SPIROANALYZER ST-95

INSTRUCTION MANUAL

FUKUDA SANGYO

December 1999

Version 1.2

This Manual must be read carefully before using the

PAGE REVISION LIST

Clause	*Page No.*	*Rev. No.*	*Amendments*	*Date mm/dd/yy*	*Authorized By*
All	All	1.0	First Issue	02/18/99	Geraldo S. Sadian
All	All	1.1	Re-issued	04/23/99	Geraldo S. Sadian
All	All	1.2	Re-issued	12/13/99	Geraldo S. Sadian

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EQUIPMENT SYMBOLS

Reference: EN 60 601-1 Appendix D

Table DI (IEC ISO 417) and Table D II (IEC ISO 417-878)

	Direct Current (DC)
	Alternating Current (AC)
	Equipotential Ground
	OFF (Power is disconnected from the mains)
	ON (Power is connected to the mains)
	Type B applied part

Chapter 1. CONTENTS

Chapter 2. INTRODUCTION

2.1.OUTLINE

The ST-95 SPIROANALYZER, belonging to Fukuda Sangyo's family of Spirometer products, is a pulmonary function testing instrument intended for performing patho-physiological breathing tests to evaluate human respiratory functionality. The instrument is used by general physicians; respiratory practitioners; or, qualified personnel in medical hospitals, medical centers, clinics, or near the patient during domiciliary visit.

The instrument carries out measurements of a patient's pulmonary Vital Capacity (VC), Forced Vital Capacity (FVC), and, Maximum Voluntary Ventilation (MVV) by capturing instantaneous air flow data at discreet intervals of time while the patient does a prescribed breathing maneuver. The flow data pattern being displayed graphically on a LCD screen display. Its capability also extends to the storage and analysis per patient for three (3) series of VC and FVC data respectively; and, two (2) series of MVV data that maybe displayed in tabulated data-form on the same LCD screen. The acquired and analyzed data may then be compared against various spirometric indices as determined from user-selectable predicted equations.

The instrument has likewise the ability to do comparative analysis required in Pre-post Medication and Bronchial Challenge Testing Regimens and a summary generation of hard-copy reports for all the tests in a manner useful for clinical analysis.

The device has multiple patient-data storage of up to fifty (50) patients' that can be selectively stored into its built-in memory. With selected measurement results, data and their corresponding waveforms may be electronically uploaded via the RS-232 port to a waiting Personal Computer (PC). Data Management Software, FS/PC-95, for the PC is available at an option. Conventional fleish-type pneumotach flow sensor is provided as a standard accessory and an optional disposal flow sensor may be used at your requisite.

Contraindication in the use of this instrument lies solely in the skill of the clinical technician to exact and be able to recognize a good patient effort and cooperation for optimal measurement results. The multiple-testing function of the instrument thus insures that a "*maximum training effect*" is achieved by the patient for measurement accuracy.

2.2.INTENDED MEASURING METHOD

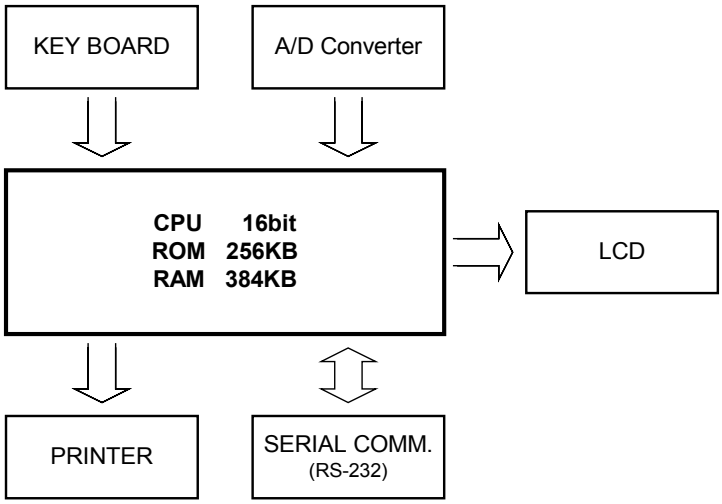
Under room condition, the patient is made to breathe air through the tubular-portion of the flow sensor following a prearranged breathing maneuver. Because the flow sensor is a low-resistance free-flow tube, no real energy transfer between the instrument and the patient is required to effect measurement. Only differential pressure in the airflow path is used to capture the needed flow data.

2.3.MEASUREMENT PRINCIPLE

Tracking the patient's breathing effort, the differential pressure generated in the flow sensor is transposed into an electrical signal by a piezo-electric resistance-type transducer. The resulting analog waveform is then digitally traced by an Analog-Digital Converter (ADC) and therewith recorded by the instrument's onboard microprocessor. The microprocessor processes the digital data and memorizes the measurement data into the instrument's memory. The requisite respiratory parametric readings are collated from the aforesaid digital measurement data and next displayed on the LCD, printed on the built-in printer, or may be transferred into a PC. All the foregoing operations controlled by the essential switches on the

front panel. A heater is fitted in the flow sensor to avoid water condensation and to keep the respiration flow at simulated body temperature.

2.4.BLOCK DIAGRAM



Warning:

The compliance to the standards may be nullified by the following actions:

- Improper use of components not approved by the manufacturer;
- Modifications or patches not expressly authorized by the manufacturer;
- Interconnection to outside equipment not explicitly sanctioned by the manufacturer.

The manufacturer is not responsible for any accident or damage occurring as a consequence of non-observance of this warning.

Chapter 3. SPECIFICATIONS

3.1.CLASSIFICATION

1)	Type of protection against electric shock	:	**Class I equipment**
2)	Degree of protection against electric shock	:	**Type B applied part**
3)	Degree of protection against water penetration	:	**Ordinary equipment**
4)	Degree of safety of application in the presence of flammable anaesthetic mixture with air or with oxygen or nitrous oxide	:	**Not suitable equipment**
5)	Mode of operation	:	**Continuous operation**

3.2.MEASUREMENT SPECIFICATION

1)	Measurement Method		
	Flow detection	:	**Pneumotach Flow Sensor**
	Volume detection	:	**Flow Integration**
2)	Measurement range		
	Flow range	:	**0 to ± 14 liters/second (l/s)**
	Volume range	:	**0 to 8 liters (l)**
3)	Measurement accuracy		
	Flow	:	**±5% indication or 0.2 l/s whichever is greater**
	Volume	:	**±3% indication or 50 ml whichever is greater**
4)	Measurements duration and times		
	Vital Capacity	:	**three (3) sets of 50-sec test**
	Forced Vital Capacity	:	**three (3) sets of 25-sec test**
	Max. Voluntary Ventilation	:	**two (2) sets of 12-sec test**
5)	Display (LCD)	:	**15 characters x 8 lines (text), 120 x 64 pixels (graphics)**
6)	Printer	:	**32 characters/line, 46 characters/second, 58mm/width**
7)	Data memory	:	**50 pre-test data or 25 pre/post test data**
8)	Output (RS-232C)	:	**1 channel for data transmission (This instrument may only be connected to PC devices meeting EN60950 Standard)**

3.3.OTHER SPECIFICATION

1) Power supply

Voltage	:	**100-240 V ~**
Frequency	:	**50/60Hz**
Power input	:	**25 VA (max)**
Fuse	:	**T 2Ax2 250V (IEC 127-2-III)**

2) Operating conditions

Temperature	:	**10 to 40°C**
Humidity	:	**Under 80% (no condensation)**

3) Transport/Stocking conditions

Temperature	:	**-25 to 70°C**
Humidity	:	**Under 95% (no condensation)**

4) Dimensions

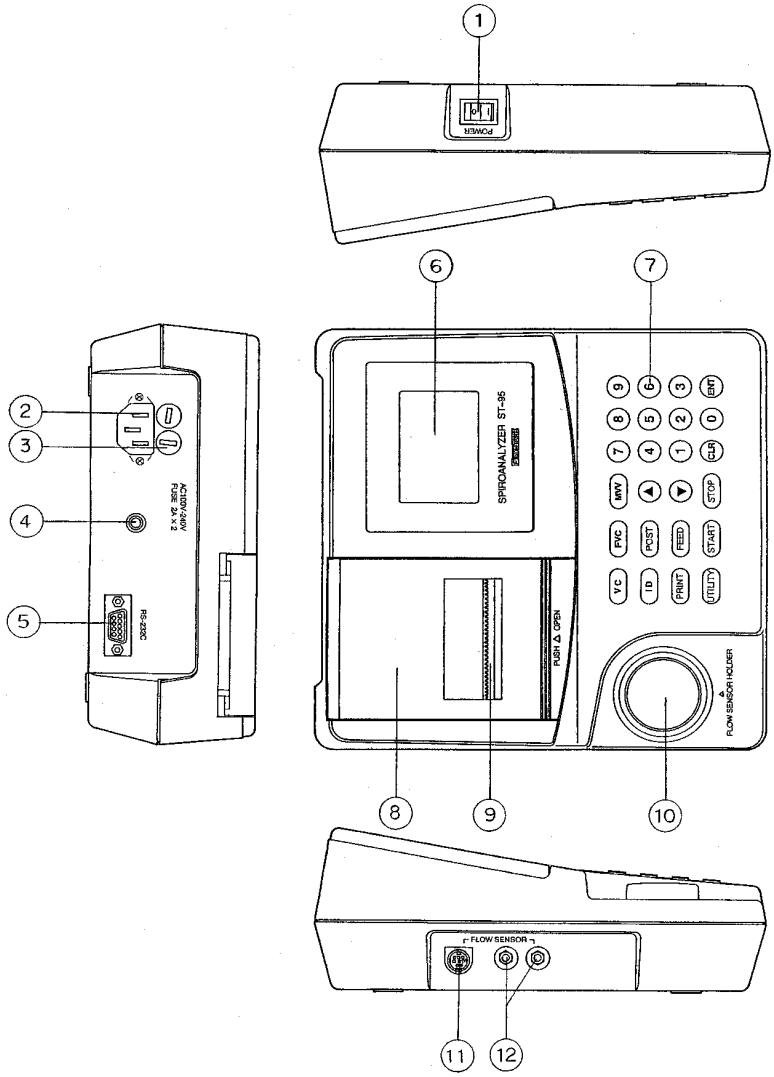
Size	:	**(W) 220mm × (D) 230mm × (H) 86mm**
Weight	:	**1,300g (Main Unit)** **500g (Flow Sensor)**

5) Casing material : **ABS (Formaldehyde free)**

6) PC connection (via RS 232C) : **This instrument may only be connected to PC devices meeting EN60950 Standard**

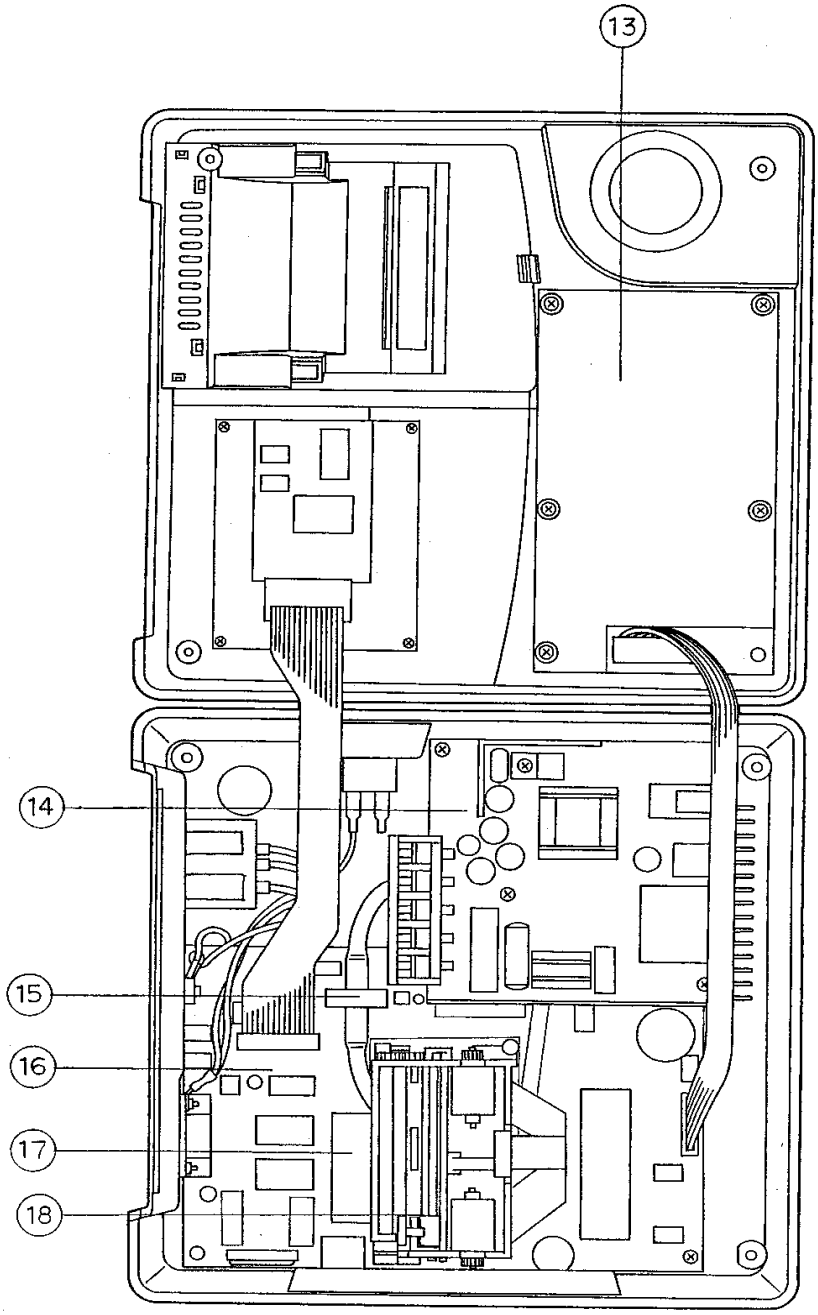
Chapter 4. PARTS IDENTIFICATION

4.1.MAIN UNIT



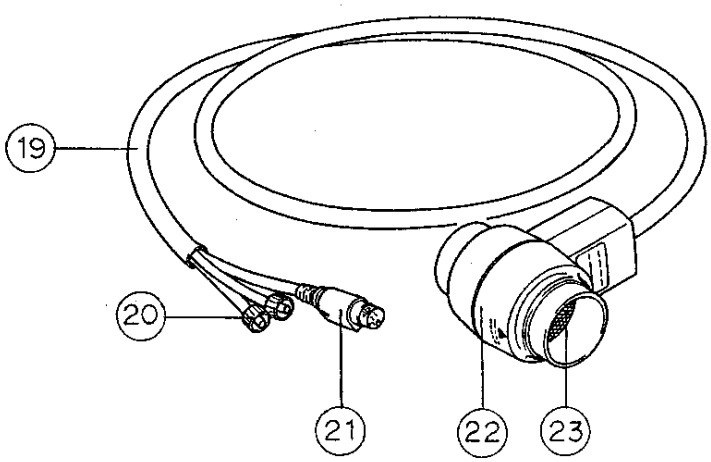
Number	Description
1	Power Switch
2	AC Inlet
3	Fuse Holder
4	Potential Equalization Terminal
5	Serial Communication (RS-232) Port
6	Liquid Crystal Display
7	Operational Keys
8	Printer Cover
9	Paper Outlet
10	Flow Sensor Holder
11	Heater Plug (female)
12	Sensor Tube Couplers (male)

4.2.INTERNAL STRUCTURE



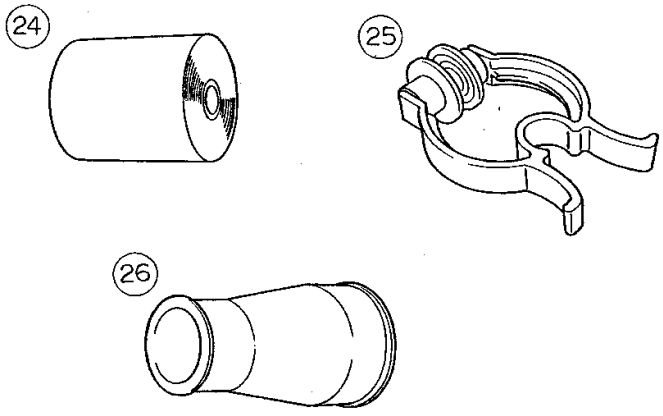
Number	Description
13	Keyboard Assembly
14	Switching Power Supply
15	Pressure Transducer
16	Main Board
17	ROM (Read Only Memory)
18	Printer

4.3.FLOW SENSOR



Number	Description
19	Complete Sensor Tube
20	Tube Couplers (female)
21	Heater Plug (Male)
22	Flowhead
23	Laminar Flow Tube

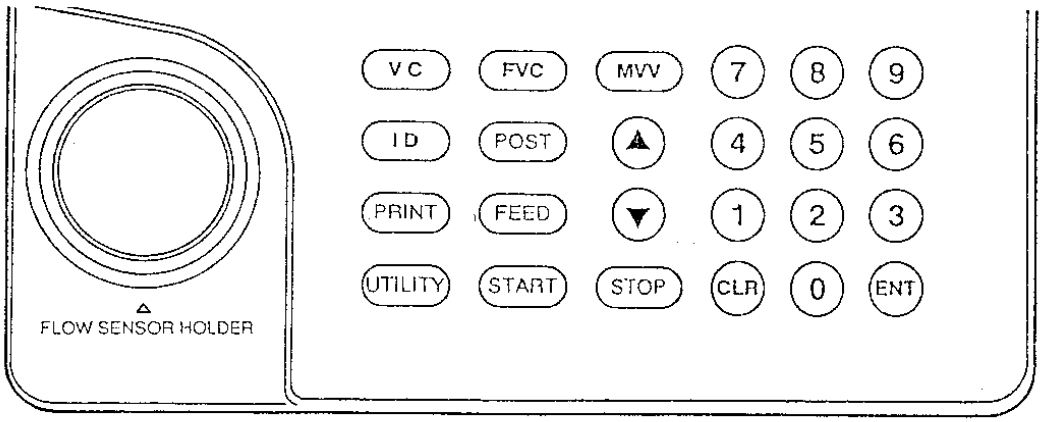
4.4.ACCESSORIES



Number	Description
24	Printer Paper (Thermal-type)
25	Nose Clip
26	Tapered Rubber Tube

NOTE: Disposable paper mouthpieces are not included as a standard accessory to this instrument.

4.5.OPERATIONAL KEYS



Key	Description
[0] ~ [9]	Type-in keys for detail information entry
[ENT]	Delimiter for key entry confirmation
[CLR]	Cancellation of key entry detail
[ID]	Patient information entry
[VC]	Launch VC measurement and display
[FVC]	Launch FVC measurement and display
[MVV]	Launch MVV measurement and display
[POST]	Initiation of post bronchodilator test mode
[START]	Action key to begin function
[STOP]	Action key to halt terminate function
[UTILITY]	Launch support function routines
[PRINT]	Print measurement results
[FEED]	Advance / feed the printer paper
[▲], [▼]	Scroll display screen

Chapter 5. CAUTIONS

5.1.GENERAL CARE

1) Read and understand the instruction manual before operating the instrument.
2) Handle the instrument with care especially during transport.
3) Do not alter or repair this instrument by yourself.
4) No user-serviceable parts are included in this instrument. Repairs must be done by authorized FUKUDA SANGYO service personnel only.

5.2.INSTALLATION

1) Locate the instrument atop a sturdy and level surface with a minimum 10cm clearing at both sides and rear.
2) Locate the instrument in a stable environment where no abrupt temperature, humidity or pressure change occurs.
3) Locate the instrument in clean surroundings where no ambient dusts, salts or ions are found.
4) Do not operate the instrument where the ambient temperature is over 40°C or under 10°C.
5) Do not immerse the instrument in water.
6) Do not expose the instrument to direct sunlight or excessive vibration.

5.3.ELECTROMAGNETIC COMPATIBILITY

This device has been proven to comply with EN60601-1-2 for Medical Electrical Equipment (under the Collateral Standard for Electromagnetic Compatibility – Requirement and Tests) in the Harmonized Standards. In order to further warrant a good level of electromagnetic immunity, it is suggested that the instrument be kept away from devices generating electromagnetic fields or interference, such as: loudspeakers; television sets; cellular telephones; other telephonic apparatus; or any similar devices.

5.4.FUSES REPLACEMENT

To replace the power fuses, perform the following procedures:

1) Turn the power switch of the Main Unit to OFF;
2) Disconnect the instrument from the ac mains;
3) On the rear side of the Main Unit, unscrew the two fuse holders clockwise using a suitable tool;
4) Remove both fuses from their receptacles;

5) Substitute the blown fuse with a known good fuse of an identical characteristic with that of the replaced fuse;
6) Restore the fuses into their receptacles and screw the fuse holder clockwise using a suitable tool;
7) Connect the instrument to the ac mains;
8) Turn the power switch to ON;

5.5.THERMAL PAPER

This instrument includes a printer device that uses thermal paper. The proper handling of new and unused thermal paper are observe by the following actions:

1) Keep away from direct sunlight or placed in a high temperature environment where the paper may discolor at about 70° C;
2) Keep away from prolonged exposure to fluorescent lighting;
3) Not to be press stored alongside a PVC film;
4) Contamination may occur on prolonged contact with a used thermal paper;
5) Used thermal paper sheets should not be carelessly thrown away in the environment but should be subjected to disposal compliance of the present normative.

5.6.PAPER MOUTHPIECE

The rubber mouthpiece of this instrument will fit any commercially available paper mouthpiece used for this purpose. Preference however may be limited to the following conditions:

1) Not less than 23.6 mm in outer diameter;
2) Not less than 72 mm in length;
3) Not less than 1.6 mm paper thickness;
4) Steady and long-term availability.

Chapter 6. DISPLAY

6.1.PARAMETER DEFINITION

Description of Parameter	Unit	LCD	Printer	Standard
Vital Capacity	l	VC	VC	√
Expiratory Reserved Volume	l	ERV	ERV	
Inspiratory Reserved Volume	l	IRV	IRV	
Tidal Volume	l	TV	TV	
Functional Residual Capacity	l	FRC	FRC	
Residual Volume	l	RV	RV	
Total Lung Capacity	l	TLC	TLC	
Ratio of RV divided by TLC	%	RV/TLC	RV/TLC	
Forced Vital Capacity	l	FVC	FVC	√
Forced Expiratory Volume at 0.5	l	FEV.5	FEV.5	√
Forced Expiratory Volume at 1.0	l	FEV1	FEV1	√
Forced Expiratory Volume at 3.0	l		FEV3	
Ratio of FEV1 divided by FVC	%	(FEV1%G)	(FEV1%G)	√
Ratio of FEV1 divided by VC	%	(FEV1%T)	(FEV1%T)	√
Ratio of FEV3 divided by FVC	%		(FEV3%G)	
Ratio of FEV3 divided by VC	%		(FEV3%T)	
Maximal Mid-Expiratory Flow	l/s	MMEF	MMEF	√
Expiratory Time	s	EX TIME	EX TIME	
Extrapolated Volume	l	V ext	V ext	
Forced Inspiratory Vital Capacity	l	FIVC	FIVC	√
Forced Inspiratory Volume at 0.5 sec	l		FIV.5	
Forced Inspiratory Volume at 1.0 sec	l		FIV1	
Ratio of FIV1 divided by FVC	%		FIV1/FVC	
Ratio of FIV1 divided by FIVC	%		FIV1/FIVC	
Peak Expiratory Flow	l/s	PEF	PEF	√
Mid (Forced)-Expiratory Flow at 75%(25%)	l/s	MEF75 (FEF25)	MEF75% (FEF25%)	√
Mid (Forced)-Expiratory Flow at 50%(50%)	l/s	MEF50 (FEF50)	MEF50% (FEF50%)	√
Mid (Forced)-Expiratory Flow at 25%(75%)	l/s	MEF25 (FEF75)	MEF25% (FEF75%)	√
Peak Inspiratory Flow	l/s	PIF	PIF	√
Inspiratory flow at 50%	l/s		MIF50% (FIF50%)	
Maximum Voluntary Ventilation	l/min	MVV	MVV	√
Respiration Rate	Resp/min	RR	RR	
Tidal Volume	l	TV	TV	

Parameters bracketed by () can be switched according to the utility setting.
Parameters marked by √ are printed on the standard print format.

6.2.LCD SCREEN

1) ID screen

```
DATE    Jun/12/95
TEMP    22  ℃
ID.#    1234567890
AGE       30 yrs
Ht       171 cm
Wt        56 kg
SEX     MALE
RACE    WHITE
```

Auto calendar
Temperature (0 to 50°C)
ID number (maximum 10 digits)
Age (1 to 99 years)
Height (90 to 220cm)
Weight (10 to 220Kg)
Sex (MALE or FEMALE)
Race (WHITE, BLACK or OTHERS)

2) Comparison data screen

```
VC DATA

No       VC
⊙     1  4.70
○     2  4.66
_     3  4.62

Pr  4.84
```

Measurement

Measurement number and Data
⊙ : Best data
○ : Second data
_ **:**Last measurement data

Predicted value

3) Selected data screen

```
FVC DATA [1]
             MEAS   %PR
       FVC   4.58    97
     FEV.5   3.16
      FEV1   3.84    96
     FEV1%   87.4    99
      MMEF   4.66    99
      TIME   7.69
```

Measurement number

Data and Predicted value

4) Selected data screen (Pre-Post)

```
[1]          MEAS   %CH
     V ext    0.12   -1
      FIVC    4.39    9
       PEF    9.85   12
     MEF75    9.69    8
     MEF50    5.85    6
     MEF25    2.17    2
       PIF    9.05    2
```

Measurement number

Data and percentage improvement

6.3.OTHER ABBREVIATION USED

Abbreviation	Meaning
%BL	Percentage (Measured Value divided by the Baseline Value)
%PR	Percentage (Measured Value divided by Predicted Value)
BSA	Body Surface Area
ENT	Enter key
Exp	Expiration
Fact	Factor
Ht	Height
ID	Identification (or Identification number)
ins	Inches
INTER	Interpretation
Insp	Inspiration
LANG	Language
lbs	Pounds
MEAS	Measured Value
p	Post Bronchodilator
PARA	Parameter
PRED	Predicted Value
Post	Post Bronchodilator
SENS	Sensor
TEMP	Temperature
TX	Transmission of data
WTX	Transmission of data with waveform
Wt	Weight
Yrs	Years

Chapter 7. SETTINGS

7.1.CONFIGURATION

Prediction equations, and interpretation algorithms are user-selectable and set as follows.

Item	Description
Predicted Equation	ITS
	Knudson
	Morris-Polgar
	ECCS
	Spain
	Oslo (Norway)
	Chilena
	Austrian
	Japan
Interpretation Algorithm	ITS
	NIOSH/OSHA
	Ellis
	Diagnosis
Unit of Height and Weight	cm/kg
	ins/lbs
Unit of Temperature	°C
	°F
Expression of Expiratory Flow	MEFx
	FEFx
Language	English
	German
	French
	Spanish
Flow Sensor	Fleish
	Disposable

Display and print formats are executed according to the above settings. Most recent settings are backed up by battery and kept in the memory until the next setting change. Setting operation is described in 8.16. OTHER OPERATIONS.

ITS prediction equation will be automatically selected by the instrument in cases where ITS or ITS (NIOSH/OSHA) interpretation is selected. No other prediction equation may be selected with the ITS or ITS (NIOSH/OSHA) interpretation setting.

Chapter 8. OPERATION

8.1.PREPARATION

1) Insure the correct connection of the flow sensor to the main unit. The WHITE and the BLACK tubes of the flow sensor secured to their matching color-coded couplers in the main unit; and, the heater plug snugly connected to the heater jack. (Should the flow sensor tubes connection to the main unit be reversed, inspiration and expiration flow data will be detected and shown in the opposite polarity.

   In case a disposable flow sensor is used, connect the flow sensor to the sensor handle insuring correct direction. An engraved wart on the side of the handle shows where the patient's mouth should be directed. We recommend using a paper mouthpiece.

2) Slide the tapered rubber tube (wide opening) to the flow sensor front-end where the rim is marked ▲. Then, insert the cylindrical paper mouthpiece inside the tapered rubber tube (smaller opening) about 2cm deep.

   A clean mouthpiece should be provided for each patient for proper infection control.

3) After the instrument has warmed up, the flow sensor's temperature is kept stable at approximately 37°C. Hand-check the flowhead temperature before passing the flow sensor to the patient.

4) It is extremely important to explain (if possible, to demonstrate) the correct measurement maneuver the patient has to undergo in order to obtain the best test result.

5) Any time a VC, FVC or MVV test routine is initiated, the instrument performs zero-level referencing at a NO FLOW CONDITION. For a few moments during this time, DO NOT breathe into or move the flow sensor to prevent the instrument from erroneously capturing zero reference at an offset. Drifting of the waveform is generally caused by this improper action.

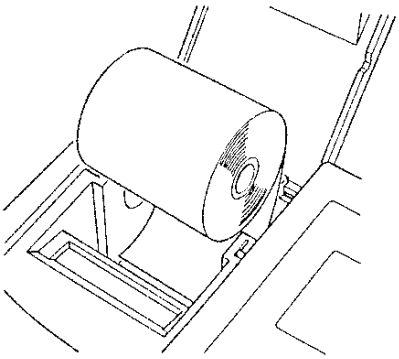
8.2.POWERING ON

The power switch of the instrument is located at the right side of the main unit. Toggle the power switch towards the front marked |. Upon powering of the main unit, the instrument boots up following the execution of a self-test routine. After a successful boot-up, an ID screen is displayed on the LCD. If an error is detected however during self-test, the device halts and the error is displayed on the LCD.

Use the instrument only after a thirty minutes warm-up time had elapsed for full electronic stabilization.

8.3.LOADING THERMAL PAPER

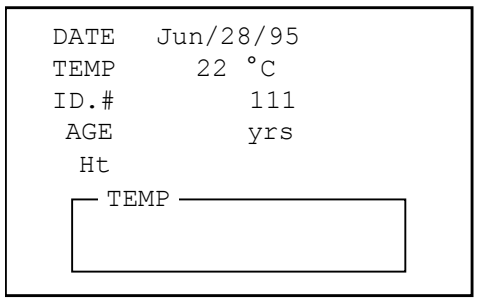
To load a roll of thermal paper, jointly press and slide rearward at the area marked "PUSH Δ OPEN" of the printer cover. The cover may then be lifted and swung open towards the back. Take the end of the paper roll (curled-up) and insert its end into the slit located at the bottom of the paper basin. Depress the FEED key several times until the paper advances out from the top opening. Grab the paper end and thread it through the paper cutter outlet of the printer cover. To secure the paper roll in the basin, close the printer cover, then jointly press and slide forward at the area marked (embossed) "PUSH Δ OPEN" of the printer cover to lock. Check that the printer paper has its print face in front when the printer cover is closed. Refer to the following picture.



8.4.ENTRY OF PATIENT'S INFORMATION

With the patient information gathered and the ID screen displayed on the LCD, depress ID key to enter the patient information.

The TEMP window pops on the display ready to accept a keyed-in entry. Depress ENT key upon completion of keyed-in entry.



The ID screen always retains and displays the last measurement data made. Only upon complete entry of the new patient information will the last measurement data be deleted. Should the previous data be needed, save the data before entering the next patient ID number.

Depress the ENT key each time a complete key- entry has been made.

1) Date of measurement
   Date is automatically provided by the built-in calendar IC.

2) Room temperature
   Accepted range is from 0 - 50°C (32 to 122°F) for room temperature. The keyed-in temperature value will automatically be the basis for BTPS correction. If a previous patient was tested, the last temperature data is displayed.

3) ID number
   Accepted range is from 0 to 9999999999 (maximum of 10 digits). The last ID number is incremented by one should a patient data still remains in memory.

4) Age
   Accepted range is from 1 to 99 years old.

5) Height
   Accepted range is from 90 to 220cms (37 to 89ins).

6) Weight
   Accepted range is from 10 to 220kgs (23 to 488lbs).

7) Sex
   Depress the ▲ or ▼ keys to move the cursor to either the MALE or FEMALE selection.

8) Race
   Press the ▲ or ▼ keys to move the cursor to either the WHITE, BLACK or OTHERS selection.

8.5.CORRECTION OF PATIENT INFORMATION ENTRY

To make a correction on the patient information ID entry, proceed in the following procedure:

1) If the erroneous entry is still in a pop-up window (where the ENT key has not yet been depressed), depress the CLR key to delete the error in the window. You may then enter the correct value and depress the ENT key to confirm the correction.

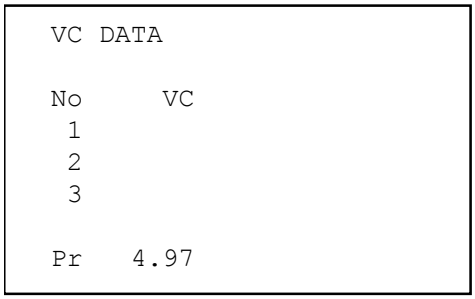
2) If the erroneous entry is already displayed in the ID screen (after an ENT key has been depressed), depress the ENT key repeatedly until you have cycled through the ID menu then to the pop-up window you wish to correct. Depress the CLR key and enter the correct value. Then depress the ENT key repeatedly until you reach the end of the ID screen.

8.6.CANCELLING OF PATIENT'S INFORMATION ENTRY

This cancellation method of currently entered patient information is only possible when done before the RACE entry information is entered. To cancel the patient information being entered, depress any of the VC, FVC or MVV keys. The patient information is wholly canceled and the last patient data is displayed instead.

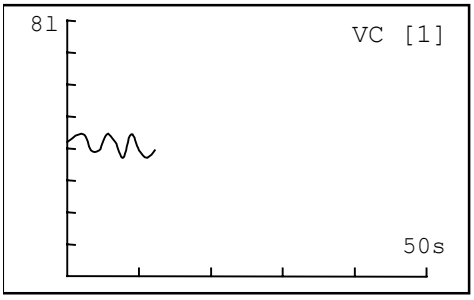
8.7.VC MEASUREMENT

1) Depress the VC key to display the VC comparison screen.

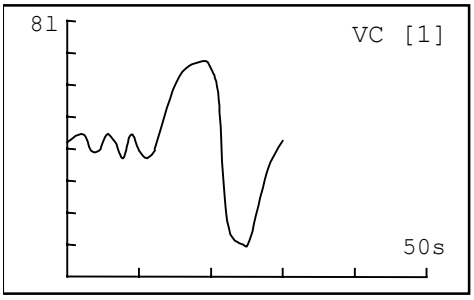


2) Do not breathe into or move the flow sensor while the instrument sets zero-level referencing at a NO FLOW CONDITION.

3) With a nose clip applied at the patient's nostril, make the patient breath in and out in a normal rhythmic manner into the flow sensor mouthpiece. Depress the START key while urging the patient to continue normal breathing. Respiratory waveform should now be seen in the screen.



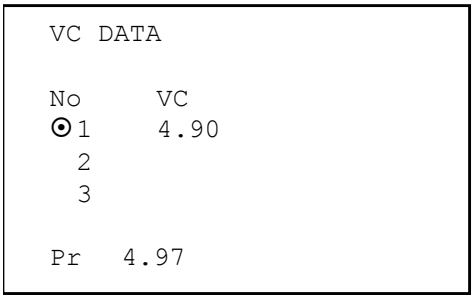
4) The instrument then beeps after detecting three (3) normal cyclical breaths. Immediately make the patient breathe in to the fullest; then breathe out completely without force; and, thereupon return to normal breathing. Depress the STOP key to end the test.



5) If the measurement is not satisfactory due to respiratory disorder or an improper maneuver, depress the START key to re-start the measurement from time zero and repeat from procedure 2). To abort measurement, depress the CLR key.

6) Duration for VC measurement is fifty (50) seconds. Depress the STOP key anytime you wish to terminate before the time limit.

7) After measurement, the data comparison screen is displayed. The best data is automatically selected and marked ⊙. If multiple measurements are performed, the second best data is marked ○ while the least well data is marked _.

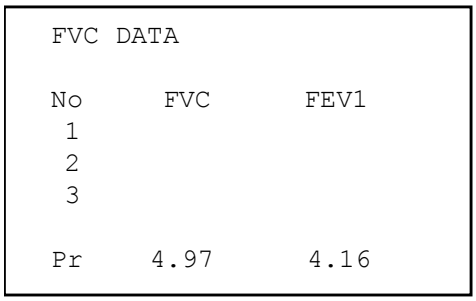


8) To repeat the VC measurement, repeat from procedure 1).

9) Three (3) measurement data may be fully stored in memory sequenced as 1 → 2 → 3. Subsequent measurement will overwrite the measurement data that is not marked with ⊙ or ○.

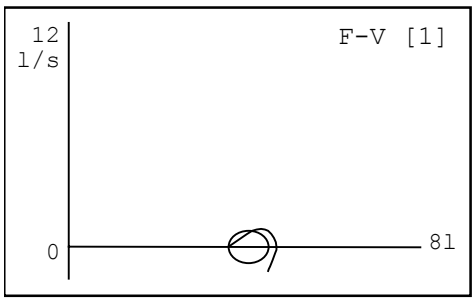
8.8.FVC MEASUREMENT

1) Depress the FVC key to display the FVC comparison screen.

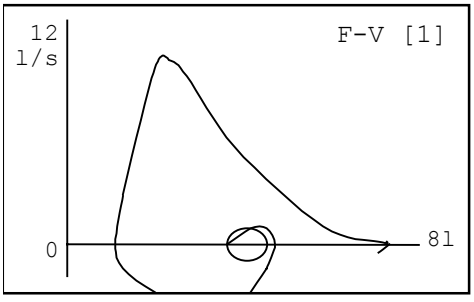


2) Do not breathe into or move the flow sensor while the instrument sets its zero-level referencing at a NO FLOW CONDITION.

3) With a nose clip applied at the patient's nostril, make the patient breath in and out in a normal rhythmic manner into the flow sensor mouthpiece. Depress the START key while urging the patient to continue normal breathing. Respiratory waveform should now be seen in the screen.



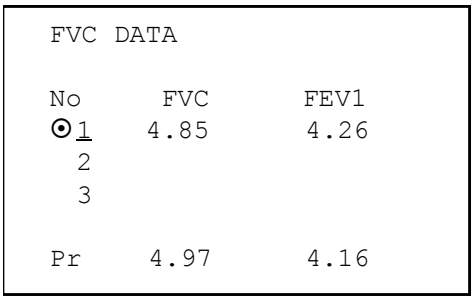
4) After a normal cyclical breath, immediately make the patient breathe in to the fullest and then breathe out completely with force. Direct the patient to continually breathe out all the air past five seconds. Thereupon, to breathe in again to the fullest at full force (for Forced Inspiratory Vital Capacity measurement); and, then return to normal breathing. Depress the STOP key to end the test.



5) If the measurement is not satisfactory due to respiratory disorder or improper maneuver, depress the START key to re-start the measurement from zero-time and repeat from procedure 2). To abort measurement, depress the CLR key.

6) Duration for FVC measurement is twenty-five (25) seconds. Should you wish to terminate before the time limit, press STOP key.

7) After measurement, the data comparison screen is displayed. The best data is automatically selected and marked ⊙. If multiple measurements were performed, the second best data is marked ○ while the least well data is marked _.



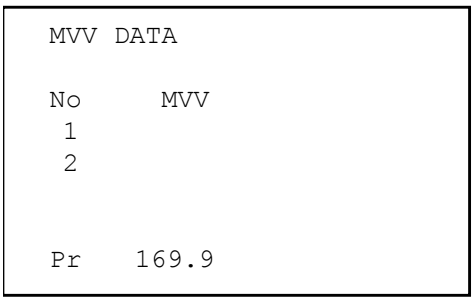
8) To repeat the FVC measurement, repeat from procedure 1).

9) Three (3) measurement data may be fully stored in memory sequenced as 1 → 2 → 3. Subsequent measurement will overwrite the measurement data that is not marked ⊙ or ○.

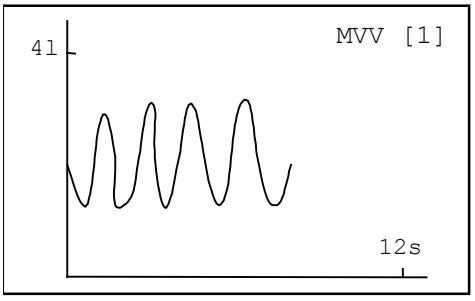
8.9.MVV MEASUREMENT

1) Depress the MVV key to display the MVV comparison screen.

2) Do not breathe into or move the flow sensor while the instrument sets its zero-level referencing at a NO FLOW CONDITION.



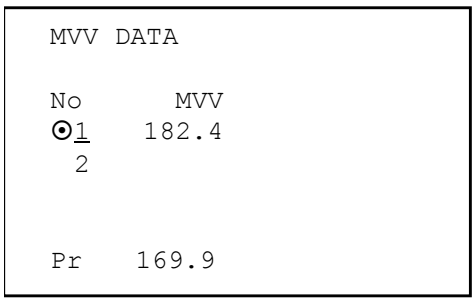
3) With a nose clip applied at the patient's nostril, make the patient breath in and out in deep and rapid rhythmic manner into the flow sensor mouthpiece. Depress the START key while urging the patient to keep the voluntary effort on a constant rhythm like one-two, one-two. Respiratory waveform should now be seen in the screen



4) If the measurement is not satisfactory due to respiratory disorder or improper maneuver, depress the START key to re-start the measurement from zero-time and repeat from procedure 2). To abort measurement, depress the CLR key.

5) Duration for MVV measurement is 12 seconds, the generally recommended test duration. To abort measurement, depress the STOP key. The instrument however requires a measurement of more than five seconds for analysis.

6) After measurement, the data comparison screen is displayed. The best data is automatically selected and marked ○ while the least well data is marked _.



7) To repeat the MVV measurement, repeat from procedure 1).

8) Two (2) measurement data may be fully stored in memory sequenced as 1 → 2. Subsequent measurement will overwrite the measurement data that is not marked ○.

8.10.POST-BRONCHODILATOR TESTING

This instrument is capable of performing post-bronchodilator testing for each measurement.

1) For single patient testing:

   a) Perform on the patient the VC, FVC, or MVV tests desired and select the best data from the measurements made. The selected measurement shall serve as the pre-bronchodilator data of the patient. If so required, the appropriate procedure for report printing or data transfer should be done now.

   b) Proceed in the administering of the medication to the patient. The post-bronchodilator test is typically conducted after a fifteen-minute period.

   c) Depress the POST key to set the patient pre-bronchodilator data into memory afterwhich the patient ID screen is displayed. The post-bronchodilator test is now ready.

d) Perform the post-bronchodilator test using the same VC, FVC, or MVV test procedure desired. The pre-bronchodilator and post-bronchodilator measurement data, as well as the response rate are thereupon displayed. [Post] is indicated on the comparison data screen.

e) Enter a new patient ID to exit Post Bronchodilator Testing.

2) For multiple patients testing:

a) Perform on the individual patient the VC, FVC, or MVV tests desired and select the best data from the measurements made. The selected measurement shall serve as the pre-bronchodilator data for each individual patient. If so required, the appropriate procedure for report printing or data transfer should be done now. Therewith, save the measurement data into memory using the procedures outlined in 8.17. OTHER FUNCTIONS.

b) Proceed in the administering of the medication to the patient.

c) Perform procedures 2.a) through 2.b) in acquiring measurements, data saving and administration of medication to the other patients in repeated order.

d) To move on to post-bronchodilator testing, read out from memory the concerned patient measurement data using the procedures outlined in 8.17. OTHER FUNCTIONS. Depress the POST key to set the patient pre-bronchodilator data into memory afterwhich the patient ID screen is displayed. The post-bronchodilator test is now ready for the concerned patient.

e) Perform post-bronchodilator test on the concerned patient using the same VC, FVC, or MVV test procedure desired. The pre-bronchodilator and post-bronchodilator measurement data, as well as the response rate are thereupon displayed. [Post] is indicated on the comparison data screen.

3) In saving the pre-and the post measurement data into the memory, there will be two data sets consisting of pre data and post data for the same patient. If the pre data is not necessary, delete the pre data.

4) Repeat the same procedure of 2.d) through 2.f) to the other patients.

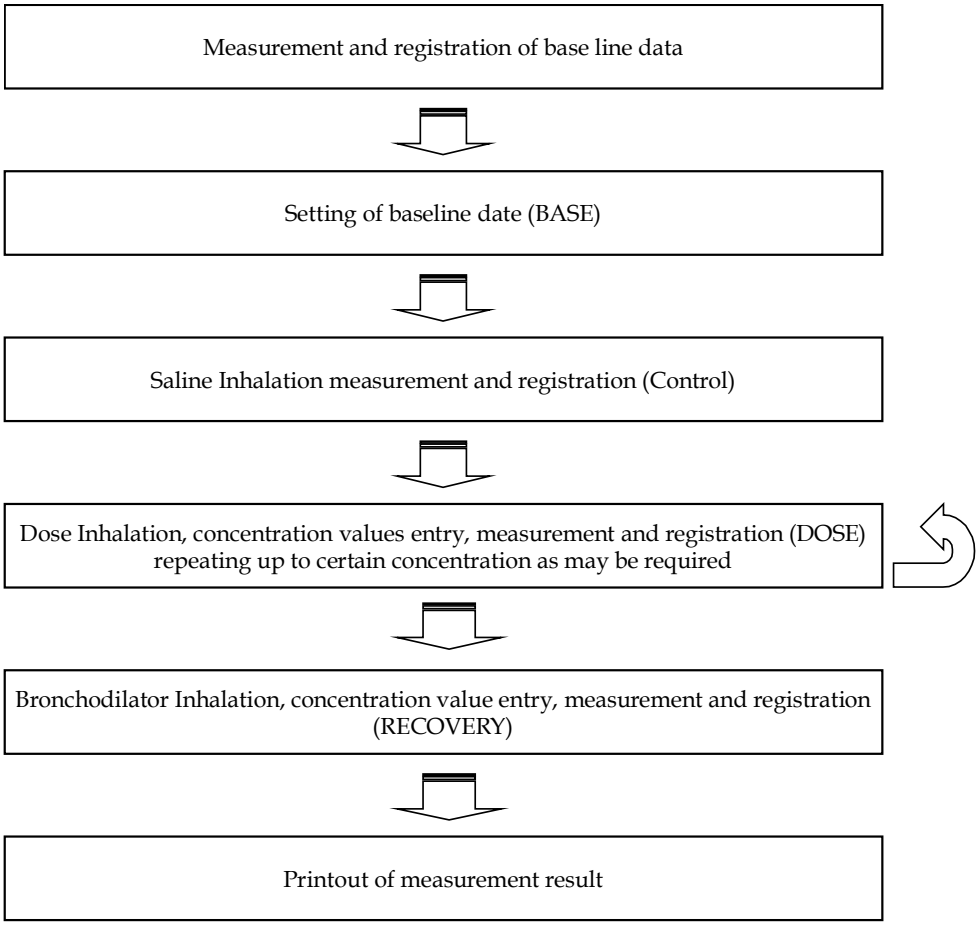
5) Enter a new patient ID to exit Post Bronchodilator Testing.

8.11.BRONCHIAL CHALLENGE TESTING

This instrument is capable of performing Bronchial Challenge test.

Warning:
Prior to subjecting a patient to Bronchial Challenge Test, check the condition of the patient, the kind and dosage interval of the medicine allowable for the patient. Always have the bronchodilator ready during the test.

1) Flow of measurement



2) Measurement and setting-up of the patient baseline data

a) Measurement

Perform FVC measurement on the patient to obtain a baseline data (commonly the best data realized from the test). VC and MVV tests may still be conducted, however measurement results will not be printed on the Bronchial Challenge test report. If required, the appropriate procedures for report printing or data transfer should be done now. Catalogue the patient

measurement data into memory by using the memory save procedure in 8.16. OTHER FUNCTIONS.

b) Setting up of the baseline data
To start baseline data set-up, depress the UTILITY key and select item 5:BASE. Select by using the numeral keys with the patient ID number earlier catalogued in procedure 2.a) from the list of displayed ID numbers. Depress the ENT key to now set the patient baseline data and upon display of the ID menu, the instrument is now prepared for Bronchial Challenge testing. This test mode is kept until a new patient ID is selected.

3) Measurement with Saline Inhalation

a) Omit this procedure and proceed to procedure 4) if the Saline measurement is not required.

b) Make the patient inhale Saline with a nebulizer as per prescribed dose.

c) Perform an FVC measurement similar to procedure 2.a) to obtain a Saline control data. If Saline Inhalation performance data is required, catalogue the patient measurement data into memory by using the memory save procedure in 8.17. OTHER FUNCTIONS.

4) Measurement with Dose Inhalation

a) Make the patient inhale Methacholine or the like with a nebulizer as per prescribed dose. Note the administered dose in milligrams.

b) Depress the UTILITY key and select item 5:DOSE from the utility menu. Enter the administered dose noted from procedure 4.a) into the dose concentration screen using the numeral keys. Depress the ENT key to confirm entry or use the CLR key to re-enter. The new concentration value is hence updated and the ID screen is displayed ready for re-test. A "NO DATA" message is momentarily displayed on screen if the Saline Inhalation Measurement was omitted.

c) The concentration entry is validated for values between the range:

0.01 to 999.98mg: DOSE MEASUREMENT

d) The concentration value entered should always be higher than the currently registered value. For instance, if the current value was 0.08, the next acceptable value should be 0.09.

e) Perform an FVC test; then select; and, store the best data into the memory. For each concentration value where Dose Inhalation performance data is required, catalogue the patient measurement data into memory by using the memory save procedure in 8.17. OTHER FUNCTIONS.

f) Increase the dose as prescribed and repeat the above measurement of procedure 4.a) through 4.e).

g) When the present FEV1 value should decrease less than 80% of the base line FEV1 data, the following message is displayed.

FEV1 %BL = ××% (××<80%)

h) Depress the ENT key to display the data screen. Use the ▼ or ▲ keys to scroll through the measured values.

In any event that the FEV1 decreases abruptly, discontinue further dose and proceed to Bronchodilator Inhalation.

5) Measurement with Bronchodilator Inhalation

a) Omit this procedure if the Bronchodilator Inhalation is not required. However, administer Bronchodilator Inhalation to the patient for recovery.

b) Make the patient inhale Bronchodilator using a nebulizer as per required dose.

c) Depress the UTILITY key and select 5:DOSE. Dose concentration screen is displayed and the last concentration value is displayed. Enter the concentration value 99999 and depress the ENT key.

999.99mg:BRONCHODILATOR MEASUREMENT

d) When the ID screen is displayed, perform FVC measurement then select and store the best data into the memory. If Bronchodilator Inhalation performance data is required, catalogue the patient measurement data into memory by using the memory save procedure in 8.17. OTHER FUNCTIONS.

e) To redo the Bronchodilator measurement, repeat the above measurement procedures 5.a) through 5.d).

6) Bronchial Challenge print data

a) Only previously catalogued measurement data during Bronchial Challenge testing mode may be printed. The printout shall consist of: base line measurement data; each measurement data for Saline Inhalation and Dose Inhalation; catalogued concentration value; ratio of performance against the baseline data; time duration from measurement of baseline data; and, graphed FEV1 changes. To enable the foregoing printout, depress the PRINT key or use the printing function of 8.17. OTHER FUNCTIONS.

7) Cancellation of Bronchial Challenge Mode

a) Cancellation of Bronchial Challenge test mode may be done through either of the following:

i) Entering of a new patient ID using the ID key function. After the entry of the full patient information, the Bronchial Challenge Mode is automatically canceled.

ii) Reloading of a patient data using the memory load function of 8.17. OTHER FUNCTIONS.

8.12.DATA PROTECTION FROM OPERATIONAL ERROR

Recovery from operational errors may be circumvented by the following:

1) Inadvertent depressing of the ID key
Whenever the ID key is depressed, the ID screen readies for the next patient entry. Depress the VC, FVC or MVV key to return display of the last patient data. However, if the new patient data have been entered up to the RACE window and the ENT key is depressed, the last patient data will already be deleted.

2) Inadvertent depressing of the START key
Whenever the START key is depressed, the measurement screen is displayed. To recover, depress the CLR key to cancel the measurement and have the data comparison screen restored in the display.

8.13.SELECTION AND DISPLAY OF DATA

This instrument stores three (3) VC, three (3) FVC and two (2) MVV data sets per patient in the memory. Each data can be selected and displayed. The best and second best data are automatically selected on each measurement under the following conditions.

Measurement	Criteria
Best VC data	The largest VC value
Best FVC data	The largest value of FVC + FEV1
Best MVV data	The largest MVV value

Data selection can be manually selected with the numerical keys 1, 2, or 3. The selected data will be marked ⊙. In the event, a measurement is conducted more than three time (3X) for both the VC and FVC tests and two times (2X) for the MVV, the data without the marks ⊙ or ○ is overwritten in the display and marked with _ by the new measurement.

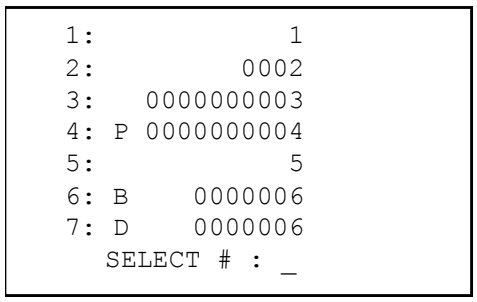
8.14.EXPANDED WAVEFORM SCALE

Where an expanded graphical scale is required, depress the ENT key to shift the graphical display to double scale (2X) during measurement or display. Selecting double scale on the display will also cause the waveform to be printed as such. To return to normal scale, depress the ENT key to toggle back.

8.15.RECORD FILING IN MEMORY

Patient data and measurement records are filed in memory using the memory save function under 8.17. OTHER FUNCTIONS.

1) Recorded data, consisting of a patient and measurement data, is automatically catalogued by a unique tag number and classified according to usage as shown where each row consists of a record entry. The three columns showing the unique tag number, record type, and associated patient ID number respectively. To view all records in storage, use the ▼ or ▲ keys to scroll over.



2) Data records are chronologically stored and are classified in the following types:

Record Type	*Record space used*	*Description*
	1	Pre Data Record
P	2	Pre/Post Data Record
B	1	Baseline Data Record
D	1	Dose Data Record

3) Where:

a) Pre data record is created when saving the typical patient VC, FVC, MVV measurement data;
b) Pre/Post data record is created when saving a Post Bronchodilator measurement result;
c) Baseline data record is a reclassified Pre data record that was utilized as baseline data for Bronchial Challenge Testing; and,
d) Dose data record is created whenever a dose test measurement result is saved.

The maximum memory capacity of the instrument is as follows:

Record Type	*Maximum Memory Capacity*
Only Pre Data Record	50 data sets
Pre/Post Data Record	25 data sets

A Pre/Post data Record, although assigned one tag number, actually uses two record spaces when saved.

8.16.PRINTING OF DATA

Depress the PRINT key to print the current measurement result. All the selected measurement data are printed on two print formats, which can be user-selected as standard or detail. The procedure for selecting the print format can be referred to 8.17. OTHER FUNCTIONS. To cancel printing, depress the PRINT key.

8.17.OTHER FUNCTIONS

Depress the UTILITY key to display the menu screen.

Select the desired function by keying the item number and depressing the ENT key to initiate operation.

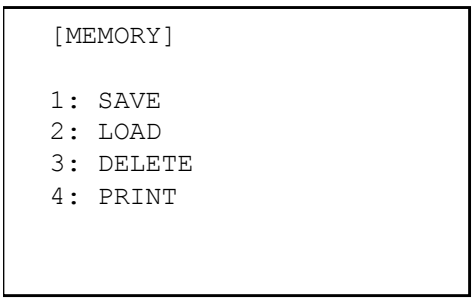
Depress the STOP key to return to the ID screen.

```
1: MEMORY
2: CALIBRATION
3: TRANSMISSION
4: FRC
5: BASE
6: PRINT
7: DATE
8: MODE
```

Use the ▼ or ▲ keys to scroll through the screens.

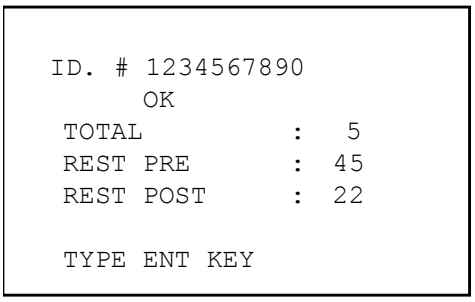
```
9: CONTRAST
```

1) Memory File Function (MEMORY)
Select option 1: MEMORY from the UTILITY menu by keying the numerical label (1) and the ENT key to do memory filing functions (saving, loading, deleting and printing of data).



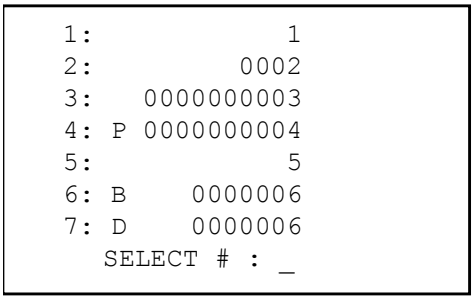
Depress the STOP key to cancel and return to the ID screen.

a) Saving of Measurement Data (SAVE)
Store or catalogue the current patient ID and measurement data into memory. Select option 1: SAVE from the MEMORY menu to initiate. Operation saves one data at a time. Successful data save operation is confirmed with the ID# confirmation screen displayed. Where the confirmation screen shows:

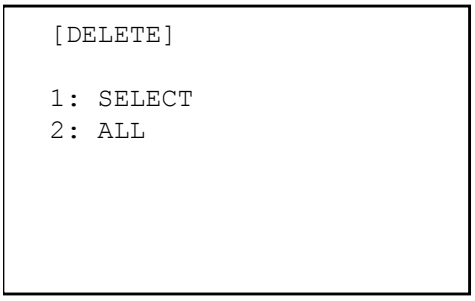


(ID. #) - the ID number of the current measurement data saved;
(TOTAL) - the total number of data saved in the memory including the current data;
(REST PRE) - the remaining memory capacity if only pre (regular) data are saved;
(REST POST) - the remaining memory capacity if pre and post data are saved.

b) Reloading of Saved Measurement Data (LOAD)
Reload a selected patient measurement data for further operation. Select option 2: LOAD from the MEMORY menu to display the ID numbers of data stored in the memory. Select the patient ID number and key in the prefixed item number and depress the ENT key. If there are seven data sets stored, depress ▲ or ▼ arrow keys to scroll through the list of ID numbers stored in the memory. Depress the STOP key to cancel and return to the ID screen.

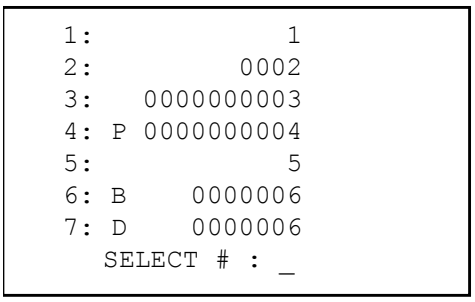


c) Deletion of Measurement Data (DELETE)
Deletes measurement data stored in the memory. Select option 3: DELETE from the MEMORY menu to initiate. Select from two deletion options namely: selective deletion; or, total deletion. Selective deletes a specific data per operation. While, total deletes all data stored in the memory.

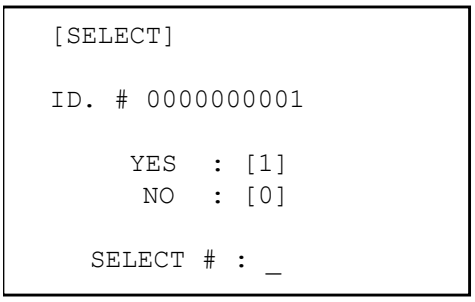


i) 1: SELECT

Select option 1: SELECT from the DELETE menu to display the ID numbers of data stored in the memory. Select the patient ID number and key in the numerical tag number and depress the ENT key. Depress the ▲ or ▼ arrow keys to scroll through the list of ID numbers in the memory.

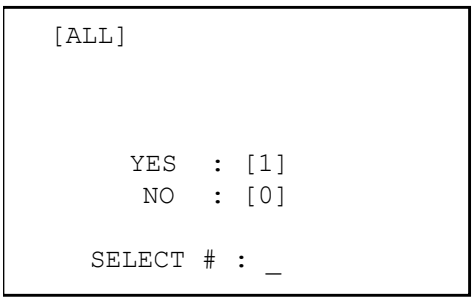


ii) When the patient data to be deleted is selected, a confirmation screen is displayed. Depress 1 key and then ENT key to confirm deletion or depress 0 key and then the ENT key to cancel deletion. Thereafter, the screen returns to the ID screen.



iii) 2:ALL

Select option 2: ALL from the DELETE menu to initiate total deletion. Confirm action by depressing 1 and then the ENT key to effect total deletion or depress 0 and then the ENT key to cancel deletion action. Thereafter, the screen returns to the ID screen.



d) Printing of Saved Measurement Data (PRINT)

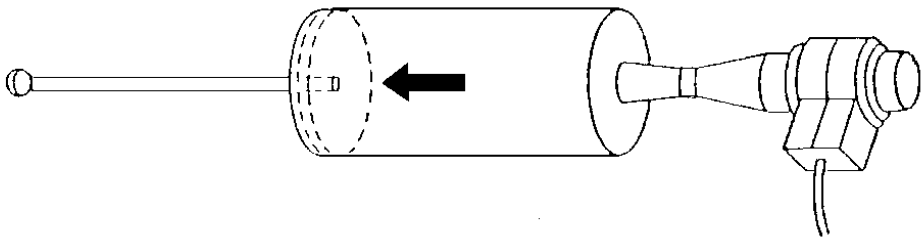
Select option 4: PRINT from the MEMORY menu to enables the printing of all saved measurement data. The printout format shall depend on the data set type; i.e., Pre data, Post data, BASE data, or DOSE data.

2) Auto calibration (CALIBRATION)

Select option 2: CALIBRATION from the UTILITY menu by keying the numerical label (2) and the ENT key to conduct calibration.

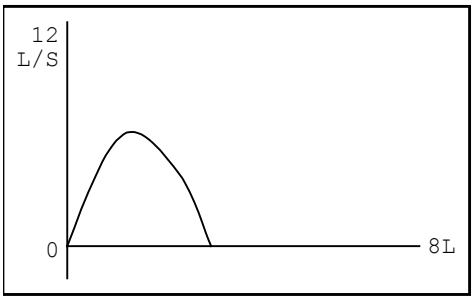
Auto calibration is done with an optional three-liter calibration syringe. Where it is recommended that calibration constancy be checked before and after each measurement session. Prior to calibration, remove the heater jack of the flow sensor from the main unit.

a) Connect the three-liter calibration syringe to the flow sensor in a level line. Pull back the shaft of the calibration syringe to its end and leave as is.

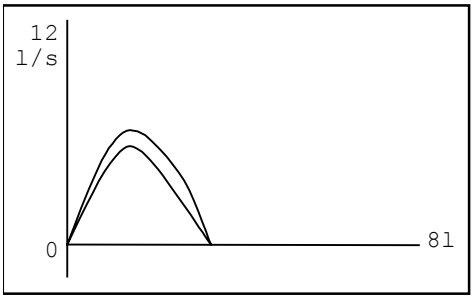


b) The zero level reference is detected at this time. Do not move the shaft of the calibration syringe. The calibration scale is displayed when ready.

c) Depress the START key.
Push the shaft of the syringe smoothly to its end to empty all three liters of air into the flow sensor. The flow volume curve is displayed on the scale.



d) Then pull the shaft of the syringe smoothly to its end to take in three liters of air through the flow sensor. In auto calibration, only the upper scale is shown on the display. The inspired and expired flow curves are thus shown superimposed on the scale. After a cycle, the two flow curves disappear and the computer beeps.



e) Repeat procedures 2.c) through 2.d) three times using varying speeds of emptying the calibration syringe to include flow linearity consistency. If you wish to cancel auto calibration, depress the STOP key. The screen returns to the ID screen.

f) When the three calibration cycles are done, the inspiratory and expiratory average values and correction factors of the three measurements are displayed. The correction factor is then registered with the software.

```
[CALIBRATION]
            Meas    Fact
    Exp     3.00   1.000
   Insp     3.01   0.997

  Target  3.00 L

    TYPE ENT KEY
```

g) Depress the ENT key to terminate the auto calibration routine.

h) The auto calibration acceptable tolerance is ± 1 liter from 3.0 liters. Taken by averaging the three autocalibration measurements for both expiration and inspiration cycles reckoned from 3.0 liters. If the average value is out of the acceptable tolerance, an error message "IMCOMPLETE" will be displayed. In this case, depress the ENT key to return to ID menu screen and check the connection of the calibration syringe and the flow sensor. Repeat the auto calibration routine.

In the event that the auto calibration procedure consistently results in an "INCOMPLETE NG" message, submit your equipment for check-up to your Fukuda Sangyo dealer.

3) Data transmission (TRANSMISSION)

Select option 3: TRANSMISSION from the UTILITY menu by keying the numerical label (3) and the ENT key to conduct data transfer operation. All the data stored in this instrument can be transferred to a PC using optional software "**FS/PC-95**". Contact your dealer about the detail specification for data transmission.

a) Before beginning data transmission, check the connection of the PC and the status of data acceptance.

b) Depress 1 key (1:TX) and then the ENT key to transfer data only.

c) Depress 2 key (2:WTX) and then the ENT key to transfer data and waveforms.

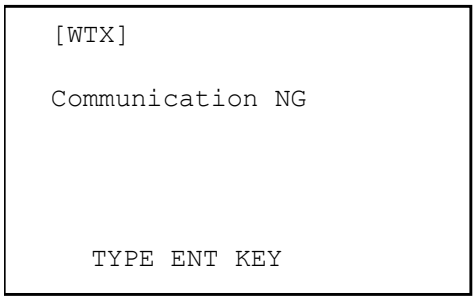
```
[TRANSMISSION]

1: TX
2: WTX



  SELECT # : _
```

d) When either transmission is selected, data transfer is started with following display. Where the screen shows the total number of data stored and the number of data sets already transferred.

e) If you wish to cancel data transmission, depress the STOP key to return to the ID screen.

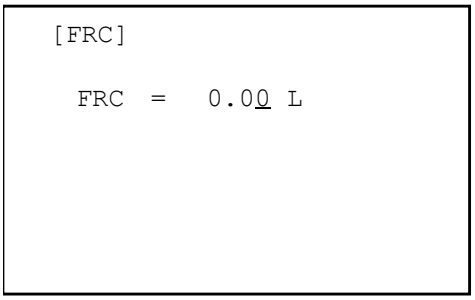
```
[WTX]

  DATA OUTPUT
    WAIT!

     XX / XX
```

f) If any problem is encountered during data transmission, the following error message is displayed.



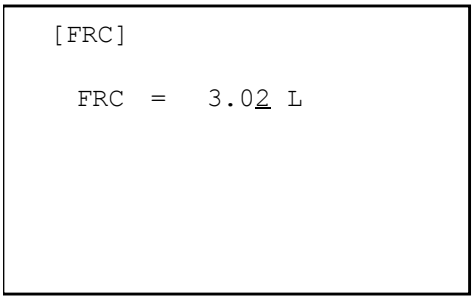
g) Depress the ENT key to return to the ID screen. Fix the problem and repeat the data transmission procedure.

4) Entry of FRC value (FRC)
Select option 4: FRC from the UTILITY menu by keying the numerical label (4) and the ENT key. FRC value, as measured by other Pulmonary Function Testing regimen, may be entered. Where RV value and associated parameters are computed from the entered FRC value and the VC data.



a) Enter the FRC value with the numeral keys.

b) On complete entry, the FRC value is interpreted as a two decimal-place number. Key entry of the number is on a first-in last-out sequence (where the digit is positioned to where the underline is). To enter an FRC value of 3.02 liters, enter the "3", "0", "2" in sequence and depress the ENT key.



c) If an erroneous value is entered, depress the CLR key and enter correct value.

d) If you wish to cancel the FRC entry, depress the STOP key to return to the ID screen.

5) Setting up Bronchial Challenge Testing (BASE) / Entry of Concentration during Bronchial Challenge Testing (DOSE)
Select option 5: BASE or DOSE from the UTILITY menu by keying the numerical label (5) and the ENT key to do Bronchial Challenge Testing.

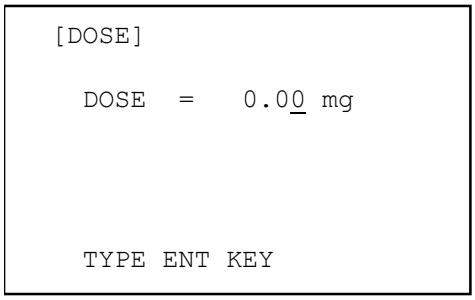
Prior to initiation of Bronchial Challenge Test Mode, UTILITY function 5: indicates BASE. Only during Bronchial Challenge Testing will UTILITY function 5: indicate DOSE.

After a baseline measurement data is loaded, the instrument automatically changes into Bronchial Challenge testing mode. Once this operation is entered, the mode is kept until a new patient ID is entered. Printing of Bronchial Challenge performance data may be done only after saving the data set as a DOSE set data.

a) When in BASE option, the ID numbers of earlier measured and saved patient data are displayed. Enter the patient ID number using the prefix numerical tag number and depress the ENT key. When the ID screen is displayed, the selected data is now loaded as the baseline data. Bronchial Challenge Testing is now ready.

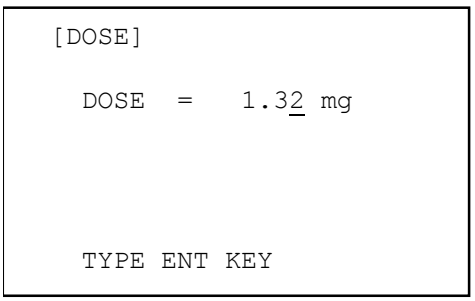
b) After administering the drug to the patient, select option 1: DOSE from the UTILITY menu by keying the numerical label (5) and the ENT key.

c) The DOSE initial setting as displayed for a patient is pre-set to 0.00 while subsequent settings displays the last entered value.



d) Enter the concentration value administered to the patient with the numeral keys.

e) On complete entry, the dose value is interpreted as a two decimal-place number. Key entry of the number is on a first-in last-out sequence where the entered digit is positioned to where the underline is). To enter a dose value of 1.32 mg, enter "1", "3", "2" in sequence and depress the ENT key.



f) If you enter the wrong value, depress the CLR key and enter the correct value. The screen returns to the ID screen.

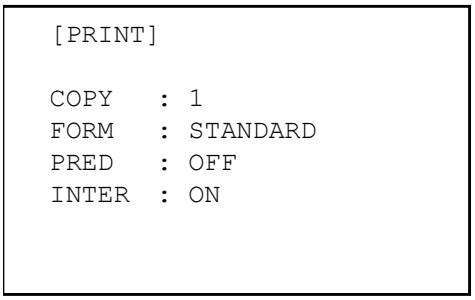
g) If you wish to cancel the DOSE entry, depress the STOP key to return to the ID screen. The last entered value is retained.

h) The entry values acceptable are listed in the following:

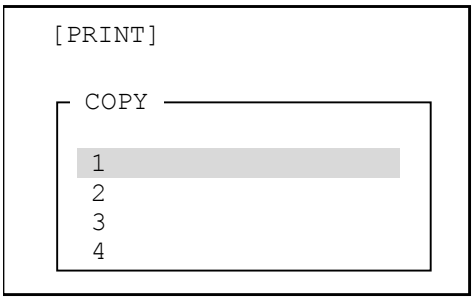
Type	Description	Accepted range
Saline	Measurement with inhalation of Saline	0.00
Dose	Measurement with inhalation of Dose	0.01 to 999.98
Recovery	Measurement with inhalation of bronchodilator	999.99

6) Setting of the Printout Format (PRINT)
Select option 6: PRINT from the UTILITY menu by keying the numerical label (6) and the ENT key to alter printing format of reports.

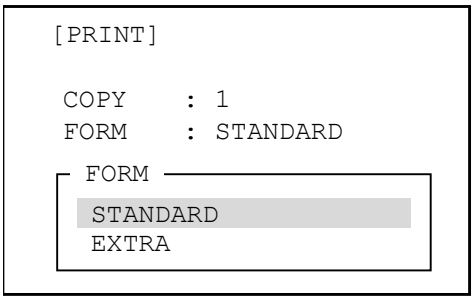
a) Upon initiation, the current print format setting is displayed. Depress the STOP key when no change to the current setting is desired. Else, depress the ENT key to display the pop up window screen. When inside the pop-up window screen, use the ▲ or ▼ keys to move the cursor to the selected item requiring the change and depress the ENT key to confirm selection.



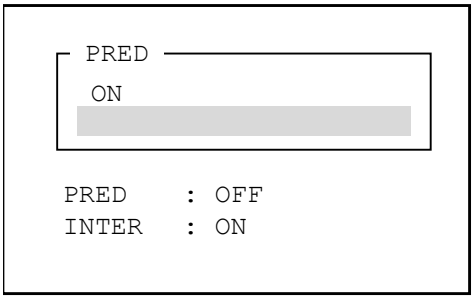
i) COPY specifies the number of report copies to be printed. User-selectable between single-copy and multiple-copy (2 – 4 sheets) printing.



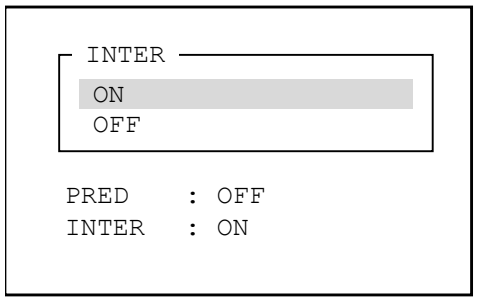
ii) FORM specifies the report format selection. User-selectable between STANDARD and EXTRA. STANDARD prints in summary report form while EXTRA prints in detail report form



iii) PRED specifies whether inclusion of the predicted curve in the FVC print report is desired. Standard setting is OFF. If ON is selected, the predicted curve is printed with the actual F-V curve on the FVC graphical scale.



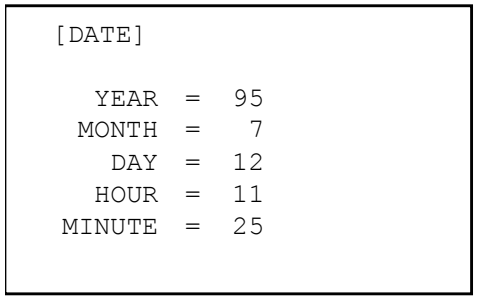
iv) INTER specifies whether inclusion of the interpretation summary in the print report is desired. Standard setting is ON, where the interpretation summary is inclusive in the print report. If OFF is selected, the interpretation summary will not be printed.



b) When the print setting is completed, the setting screen is displayed. Check the setting. Depress the STOP key to end the print setting. The screen returns to the ID screen. Setting is backed up by battery until new setting is changed.

7) Setting of date and time (DATE)
Select option 7: DATE from the UTILITY menu by keying the numerical label (7) and the ENT key to change date and time settings.

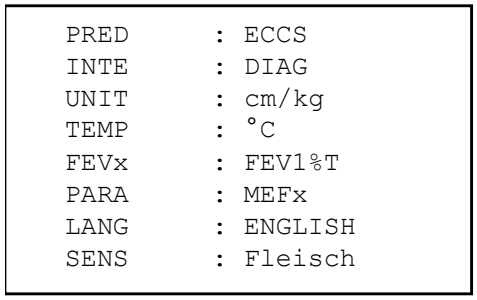
a) Upon entering, the currently set date and time are displayed. A change may be made at the item where the cursor is positioned. Enter the change with the numeral keys and depress the ENT key to move the cursor to the successive item.



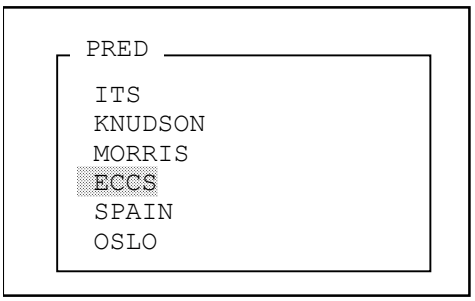
b) Depress the STOP key to end the DATE setting. The screen returns ID screen. This setting is backed up by battery until a new setting is made.

8) Setting of system mode (MODE)
Select option 8: MODE from the UTILITY menu by keying the numerical label (8) and the ENT key to select desired prediction equations, interpretation programs and measuring parameters.

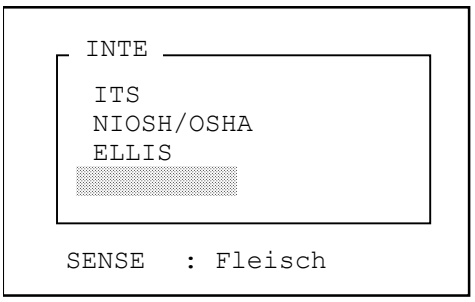
a) Upon entering, the current mode setting is displayed. Depress the STOP key when no change to the current setting is desired. Else, depress the ENT key to display the pop-up window screen. When inside the pop-up window screen, use the ▲ or ▼ keys to move the cursor to the selected item requiring the change and depress the ENT key to confirm selection.



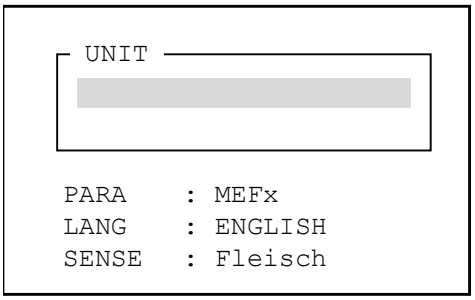
i) PRED specifies the predicted equation to apply. Where applicable sets of prediction equations may be user-selectable. In cases however that ITS or ITS (NIOSH/OSHA) interpretation is selected, only ITS prediction equation may be selected.



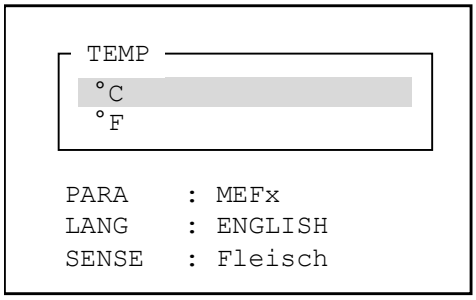
ii) INTE specifies the interpretation algorithm to use. Where four (4) kinds of interpretation may be user-selectable.



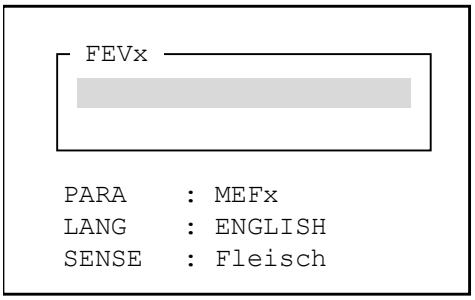
iii) UNIT specifies the height and weight units that are used during patient ID entry. Where selection may be Metric (cm/kg) or English (ins/lbs).



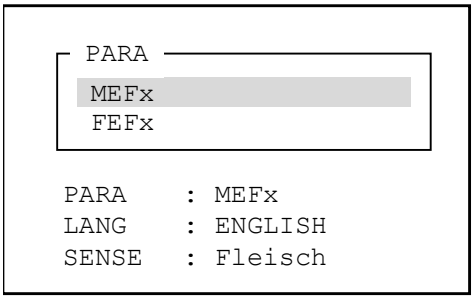
iv) TEMP specifies the temperature unit that is used during patient ID entry. Where selection may be Centigrade (°C) or Fahrenheit (°F).



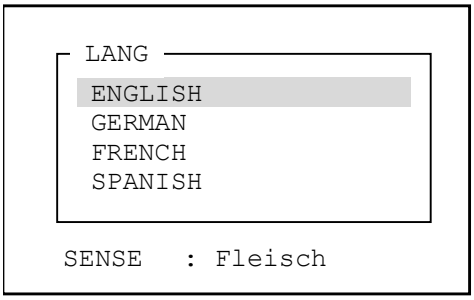
v) FEVx specifies which expression of FEV1%T(FEV1/VC) & FEV3%T(FEV3/VC) or FEV1%G(FEV1/FVC) & FEV3%G(FEV3/FVC) during FVC measurement to use. Where FEVx%T or FEVx%G may be selected.



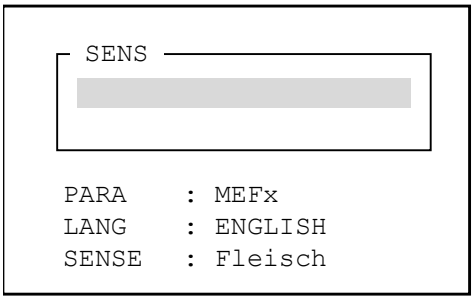
vi) PARA specifies which expression of Maximum (Forced) Expiratory Flow on FVC measurement to use. Where MEFx or FEFx may be selected.



vii) LANG specifies the language to be use. Where four (4) languages may be selected.



viii) SENS specifies the kind of sensor to be used. Where FLEISCH or DISPO may be selected depending on the type of flowhead the patient intends to use.



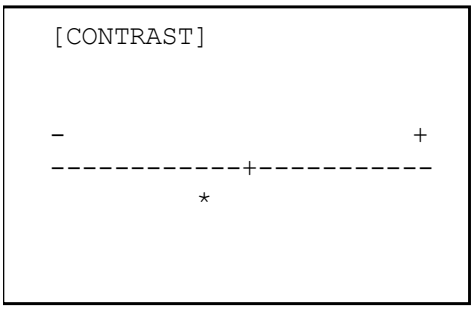
b) On completion of the mode setting, the setting screen is displayed. Check each setting. Depress the STOP key to end the mode setting. The screen returns to the ID screen. The current setting is backed up by battery until a new setting is changed.

9) Contrast Adjustment (CONTRAST)
Select option 9: CONTRAST from the UTILITY menu by keying the numerical label (9) and the ENT key to adjust the LCD display contrast.

a) Upon entering, the contrast display line is shown.

b) Depress the ▲ key to darken or the ▼ key to lighten the display. An "*" mark will move right or left according to the contrast adjustment.

c) Depress the ENT key to end the contrast adjustment. The screen returns to the ID menu screen.



Chapter 9. SAFEKEEPING

9.1.Stowing

For prolonged storage of the instrument, the following prior action should be conducted:

1) Insure that the instrument power switch is set to off. Disconnect the power cord from a wall socket.

2) If the instrument is soiled, wipe clean using a mild detergent in a dampen cloth. Then wipe off with a dry cloth until no detergent remains.

3) Do not immerse the instrument in water, expose to direct sunlight or subject to excessive vibration at any time.

4) For best storage protection, store the instrument in its original packaging and seal.

5) Do not store the instrument on places where a large temperature, humidity or pressure change occurs; or, where ambient dusts, salts or ions are found.

6) Check all the accessories and keep with the main unit.

Warning:
If the main unit or flow sensor is dropped, it is mandatory that a thorough check of the system be performed by an authorized Fukuda Sangyo service personnel. Further use of the instrument should only be done after a satisfactory inspection.

Chapter 10. CLEANING AND STERILIZING

Before using the instrument and for each patient perform the following:

- Replace the paper mouthpiece.(disposable accessory)
- Sterilize the laminar flow tube and the tapered rubber tube

  The laminar flow tube (metal) can be easily slipped out the flow head.

10.1.CLEANING THE EXTERNAL OF THE INSTRUMENT

Warning:

- **Always unplug the instrument before cleaning!**
- **Do not use any scrubbing agents or solvents (alcohol, acetone) to clean the instrument or its accessories.**
- **Generally, any cleaning procedure that heats the materials above 45°C may affect the life of the material.**

1) You may clean the external surfaces of the instrument with a damp cloth or sponge safeguarding however that no drips flows along the surface of the instrument.
2) Insure that the instrument is completely dry following a cleaning procedure.

10.2.TAPERED RUBBER TUBE

Pull out the rubber tube from the flow sensor to free.

1) Do not use Ethylene Oxide gas to sterilize the tapered rubber tube. The gas may cause incursion into the material where toxicity may remain.
2) Do not use alcohol or alcohol-based solutions to clean the tapered rubber tube. These solutions may cause hardening of the material thus reduce the life of the material.
3) The sterilization procedure for the tapered rubber tube can be done using a detergent water solution containing a maximum volume percentage of 20% of Cidex, Citrosil, or the like.

Push in the rubber tube into the front side of the flow sensor to ready.

10.3.LAMINAR FLOW TUBE (METAL)

To remove the laminar tube from the flowhead, hold the flowhead rigidly with its front side towards you and grasp the laminar tube with the free hand. Rotate the laminar tube about one-

eight clockwise. Turning the flowhead on its backside, push out the laminar tube until clear of the flowhead. Proceed to the cleaning of the bare laminar flow tube using the following methods:

1) You may use Ethylene Oxide gas to sterilize the laminar flow tube.
2) You may autoclave the laminar flow tube up to 132°C of temperature (2 bar, 10 minutes).
3) The sterilization procedure for the laminar tube can be done using a detergent water solution containing a maximum volume percentage of 20% of Cidex, Citrosil, or the like.

> Make sure that the laminar flow tube is completely dry before reusing. Remaining water drops (even in small amounts) may cause measurement errors. Shake the laminar flow tube to remove water drops.

To re-install the laminar tube into the flowhead, position the laminar tube to the front side of the flowhead with the locking lug of the laminar tube located at your left and near side. Push slide the laminar tube until the locking lug firmly sets into the flowhead slit. With the flowhead rigidly with its front side towards you, grasp the laminar tube with the free hand and rotate one-eight clockwise to lock.

10.4.NOSECLIP CLEANING

> The nose clip must be cleaned before each patient use with alcohol or a detergent solution.

Chapter 11. PREDICTED EQUATIONS

11.1.ITS (Intermountain Thoracic Society)

Parameter	Sex	Age	Predicted Equation	95% CI	Reference
VC (l)		(all)	Pred VC = Pred FVC		
FVC (l)	M	7-18 W	$3.58\times10^{-4}\times H^{3.18}\div1000$	13	1 (Hsu)
	M	7-18 B	$1.07\times10^{-3}\times H^{2.93}\div1000$	17	1 (Hsu)
	M	19+	0.0600×H−0.0214×A−4.650	1.12	1 (Crapo)
	F	7-18 W	$2.57\times10^{-3}\times H^{2.78}\div1000$	14	1 (Hsu)
	F	7-18 B	$8.34\times10^{-4}\times H^{2.98}\div1000$	15	1 (Hsu)
	F	19+	0.0491×H−0.0216×A−3.590	0.68	1 (Crapo)
FEV.5 (l)	M	19+	0.0327×H−0.0152×A−1.914	0.71	1 (Crapo)
	F	19+	0.0238×H−0.0185×A−0.809	0.51	1 (Crapo)
FEV1 (l)	M	7-18 W	$7.74\times10^{-4}\times H^{3.00}\div1000$	13	1 (Hsu)
	M	7-18 B	$1.03\times10^{-3}\times H^{2.92}\div1000$	17	1 (Hsu)
	M	19+	0.0414×H−0.0244×A−2.190	0.84	1 (Crapo)
	F	7-18 W	$3.79\times10^{-3}\times H^{2.68}\div1000$	14	1 (Hsu)
	F	7-18 B	$1.14\times10^{-3}\times H^{2.89}\div1000$	15	1 (Hsu)
	F	19+	0.0342×H−0.0255×A−1.578	0.56	1 (Crapo)
FEV3 (l)	M	19+	0.0535×H−0.0271×A−3.512	1.02	1 (Crapo)
	F	19+	0.0442×H−0.0257×A−2.745	0.62	1 (Crapo)
FEV1%G (%)	M	19+	−0.1300×H−0.152×A+110.49	8.3	1 (Crapo)
	F	19+	−0.2020×H−0.252×A+126.58	9.1	1 (Crapo)
FEV3%G (%)	M	19+	−0.0627×H−0.145×A+112.09	4.6	1 (Crapo)
	F	19+	−0.0937×H−0.163×A+118.16	5.4	1 (Crapo)
MMEF (l/s)	M	7-18 W	$7.98\times10^{-4}\times H^{2.46}\div60$	26	1 (Hsu)
	M	7-18 B	$3.61\times10^{-4}\times H^{2.60}\div60$	36	1 (Hsu)
	M	19+	0.0204×H−0.0380×A+2.133	1.67	1 (Crapo)
	F	7-18 W	$3.79X10^{-3}\times H^{2.16}\div60$	28	1 (Hsu)
	F	7-18 B	$1.45X10^{-3}\times H^{2.34}\div60$	30	1 (Hsu)
	F	19+	0.0154×H−0.0460×A+2.683	1.36	1 (Crapo)
PEF (l/s)	M	7-18 W	$3.35\times10^{-4}\times H^{2.79}\div60$	18	1 (Hsu)
	M	7-18 B	$1.74\times10^{-4}\times H^{2.92}\div60$	22	1 (Hsu)
	M	19-24	0.078×H+0.166×A−8.060		K1
	M	25+	0.094×H−0.035×A−5.993		K1
	F	7-18 W	$2.58\times10^{-3}\times H^{2.37}\div60$	18	1 (Hsu)
	F	7-18 B	$5.51\times10^{-4}\times H^{2.68}\div60$	20	1 (Hsu)
	F	19	0.049×H+0.157×A−3.916		K1
	F	20+	0.049×H−0.025×A−0.735		K1

Continued…

Parameter	Sex		Predicted Equation	95% CI	Reference
FEF25% (l/s)	M	7-24	0.070×H+0.147×A−7.054		K1
	M	25+	0.088×H−0.035×A−5.618		K1
	F	7-19	0.044×H+0.144×A−3.365		K1
	F	20+	0.043×H−0.025×A−0.132		K1
FEF50% (l/s)	M	7-11	0.0378×H−2.5454	94.789	K2
	M	12-24	0.0543×H+0.1150×A−6.3851	96.052	K2
	M	25+	0.0684×H−0.0366×A−5.5409	92.734	K2
	F	7-10	0.1846×A+0.7362	93.286	K2
	F	11-19	0.0288×H+0.1111×A−2.3040	95.109	K2
	F	20-69	0.0321×H−0.0240×A−0.4371	95.065	K2
	F	70+	0.0118×H−0.0755×A+6.2402	95.144	K2
FEF75% (l/s)	M	7-11	0.0171×H−1.0149	92.505	K2
	M	12−24	0.0397×H−0.0057×A−4.2421	94.591	K2
	M	25+	0.0310×H−0.0230×A−2.4827	90.674	K2
	F	7-10	0.0109×H−0.1657	90.705	K2
	F	11-19	$0.0243\times H+0.2923\times A-4.401-0.0075\times A^2$	94.465	K2
	F	20-69	0.0174×H−0.0254×A−0.1822	91.473	K2
	F	70+	−0.0172×A+1.8894	92.742	K2
MVV (l/min)	M	7-18	Pred FEV1×40		2
	M	19+	1.34×H−1.26×A−21.4	±56.8	1 (Kory)
	F	7-18	Pred FEV1×40		2
	F	19+	0.807×H−0.57×A−5.50	±21.0	1 (Lindall)
FRC (l)	M	15-91	0.0472×H+0.0090×A−5.290	±1.46	1 (Crapo)
	F	17-84	0.0360×H+0.0031×A−3.182	±1.06	1 (Crapo)
RV (l)	M	15-91	0.0216×H+0.0207×A−2.840	±0.76	1 (Crapo)
	F	17-84	0.0197×H+0.0201×A−2.421	±0.78	1 (Crapo)
TLC (l)	M	15-91	0.0795×H+0.0032×A−7.333	±1.61	1 (Crapo)
	F	17-84	0.0590×H−4.537	±1.08	1 (Crapo)
RV/TLC (%)	M	15-91	0.3090×A+14.060	±8.80	1 (Crapo)
	F	17-84	0.4160×A+14.350	±11.0	1 (Crapo)
BSA (m^2)		(all)	$W^{0.425}\times H^{0.725}\times 71.84\times 10^{-4}$		

Symbol	Definition	Unit	Range		
A	Age	years	M	7-91	
			F	7-84	
H	Height	cm	M	7-18	111-190cm
			M	19+	157-194cm
			F	7-18	111-180cm
			F	19+	146-178cm
W	Weight	kg			

Continued…

Reference:

1*(author)*=	: Hsu, Crapo, Lindall, and Kory. CLINICAL PULMONARY FUNCTION TESTING 2nd Edition 1984, IntermountainThoracic Society.
K1=	: Knudson, R. J., et al. The Maximal Expiratory Flow - Volume Curve Normal Standards, Variability, and Effects of Age. AM REV RESPIR DIS 1976; 113:587-600.
K2=	: Knudson, R. J., et al. Changes in the Normal Maximal Expiratory Flow-Volume Curve with Growth and Aging. AM REV RESPIR DIS 1983; 127:725–734.
2=	: Anonymous, Not-Published.

11.2.Knudson

Parameter	Sex	Age	Predicted Equation	95% CI	Reference
VC(l)		(all)	Pred. VC = Pred. FVC		
FVC (l)	M	6-11	0.0409×H−3.3756	96.413	K2
	M	12-24	0.0590×H+0.0739×A−6.8865	98.100	K2
	M	25+	0.0844×H−0.0298×A−8.7818	94.653	K2
	F	6-10	0.0430×H−3.7486	95.539	K2
	F	11-19	0.0416×H+0.0699×A−4.4470	96.885	K2
	F	20-69	0.0444×H−0.0169×A−3.1947	96.493	K2
	F	70+	0.0313×H−0.0296×A−0.1889	96.614	K2
FEV.5 (l)	M	6-24	0.030×H+0.043×A−3.054		K1
	M	25+	0.037×H−0.017×A−2.746		K1
	F	6-19	0.019×H+0.061×A−1.738		K1
	F	20+	0.019×H−0.014×A−0.406		K1
FEV1 (l)	M	6-11	0.0348×H−2.8142	96.997	K2
	M	12-24	0.0519×H+0.0636×A−6.1181	97.970	K2
	M	25+	0.0665×H−0.0292×A−6.5147	95.551	K2
	F	6-10	0.0336×H−2.7578	96.300	K2
	F	11-19	0.0351×H+0.0694×A−3.7622	97.073	K2
	F	20-69	0.0332×H−0.0190×A−1.8210	96.944	K2
	F	70+	0.0143×H−0.0397×A+2.6539	97.048	K2
FEV3 (l)	M	6-24	0.052×H+0.066×A−5.531		K1
	M	25+	0.063×H−0.031×A−5.245		K1
	F	6-19	0.033×H+0.086×A−3.417		K1
	F	20+	0.035×H−0.023×A−1.633		K1
FEV1%G (%)	M	6-24	−0.0813×H+100.4389	99.035	K2
	M	25+	−0.1050×A+86.6862	98.348	K2
	F	6-19	−0.1909×H+0.6655×A+109.9739	98.687	K2
	F	20+	−0.1852×H−0.1896×A+121.6777	98.742	K2
MMEF (l/s)	M	6-11	0.0338×H−2.3197	94.410	K2
	M	12-24	0.0539×H+0.0749×A−6.1990	95.975	K2
	M	25+	0.0579×H−0.0363×A−4.5175	92.814	K2
	F	6-10	0.0220×H−0.8119	92.630	K2
	F	11-19	0.0279×H+0.1275×A−2.8007	95.015	K2
	F	20-69	0.0300×H−0.0309×A−0.4057	94.559	K2
	F	70+	−0.0615×A+6.3706	93.714	K2
PEF (l/s)	M	6-24	0.078×H+0.166×A−8.060		K1
	M	25+	0.094×H−0.035×A−5.993		K1
	F	6-19	0.049×H+0.157×A−3.916		K1
	F	20+	0.049×H−0.025×A−0.735		K1

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Parameter	Sex	Age	Predicted Equation	95% CI	Reference
FEF25% (l/s)	M	6–24	0.070×H+0.147×A-7.054		K1
	M	25+	0.088×H-0.035×A-5.618		K1
	F	6–19	0.044×H+0.144×A-3.365		K1
	F	20+	0.043×H-0.025×A-0.132		K1
FEF50% (l/s)	M	6–11	0.0378×H–2.5454	94.789	K2
	M	12–24	0.0543×H+0.1150×A–6.3851	96.052	K2
	M	25+	0.0684×H–0.0366×A–5.5409	92.734	K2
	F	6–10	0.1846×A+0.7362	93.286	K2
	F	11–19	0.0288×H+0.1111×A–2.3040	95.109	K2
	F	20–69	0.0321×H–0.0240×A–0.4371	95.065	K2
	F	70+	0.0118×H–0.0755×A+6.2402	95.144	K2
FEF75% (l/s)	M	6–11	0.0171×H–1.0149	92.505	K2
	M	12–24	0.0397×H–0.0057vA–4.2421	94.591	K2
	M	25+	0.0310×H–0.0230×A–2.4827	90.674	K2
	F	6–10	0.0109×H–0.1657	90.705	K2
	F	11–19	$0.0243\times H+0.2923\times A-4.401-0.0075\times A^2$	94.465	K2
	F	20–69	0.0174×H–0.0254×A–0.1822	91.473	K2
	F	70+	–0.0172×A+1.8894	92.742	K2
MVV (l/min)	M	6–19	Pred. FEV1×40		Anon
	M	20+	1.15×H–1.27×A+14		Comp
	F	6–19	Pred. FEV1×40		Anon
	F	20+	0.55×H–0.72×A+50		Comp
FRC (l)	M	15–91	0.0472×H+0.0090×A–5.290	±1.46	Crapo
	F	17–84	0.0360×H+0.0031×A–3.182	±1.06	Crapo
RV (l)	M	15–91	0.0216×H+0.0207×A–2.840	±0.76	Crapo
	F	17–84	0.0197×H+0.0201×A–2.421	±0.78	Crapo
TLC (l)	M	15–91	0.0795×H+0.0032×A–7.333	±1.61	Crapo
	F	17–84	0.0590×H–4.537	±1.08	Crapo
RV/TLC (%)	M	15–91	0.3090×A+14.060	±8.80	Crapo
	F	17–84	0.4160×A+14.350	±11.0	Crapo
BSA (m^2)		(all)	$W^{0.425}\times H^{0.725}\times 71.84\times 10^{-4}$		

Symbol	Definition	Unit
A	Age	years
H	Height	cm

Reference:

K1= : Knudson, R. J., et al. The Maximal Expiratory Flow - Volume Curve Normal Standards, Variability, and Effects of Age. AM REV RESPIR DIS 1976; 113:587-600.

Continued…

K2= : Knudson, R. J., et al. Changes in the Normal Maximal Expiratory Flow-Volume Curve with Growth and Aging. AM REV RESPIR DIS 1983; 127:725–734.

Comp= : Composite of Kory, Cherniack, and Armstrong studies.

Crapo= : R. O. Crapo, A. H. Morris. Lung Volumes in Healthy Nonsmoking Adults. BULL EUROP PHYSIOPATHOL RESPIR 1982; 18: 419–425

Anon= : Anonymous, Not-Published.

11.3.MORRIS/POLGAR

Parameter	Sex	Age	Predicted Equation	95% CI	Reference
VC (l)		(all)	Pred VC = Pred FVC		
FVC (l)	M	5-17	$4.4\times10^{-3}\times H^{2.67}\div1000$		P
	M	18+	$0.058\times H-0.025\times A-4.241$		M
	F	5-17	$3.3\times10^{-3}\times H^{2.72}\div1000$		P
	F	18+	$0.045\times H-0.024\times A-2.852$		M
FEV0.5 (l)	M	6-24	$0.030\times H+0.043\times A-3.054$		K1
	M	25+	$0.037\times H-0.017\times A-2.746$		K1
	F	6-19	$0.019\times H+0.061\times A-1.738$		K1
	F	20+	$0.019\times H-0.014\times A-0.406$		K1
FEV1.0 (l)	M	5-17	$2.1\times10^{-3}\times H^{2.80}\div1000$		P
	M	18+	$0.036\times H-0.032\times A-1.260$		M
	F	5-17	$2.1\times10^{-3}\times H^{2.80}\div1000$		P
	F	18+	$0.035\times H-0.025\times A-1.932$		M
FEV1%G (%)	M	18+	$-0.123\times H-0.2422\times A+107.12$		M
	F	18+	$-0.027\times H-0.1815\times A+88.70$		M
MEFR (l/s)	M	18+	$0.043\times H-0.047\times A+2.010$		M
	F	18+	$0.057\times H-0.036\times A-2.532$		M
MMEF (l/s)	M	5-17	$(2.621\times H-207.70)\div60$		P
	M	18+	$0.019\times H-0.045\times A+2.513$		M
	F	5-17	$(2.621\times H-207.70)\div60$		P
	F	18+	$0.024\times H-0.030\times A+0.551$		M
PEF (l/s)	M	5-17	$(5.2428\times H-425.5714)\div60$		P
	F	5-17	$(5.2428\times H-425.5714)\div60$		P
FEF25% (l/s)	M	6–24	$0.070\times H+0.147\times A-7.054$		K1
	M	25+	$0.088\times H-0.035\times A-5.618$		K1
	F	6–19	$0.044\times H+0.144\times A-3.365$		K1
	F	20+	$0.043\times H-0.025\times A-0.132$		K1
FEF50% (l/s)	M	6–11	$0.0378\times H-2.5454$	94.789	K2
	M	12–24	$0.0543\times H+0.1150\times A-6.3851$	96.052	K2
	M	25+	$0.0684\times H-0.0366\times A-5.5409$	92.734	K2
	F	6–10	$0.1846\times A+0.7362$	93.286	K2
	F	11–19	$0.0288\times H+0.1111\times A-2.3040$	95.109	K2
	F	20–69	$0.0321\times H-0.0240\times A-0.4371$	95.065	K2
	F	70+	$0.0118\times H-0.0755\times A+6.2402$	95.144	K2
FEF75% (l/s)	M	6–11	$0.0171\times H-1.0149$	92.505	K2
	M	12–24	$0.0397\times H-0.0057vA-4.2421$	94.591	K2
	M	25+	$0.0310\times H-0.0230\times A-2.4827$	90.674	K2
	F	6–10	$0.0109\times H-0.1657$	90.705	K2
	F	11–19	$0.0243\times H+0.2923\times A-4.401-0.0075\times A^2$	94.465	K2
	F	20–69	$0.0174\times H-0.0254\times A-0.1822$	91.473	K2
	F	70+	$-0.0172\times A+1.8894$	92.742	K2

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Parameter	Sex	Age	Predicted Equation	95% CI	Reference
MVV (l/min)	M	7-17	1.276×H−99.5		P
	M	18+	1.34×H−1.26×A−21.4		Kory
	F	7-17	1.276×H−99.5		P
	F	18+	0.807×H−0.57×A−5.50		Lindall
FRC (l)	M	7-17	$0.75\times10^{-3}\times H^{2.92}\div1000$		P
	M	18−91	0.0472×H+0.0090×A−5.290	±1.46	Crapo
	F	7-17	$1.78\times10^{-3}\times H^{2.74}\div1000$		P
	F	18-84	0.0360×H+0.0031×A−3.182	±1.06	Crapo
RV (l)	M	7-17	$4.11\times10^{-3}\times H^{2.41}\div1000$		P
	M	18−91	0.0216×H+0.0207×A−2.840	±0.76	Crapo
	F	7-17	$4.11\times10^{-3}\times H^{2.41}\div1000$		P
	F	18-84	0.0197×H+0.0201×A−2.421	±0.78	Crapo
TLC (l)	M	7-17	$5.6\times10^{-3}\times H^{2.67}\div1000$		P
	M	18−91	0.0795×H+0.0032×A−7.333	±1.61	Crapo
	F	7-17	$4.0\times10^{-3}\times H^{2.73}\div1000$		P
	F	18-84	0.0590×H−4.537	±1.08	Crapo
RV/TLC (%)	M	15−91	0.3090×A+14.060	±8.80	Crapo
	F	17−84	0.4160×A+14.350	±11.0	Crapo
BSA (m^2)		(all)	$W^{0.425}\times H^{0.725}\times71.84\times10^{-4}$		

Symbol	Definition	Unit
A	Age	years
H	Height	cm
W	Weight	kg

Reference:

P= : George Polgar, M.D. and Varuni Promadhat, M.D. Pulmonary Function Testing In Children: Techniques And Standard, 1971.

M= : James F. Morris, Arthur Koski, and Lavon C.Johnson. Spirometric Standards for Healthy Nonsmoking Adults. AM REV RESPIR DIS 1971; 103:57–67.

K1= : Knudson, R. J., et al. The Maximal Expiratory Flow - Volume Curve. Normal Standards, Variability, and Effects of Age. AM REV RESPIR DIS 1976; 113:587-600.

K2= : Knudson, R. J., et al. Changes in the Normal Maximal Expiratory Flow-Volume Curve with Growth and Aging. AM REV RESPIR DIS 1983; 127:725–734.

Crapo= : R. O. Crapo, and A. H. Morris. Lung Volumes in Healthy Nonsmoking Adults. BULL EUROP PHYSIOPATHOL RESPIR 1982; 18: 419–425

11.4.ECCS (European Community for Coal and Steel)

Parameter	Sex	Age	Predicted Equation	RSDm	R	RSD2	Remarks
VC (l)	M	7-17	= FVC				1, 2, 4
	M	25-70	6.103×H−0.028×A−4.654	0.251	0.94	0.56	6
	F	7-17	= FVC				1, 2, 4
	F	25-70	4.664×H−0.024×A−3.284	0.270	0.90	0.42	6
FVC (l)	M	7-17	$1.00\times H^{2.7}$				1, 2, 4
	M	25-70	5.757×H−0.026×A−4.345	0.304	0.92	0.61	6
	F	7-17	$0.95\times H^{2.7}$				1, 2, 4
	F	25-70	4.426×H−0.026×A−2.887	0.234	0.93	0.43	6
FEV1 (l)	M	7-17	$0.84\times H^{2.7}$				1, 2
	M	25-70	4.301×H−0.029×A−2.492	0.258	0.93	0.51	6
	F	7-17	$0.81\times H^{2.7}$				1, 2
	F	25-70	3.953×H−0.025×A−2.604	0.205	0.94	0.38	6
FEV1%T (%)	M	7-17	0.84				1, 2, 4
	M	25-70	−0.179×A+87.21	3.85	0.53	7.17	6
	F	7-17	0.84				1, 2, 4
	F	25-70	−0.192×A+89.1	3.73	0.59	6.51	6
MMEF (l/s)	M	25-70	1.944×H−0.043×A+2.699	0.683	0.66	1.04	6
	F	25-70	1.252×H−0.034×A+2.924	0.437	0.73	0.85	6
PEF (l/s)	M	7-17	8.2×H−6.8				1, 3, 4
	M	25-70	6.146×H−0.043×A+0.154	0.787	0.74	1.21	6
	F	7-17	6.7×H−5.3				1, 3, 4
	F	25-70	5.501×H−0.030×A−1.106	0.707	0.69	0.90	6
MEF75% (l/s)	M	25-70	5.459×H−0.029×A−0.470	0.534	0.80	1.71	6
	F	25-70	3.218×H−0.025×A+1.596	0.230	0.90	1.35	6
MEF50% (l/s)	M	7-17	5.6×H−4.4				1, 3, 4
	M	25-70	3.794×H−0.031×A−0.352	0.934	0.54	1.32	6
	F	7-17	4.6×H−3.3				1, 3, 4
	F	25-70	2.450×H−0.025×A+1.156	0.532	0.53	1.10	6
MEF25% (l/s)	M	25-70	2.605×H−0.026×A−1.336	0.721	0.54	0.78	6
	F	25-70	1.050×H−0.025×A+1.107	0.512	0.58	0.69	6
MVV (l/s)	M	5-17	1.276×H−99.507		(Polger)		
	M	18+	1.34×H−1.26×A−21.4		(Kory)		
	F	5-17	1.276×H−99.507		(Polger)		
	F	18+	0.807×H−0.57×A−5.5		(Lindall)		
FRC (l)	M	7-17	$0.58\times H^{2.7}$				1, 2, 4, 5
	M	25-70	2.348×H+0.009×A−1.093	0.443	0.51	0.60	6
	F	7-17	$0.56\times H^{2.7}$				1, 2, 4, 5
	F	25-70	2.245×H+0.001×A−1.003	0.285	0.59	0.50	6

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Parameter	Sex	Age	Predicted Equation	RSDm	R	RSD2	Remarks
RV (l)	M	7-17	$0.25\times H^{2.7}$				1, 2, 4
	M	25-70	$1.310\times H+0.022\times A-1.232$	0.308	0.73	0.41	6
	F	7-17	$0.24\times H^{2.7}$				1, 2, 4
	F	25-70	$1.812\times H+0.016\times A-2.003$	0.196	0.77	0.35	6
TLC (l)	M	7-17	$1.23\times H2.7$				1, 2, 4
	M	25-70	$7.992\times H-7.081$	0.480	0.87	0.70	6
	F	7-17	$1.17\times H2.7$				1, 2, 4
	F	25-70	$6.602\times H-5.791$	0.221	0.94	0.60	6
RV/TLC (%)	M	25-70	$0.387\times A+13.96$	3.87	0.80	5.46	6
	F	25-70	$0.335\times A+18.96$	3.62	0.80	5.83	6
BSA (m^2)		(all)	$W^{0.425}\times H^{0.725}\times 71.84\times 10^{-4}$				

Symbol	Definition	Unit
A	Age	years
H	Height	m
H (MVV)	Height	cm
W	Weight	kg

Predicted values between 18 and 24 years are calculated as 25 years except MVV.

Reference:

1= : Cotes, J. E. Lung Function, 3rd Edition, Blackwell, Oxford, 1975.

2= : George Polgar, M.D. and Varuni Promadhat, M.D. Pulmonary Function Testing in Children, W. B. Sauders Co., Philadelphia, 1971.

3= : Sorbini, C. A.; Casucci, G.; Todisco, T. BULL PHYSIOPATH RESP; 11, 195P, 1975.

4= : Zapletal, A.; Motoyama, E. K.; v.d. Woestijne, K. P.; Hunt, V. R.; Bouhuys, A J APPL PHYSIOL; 26, 308, 1969.

5= : Taussig, L. M.; Harris, T. R.; Lebowitz, M. D. AM REV RESPIR DIS; 116, 233, 1977.

6= : Official Statement of the European Respiratory Society. Standardized Lung Function Testing; EUR RESPIR J; 1983, 6, Suppl. 16

11.5.SPAIN

Parameter	Sex	Age	Predicted Equation	SD	SEE	Remarks
SVC (l)	M	3-19	= FVC			
	M	20-70	0.06103×H−0.028×A−4.654		0.56	ECCS [1]
	F	3-19	= FVC			
	F	20-70	0.04664×H−0.024×A−3.284		0.42	ECCS [1]
FVC (l)	M	3-19	0.028×H+0.03451×W+0.05728×A−3.21			
	M	20-70	0.0678×H−0.0147×A−6.0548	0.768	0.53	1
	F	3-19	0.03049×H+0.022×W+0.0355×A−3.04			
	F	20-70	0.0454×H−0.0211×A−2.8253	0.608	0.403	1
FEV1 (l)	M	3-19	0.02483×H+0.02266×W+0.07148×A−2.91			
	M	20-70	0.0499×H−0.0211×A−3.837	0.665	0.44	1
	F	3-19	0.02866×H+0.01713×W+0.02955×A−2.87			
	F	20-70	0.0317×H−0.025×A−1.2324	0.533	0.307	1
FEV3 (l)	M	3-19	(−0.022×A+0.0469×H−2.815)×0.93			
	M	20-90	(0.0678×H−0.0147×A−6.0548)×0.93			
	F	3-19	(−0.022×A+0.0366×H−1.924)×0.93			
	F	20-90	(0.0454×H−0.0211×A−2.8253)×0.93			
FEV1%T (%)			−0.16×A+85.62			
			−0.24×A+91.02			
FEV1%G (%)	M	20-70	−0.1902×A+85.58	5.85	5.36	1
	F	20-70	−0.224×A−0.1126×W+94.88	6.29	5.31	1
MMEF (l/s)	M	3-19	0.038×H+0.14×A−4.33			
	M	20-70	0.0392×H−0.043×A−1.16	1.21	1	1
	F	3-19	0.046×H+0.051×A−4.3			
	F	20-70	0.023×H−0.0456×A+1.1055	0.96	0.68	1
PEF (l/s)	M	3-19	0.075×H+0.275×A−9.08			
	M	20-70	0.0945×H−0.0209×A−5.7732	1.67	1.47	1
	F	3-19	0.73×H+0.134×A−7.57			
	F	20-70	0.0448×H−0.0304×A+0.3496	1.18	1.04	1
FEF25% (l/s)	M	3-90	−0.031×A+2.88×B+3.38			
	F	3-90	−0.024×A+0.105×H−0.3			
FEF50% (l/s)	M	3-19	0.017×H+0.157×A+0.029×W−2.17			
	M	20-70	0.0517×H−0.0209×A−2.4	1.47	1.3	1
	F	3-19	0.046×H+0.067×A−4.17			
	F	20-70	0.0242×H−0.0418×A+1.6151	1.11	0.925	1
FEF75% (l/s)	M	3-19	0.024×H+0.066×A−2.61			
	M	20-90	0.0190×H−0.0356×A−0.1405			
	F	3-19	0.027×H+0.032×A−2.68			
	F	20-90	0.02×H−0.031×A−0.0062×W−0.212			
PIF (l/s)	M	20-90	−0.023×A−0.006×W+1.19×B+3.87			
	F	20-90	−0.014×A+1.15×B+2.73			

Continued…

Parameter	Sex	Age	Predicted Equation	SD	SEE	Remarks
MVV (l)	M	3-90	1.276×H−99.5			
	F	3−19	1.276×H−99.5			
	F	20−90	0.807×H−0.57×A−5.5			
FRC (l)	M	7-17	$0.58\times H^{2.7}$			ECCS [1]
	M	25-70	2.348×H+0.009×A−1.093			ECCS [1]
	F	7-17	$0.56\times H^{2.7}$			ECCS [1]
	F	25-70	2.245×H+0.001×A−1.003			ECCS [1]
RV (l)	M	7-17	$0.25\times H^{2.7}$			ECCS [1]
	M	25-70	1.310×H+0.022×A−1.232			ECCS [1]
	F	7-17	$0.24\times H^{2.7}$			ECCS [1]
	F	25-70	1.812×H+0.016×A−2.003			ECCS [1]
TLC (l)	M	7-17	1.23×H2.7			ECCS [1]
	M	25-70	7.992×H−7.081			ECCS [1]
	F	7-17	1.17×H2.7			ECCS [1]
	F	25-70	6.602×H−5.791			ECCS [1]
RV/TLC (%)	M	25-70	0.387×A+13.76			ECCS [1]
	F	25-70	0.335×A+18.96			ECCS [1]
BSA (m^2)		(all)	$W^{0.425}\times H^{0.725}\times 71.84\times 10^{-4}$			

Symbol	Definition	Unit
A	Age	years
B	BSA	m^2
H	Height	cm
H (ECCS)	Height	m
W	Weight	kg

[1] Equations of the predicted values as ECCS to be applied.
Predicted values between 18 and 24 years are calculated as 25 years.

Reference:

1= : J. Roca, J. Sanchis, A. Agusti-Vidal, F. Segarra, D. Nvajas, R. Rodriguez-Roisin, P. Casan, S. Sans. Spirometric Reference Values from a Mediterranean Population. BULL EUROP PHYSIOPATHOL RESPIR 1986, 22, 217-224.

2= : Cotes, J. E. Lung Function, 3rd Edition, Blackwell, Oxford, 1975.

3= : George Polgar, M.D. and Varuni Promadhat, M.D. Pulmonary Function Testing in Children; W. B. Sauders Co., Philadelphia, 1971.

4= : Sorbini, C. A.; Casucci, G.; Todisco, T. BULL PHYSIOPATH RESP; 11, 195P, 1975.

5= : Zapletal, A.; Motoyama, E. K.; v.d. Woestijne, K. P.; Hunt, V. R.; Bouhuys, A. J. APPL PHYSIOL; 26, 308, 1969.

6= : Taussig, L. M.; Harris, T. R.; Lebowitz, M. D. AM REV RESPIR DIS; 116, 233, 1977.

ECCS= : Official Statement of the European Respiratory Society. Standardized Lung Function Testing; EUR RESPIR J; 1983, 6, Suppl 16

11.6.OSLO(NORWAY)

Parameter	Sex	Age	Predicted Equation	Remarks
VC (l)	All	3-19	Pred VC= Pred FVC	
FVC (l)	M	7-14	$1.00\times H^{2.7}$	1, 2, 4
	M	25+	7.40×H–0.029×A–6.68	
	F	7-14	$0.95\times H^{2.7}$	1, 2, 4
	F	25+	5.22×H–0.021×A–4.10	
FEV1 (l)	M	7-14	$0.84\times H^{2.7}$	1, 2, 4
	M	25+	5.74×H–0.034×A–4.54	
	F	7-14	$0.81\times H^{2.7}$	1, 2, 4
	F	25+	3.29×H–0.027×A–1.22	
FEV1%T (%)	M	7-14	0.84	1, 2, 4
	M	25+	0.18×A+87.21	ECCS [1]
	F	7-14	0.84	1, 2, 4
	F	25+	0.19×A+89.10	ECCS [1]
MMEF (l/s)	M	25+	6.08×H-0.044xA-4.73	
	F	25+	0.051×A+5.41	
PEF (l/s)	M	7-14	8.2xH-6.8	1, 3, 4
	M	25+	(354xH-1.97xA+9)/60	
	F	7-14	6.7×H-5.3	1, 3, 4
	F	25+	(274xH-2.04xA+59)/60	
MEF75% (l/s)	M	25+	5.46×H-0.029xA-0.47	ECCS [1]
	F	25+	3.22×H-0.025xA-1.60	ECCS [1]
MEF50% (l/s)	M	7-14	5.6×H-4.4	1, 3, 4
	M	25+	3.79×H–0.031×A–0.35	ECCS [1]
	F	7-14	4.6×H-3.3	1, 3, 4
	F	25+	2.45×H–0.025×A+1.16	ECCS [1]
MEF25% (l/s)	M	25+	2.61×H-0.026xA-1.34	ECCS [1]
	F	25+	1.05×H-0.025xA+1.11	ECCS [1]
BSA (m^2)		All	$W^{0.425}\times H^{0.725}\times 71.84\times 10^{-4}$	

Symbol	Definition	Unit
H	Height	m
H (BSA)	Height	m
A	Age	yrs
W	Weight	kg

[1] Equations of the predicted values as ECCS to be applied.
Predicted values between 15 and 24 years are calculated as 25 years.

Continued…

Reference:

1= : Cotes, J. E. Lung Function, 3rd Edition, Blackwell, Oxford, 1975.

2= : George Polgar, M.D. and Varuni Promadhat, M.D. Pulmonary Function Testing in Children; W. B. Sauders Co., Philadelphia, 1971.

3= : Sorbini, C. A.; Casucci, G.; Todisco, T. BULL PHYSIOPATH RESP; 11, 195P, 1975.

4= : Zapletal, A.; Motoyama, E. K.; v.d. Woestijne, K. P.; Hunt, V. R.; Bouhuys, A. J. APPL PHYSIOL; 26, 308, 1969.

5= : Taussig, L. M.; Harris, T. R.; Lebowitz, M. D.; AM REV RESPIR DIS; 116, 233, 1977.

ECCS= : Official Statement of the European Respiratory Society. Standardized Lung Function Testing; EUR RESPIR J; 1983, 6, Suppl 16

11.7.CHILENA

Parameter	Sex	Age	Predicted Equation	Remarks
VC (l)		All	Pred VC = Pred FVC	
FVC (l)	M	5 – 12	-3.4300+0.429xH	
	M	13 – 18	-8.8542+0.1572xA+0.668xH	
	M	19+	-8.3919-0.0143xA+0.0826xH	
	F	5 – 12	-3.6955+0.442xH	
	F	13 – 20	-6.6843+0.0672xA+0.0588xH	
	F	21+	-2.8821-0.0205xA+0.0465xH	
FEV1 (l)	M	5 – 12	-2.6975+0.0353xH	
	M	13 – 18	-8.4980+0.0927xA+0.0672xH	
	M	19+	-5.0391-0.0240xA+0.0594xH	
	F	5 – 12	-3.2392+0.0391xH	
	F	13 – 20	-5.4527+0.0332xA+0.0519xH	
	F	21+	-1.1219-0.0264xA+0.0327xH	
FEV1%T (%)	M	5 – 12	103.6481+(-0.1147xH)	
	M	13 – 18	71.077+(-0.8651xA)+(0.1821xH)	
	M	19+	74.564+(-0.2614xA)+(0.0996xH)	
	F	5 – 12	96.073+(-0.0451xH)	
	F	13 – 20	103.892+(-0.6766xA)+(-0.023xH)	
	F	21+	114.015+(-0.2895xA)+(-0.1306xH)	
MMEF (l/s)	M	5 – 12	-2.7763+0.0388xH	
	M	13 – 18	-10.6613+0.0927xH	
	M	19+	0.1980-0.0496xA+0.0347xH	
	F	5 – 12	-4.3043+0.0514xH	
	F	13 – 20	-4.2533+0.0525xH	
	F	21+	5.1952-0.0517xA	

Symbol	Definition	Unit
H	Height	cm
A	Age	yrs
W	Weight	kg

11.8.AUSTRIAN

Parameter	Sex	Age	Predicted Equation	Remarks
VC (l)		All	Pred VC = Pred FVC	
FVC (l)	M	≤ 17	$e^{(-1.142+1.259xH+0.004070xAx(W^{**}½))}$	
	M	≥ 18	-11.606+8.172xH-0.0339xAxH+1.2869xln(A)	
	F	≤ 15	$e^{(-3.842+4.1632x(H^{**}½)+0.1485x(A^{**}½)-1.322xFi)}$	
	F	≥ 16	-10.815+6.640xH-0.0408xAxH+1.7293xln(A)	
FEV1 (l)	M	≤ 17	$e^{(-1.178+1.221xH+0.003841xAx(W^{**}½))}$	
	M	≥ 18	-8.125+6.212xH-0.0300xAxH+0.9770xln(A)	
	F	≤ 15	$e^{(-3.877+3.9809x(H^{**}½)+0.1485x(A^{**}½)-1.322xFi)}$	
	F	≥ 16	-6.995+5.174xH-0.0314xAxH+1.0251xln(A)	
FEV1%G (%)	M	≤ 17	101.99-1.191x(H**2)-3.962xln(A)	
	M	≥ 18	101.99-1.191x(H**2)-3.962xln(A)	
	F	≤ 15	92.33	
	F	≥ 16	118.993-3.0320x(H**2)-6.9053xln(A)	
PEF (l/s)	M	≤ 17	$e^{(-0.214+0.921xH+0.0467xA+0.0020xW)}$	
	M	≥ 18	(1.798+2.311xln(H)+0.0159xA-0.000248x(A**2))**2	
	F	≤ 15	$e^{(-0.411+1.793xln(H)+0.4251xln(A)-0.910xFi)}$	
	F	≥ 16	(1.832+1.838xln(H)+0.0078xA-0.000172x(A**2))**2	
MEF75% (l/s)	M	≤ 17	$e^{(-0.077+0.770xH+0.0373xA+0.0025xW)}$	
	M	≥ 18	(1.581+1.854xln(H)+0.0213xA-0.000283x(A**2))**2	
	F	≤ 15	$e^{(0.455+1.616xln(H)+0.3738xln(A)-0.861xFi)}$	
	F	≥ 16	(1.779+1.421xln(H)+0.0096xA-0.000179x(A**2))**2	
MEF50% (l/s)	M	≤ 17	$e^{(-0.522+0.843xH+0.0300xA+0.0035xW)}$	
	M	≥ 18	(1.490+1.290xln(H)+0.0125xA-0.000218x(A**2))**2	
	F	≤ 15	$e^{(0.256+1.643xln(H)+0.3481xln(A)-1.089xFi)}$	
	F	≥ 16	(1.561+1.177xln(H)+0.0045xA-0.000140x(A**2))**2	
MEF25% (l/s)	M	≤ 17	$e^{(-1.576+1.166xH+0.0219xA+0.0021xW)}$	
	M	≥ 18	(1.314+0.898xln(H)-0.0083xA-0.000026x(A**2))**2	
	F	≤ 15	$e^{(-0.722+2.002xln(H)+0.3063xln(A)-0.409xFi)}$	
	F	≥ 16	(1.372+0.938xln(H)-0.0152xA+0.000036x(A**2))**2	
TLC (l)	M	≤ 17	(1.388-0.77xH)xVC	
	M	≥ 18	(1.1340+0.0053xA)xVC	
	F	≤ 15	(1.388-0.77xH)xVC	
	F	≥ 16	(1.2413+0.0036xA)xVC	

Symbol	Definition	Unit	Range
H	Height	m	M ≤ 17 1.09 – 1.96 m
			M ≥ 18 1.44 – 2.00 m
			F ≤ 15 1.10 – 1.82 m
			F ≥ 16 1.40 – 1.90 m
A	Age	yrs	M; F 5 – 90
W	Weight	kg	
Fi	$H/W^{2/3}$		

11.9.JAPAN

Parameter	Sex	Age	Predicted Equation	Reference
VC (l)	M	6-12	(34.0×H−2487)÷1000	Ishida
	M	13	(1.40×A−1.20)×H÷1000	Kanagami
	M	14-17	(0.48×A+17.18)×H÷1000	Kanagami
	M	18+	(27.63−0.112×A)×H÷1000	Baldwin
	F	6-12	(34.3×H−2609)÷1000	Ishida
	F	13	(1.70×A−6.70)×H÷1000	Kanagami
	F	14-17	(A+3.10)×H÷1000	Kanagami
	F	18+	(21.78−0.101×A)×H÷1000	Baldwin
FEV1 (l)	M	7-17	$0.782\times H3\times10^{-6}-0.011$	J. Bjure
	M	18+	0.0344×H−0.033×A−1.00	Berglund
	F	7-17	$0.683\times H3\times10^{-6}+0.221$	J. Bjure
	F	18+	0.0267×H−0.027×A−0.54	Berglund
FEV1%G (%)	M	18+	91.79−0.373×A	Berglund
	F	18+	92.11−0.261×A	Berglund
MMEF (l/s)	M	5-17	(37.01×H−2614)÷1000	Dickman
	M	18+	(20.08×H−46×A+2954)÷1000	Schmidt
	F	5-17	(34.25×H−2389)÷1000	Dickman
	F	18+	(16.93×H−37×A+2243)÷1000	Schmidt
PEF (l/s)	M	15+	0.05666×H−0.02403×A+0.22544	Cherniack
	F	15+	0.03594×H−0.01776×A+1.13160	Cherniack
MEF75% (l/s)	M	15+	0.03555×H−0.01987×A+2.72554	Cherniack
	F	15+	0.02707×H−0.01926×A+2.14653	Cherniack
MEF50% (l/s)	M	15+	0.02569×H−0.03049×A+2.40337	Cherniack
	F	15+	0.02449×H−0.02344×A+1.42640	Cherniack
MEF25% (l/s)	M	15+	0.01411×H−0.04142×A+1.98361	Cherniack
	F	15+	0.00919×H−0.03450×A+2.21596	Cherniack
MVV (l/min)	M	11-15	108×BSA−60	Needham
	M	16+	(86.5−0.522×A)×BSA	Baldwin
	F	11-15	77×BSA−24	Needham
	F	16+	(71.3−0.474×A)×BSA	Baldwin
FRC (l)	M	18+	(0.005×A+1.67)×H÷100	Nishida
	F	18+	(0.007×A+1.20)×H÷100	Nishida
RV (l)	M	18+	(0.010×A+0.55)×H÷100	Nishida
	F	18+	(0.009×A+0.42)×H÷100	Nishida
TLC (l)	M	18+	3.40×H÷100	Nishida
	F	18+	2.51×H÷100	Nishida
RV/TLC (%)	M	18+	0.330×A−0.140×W+23.4	Grimby
	F	18+	0.280×A+0.270×H−28.0	Grimby
BSA(m^2)		(all)	$W^{0.425}\times H^{0.725}\times71.84\times10^{-4}$	

Continued…

Symbol	Definition	Unit
A	Age	years
H	Height	cm
W	Weight	kg

Chapter 12. ERROR MESSAGES

When any trouble occurs, an error message is displayed.

	ERROR MESSAGE	*TROUBLE*	*SOLUTION*
1	BACK UP RAM NG	The memory device of the instrument may be defective.	Turn off then turn on the power switch to reset. If the same message is displayed, contact your Fukuda Sangyo dealer.
2	Extrapolated Volume NG	V_{ext} value exceeds the standard value of 10% under FVC or 0.1 liter, whichever is greater.	Depress the ENT key to display the actual measurement result. Coach the patient to exhale forcefully as soon the maximum inspired level is reached.
3	ID DATA FULL	The memory capacity is full and unable to further store data.	Depress the ENT key to return to the ID screen. Delete unnecessary data and retry the data storage procedure.
4	NO DATA	No data is stored in the memory.	Depress the ENT key to return to the ID screen.
5	DATA OUTPUT NG	Error in transmission of measurement data encountered.	Depress the ENT key to return ID screen. Check interconnection with the host computer and retry data transmission.