# SPIROMETER OPERATION MANUAL (Ver.1.0)

# **Terms of Warranty**

- This product is manufactured and passed through strict quality control and thorough inspection. Compensation standard concerning repair, replacement, refund of the product complies with "Consumer's protection law" noticed by Ministry of Finance and Economy.
- EKG 3000S is warranted by Bionet Co.,Ltd to be free from defects in material and workmanship for one year from date of purchase.
- Warranty repair or replacement will be made by Bionet Service Center at no charge for warranty period if properly used under normal condition in accordance with the instructions for use.
- In the event of a malfunction or failure during warranty period, customer should inform Bionet Co.,Ltd of the model name, serial number, date of purchase and explanation of failure of the defective equipment.

# How to reach us ...

| Service calls                   | Following are telephone numbers and addresses for<br>ro contacting various service, product supplies and<br>sales s personnel.                                                    |  |  |  |  |  |
|---------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|--|--|
|                                 | To open a Service call with Bionet Co.,Ltd, contact the numbers listed below.                                                                                                     |  |  |  |  |  |
|                                 | Product and Purchase Inquiry                                                                                                                                                      |  |  |  |  |  |
|                                 | Service Center                                                                                                                                                                    |  |  |  |  |  |
|                                 | Bionet Co.,Ltd - Tel : +82-2-6300-6418                                                                                                                                            |  |  |  |  |  |
|                                 | Fax : +82-2-6499-7789                                                                                                                                                             |  |  |  |  |  |
|                                 |                                                                                                                                                                                   |  |  |  |  |  |
|                                 | In the event of a malfunction or failure, contact<br>Service Dept. of Bionet Co.,Ltd along with the model<br>name, serial number, date of purchase and explanation<br>of failure. |  |  |  |  |  |
| Supply<br>products and<br>Order | Contact Bionet Co.,Ltd or Sales agency for supplying products and ordering other accessories.                                                                                     |  |  |  |  |  |
| accessories                     | Tel : +82-2-6300-6418                                                                                                                                                             |  |  |  |  |  |
|                                 |                                                                                                                                                                                   |  |  |  |  |  |
| Technical<br>Support            | For any technical questions or problems on the equipment, call ;                                                                                                                  |  |  |  |  |  |
|                                 | Tel : +82-2-6300-6419                                                                                                                                                             |  |  |  |  |  |

# **Definition of Warning, Caution, Note**

• For a special emphasis on agreement, terms are defined as listed below in operation manual. Users should operate the equipment according to all the Warning and Caution.

• Manufacturer or Sales agency takes no responsibility for any kind of damage or breakdown that is caused by misuse and failure to maintain the equipment. To inform that it may cause no harm in life but lead to injury against the "Caution" sign.

#### Warning

To inform that it may cause serious injury or death to the patient, property damage, material losses against the "Warning" sign.

#### Caution

To inform that it may cause no harm in life but lead to injury against the "Caution" sign.

#### Note

To inform that it is not dangerous but important for proper installation, operation, and maintenance of the equipment.

# **Service Requirements**

Refer servicing for equipment to Bionet Co., Ltd authorized service personnel. Any attempt to repair equipment under warranty will void that warranty.

It is the responsibility of users requiring service to report the need for service to Bionet Co., Ltd., or to one of their authorized agents.

Failure on the part of the responsible individual, hospital, or institution using this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

If there are any problems with the equipment, please follow the steps below :

- Contact the Bionet Oversea Service Department immediately. After gathering the model name, Serial Number, date of purchase, and description of the problem contact Bionet with the information shown below.
- Try to solve the problem over the phone with the service department personnel. If the problem cannot be solved over the phone, the service personnel can came and fix the problem directly.
- Bionet or local distributor will make available on request circuit diagrams, component part lists, descriptions, calibration instructions or other information which will assist your appropriately qualified technical personnel to repair those parts of equipment which are designated by Bionet as repairable.

# **General Precaution on Environment**

• Do not keep or operate the equipment in the environment listed below.

|                | Avoid placing in an area<br>exposed to moist. Do not<br>touch the equipment with<br>wet hand .                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Avoid exposure to direct<br>sunlight                                                                    |
|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|
|                | Avoid placing in an area<br>where there is a high<br>variation of temperature.<br>Operating<br>temperature ranges<br>from 10°C to 40°C.<br>Operating humidity<br>ranges from 30% to<br>85%. |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Avoid in the vicinity of<br>Electric heater                                                             |
|                | Avoid placing in an area<br>where there is an<br>excessive humidity rise<br>or ventilation problem.                                                                                         | A CONTRACTOR                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Avoid placing in an area<br>where there is an excessive<br>shock or vibration.                          |
|                | Avoid placing in an<br>area where chemicals<br>are stored or where<br>there is danger of gas<br>leakage.                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Avoid being inserted dust<br>and especially metal<br>material into the<br>equipment                     |
| CONTA<br>CONTA | Do not disjoint or<br>disassemble the<br>equipment. Bionet Co.Ltd<br>takes no responsibility for<br>it                                                                                      | Rectified and the second secon | Power off when the<br>equipment is not fully<br>installed.<br>Otherwise, equipment<br>could be damaged. |

# **General Precaution on Electric Safety**

Check the items listed below before operating the equipment.

- Be sure that AC power supply line is appropriate to use. (100 240V AC).
- Be sure that the entire connection cable of the system is properly and firmly fixed.
- Be sure that the equipment is completely grounded. (Otherwise, noise could result.)

| Note                                                                                                                                                                                              |    |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| The equipment should not be placed in the vicinity of electric generator, X-ray broadcasting apparatus to eliminate the electric noise during operation Otherwise, it may cause incorrect result. | ′, |
| Self-power line and stabile grounding is important for EKG 3000.                                                                                                                                  | ∙- |
| To use same power source with other electric instruments may cause incorrect result.                                                                                                              | ;t |

#### Note

EKG 3000S is classified as listed below ;

- This equipment conforms to Class I, Type-BF. The equipment should be grounded to protect the patient from electrical shock.
- Do not use the equipment in the vicinity of flammable anesthetics and solvents.
- The equipment conforms to Class I according to IEC/EN 60601-1 (Safety of Electric Medical Equipment)

This equipment conforms to Class A according to IEC/EN 60601-1-2 (Electromagnetic Compatibility Requirements)

Note

Diagnosis have to be confirmed by the doctor.

#### Note

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 950 for data processing equipment and IEC 601-1 for medical equipment). Furthermore all configurations shall comply with the system standard EN 60601-1-1:1993.

Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the system standard IEC 601-1-1:1993. If in doubt, consult the technical service department or your local representative.Diagnosis have to be confirmed by the doctor.

# **Safety Symbols**

The International Electrotechnical Commission (IEC) has established a set of symbols for medical electronic equipment which classify a connection or warm of any potential hazards. The classifications and symbols are shown below.

### Save these instructions.

| Symbols                | Contents                                                                                                                                                                   |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| $\mathbf{\dot{\star}}$ | Isolated patient connection. (IEC 601-1-Type BF)                                                                                                                           |
| $oldsymbol{eta}$       | Device part switched off.                                                                                                                                                  |
| Ò                      | Device part switched on.                                                                                                                                                   |
| Ĩ                      | This symbol identifies a safety note. Ensure you understand the function of this control before using it. Control function is described in he appreciate operation manual. |
| $\bigvee$              | Conductor provides a connection between equipment and the potential equalization busbar of the electrical installation                                                     |
|                        | External Signal IN/OUT Port                                                                                                                                                |
| $\sim$                 | EKG Signal Input Port                                                                                                                                                      |

# **Table of Contents**

| 1. Install Spirometer                       | 11 |
|---------------------------------------------|----|
| 1.1 Connect to spirometer handle            | 12 |
| 1.2 Appearance of spirometer handle         | 13 |
| 1.3 Confirm actions of spirometer handle    | 17 |
| 1.4 Put in and put out mouthpiece           | 17 |
| 1.5 Connect the spirometer to the main body | 18 |
| 2. Use Spirometer                           | 19 |
| 1. Enter patient information                | 20 |
| 1.1 Enter ID                                | 21 |
| 1.2 Enter NAME                              | 21 |
| 1.3 Enter Age                               | 22 |
| 1.4 Enter Gender                            | 22 |
| 1.5 Enter Height                            | 23 |
| 1.6 Enter Weight                            | 23 |
| 1.7 Enter Race                              | 23 |
| 1.8 Enter Smoke                             | 24 |
| 2. FVC(Forced Vital Capacity)TEST           | 25 |
| 3. SVC(Slow Vital Capacity)TEST             | 32 |
| 4. MVV(Maximum Voluntary Ventilation)TEST   | 34 |
| 5. CALIBRATION                              | 36 |
| 6. MAINTENANCE                              | 38 |
| 7. SPECIFICATION                            | 39 |

# 1. Install Spirometer



Appearance of Spirometer

## **1.1 Connect to Spirometer handle**

The picture above shows status where initial screen of the spirometer is selected while spirometer handle is connected to terminal connected to (5) external monitor coupling hole shown in the plan of the back of the main body as shown below.



#### Plan of the back of the main body

- ① Grounding terminal : Part connected to external grounding terminal when there is no protection grounding in a socket.
- ② Serial cable connection port: Connected part when it is connected to PC or spirometer handle.
- ③ Power switch : Switch that turns on or off the power.
- ④ Power cable connection port : Part to which AC input power is connected.
- ⑤ LAN cable connection port : Connected part connected when information is entered through network.

## 1.2 Appearance of spirometer handle

1) Plan of the front part of spirometer handle



- 1. Uppercover : Uppercover that fixes mouthpiece.
- 2. Uppercover lock : Part that locks uppercover fixing the mouthpiece.
- 3. Action lamp : Lamp showing action status(green)
- 4. Connection conductor : Conductor connected to serial cable connection hole of serial cable in the back of the main body.
- 5. Power switch : Switch that turns on or off the power.
- 6. Mouthpiece insertion hole : Hole into which the mouthpiece is inserted.

2) Plan of left side of spirometer handle



- 1. Uppercover : Uppercover that fixes mouthpiece.
- 2. Uppercover lock : Part that locks uppercover fixing the mouthpiece.
- 3. Connection conductor : Conductor connected to serial cable connection hole in the back of the main body.
- 4. Mouthpiece insertion hole : Hole into which the mouthpiece is inserted.

3) Plan of right of spirometer handle



- 1. Uppercover : Uppercover that fixes the mouthpiece.
- 2. Power switch : Switch that turns on or off the power.
- 3. Connection conductor : Conductor connected to serial cable connection hole in the back of the main body.
- 4. Mouthpiece insertion hole : Hole into which the mouthpiece is inserted.

4) Plan of the back of the spirometer handle



- 1. Uppercover : Uppercover that fixes the mouthpiece.
- 2. Uppercover lock : Part that locks uppercover fixing the mouthpiece.
- 3. Power switch : Switch that turns on or off the power.
- 4. Connection conductor : Conductor connected to serial cable connection hole in the back of the main body.
- 5. Mouthpiece insertion hole : Hole into which the mouthpiece is inserted.

## 1.3 Confirm actions of spirometer handle

if you turn on power switch in the right side of spirometer handle, the lamp turns green for three seconds before it blinks at intervals of three seconds and it indicates that the spirometer handle normally operates.

## 1.4 Put in and out mouthpiece

Fix disposable mouthpiece in the upper side of the spirometer handle to take measurement. First, press 'Uppercover lock' in the upper left side of spirometer handle and open semicircle uppercover and insert the mouthpiece into a groove made in open side. And then, close the uppercover again by giving a little pressure. In order to fix the mouthpiece correctly, pipe in the front side of the spirometer handle should be longer than that in the back side.

<u>\*The mouthpiece is disposable.</u>

**\***Refer to plan of the spirometer handle.

### Caution

Please, Don't close the upper cover,

a condition of pushing down the Cover Lock Switch.



## 1.5 Connect the spirometer to the main body

<Connect the power cable to the spirometer cable>

- (1) As the picture above, connect the power cable to the spirometer cable in the main body.
- (2) Connect spirometer handle to main body while the power of the main body is off.
- (3) Turn on power switch of spirometer handle.
- (4) Turn on power switch of main body.
- (5) After completion of system initialization, screen such as <spirometer operation screen> appears on LCD of the main body.

# 2. Use Spirometer

And then, if you turn on power switch of main body, following screen appears



<초기화면>

Connect spirometer handle to serial cable connection terminal in the back of the main body and turn it on. Choose one among the two, **ECG** or **SPIRO** by turning lottery switch, and then enter each menu by pressing lottery switch.

If you choose spirometer in initial menu, following initial menu appears on the LCD of the main body.



#### < Picture1 > Spirometer initial menu screen

Selected menu item is highlighted and if you choose wanted item by turning lottery encoder and press lottery encoder, the selected item executes its function. All functions are selected and excuted through use of items that appear on the screen above and switch and lottery encoder and touch screen at the bottom of the screen

#### Descriptions of each menu are as follows.

## 1. Enter patient information



Make sure to enter patient's personal information because it is necessary to predict pulmonary functions of patients. Make sure to enter especially the Age, Gender, Height, Weight items that is ticked.

Enter followings by using lottery switch and keyboard that appears on the LCD.

After you complete entry or if you press 'Cancel' key while entering information, the screen turns to the main screen without saving.

If you press "New" key, information that entered in advance is initialized.

|                | Patient in | formation        |     |  |
|----------------|------------|------------------|-----|--|
|                | ID         | : KOR1234        |     |  |
|                | Name       | : UNKNOWN        |     |  |
|                | Age        | : <u>33</u>      |     |  |
| Pa             | Gender     | : <u>Male</u>    |     |  |
|                | Height     | : <u>170 </u> cm |     |  |
|                | Weight     | : <u>78 </u> Kg  |     |  |
|                | Race       | : Oriental       |     |  |
|                | Smoke      | : <u>No</u>      |     |  |
|                | OK         | Cancle           | New |  |
|                |            |                  |     |  |
| Select Test It | em & Push  | Rotary           |     |  |

<Picture> Patient Info main screen

## 1.1 Enter ID

Enter ID number used in the hospital to classify examination result. You can enter the number consisting of as many as 20 digits of alphabet capital letters and numbers by using lottery switch and touch. If you select "Enter ID", letter entry space that consists of alphabet and numbers appears on the screen.

If you turn the lottery switch to the right, cursor moves consecutively from left top to right bottom.

Letters or numbers on which the cursor is placed are highlighted on the screen. If you press the lottery switch or touch here, the selected letters or numbers are entered.

If you place "OK" on the cursor and press the lottery switch after completing entry, the ID numbers entered in advance are saved and the letter entry space disappears from the screen. If you turn the lottery switch to the right, the cursor moves to "NAME" entry space.

| Edit ID            |                        |                                          |                                                  |                                                           |                                                                              |                                                                                           |                                                                                                     |                                                                                                                 |                                                                                                                       |
|--------------------|------------------------|------------------------------------------|--------------------------------------------------|-----------------------------------------------------------|------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|
|                    | KOR12                  | 34                                       |                                                  |                                                           |                                                                              |                                                                                           |                                                                                                     |                                                                                                                 |                                                                                                                       |
| 1                  | 2                      | 3                                        | 4                                                | 5                                                         | 6                                                                            | 7                                                                                         | 8                                                                                                   | 9                                                                                                               | 0                                                                                                                     |
| q                  | w                      | е                                        | r                                                | t                                                         | У                                                                            | u                                                                                         | i                                                                                                   | 0                                                                                                               | р                                                                                                                     |
| а                  | S                      | d                                        | f                                                | g                                                         | h                                                                            | j                                                                                         | k                                                                                                   |                                                                                                                 | •                                                                                                                     |
| Z                  | x                      | С                                        | v                                                | b                                                         | n                                                                            | m                                                                                         | ,                                                                                                   | •                                                                                                               | /                                                                                                                     |
| SFT CAP SPACE i OK |                        |                                          |                                                  |                                                           |                                                                              |                                                                                           |                                                                                                     |                                                                                                                 |                                                                                                                       |
|                    |                        |                                          |                                                  |                                                           |                                                                              |                                                                                           |                                                                                                     |                                                                                                                 |                                                                                                                       |
|                    | 1<br>q<br>a<br>z<br>SF | KOR12<br>1 2<br>q W<br>a s<br>z X<br>SFT | KOR1234   1 2 3   q w e   a s d   z x c   SFT C/ | KOR1234   1 2 3 4   q w e r   a s d f   z x c v   SFT CAP | Edit   KOR1234   1 2 3 4 5   q w e r t   a s d f g   z x c v b   SFT CAP SPA | Edit ID   KOR1234   1 2 3 4 5 6   q w e r t y   a s d f g h   z x c v b n   SFT CAP SPACE | Edit ID   KOR1234   1 2 3 4 5 6 7   q w e r t y u   a s d f g h j   z x c v b n m   SFT CAP SPACE i | Edit ID   KOR1234   1 2 3 4 5 6 7 8   q w e r t y u i   a s d f g h j k   z x c v b n m ,   SFT CAP SPACE i i i | Edit ID   KOR1234   1 2 3 4 5 6 7 8 9   q w e r t y u i o   a s d f g h j k I   z x c v b n m , .   SFT CAP SPACE i O |

#### <ID entry space>

### 1.2 Enter NAME

Enter NAME in the same way as ID entry.

## 1.3 Enter Age



#### Number entry space

If you select "Age" and click, number entry space as seen above. Press "OK" key, after entering patient's age.

## **1.4 Enter Gender**

If you press the lottery switch, gender of the patient appears alternatively as "male" and "female". If you turn the lottery switch to the right after selecting patient's gender, cursor moves to "Height" entry space.

| Patient Information |                   |   | Patient Information |                   |  |
|---------------------|-------------------|---|---------------------|-------------------|--|
| ID                  | : <u>KOR1234</u>  |   | ID                  | : <u>KOR1234</u>  |  |
| Name                | :                 |   | Name                | :                 |  |
| l Age               | : <u>33</u>       |   | I Age               | : <u>33</u>       |  |
| l Gender            | : Male            |   | I Gender            | : Female          |  |
| l Height            | : <u>170 </u> cm  |   | I Height            | : <u>170 </u> cm  |  |
| l weight            | : <u>78 K</u> g   |   | I weight            | : <u>78 </u> Kg   |  |
| Race                | : <u>Oriental</u> |   | Race                | : <u>Oriental</u> |  |
| Smoke               | : <u>No</u>       |   | Smoke               | : <u>No</u>       |  |
|                     |                   |   |                     |                   |  |
| OK                  | Cancle Ne         | w | OK                  | Cancle New        |  |

## **1.5 Enter HEIGHT**

Enter HEIGHT in the same way as Age entry. After completion of the entry, if you place "OK" on the cursor and press the lottery switch or click touch, entered information is saved. If you turn the lottery switch to the right, the cursor moves to "WEIGHT" entry space.

| Patient Information |                   |     |  |  |  |  |
|---------------------|-------------------|-----|--|--|--|--|
| ID                  | : <u>KOR1234</u>  |     |  |  |  |  |
| Name                | :                 |     |  |  |  |  |
| I Age               | : <u>33</u>       |     |  |  |  |  |
| I Gender            | : <u>Female</u>   |     |  |  |  |  |
| I Height            | : 170 cm          |     |  |  |  |  |
| l weight            | : <u>78 </u> Kg   |     |  |  |  |  |
| Race                | : <u>Oriental</u> |     |  |  |  |  |
| Smoke               | : <u>No</u>       |     |  |  |  |  |
|                     |                   |     |  |  |  |  |
| OK                  | Cancle            | New |  |  |  |  |

## **1.6 Enter WEIGHT**

Enter weight in the same way as "HEIGHT" entry.

## **1.7 Enter RACE**

Enter patient's race. The race is registered as Oriental, Black and Caucasian.

If you press the lottery switch in the same way as you did when you entered patient's gender, above-mentioned races appear one after another. If you turn the lottery switch to the right, the cursor moves to "SMOKE" entry status.

| Patient Information |                  |     |  |  |  |  |  |
|---------------------|------------------|-----|--|--|--|--|--|
| ID                  | : <u>KOR1234</u> |     |  |  |  |  |  |
| Name                | :                |     |  |  |  |  |  |
| I Age               | : <u>33</u>      |     |  |  |  |  |  |
| I Gender            | : <u>Female</u>  |     |  |  |  |  |  |
| I Height            | : <u>170 </u> cm |     |  |  |  |  |  |
| l weight            | : <u>78 </u> Kg  |     |  |  |  |  |  |
| Race                | : Oriental       |     |  |  |  |  |  |
| Smoke               | : <u>No</u>      |     |  |  |  |  |  |
|                     |                  |     |  |  |  |  |  |
| OK                  | Cancle           | New |  |  |  |  |  |

## 1.8 Enter SMOKE

Enter whether the patient smokes or not.

If you select "Yes", another small window as below appears.

Pack/day indicates the smoking volume of the patient per day.

Select one of "1/4", "1/2", "1", "2", "2more" by pressing lottery switch. If you turn the switch to clockwise, it is placed on "Years".

Enter the period that the patient have smoked at "Years". If you click it, number entry space that appeared when entering Age, Height and Weight appears.

| Patient Information |                                                 |                       |                                                 |                        |      |             |
|---------------------|-------------------------------------------------|-----------------------|-------------------------------------------------|------------------------|------|-------------|
| <br> <br>           | ID<br>Name<br>Age<br>Gender<br>Height<br>Weight | :<br>:<br>:<br>:<br>: | KOR123<br>UNKNO<br>33<br>Male<br>170 cr<br>78 k | 34<br>WN<br>m<br>Smoke | Info |             |
|                     | Race<br>Smoke<br>OK                             | :                     | Orienti<br>Yes<br>Canc                          | Pack/[<br>Years<br>OK  | Day  | :<br>Cancel |

Press"OK"after completing entry

## 2. FVC(Forced Vital Capacity) TEST

Select "FVC TEST" by turning the lottery switch to the right from the initial menu and press the lottery switch.

| FVC              | S/           | /C/VC | MVV     |
|------------------|--------------|-------|---------|
| PAT              | CALIB        | SETUP | List[3] |
| Select Test Item | & Push Rotar | у     |         |

Once you begin to take measurement, message appear in the screen in following orders.





If the following screen appears on the screen, the spirometer is all set to take the measurement.

After pressing "Start", if the patient puts the mouthpiece into his or her mouth and begins to breathe, the machine takes measurement.

If spirometer handles are not connected or power is off , following message appears. This message appears as the same in SVC test and MVV test.



Return main menu by pressing "Exit" by touch or lottery switch and check handle. And then, start again. Make sure to follow orders described below to make accurate measurement.

#### How to breathe in times of FVC measurement

(1) Take normal breaths three times or more.

Prepare for measurement by taking normal breaths. It is recommended for accurate measurement.

(2) Inhale as much as possible(TLC level)

Make sure to inhale as much as possible regardless of speed. Instruct the patient to inhale as much as possible.

#### (3) Exhale as fast and much as possible (Forced expiration)

Make sure for the patient to exhale as fast as possible until he or she reaches the point where no more exhalation is possible.

#### (4) Inhale as fast and much as possible to the end (Forced inspiration)

It is natural to inhale fast if you become out of breath. You should inhale as much as possible to avoid panting.

# (5) After that, you should signal the machine that you have finished taking the measurement by pressing the stop button on the screen.

If you have difficulties in taking breaths in above-mentioned orders, you can take measurement in following orders.

- 1) Take normal breath at least once and then,
- 2) Inhale as much as possible,
- 3) Exhale as much as possible,
- 4) Inhale again.
- 5) Press the stop button.

If you take breaths in above-mentioned orders, a graph showing the result of normal breaths appears in small size. If you go ahead with step 2 to 4, a big graph is drawn in the screen. If the user presses the button, one round of measurement is finished. Since the graph drawn while you take measurement dose not correspond with actual data of breaths, and it just indicates the fact that the patient is breathing, shape is not important.



<Screen in FVC measurement>

The Graph drawn while you took final measurement is removed, and Flow-Volume graph of maximal breaths shown below is drawn, and Volumes, Flows, Times and Ratios appear in about one and a half seconds.

#### Result screen

Signal the machine that measurement is finished by pressing "Stop" button by lottery switch or touch, after you complete measurement. Then, it turns to screen that indicate measurement results.



<Screen in the Measurement result>

If you have difficulties in taking measurement in above-mentioned orders, you can take measurement in following orders.

- 1) Take normal breath at least one time and then
- 2) Inhale as much as possible,
- 3) Exhale as much as possible,
- 4) Inhale again.
- 5) Press the lottery button.

## **RESULT screen menu**

#### New

The machine begins to take new measurement.

-Use "New" menu in beginning the 2<sup>nd</sup> Test after completion of the 1<sup>st</sup> measurement.



<Screen after "NEW" is clicked>

If you click "Yes" here, screen begins the second measurement as below.

Then press "Start" again and begin.



### Print

It prints the measurement result.

-It prints the measurement result.

### View

It shows the measurement result in graph and chart.

-You can view the detailed graph on the result.



FVC measurement result screen (View 1)

At this status, if you click lottery switch once more or press NEXT by touch, screen of detailed figures on the result appears.

| FVC Test                                                                        |                                                                       |                                                                       |     |      |  |
|---------------------------------------------------------------------------------|-----------------------------------------------------------------------|-----------------------------------------------------------------------|-----|------|--|
| F[L/s]                                                                          | REF                                                                   | 1st                                                                   | 2nd | 3rd  |  |
| PEF<br>FVC<br>FIVC<br>FEV1<br>FEF100<br>FEV1/FVC<br>FEF25%-75%<br>PIF<br>FIF50% | 8.83<br>4.84<br>4.84<br>3.84<br>0.00<br>79.38<br>4.17<br>0.00<br>4.88 | 0.56<br>0.24<br>4.88<br>0.15<br>1.23<br>61.27<br>0.31<br>7.34<br>3.81 |     |      |  |
|                                                                                 |                                                                       |                                                                       |     | EXIT |  |

FVC measurement result screen (View 2)

If you click Exit again, it returns to the measurement result result screen in advance.

### EXIT

It finishes measurement.



<Screen after Exit button is pressed>

If you press "Yes" after finishing all the measurement, the machine goes out into main screen.

## 3. SVC(Slow Vital Capacity) TEST

If you select SVT TEST in the initial menu and press lottery encoder or touch, the machine begins to take SCV measurement.



Once you begin to take measurement, message appear in the screen in following orders.

Make sure for the patient to put the mouthpiece into his or her mouth and take breaths in following orders described below. Unless the patient follows the orders, accurate measurement cannot be taken.

(1)Take normal breaths at least four times or more. If the machine senses four times or more of normal breath, it beeps.

- (2)Exhale slowly as much as possible to the end.(RV level)
- (3)Inhale slowly as much as possible to the end.(TLC level)

(4)Return to normal breathing.

If you breathe in above-mentioned orders, a graph of breathing speed (F-T) appears first. If you take a small normal breath while taking a big breath according to step 2 to 3, a big graph is redrawn.

Speed in the positive side(F[L/s]) of the screen indicates exhalation and that in the negative side inhalation. If you press "ESC" key while you are taking measurement, the machine stops taking the measurement, and screen turns to spirometer initial menu.



<Screen in SVC TEST>

If the measurement is finished, a graph(V-T) showing change in volume of lung is drawn as follows according to passage of time.



<SVC TEST result screen>

Remained four menus like New, Print, View, Exit are used in the same way as FVC test measurement.

## 4. MVV(Maximum Voluntary Ventilation) TEST



If you select MVV TEST in the initial menu and press lottery or touch, following screen appears. If you press Start in following screen, the machine begins to take the first MVV measurement.



Make sure for the patient to put the mouthpiece into his or her mouth and then breathe in following orders. Unless the patient follows the orders, it is not possible to take accurate measurement.

- (1) Begin to take measurement of vital capacity.
- (2) Instruct the patient to breathe as fast and much as possible.(NVV)
- (3) Make sure for the patient to breathe as fast and much as possible, and enter measurement starting key(press diagnosis output key)
- (4) After a specified measurement time (TMVV), the machine concludes the measurement, and result values appear in the screen. (Set as TMVV=12[sec]in advance)
- (5) Return to normal breathing.

If you breathe in orders above, Volume-Time graph is drawn in the screen. The volume is the result of adding amount of inhalation and that of exhalation.







MVV test

Press "Stop" button after completing measuring. If you press "Stop" button, the result screen as below appears.



## **5. CALIBRATION**

CALIBRTION should be conducted once everyday to maintain accuracy of the measurement. (calibrator should be purchased optionally by user)

If the correct result and existing result are within a margin of  $\pm$ -5%,

new correction result does not have to be applied.



If you choose CALIBRATION in the initial menu and press rotary encoder, following CALIBRATION menu appears.

If you choose and press each item(Pressure, Temperature, Syringe Size) by rotary switch or touch, number entry space that in times of patient Info appears.

Enter the responsible value for each item. After the entry, if you select Start, the machine begins to check handle and start correction.

Touch Screen Set is the same way as touch Setup of main body.

"Formula" is the diagnosis standard in FVC test. Please select "Formula" by rotary switch or touch. As seen below. You can use by selecting one method among Morris/Polgar, Knudson/ITS, ECCS/Quanjer.

| Calibration                  |       |
|------------------------------|-------|
| <u>Pressure : 760mmHg</u>    | Start |
| <u>Temperature : 25'C</u>    |       |
| <u>Syringe Size : 3000cc</u> |       |
| <u>Formula Morris/Polgar</u> |       |
|                              | Exit  |

| Standards       | Formula       | Description                                    |
|-----------------|---------------|------------------------------------------------|
| USA and Canada  | Morris/Polgar | Previous method used to diagnosis              |
|                 | Knudson/ITS   | Most common method/extended formula            |
| Outside the USA | ECCS/Quanjer  | Widely used method in Europe/Pediatric formula |

Description for each Formula were as follows.

The CALIBRATION proceeds in following orders:

- (1) Connect conductor of measurement part of spirpmeter to the main body.
- (2) Choose CALIBRATION item in the main body.
- (3) Connect the mouthpiece installed in the spirometer handle to mouth of syringe. Insert it tightly to prevent leakage.
- (4) Enter air pressure, temperature and syringe amount.(cc)
- (5) Press start button. If the machine is ready for the calibration, it beeps.
- (6) Move syringe handle back and forth ten times each.
- Make sure to move the handle after you hear the machine beep.
- (7) Decide whether to apply the correction result.



<Screen in calibration>



Everytime the syringe moves, a dot appears in the screen everytime one action is taken. Make sure to take subsequent action after a dot appears in the screen for accurate calibration. If you move the syringe ten times, prior volume measurement result and margin of error(%) appear in the screen. If the dot doesn't appear in the screen whenever the syringe moves please reset the calibration and then restart. The procedure of reset is as follows. Press Start] and Calib menu and then select Exit. If so, the reset will be done showing 100% range of difference. If you go through procedures of confirming whether to apply new coefficient, result values are entered into the measurement part of the spirometer, and the initial menu appears. Otherwise, the initial menu immediately appears.

If the touch screen dosen't work properly please enter 'Touch Screen Set' by using rotary key and then please touch '<- Touch rectangle' which appears on the left of the top and touch 'Touch rectangle' appears on the right of the bottom.

## 6. MAINTENANCE

#### 1) Maintenance and Cleaning

You can keep the device clean in many different ways. Use the following recommendations to avoid the damage or stain to the machine. If the material (not approved material) that may cause damage to the product is used, the product is not guaranteed even within the period of guarantee is not expired.

| Note                                                                                                   |
|--------------------------------------------------------------------------------------------------------|
| Check the main unit and probes thoroughly after cleaning.<br>Do not use the old and damaged equipment. |

To keep the machine clean, apply alcohol on a soft cloth and scrub the body and the measuring probes once a month. Do not use lacquer, thinner, ethylene, or the oxidizing substance.

Keep the cable from dust or stain. Wipe the cable with a soaked cloth that is wet with warm water ( $40^{\circ}C/104^{\circ}F$ ), and with the clinical alcohol once a week.

Do not soak the machine or the probe cable into any liquid or detergent. Keep the machine or the probe cable away from any liquid.

### **Disposal of your old appliance**



- 1. When this crossed out wheeled bin symbol is attached to a product it means the product is covered by the European Directive 2002/96/EC.
- 2. All electrical and electronic products should be disposed of separately from the municipal waste stream via designated collection facilities appointed by the government or the local authorities.
- 3. The correct disposal of your old appliance will help prevent potential negative consequences for the environment and human health.
- 4. For more detailed information about disposal of your old appliance, please contact your city office, waste disposal service or the shop where you purchased the product.

#### 2) Regular Inspection

Perform the periodical safety inspection on Spirometer once a year. For the inspection details, see the service manual provided by Bionet.

## 7. Specification

| Dimension           | 47(W) x 200(H) x 34(D)mm, approx. 250g                      |
|---------------------|-------------------------------------------------------------|
| Measuring values    | FVC: FVC, FEV 1.0, FEV 1/FVC, FEF 0.2-1.2L, FEF 25-75%, FEF |
|                     | 75-85%, PEF, FEF 25%, FEF 50%, FEF 75%, FIVC, FIF 50%, PIF, |
|                     | FET 100%                                                    |
|                     | SVC: SVC, ERV, IRV, TV, EC, IC, RC                          |
|                     | MVV: MVV, FB, TV, RR                                        |
| Presentation        | Flow volume loop                                            |
|                     | Flow time plot                                              |
|                     | Measurement values table                                    |
| Measuring range     | Flow: 0 to ±14 l/s                                          |
|                     | Volume: 0 to ±11 l                                          |
| Measuring method    | Differential pressure method                                |
| Prediction equation | Morris-Polgar, ECCS-Quanjer, Knudson-ITS                    |
| Sample rate         | 200 samples/sec                                             |

| Flow impedance     | < 0.2 mbar s/l at 12 l/s                                   |
|--------------------|------------------------------------------------------------|
| Measuring accuracy | Complies with ATS(American Thoracic Society)               |
| Environment        | Ambient temperature : 15 to 40 ℃(59 to 104°F)              |
|                    | Relative humidity : 10 to 90%(non-condensing)              |
|                    | Atmospheric pressure : 700 to 1060hPa                      |
| Standard accessory | Disposable mouthpiece 2 EA, Nose clip 1 EA, Adapter 2 EA,  |
|                    | Operation manual 1 EA, Disposable mouthpiece 1 box(100 EA) |

| Product | Warranty |
|---------|----------|
|---------|----------|

| Product Name  | 9                                      | Spirometer                   |
|---------------|----------------------------------------|------------------------------|
| Model Name    |                                        | SPM-300                      |
| Approval No.  |                                        |                              |
| Approval Date | Э                                      |                              |
| Serial No.    |                                        |                              |
| Warranty Peri | od                                     | 1 year from date of purchase |
| Date of Purch | ase                                    |                              |
| Customer      | Hospital<br>Address<br>Name :<br>Tel : |                              |
| Sales Agency  | ,                                      |                              |
| Manufacturer  |                                        |                              |

- \* Thank you for purchasing Spirometer.
- \* This product is manufactured and passed through strict quality control and inspection..
- Compensation standard concerning repair, replacement, refund of the product complies with "Consumer's protection law" noticed by Ministry of Finance & Economy.

#### **International Sales & service**

Bionet Co., Ltd. : #11F, E&C DREAM TOWER III, 197-33, Guro-Dong, Guro-Gu, Seoul, South Korea Tel : +82-2-6300-6418 / Fax : +82-2-6499-7789 / e-mail: sales@ebionet.com Website: www.ebionet.com

#### U.S.A sales & service representative BIONET AMERICA Inc. :

2691, DOW AVENUE SUITE, TUSTIN, CA 92780 U.S.A. TEL : +1(714)734-1760 / FAX : +1(714)734-1761 / e-mail: sales@ebionetus.com Website: www.bionetus.com

#### European sales & service representative MGB Endoskopische Geräte GmbH Berlin :

Schwarzschildstraße 6 D-12489 Berlin, Germany Tel. +49(0)306392-7000 / Fax. +49(0)306392-7011 / e-mail: sales@mgb-berlin.de Website: www.mgb-berlin.de

## Bionet Co.,Ltd Model Name : SPIROMETER