desire” – “Urgent micturition desire” as indicated in the bottom of the screen. Make FD, SD and UR marks in turns at an appropriate moment. When the patient shows an urgent micturition desire (bladder painful distension), max. bladder capacity is reached.

Make CC mark at “Max. bladder capacity”, and stop the filling pump immediately. Allow micturition to start determination over the micturition period.

Note: when the obtained bladder pressure arrives at 150cmH2O during filling, the filling pump will automatically stop to protect the patient from injury. It is allowed to create a new testing permitting re-determination by means of “Exit” during determination.

Fig. XXXI

Fig. XXXII

Fig. XXXIII

(4) Click on “Analyze data” after micturition so that the instrument stops data acquisition and automatically stores the determination data. A dialog box below will appear.

Click on “Yes (Y)” to allow re-entry. The determination curve is automatically zoomed out in a screen so that the horizontal scale will vary accordingly. In addition to described FD, SD, UR and CC marks, make VB and VE marks manually. The instrument will automatically make MF and MP marks in the curve.

Fig. XXXIV

Fig. XXXV

In the case of need to re-mark, press with mouse to hold the marker line, and drag it to a location requiring marking. Right click on the mouse to obtain items permitting marking, followed by left click on the mouse. Press on “Store marking” after marking. Otherwise, marking may become invalid.

Fig. XXXVI

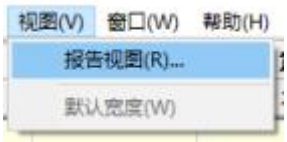


Fig. XXXVII

Click on "Report view" to obtain determination values. Enter the remaining urine volume in the remaining urine volume column of determination result page.

Fig. XXXVIII

Click on "Plot P-Q graph" to obtain the pressure-flowrate graph. Similarly, it is possible to plot A-G graph, LPURR graph and URA graph.

PQ	Pressure/flowrate analysis
AG	Pressure/flowrate analysis
LPURR	Linear passive urethral resistance ratio graph
URA	Pressure/flowrate analysis

Fig. XXXIX

Click on "Print" to obtain the printed graphic result output on the determination curve and determination value.

Click on "Close" to exit the determination interface.

2) Bladder pressure determination in the filling period

a) Required assemblies: pressure sensor P1 (Pves) and P2 (Pabd), filling pump, urodynamics tube and anorectal manometry tube.

b) Patient preparation: Patient shall drain the bladder as much as possible, and lie on the bed in preparation for testing.

c) Preparations:

(1) Confirm that the pressure sensor has been wired to the host computer.

(2) Put the filling system in good condition by ensuring that the filling channel is working well.

(3) Remove air out of the pressure sensor and pressure transfer tube.

(4) Start the instrument for calibration of the pressure sensor and filling pump (calibration whenever required).

(5) Connection of pressure measurement tube:

① As instructed, attach the green port of urodynamics tube to the filling tube, and the red port to the bladder pressure sensor P1 (Pves);

② As instructed, attach the anorectal manometry tube completing air removal to the abdominal pressure sensor P2 (Pabd).

(6) Conduct the bladder and rectal intubation under the sterile condition:

① Put the urodynamics tube into the patient’s bladder.

Deal with any possible urine with a small cup during operation. Figure out the remaining urine volume with a graduated cylinder, to be entered in the result page after determination.

② Put the anorectal manometry tube into the patient's anus.

(7) Fix with ribbon the urodynamics tube, anorectal manometry tube and electrode lead onto the patient’s leg to prevent dislocation of the inserted tubes.

Enter the patient's medical records after operation mentioned above. Proceed to the filling bladder pressure determination page for determination.

d) Determination steps:

(1) Setting of determined parameters (refer to the setting of simultaneously determined parameters)

(2) Click on "Zero clearing" so that the system automatically performs zero calibration on 3 test channels. Zero calibration ends about 8sec. later.

(3) Click on “Start” to start determination. Provide the real-time indication of determination curve and filling volume in the screen. Ask the patient if he/she has micturition desire across the determination. Click on “Initial micturition desire” – “Strong micturition desire” – “Urgent micturition desire” as indicated in the bottom of the screen. Make FD, SD and UR marks in turns at an appropriate moment. When the patient shows an urgent micturition desire (bladder painful distension), max. bladder capacity is reached. Make CC mark at “Max. bladder capacity”, and stop the filling pump immediately. It is allowed to create a new testing permitting re-determination by means of “Exit” during determination. (Note: when the obtained bladder pressure arrives at 150cmH2O during filling, the filling pump will automatically stop to protect the patient from injury.)

(4) Click on “Analyze data” after filling so that the instrument stops data acquisition and automatically stores the determination data. A dialog box below will appear. Click on “Yes (Y)” to allow re-entry. The determination curve is automatically zoomed out in a screen so that the horizontal scale will vary accordingly.

(5) Marking (refer to Note in the simultaneous determination method): click on "Report view" to obtain determination values. Press on the arrow to select the bladder compliance (set high, low, normal options) in the determination result page. Enter the remaining urine volume in the remaining urine volume column of determination result page. Click on "Print" to obtain the printed graphic result output on the determination curve and determination value. Click on “Close” to return to the preceding interface.

3) Urethral function determination

a) Required assemblies: pressure sensor P1 and P3, filling pump (injection pump), hauling device, urodynamics tube and Y type tee.

b) Patient preparation: Patient shall lie on the bed in preparation for testing.

Precautions:

(1) Confirm that the pressure sensor has been wired to the host computer.

(2) Put the filling system in good condition by ensuring that the filling channel is working well.

(3) Remove air out of the pressure sensor and pressure transfer tube.

(4) Start the analyzer for calibration of pressure sensor, filling pump and hauling device (whenever necessary).

(5) Connection of pressure measurement tube:

① As instructed, attach the green port of urodynamics tube to the bladder pressure sensor P1 (Pves), and the red port to an end of Y type tee.

② Connect other two ends of Y type tee to the filling tube and urethral pressure sensor P3 (Pura) separately. Ensure full air removal out of the tube.

(6) Fix the assembled urodynamics tube with clamp on the hauling device.

(7) Conduct the bladder intubation under the sterile condition. (Note: test hole must remain inside the bladder when the urodynamics tube is inserted.)

c) Determination steps:

(1) Setting of determined parameters (refer to the setting of simultaneously determined parameters)

(2) Go to the determination interface by selecting filling or injection. Now, the hauling device head automatically resets to the start position. Click on "Zero clearing" so that the system automatically performs zero calibration on 3 test channels. Zero calibration ends about 8sec. later.

(3) Click on “Start” to start determination. Provide the real-time indication of determination curve in the screen as both the filling pump and hauling device start operation at the same time. The patient may be asked to cough or conduct abdomen in conducive to increased abdominal pressure if required during determination. Mark appropriately.

(4) Stop pressure measurement once the urodynamics tube side hole is exposed beyond the external urethral orifice. Click on “Analyze data” so that the instrument stops data acquisition and automatically stores the determination data. A dialog box below will appear. Click on “Yes (Y)” to allow re-entry. The determination curve is automatically zoomed out in a screen so that the horizontal scale will vary accordingly. Make PB, PE, P1 and P2 marks manually. The instrument will automatically make MC and MU marks in the curve.

(5) Marking (refer to Note in the simultaneous determination method): click on "Report view" to obtain determination values. Click on "Print" to obtain the printed graphic result output on the determination curve and determination value. Click on “Close” to return to the preceding interface.

Note: the bladder neck pressure mark P1 must be added to this determination. Seminal hillock pressure mark P2 must be added for male patient. Otherwise, no determined parameters are obtained.

4) Urinary flowrate determination device

a) Connect the urinary flowrate device to the channel unit.

b) Determination steps:

(1) Setting of determined parameters (refer to the setting of simultaneously determined parameters)

(1) Click on "Zero clearing" so that the system automatically conducts zero calibration on urinary flowrate. The zero calibration ends about 8sec. later.

(3) Click on “Start” to start determination. The patient may have micturition in the course of determination. Provide the real-time indication of determination curve.

(4) Click on “Analyze data” after micturition so that the instrument stops data acquisition and automatically stores the determination data. A dialog box below will appear. Click on “Yes (Y)” to allow re-entry. The determination curve is automatically zoomed out in a screen so that the horizontal scale will vary accordingly.

(5) Marking (refer to Note in the simultaneous determination method): click on "Report view" to obtain determination values. Click on "Print" to obtain the printed graphic result output on the determination curve and determination value. Click on “Close” to return to the preceding interface.

Chapter9 Testing method and parameter

1. Determination graph

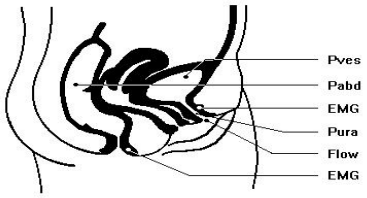


Fig. XL

Calculated curve: Pdet, PuraDif, Volum and EMGave.

In which: Pdet = Pves - Pabd PuraDif = Pura - Pves

Volum = ∫ Flow * dt EMGave = ∫ | EMG | * dt

All determined parameters for the analyzer are defined as specified by the International Continence Society (ICS).

Name	Meaning	Unit
Pves (bladder pressure curve)	The bladder pressure is sum of abdominal pressure and bladder detrusor pressure, plotted in a curve from actual measurement.	cmH_2O
Pabd (abdominal pressure curve)	Represented by the rectal pressure or vaginal pressure, and plotted in a curve from actual measurement.	cmH_2O
Pdet (bladder detrusor pressure curve)	Detrusor pressure is obtained from the actually measured bladder pressure minus the actually measured abdominal pressure, which is a calculated curve.	cmH_2O
Pura (urethral pressure curve)	Urethral pressure is pressure inside the urethral cavity, which is plotted in curve from actual measurement.	cmH_2O
PuraDif (urethral closure pressure curve)	Urethral closure pressure is obtained from the actually measured urethral pressure minus the actually measured bladder pressure, which is a calculated curve.	cmH_2O
Flow (urinary flowrate curve)	It is a curve indicating the micturition volume during micturition.	mL/s
Volum (micturition volume curve)	Micturition volume is obtained from the actually measured urinary flowrate, which is a calculated curve.	mL
EMG (electromyography)	Collect bio-electricity signals being generated from the urethral rhabdosphincter (or sphincter ani externus muscle).	uV
EMGave (processed electromyography)	Processed electromyography	uV

2. Determination method, parameter determination, reference value, typical graph and mark

1) Urinary flowrate determination device

a) Determination method

(1) Standing posture (mainly male);

(2) Kneeling-squatting posture (mainly female);

(3) Supine posture (for patients with urinary catheter)

b) Parameter determination

Name	Meaning	Unit
Max. urinary flowrate (MF)	Max. value or peak value obtained from determination of urinary flowrate	mL/s
Average urinary flowrate	Quotient obtained from the total urine volume divided by the micturition time. This parameter may be workable provided there is uninterrupted micturition free of dripping discharge urine.	mL/s
Urine flow time	Time period on urine flow measured from micturition	s
Micturition time	Entire time period on micturition, including micturition interruption time. If there is a totally uninterrupted micturition process, the micturition time is just the urine flow time.	s
Max. urinary flowrate time	Time period starting from the urine flow until max. urinary flowrate (MF) is reached	s
Total urine volume	Total volume of urine being drained out of the body via urethra during determination	mL

c) Marking

Name	Meaning	
VB micturition start	A moment marked to indicate that the urinary flowrate has been present and detected. Typically, urinary flowrate beyond 0.5mL/s within 0.5s is deemed to be present.	
MF max. urinary flowrate	Mark a moment that max. urinary flowrate is present.	
VE micturition stop	A moment marked to indicate micturition stop, i.e. a moment that urinary flowrate beyond 0.5mL/s is present at the end of micturition.	
C1	First cough	
C2	Second cough	
S1	Abdomen in	

d) Typical graph and mark

(1) Normal curve: in a parabolic shape, as illustrated in Fig.XLI.

(2) Abnormal curve:

① Intermittent micturition, as illustrated in Fig. XLII.

② In a platform shape, as illustrated in Fig. XLIII.

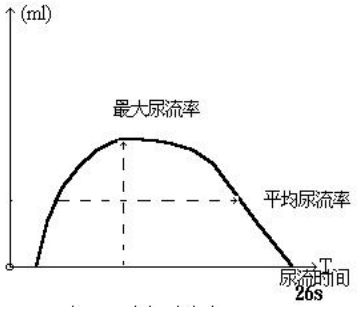


Fig. XLI Normal urinary flowrate

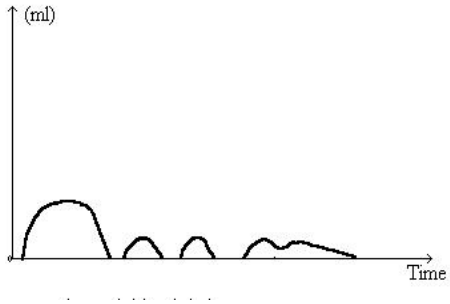


Fig. XLII Intermittent urinary flowrate

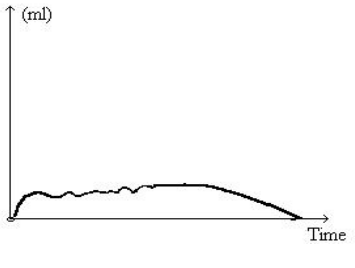


Fig. XLIII Low urinary flowrate

2) Plotting of urethral pressure graph

a) Method: Supine posture, filling flowrate at 2-10mL/min, hauling speed at 2mm/s.

b) Parameter determination

Determination of the following parameters is performed via plotting of urethral pressure graph (refer to Fig. XLIV):

Name of determined parameter	Meaning	Unit
Max. urethral pressure	Max. pressure obtained in the course of urethral pressure determination	cmH_2O
Max. urethral closure pressure	Difference from max. urethral pressure minus bladder pressure during simultaneous determination of urethral pressure and bladder pressure	cmH_2O
Bladder neck pressure	First peak position at the posterior urethra, 1/3 between the bladder outlet and max. urethral pressure	cmH_2O
Functional urethral length	A urethral length higher than the bladder internal pressure at the posterior urethra	cm
Urethral control zone length (female)	A distance from an initial point higher than the internal bladder pressure at the posterior urethra to max. urethral closure pressure point	cm
Prostatic length (male)	A distance from the urethral orifice to max. urethral closure pressure point	cm
Seminal hillock pressure (male)	Pressure at the seminal hillock of the posterior urethra	cmH_2O

c) Marking

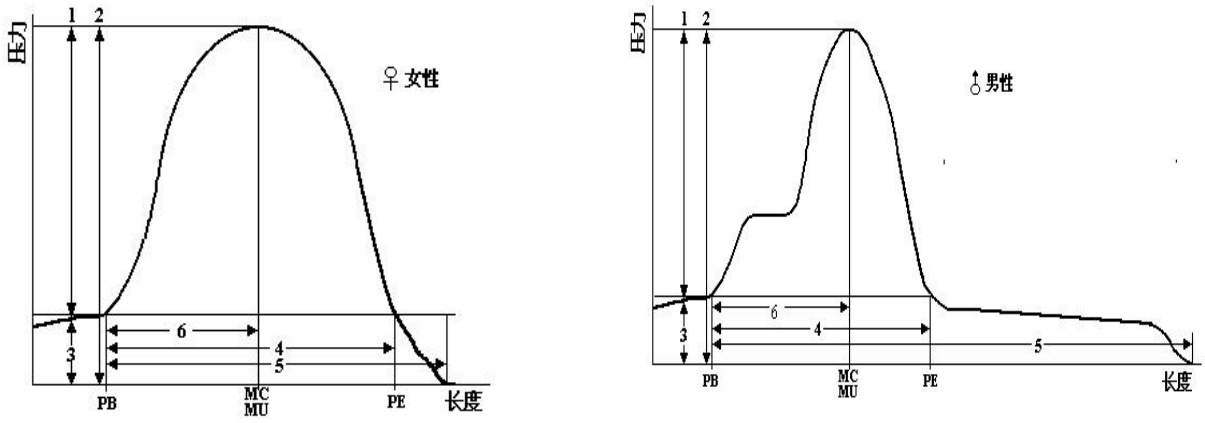
Name of determined parameter	Meaning	Unit
PB plotting start	A position marking the internal urethral orifice. In the determination curve, the internal urethral orifice is typically set at a position where the urethral pressure rises beyond the urethral initial pressure by 1cmH2O within 2sec.	cmH_2O
MU max. urethral pressure	A position marking max. urethral pressure	cmH_2O
MC max. urethral closure pressure	A position marking max. urethral closure pressure	cmH_2O
PE plotting end	A position marking the urethral end. In the determination curve, the urethral end is typically set at a position where the urethral pressure drops below the urethral initial pressure.	cm
P1 bladder neck pressure	A position marking the bladder neck	cmH_2O
P2 seminal hillock pressure	A position marking the male seminal hillock. In the male urethral pressure plotting graph, the seminal hillock is typically set at a position where a pressure before max. urethral pressure is reached arrives.	cmH_2O
C1 first cough/C2 second cough/S1 abdomen in		

d) Typical graph and mark

(1) Normal curve:

① Parabolic shape for female, as illustrated in XLIV.

② Saddle or trapezoid shape for male, as illustrated in XLIV.



1. Max. urethral closure pressure 2. Max. urethral pressure 3. Internal bladder pressure

4. Functional urethral length 5. Determination length 6. Urethral control zone length (female)

Fig. XLIV Schematic of male and female urethral pressure

(2) Abnormal curve

① There are 4 types of abnormal curve for female, as illustrated in Fig. XLV, XLVI, XLVII and XLVIII separately;

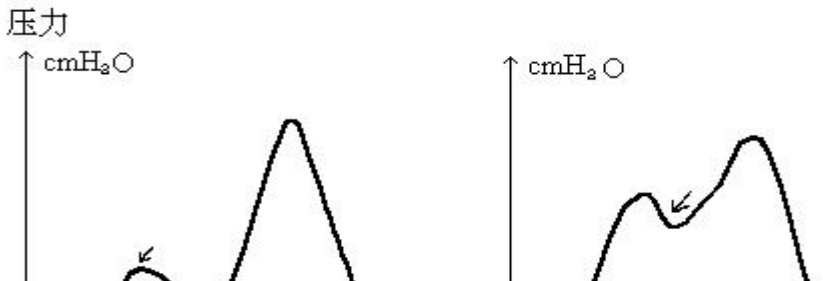
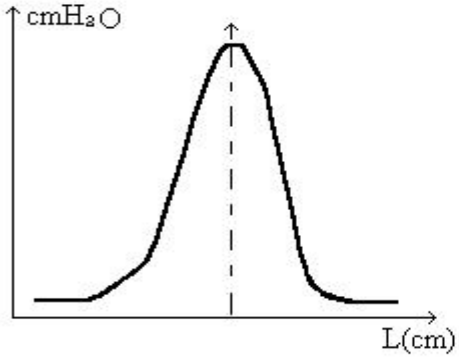


Fig. XLV Bladder neck obstruction Fig. XLVI Urethrocele



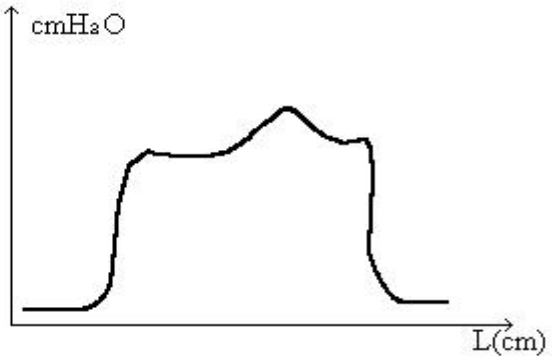
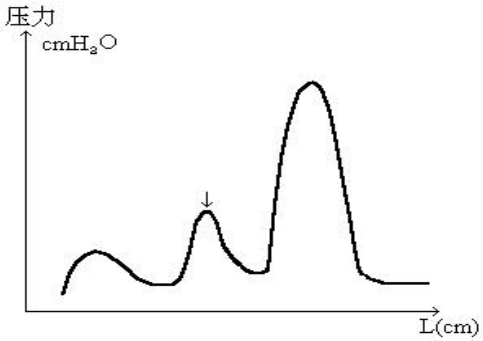


Fig. XLVII Distal urethral stenosis Fig. XLVIII Urethral tumour

② There are 4 types of abnormal curve for male, as illustrated in Fig. XLIX, L, LI and LII separately;



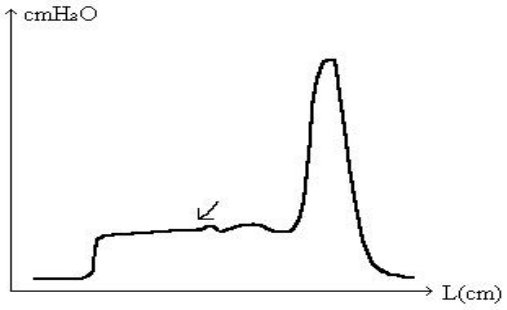
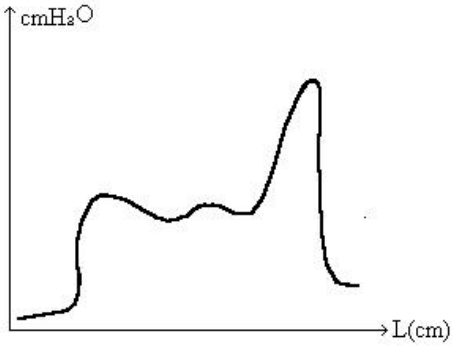


Fig. XLIX Seminal hillock hypertrophy Fig. L BPH (middle lobe hypertrophy protruding into the bladder)



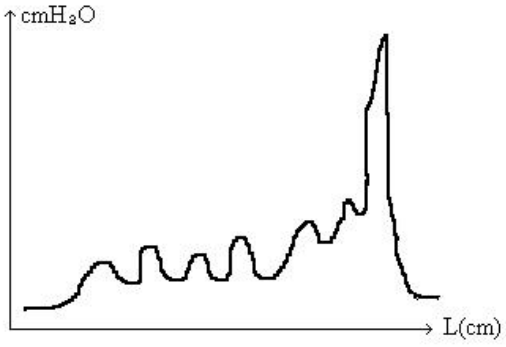


Fig. LI BPH (intraurethral type) Fig. LII Prostatitis

3) Bladder pressure determination in the filling period

a) Determination method

Supine posture, typical urethral catheterization and disinfection, catheter, filling flowrate at 50-80mL/min., furacilin solution or normal saline for external use at a concentration of 1/5000 as medium.

b) Parameter determination

Name of determined parameter	Meaning	Unit
Remaining urine volume	Operator entered value, i.e. urine volume remaining in the bladder soon after micturition	mL
Bladder capacity	Capacity marked at each moment in the bladder as it is being filled	mL
Detrusor pressure	Pressure marked at each moment in the detrusor of bladder as it is being filled	cmH_2O
Bladder stability	Value selection after manual judgment, i.e. normal, high and low options, giving an indication of bladder stability	

c) Marking

Name of determined parameter	Meaning	Unit
FD Initial micturition desire	Bladder's sensory transduction function as the bladder is being filled	
SD strong micturition desire		
UR urgent micturition desire		
CC max. bladder capacity	Bladder capacity marked to indicate that patients have irresistible micturition desire. CC relates to the filling speed B, neurosensory function and detrusor function. Individuals differ in the physiological urine volume being drained each time.	
C1 first cough		
C2 second cough		
S1 abdomen in		

Note: FD, SD, UR and CC marks can be made only in the course of determination!

d) Typical graph and mark

(1) Normal micturition pressure graph, as illustrated in Fig. LIII

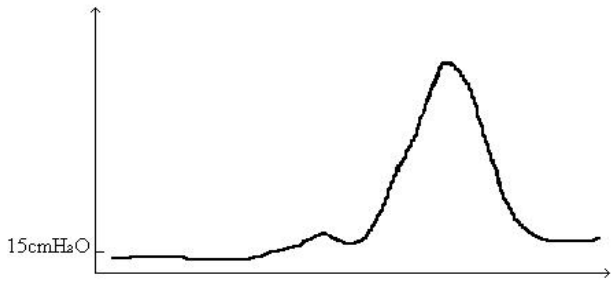


Fig. LIII Normal micturition pressure graph

(2) Abnormal curve as illustrated in Fig. LIV, LV, LVI and LVII.

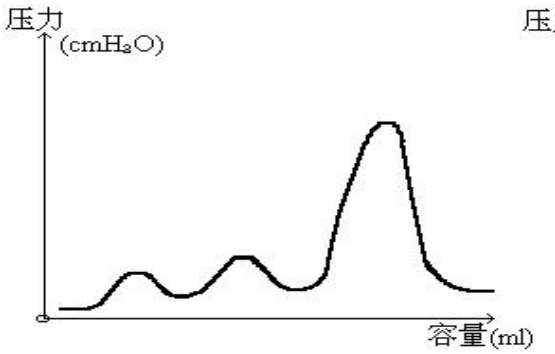


Fig. LIV Unstable bladder

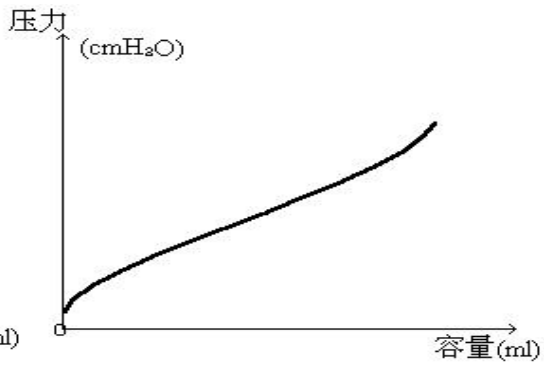


Fig. LV Low compliance bladder

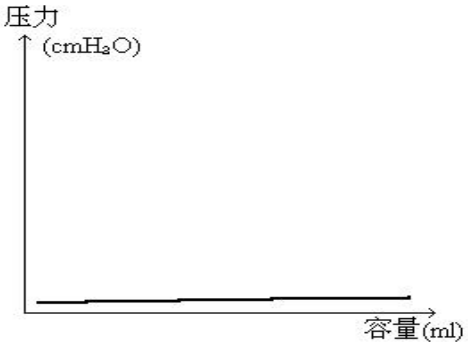


Fig. LVI High compliance bladder (detrusor weakness)

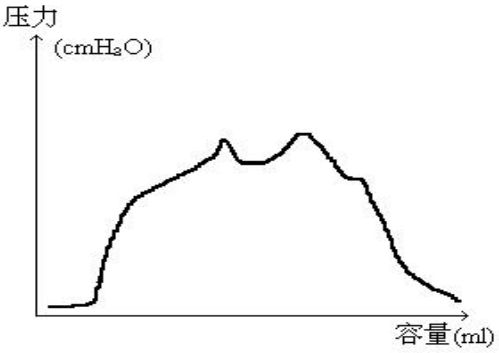


Fig. LVII High tension bladder (detrusor hyperfunction)

Pressure - flowrate - EMG simultaneous determination

a) Parameter determination

① Parameter determination in the urine storage period:

Name of determined parameter	Meaning	Unit
Remaining urine volume	Operator entered value, i.e. urine volume remaining in the bladder soon after micturition	mL
Bladder capacity	Capacity marked at each moment in the bladder as it is being filled	mL
Detrusor pressure	Pressure marked at each moment in the detrusor of bladder as it is being filled	cmH_2O
Bladder stability	Value selection after manual judgment, i.e. normal, high and low options, giving an indication of bladder stability	

② Parameter determination in the micturition period:

Name of determined parameter	Meaning	Unit
Max. urinary flowrate (MF)	Max. value or peak value obtained from determination of urinary flowrate	mL/s
Average urinary flowrate	Quotient obtained from the total urine volume divided by the micturition time. This parameter may be workable provided there is uninterrupted micturition free of dripping discharge urine.	mL/s
Micturition volume	Total volume of urine being drained out of the body via urethra during determination	mL
Urine flow time	Time period of urine flow being measured during micturition	s
Micturition time	Entire time frame on micturition, including micturition interruption time. If there is a totally uninterrupted micturition process, the micturition time is just the urine flow time.	s
Max. urinary flowrate time	Time frame starting from the urine flow until max. urinary flowrate (MF) is reached	s
Bladder pressure (VB) in the beginning of micturition	Pressure at a moment that urine flowrate is present	cmH_2O
Bladder pressure (MF) at max. urine flowrate	Bladder pressure at a moment of max. urine flowrate	cmH_2O
Detrusor pressure (MF) at max. urine flowrate	Bladder detrusor pressure at max. urine flowrate	cmH_2O
Max. detrusor pressure	Max. detrusor pressure present across the entire course of micturition	cmH_2O

b) Marking

Name of determined parameter	Meaning	Unit
FD Initial micturition desire/SD Strong micturition desire/UR Urgent micturition desire	Bladder's sensory transduction function as the bladder is being filled	
CC max. bladder capacity	Bladder capacity marked to indicate that patients have irresistible micturition desire. CC relates to the filling speed B, neurosensory function and detrusor function. Individuals differ in the physiological urine volume being drained each time.	
VB micturition start	A moment marked to indicate that the urinary flowrate has been present and detected. Typically, urinary flowrate beyond 0.5mL/s within 0.5s is deemed to be present.	
MF max. urinary flowrate	Mark a moment that max. urinary flowrate is present.	
VE micturition stop	A moment marked to indicate micturition stop, i.e. a moment that urinary flowrate beyond 0.5mL/s is present at the end of micturition.	
MP max. detrusor pressure	A moment that max. detrusor pressure is present during micturition	
C1 first cough/C2 second cough/S1 abdomen in		

Note: FD, SD, UR and CC marks can be made only in the course of determination!

Chapter10 Maintenance and repair

1. Instrument maintenance

1) Instrument maintenance

2) Apply the cleansing cream to the outer surface of the instrument every 3 months.

3) The instrument, if put offline for an extended period, may be preferably filled with the distilled water in its liquid circuit to prevent formation of crystal substances due to presence of filling fluid in the liquid circuit, which otherwise may block the liquid circuit and lead to operation upset.

4)The Urodynamic Urocap should be charged at least once per three months. The batteries should be check per year.

2. Software maintenance

Ndly 11B operates with Windows XP-based operating system. Failure to proceed to the Ndly 11B software system after computer self-test is anticipated in the case of Windows XP operating system collapse. Conduct target diagnosis on the system prior to software maintenance.

In the case of failure to proceed to the Ndly 11B software system when the instrument is switched on, conduct inspection and maintenance in steps below.

1) Failure 1:

The display light remains yellow when the instrument is switched on. Check whether the display signal plug is properly attached to the hose computer port. If so, the motherboard in the host computer may be the source of failure. Contact the manufacturer for repair.

2) Failure 2:

<No System Disk!> appears in the display when the instrument is switched on. It means that the booting system collapses. Conduct repair in steps below:

a) You are asked to press on Delete key after system boot to get access to CMOS setting for hard disk test. Check if the hard disk can be identified. If not, it means that the hard disk is damaged or the hard disk signal cable is damaged and improperly attached. Contact the dealer or manufacturer for solution. If the hard disk can be identified, store the hard disk parameters and proceed to the next step. [refer to related computer information]

b) Assume that the system FDD is working well before proceeding to this step. Conduct system boot with DOS startup disk (free of virus). When A:> appears in the screen, press on C:> and enter. If <invalid driver> appears in the screen, it indicates damaged hard disk files. Enter DOS command fdisk (refer to DOS command on fdisk operation) to perform hard disk partition again (hard disk crash if hard disk partition fails), followed by software reinstallation (installation of Windows XP before installation of Ndly-11B software). By doing so, the original files cannot be recovered. If C:> prompt appears in the screen, reinstallation of Windows XP operating system is Ok.

3) Failure 3:

It is unable to proceed to windows operating system as expected.

Reinstall the Windows operating system:

3. Disinfection

Instrument disinfection

When the analyzer is put into clinical application for the first time or resumes operation after shutdown for an extended period, perform cleaning and disinfection of the filling channel and pressure sensor channel to protect patients from infection.

Methods:

a) Switch off the analyzer to ensure that the entire system is power off;

b) Open the gate of the filling pump to ensure that the filling piping is working well;

c) Fill the liquid circuit with 1/5000 furacilin solution or 0.05 chlorhexidine lotione, and maintain filling for 3-5h;

d) Fill with 1/5000 furacilin solution or 0.05 chlorhexidine lotion 20mL injectors mounted on 3 sensors. Open the pipe valve in the sensor, and fill with disinfectant the sensor liquid circuit pipe with use of injector. Maintain filling for 3-5h;

e) Drain all pipes after disinfection. Flush with normal saline for external use (0.9%NaC1) or 1/5000 furacilin solution the entire liquid circuit pipe.

Note: 1. Ensure the entire liquid circuit free of obstructions, blocking and leak during cleaning and disinfection.

2. The impeller of filling pump shall be flushed with water after operation for a period to ensure access to accurate test data!

4. Troubleshooting

Carefully read the preceding descriptions on instrument connection and operation before inspection below. In case of failure to address your problems, please contact our office in your regions or directly contact HQ.

We will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair.

Replacement of a component could result in an unacceptable risk, please contact our authorized maintenance personnel for the replacement.

Failure	Cause	Solution
1. Power On/Off button not working well	A Power outage B Power fuse and knife switch short-circuit C Power plug not in place	A Remove the power plug, and replug after power restoration B Try again after troubleshooting C Put power plug in place
2. No images in the monitor screen	A Monitor power cable not attached B Monitor's brightness knob switched to min.	A Put the monitor power plug in position B Switch the brightness knob to an appropriate position
3. No curve or abnormal curve during pressure - flowrate - myoelectricity determination	A No sensor in position B Sensor incorrectly wired C Presence of air bubbles in the sensor tube	A Put the sensor in position B Reconnect sensors in position C Remove air bubbles out of the tube
4. No curve or abnormal curve during determination of urethral pressure	A Tube blocked B No sensor in position C Sensor tube incorrectly attached D Presence of air bubbles in the sensor tube E Calibration coefficient being revised F Filter paper in pressure transfer tube not removed	A Put the sensor in position B Reconnect sensor tube C Unblock D Remove air bubbles out of the tube E Recalibrate the filling pump F Remove the filter paper
5. No curve or abnormal curve during determination of urinary flowrate	A No sensor in position B Urine cup holder not properly aligned C Funnel paper blocked D Software collapse	A Put the sensor in position B Align the urine cup C Unblock D Virus killing or software reinstallation and recalibration of urinary flowmeter
6. Significant data error or filling pump water tube leak	A Filling pump leak B Filling pump water tube damaged C Pipe blockage D Calibration coefficient being revised E Software collapse F Outlet pipe filter paper blocked	A Adjust the set screw at the bottom of the pump and recalibrate the filling pump B Replace the water pipe and recalibrate the filling pump C Unblock D Recalibrate the filling pump E Virus killing or software reinstallation F Replace the outlet pipe with filter paper

Failure	Cause	Solution
7.The power supply of urinary flowrate determination device runs out or fails quickly	A The 18650 batteries were aged or failed.	A Please contact to our or authorized technical staff.

Chapter11 Storage and transportation requirements

Climate and environmental conditions

Temp.: -40℃～55℃;

Relative humidity: ≤93%;

Range of atmospheric pressure: 86kPa-106kPa.

Transportation: typical mode of transport by truck, train, ship and airplane is suitable to this analyzer;

Provision against violent vibration and collision, rollover and falling during transportation shall be made. Handle with care without upside down and rain exposure.

Storage:

-----The analyzer shall be stored in well ventilated rooms free of corrosive gases;

-----The analyzer shall be cleaned and covered for storage if it is not used for a long time. Switch it on once a year to prevent performance degradation as a result of exposure to moisture or mould formation.

Chapter12 Impact on the environment and energy

The analyzer used for testing purpose operates with no negative impact on the environment and energy.

Used effluent and other wastes are infectious medical wastes, which shall be properly disposed of pursuant to the Measures for Management of Wastes from Medical and Health Institutions.

The equipment and accessories at the end of their expected service life may not be disposed of as domestic waste.It could be recycled or disposed of according to local regulations.

Chapter13 Manufacturer's responsibilities

1. It is our responsibility for repair, replacement or refunding of the product not complying with the registered product standard;

2. We are obliged to assume responsibility for any loss arising from our defective product;

3. Under one of the following circumstances, we assume no responsibilities:

a) Where users fail to operate the analyzer as instructed;

b) Other operation against rules.

Chapter14 Statement

1. Basic performance indicators

Urinary flowrate	a) Range of determination of total urine volume: 0mL-1000mL, ±2% error

	b) Range of voiding time determination: 0s-240s, ±1% error c) Range of average urinary flowrate determination: 0mL/s-50mL/s, ±5% error
Range of pressure determination	Range of pressure: -50cmH20～200cmH20, ±3% error
Hauling machine	a) Hauling length: ≥280mm b) Hauling velocity: 0.5mm/s, 1.0mm/s, 2.0mm/s and 4.0mm/s ±3% error
Injection pump	Injection flowrate: 2mL/min～5mL/min (rise in a rate of 1mL/min.); ±3% error
Filling pump	Range of filling flowrate setting: 2mL/min～10mL/min (rise in a rate of 1mL/min.); 10mL/min～80mL/min (rise in a rate of 5mL/min.). Filling flowrate error: 0mL/min～50mL/min. ±3% error; >50mL/min ±5% error
Analyzer function	a) To create medical records; b) To facilitate control and display of parametric measurement process; c) To perform auto analysis and report printing; d) To put patients records under custody; e) To provide the bladder pressure over-limit protection at a threshold setting of 150cmH2O.

2. Electromagnetic compatibility

Note:

The analyzer conforms to requirements of electromagnetic compatibility set out in YY0505 standard;

Users shall follow electromagnetic compatibility descriptions in documents complete with shipment during installation and operation;

Operate the analyzer in a way free of exposure to the intense electromagnetic interference as it may not work well with presence of portable and mobile RF communication devices, such as mobile phone, microwave oven, etc.;

The guideline and manufacturer statement are given below.

Warning:

- The product shall not operate in the vicinity of other devices or in a stacking way. If not, check whether it can operate well under the specified configuration;
- Class A equipment is designed for operation in the industrial environment. Be aware that proper electromagnetic compatibility may be potentially challenged for operation under other conditions relating to conducted emission and radiation disturbance.
- Except for cable sold by the OE manufacturer as spare parts of internal components, use of other unauthorized accessories and cables may lead to increased emission or reduced resistance to interference.

Guideline and manufacturer statement - electromagnetic emission		
If the equipment is intended to operate under the following electromagnetic conditions, buyers or users shall assure proper operation under such environment:		
Emission test	**Conformance**	**Electromagnetic environment - guideline**
RF emission GB 4824	Group 1	The equipment consumes RF energy for the purpose of assuring its internal functions only. Thus, it operates at a low level of RF emission so that it is unlikely to interfere with neighboring electronic devices.
RF emission GB 4824	Class A	The equipment is suitable for use in all devices other than for household purpose and those not directly attached to the public housing LV power grid for household purpose.
Harmonic emission GB 17625.1	N/A	
Voltage upset/flash emission GB 17625.2	N/A	

Guideline and manufacturer statement - electromagnetic immunity			
If the equipment is intended to operate under the following electromagnetic conditions, buyers or users shall assure proper operation under such environment:			
Immunity test	**IE 60601 test level**	**Conformance level**	**Electromagnetic environment - guideline**
Electrostatic discharge GB/T 17626.2	±6kV contact discharge ±8kV air discharge	±6kV contact discharge ±8kV air discharge	The floor shall be covered with wood, concrete or ceramic tile. For floor covered with synthetic material, set min. 30% relative humidity.
Electrical fast transient burst GB/T 17626.4	±2kV to power cable ±1kV to input/output cable	±2kV to power cable	The network shall be electrically supplied at a level suitable for use under typical commercial or hospital condition.
Surge GB/T 17626.5	±1kV cable-to-cable ±2kV cable-to-ground	±1kV cable-to-cable ±2kV cable-to-ground	The network shall be electrically supplied at a level suitable for use under typical commercial or hospital condition.
Voltage sag, short interruption and voltage variation in the power input cable GB/T 17626.11	<5 % UT, for a duration of 0.5 cycle (on UT, >95% sag) 40% UT, for a duration of 5 cycles (on UT, 60% sag) 70% UT, for a duration of 25 cycles	<5 % UT, for a duration of 0.5 cycle (on UT, >95% sag) 40% UT, for a duration of 5 cycles (on UT, 60% sag) 70% UT, for a duration of 25 cycles	The network shall be electrically supplied at a level suitable for use under typical commercial or hospital condition. In case of need to maintain uninterrupted operation during power outage,

	(on UT, 30% sag) <5 % UT, for a duration of 5s (on UT, >95% sag)	(on UT, 30% sag) <5 % UT, for a duration of 5s (on UT, >95% sag)	recommend to use UPS or battery-based power supply.
Power frequency magnetic field (50/60Hz) GB/T 17626.8	3A/m	3A/m,50Hz	Power frequency magnetic field shall operate at a level suitable for use under typical commercial or hospital condition.
Note: UT refers to AC grid voltage before application of test voltage.			

Guideline and manufacturer statement - electromagnetic immunity

If the equipment is intended to operate under the following electromagnetic conditions, buyers or users shall assure proper operation under such environment:

Immunity test	IE 60601 test level	Conformance level	Electromagnetic environment - guideline
RF conduction GB/T 17626.6 RF radiation GB/T 17626.3	3V (effective value) 150 kHz～80 MHz 3 V/m 80 MHz～2.5 GHz	3V (effective value) 3 V/m	Portable and mobile RF communication devices shall not be used for any parts and components attached to the equipment at a distance closer than the recommended isolation distance, such as cable. This distance shall be figured out with an equation suitable to the emitter frequency. **Recommended isolated distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz～800 MHz $d = 2.3\sqrt{P}$ 800 MHz～2.5 GHz In which: P max. rated output power of the emitter as defined by the emitter manufacturer, in W; d-recommended isolation distance, in m. The field intensity of stationary RF emitter is defined through survey a in the electromagnetic field, which shall be less than the conformance level within each range of frequency b.  Interference may be present around the equipment marked in this symbol.
Note 1: An equation at high frequency is utilized at 80MHz and 800MHz. Note 2: These guidelines may not cover all conditions. Electromagnetic propagation is affected by absorption by building, objects and humans.			

a For stationary emitters, such as wireless (cell/radio) phone and ground mobile radio base station, amateur radio, amplitude-modulation and frequency-modulation radio and television broadcast, etc., prediction of an accurate field intensity is impossible theoretically. Survey of an electromagnetic field shall be taken into account in evaluation of electromagnetic environment where the stationary RF emitter operates. If the measured field intensity at workplace is higher than the above acceptable RF conformance level, closely monitor how well the equipment operates. In case of upset being detected, it is necessary to take additional measures, such as repositioning or relocation.

b The field intensity shall be less than 3V/m across the entire frequency range of 150KHz-80MHz.

RF emission frequency: (2.400 – 2.483) GHz Type of modulation: GFSK modulation

Frequency characteristic: long-distance transmission, two-way transmission, strong resistance to interference, effective radiation power: 15dBm

Received frequency: (2.400 – 2.483) GHz Preferred frequency: 2.4GHz Received bandwidth: 1.5Mbps

Recommended isolation distance between portable and mobile RF communication devices and the equipment

The equipment is expected to operate under the electromagnetic environment where the RF radiation disturbance is well managed. Buyers or users may, by taking into account max. rated output power of communication devices, deal with electromagnetic interference by following the recommended min. distance between the portable and mobile RF communication devices (emitter) and the equipment, as detailed below:

Emitter's max. rated output power W	**Isolation distance/m corresponding to emitter's different frequencies**		
	150 kHz ～ 80 MHz $d = 1.2\sqrt{P}$	**80 MHz ～ 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz～ 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For emitter’s rated max. output power not provided above, recommend to use an isolation distance d, in meter (m), which may be defined with equation suitable to the appropriate emitter frequency. Here, P is emitter’s rated max. output power defined by the emitter manufacturer, in watt (W).

Note 1: An equation at high frequency is utilized at 80MHz and 800MHz.

Note 2: These guidelines may not cover all conditions. Electromagnetic propagation is affected by absorption by building, objects and humans.

Cable's max. length

Cable name	Max. length (m)
POWER CABLE	2 m
Pressure sensor cable	0.7 m
Adaptor cable	1.6 m