



## BAL2055 Agility Traction Head Traction Unit

### Operating Instructions



#### Caution:

Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device

V1.0 Mar. 25, 2011

# CONTENT

## 1. WARNING

- 1.1 CONTRAINDICATION
- 1.2 PRECAUTION
- 1.3 CAUTION

## 2. GENERAL DESCRIPTION

- 2.1 INTRODUCTION
- 2.2 INDICATION FOR USE (IFU)
- 2.3 EFFECTS OF TRACTION
- 2.4 SAFETY NOTES
- 2.5 CLASSIFICATION
- 2.6 ENVIRONMENTAL CONDITIONS
- 2.7 FUNCTIONAL DESCRIPTION
- 2.8 TECHNICAL DATA

## 3. DESCRIPTION OF CONTROLS

- 3.1 INDICATIONS OF CONTROLLING PANELS
- 3.2 IDENTIFICATION OF COMPONENTS AND FUNCTION
- 3.3 CONFIGURATION

## 4. OPERATING INSTRUCTIONS

- 4.1 INTRODUCTION
- 4.2 OPERATING PROCEDURE
- 4.3 FAULT CONDITION
- 4.4 ACCESSORY
- 4.5 MODES

## 5. MAINTENANCE INSTRUCTIONS

- 5.1 AUTHORIZED REPRESENTATIVE IN THE UNITED STATES
- 5.2 HOW TO CLEAN THE UNIT
- 5.3 CALIBRATION OF TRACTION FORCE

# 1. Warning

## 1.1 CONTRAINDICATION

- a. Do not use traction on patients with structural disease due to tumors or infection (e.g., osteomyelitis, spinal caries, and ankylosing spondylitis).
- b. Do not use on patients with joint instability, hyper mobility or spinal fracture.
- c. Do not use traction on patient with osteoporosis.
- d. Traction should not be administered to individuals who are or may be pregnant.
- e. Do not use on patients with severe cardiovascular disease, vascular compromise, aortic aneurysm or severe respiratory disease.
- f. Do not use traction on patients where movement is contraindicated.
- g. Do not use on patient with acute sprains, strains or inflammation that could be aggravated by traction.
- h. Stop traction if there is an increase in radiated pain to the extremities (radicular pain)
- i. Do not use lumbar traction on patient with hiatal or abdominal hernias.

## 1.2 PRECAUTION

Use care on patients who do not tolerate prone or supine positions, they may not be good candidates for traction therapy

## 1.3 CAUTION

- a. The treatment should only be administered under the presence of a doctor or therapist.
- b. The doctor or therapist should be present all the time and supervise the treatment very carefully.
- c. Never leave the patient alone during the treatment.
- d. Check up if the local voltage is appropriate with the input power of the machine before mounting the power plug and turning on the unit.
- e. The unit may only be opened by authorized personnel. Always remove the main plug prior to opening the unit.
- f. Unit is not designed for use in hazardous locations.
- g. Never spray the unit when cleaning it.
- h. No water or liquid cleaning agents may enter the unit, since this may cause damage to the unit and may endanger the life of the patient.
- i. The device SHOULD not be used along with other equipment.
- j. Please study the operation manual carefully.
- k. The device can only be used in the presence of a doctor or therapist.
- l. Please inform distributor when operation manual is incomplete or defective.

- m. If the instruction manual is missing pages or of poor quality, please contact the distributor for replacement.
- n. The unit should be sent to the local service agent for calibration after the product has been used for more than one year.
- o. Please use an easy unlocked Traction-Belt so that it can be easily taken off from the patient in case the main power of the unit fails. (see the section of TRACTION BELT on OPERATION INSTRUCTIONS in this manual).

## 2. GENERAL DESCRIPTION

### 2.1 INTRODUCTION

This manual contains operating instructions for microprocessor- controlled traction system.

**NOTE: KEEP ONE COPY OF THIS MANUAL WITH THE UNIT AT ALL TIMES.**

### 2.2 INDICATION FOR USE (IFU)

The Everyway Traction System, model BAL2055 Agility Traction Unit is intended for medical purpose for use in conjunction with traction accessories, such as belts and harnesses , to exert therapeutic pulling forces on the patient's body.

### 2.3 EFFECTS OF TRACTION

- a. Distraction or separation of the vertebral bodies.
- b. A combination of distraction and gliding of the facet joints.
- c. Tensing of the ligamentous structures of the spinal segment.
- d. Widening of the intervertebral foramen.
- e. Straightening of spinal curves.
- f. Stretching of the spinal musculature.

## 2.4 SAFETY NOTES

### a. Information Signs



Attention, see operating instructions.

This is refers the user to the operating instructions.

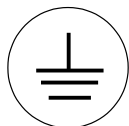


Attention, see instructions for use

This is refers the user to the documents accompanying the unit.



This symbol identifies the unit as a BF type equipment.



This symbol identifies the PE.

## 2.5 CLASSIFICATION

EQUIPMENT shall be classified by marking and/or identification as described as below:

- a. Type of protection against electric shock:  
Equipment energized from an external electrical power source: Class I equipment.
- b. Degree of protection against electric shock: Type BF equipment.
- c. Degree of protection against harmful ingress of water: Ordinary
- d. Equipment (enclosed equipment without protection against ingress of water).
- e. The equipment not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE.
- f. Mode of operation: Continuous operation.

## 2.6 ENVIRONMENTAL CONDITIONS

- a. Transport and storage
  - (1) An ambient temperature range of  $-10^{\circ}$  to  $60^{\circ}$  C.
  - (2) A relative humidity range of 10% to 100%, including condensation.
  - (3) An atmospheric pressure range of 500hPa to 1060hPa.
- b. Operation
  - (1) An ambient temperature range of  $10^{\circ}$  to  $40^{\circ}$  C.
  - (2) A relative humidity range of 30% to 75%.
  - (3) An atmospheric pressure range of 700hPa to 1060hPa.

## 2.7 FUNCTIONAL DESCRIPTION

The Traction Unit provides the following function:

### a. Force Setting System

- (1) For cervical traction (upright position), the setting force SHOULD not exceed 40 lbs.(20kgs).
- (2) For lumbar traction, the setting force SHOULD not exceed 200 lbs(91kg).
- (2) Rear switch kg/lb provides dual scales for kilograms and pounds.
- (3) LED-displays the actual tension of the cord, Scales for kilogram and pound are interchangeable by using the “kg/lb” switch on the rear panel of the unit.
- (4) Turning the knob of hold or rest force, will cause the LED-displays to show the set value.

### b. Control System

- (1) The unit is equipped with a variable speed motor. This enables the therapist to have an infinite speed adjustment in the PULL and RELAX modes.
- (2) HOLD / RELAX times are set separately by independent two-digit-push-button- switches. The times can range independently from 00~99 seconds each other. If static traction is required, set HOLD-timer switch to "--".
- (3) START/RESET buttons. Press “START” to begin the treatment after all the parameters are programmed into the unit.  
Press "RESET" to release traction cord gradually, to zero out treatment time, and shut off warning beeper.
- (4) Traction cord pulls out easily for patient setup.
- (5) The selection of lb, kg: lb/kg are selected based on the force unit required. The signal light will show the current selected unit.
- (6) Volume control: Total 3 sections levels as Mute/Mid/Max

### c. Timer System

- (1) Treatment time is set by a two-digit push button switches (i.e., treatment time can be selected from 01-99 min.).
- (2) During operation, the remaining treatment time is shown on the TIME (Min.) display. A decimal point flashes once per second.
- (3) If an error occurs, the Traction Cord is released automatically, the timer will stop, and the WARNING lights up till the error is removed and the RESET button is pushed.



d. Safety System

(1) Warning alarm and indication lamps will be activated if any of the following situations occur:

- Actual traction force exceeds preset force by approximate 8 lb.(3.6kg)
- The remote switch is pressed.
- REST force is set exceeding or equal to that of PULL force.
- Malfunction! Motor shuts down and the unit needs service.

(2) Traction safety devices are overriding all other controls. The safety devices include:

- Manual release: Activated by pushing patient safety remote button.
- Auto shutdown: Occurs when the circuit malfunction is detected. (service)
- Safe protect: If machine is out of control and traction force exceeds  $200\pm 4\text{lb.}$  ( $91\pm 2\text{kg}$ ), machine will stop till repaired.

e. Indication System

Two LED lights indicate PULL and RELAX position. During the HOLD and REST position, the timing unit of every level will appear on the screen with indicating light flashing every 0.5 second until the end of time set. The order of force status is PULL, HOLD, RELAX, REST.

## 2.8 TECHNICAL DATA

Traction force	The maximum traction force is 200 lb. (approximately 91kg)±5 lb (2.5kg)
Traction force compensation	Computerized automatic compensation
Force display	Actual force / preset force – automatic switching display
Traction speed	Step-less, continuous and adjustable
Continuous traction/release time	00-99 seconds, by static traction force “--” selection.
Therapy mode	Intermittent Static Harmonic
Treatment time	1-99 minutes ±2%
Safety system	Multiple protection alarms
Power supply	100~120VAC (60Hz)
Current	1.2A (100~120VAC)
Power consumption	150Watts max.
Allowable voltage fluctuation	Max±10%
Mains fuses	F2.0A, 250V (100~120VAC)
Casing leakage of electricity	< 100μA
Ground resistance	< 0.1Ω
Electric safety degree	Class I / Type BF (IEC 60601-1)
EMC tested	IEC 60601-1-2
Classification of equipment	Class II (FDA, ITH, 890.5900)
CE Marking	CE0434
Weight	23 lb. (10.5kg)
Dimensions	29(L) x 28(W) x 24.4(H) cm

### 3. DESCRIPTION OF CONTROLS

#### 3.1 INDICATIONS OF CONTROLLING PANELS

(See Fig. 3.1, Fig. 3.2 and Fig. 3.3)

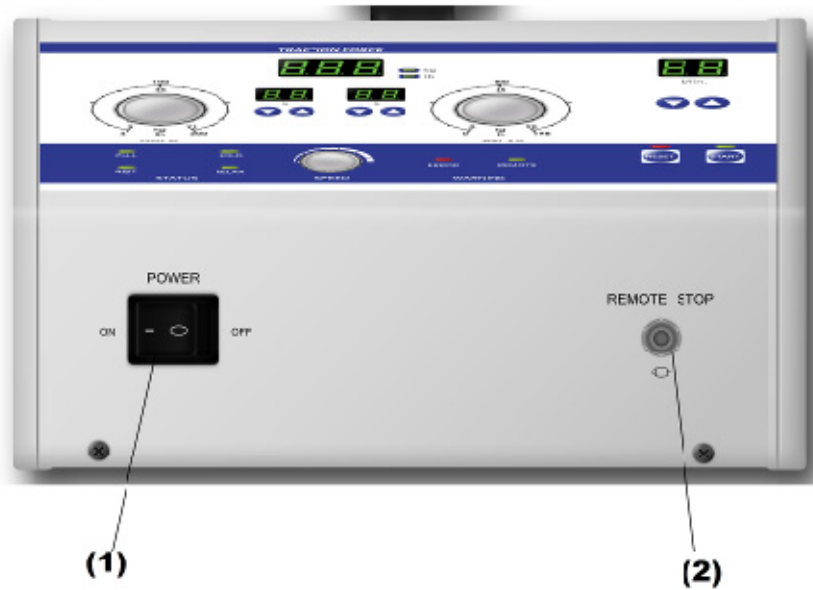


Fig. 3.1 Front control buttons

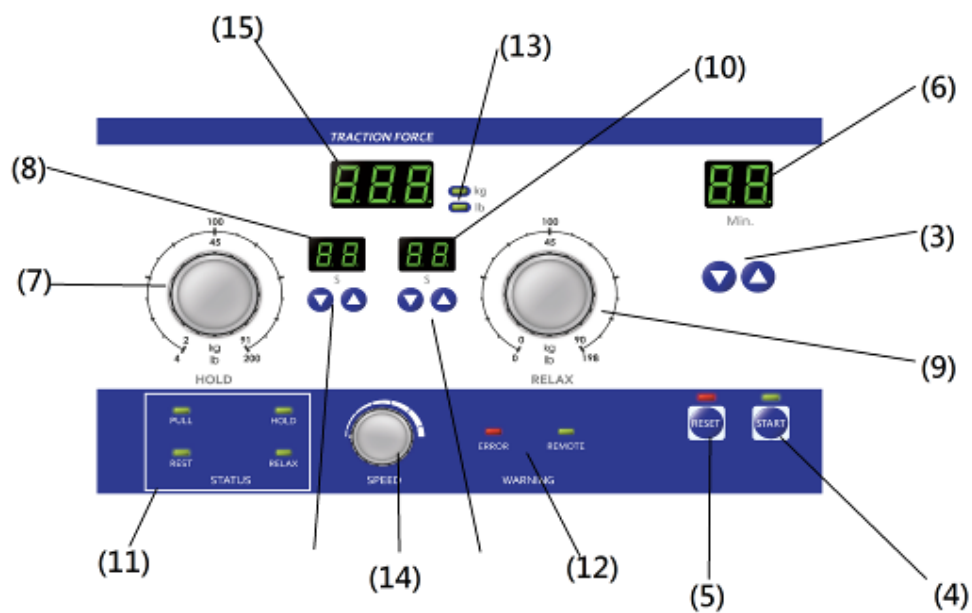


Fig. 3.2 Front control panel

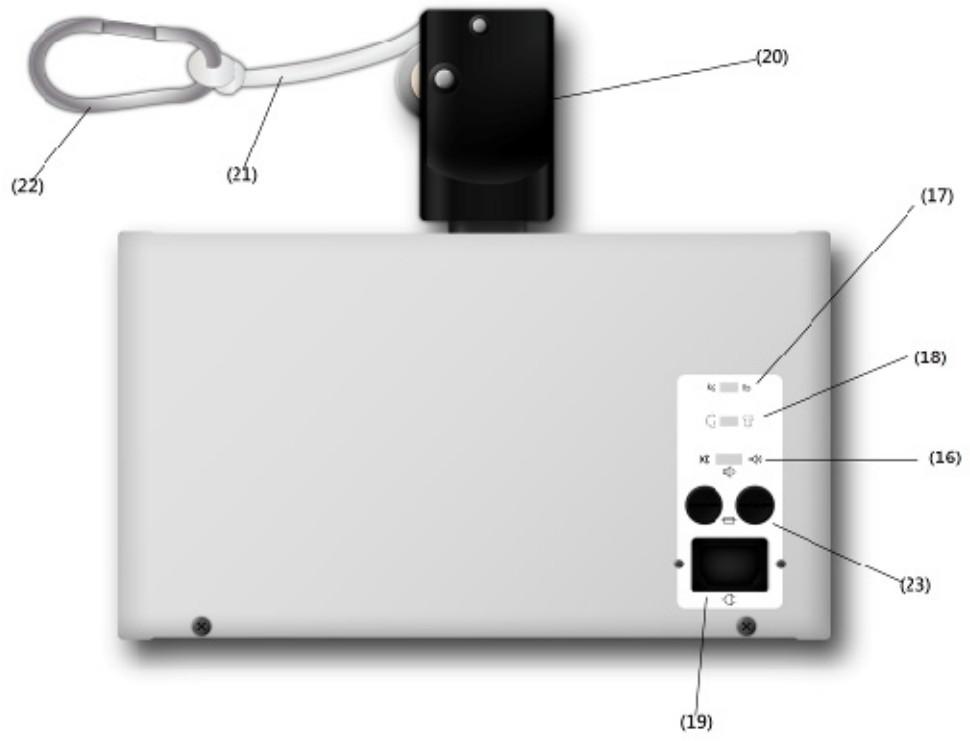


Fig. 3.3 Rear control panel

### 3.2 IDENTIFICATION OF COMPONENTS AND FUNCTION

a. POWER switch (1)

the switch " | " indicates mains power "ON" position.,  
the switch "O" indicates mains power "OFF" position.



b. REMOTE STOP and Controller(2)

Remote controller link to the connector of  
"REMOTE STOP" and hold by patient  
during treatment. Patient can stop the  
machine in any time during treatment by  
pushing the red button (Emergency Stop)  
on the top of remote controller and the  
highlight green LED indicator of "REMOTE"  
will lights up. (see point j)



**CAUTION:** *Notify the patient before the start of therapy, that if the patient feels any of the conditions below to press the REMOTE STOP:*

**(1) If the traction force is stronger than last cycle during treatment.**

**(2) If tension exceeds patient's tolerance**

**(3) The machine malfunctions – strange sounds, smoke etc.**

c. TIME readout (6) and setting (3)

Select Up ▲ /Down ▼ buttons to setup the total treatment time of therapy period from 01 to 99 minutes.



Adjust the therapy timer (minute):

Up button ▲: Each press will increase one min. from the timer is "00" min., then the timer will increased to max. time on "99" min.

Holding the button for 0.6 seconds will speed the timing with 10 min. increments. Without releasing the button a further increase with 10 min. increments per 0.4 seconds.

Down button ▼: Each press will decrease one min., from max. timer is "99" min., then the timer will decreased to min. time on "0" min.

Holding the button for 0.6 seconds will speed the timing with 10 min. decrements. Without releasing the button a further increase with 10 min. decrements per 0.4 seconds.

2 highlight green 7-segments digital number LED indicate the setting number of minutes.

Down-counts the prescribed time of treatment by digital readout when "START" button is pressed.



d. START button (4)

After setting down related parameters (Timer, Hold force, Hold time, Relax force, Relax time) then push "START" button, the machine will start and follow parameters during therapy period.

Timer also automatically turns on when button is pushed, and a beeper (speaker) signal sounds when treatment is finished. The function indicated by highlighted green LED.



e. RESET button (5)

When push the “RESET” button, the treatment will be interrupted immediately and release the tension. Then machine is in standby mode. The function indicated by highlighted red LED.

f. kg / lb unit indicators (13) and Traction force readout (15)

The unit indicate the kilograms (kg) or pounds (lb) of f traction force by 2 highlight green LED. Either on "HOLD" or "RELAX" force conditions and setting by 3 green 7-segments digital number LED indicate the force of treatments mentioned as below:



In rest (standby) mode, the digital displays '000'. It can readout the value while dialing either HOLD or RELAX knob to desired hold and relax of traction values, then the LED will automatically turn back to '000' in two seconds later.

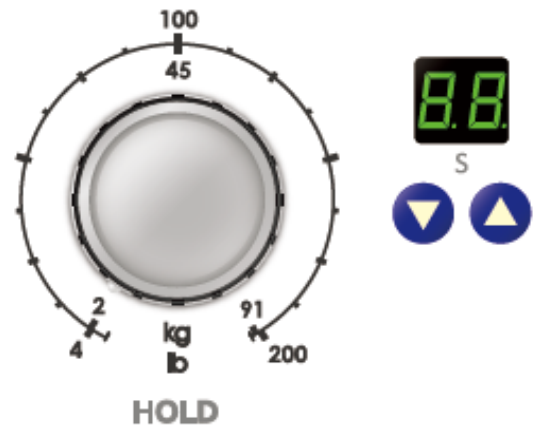
Traction forces can be altered by dialing the HOLD or RELAX knob. After pressing the “START” button, the digital readout displays the current traction force of hold or relax of machine during the therapy period that following the setting traction values.

**CAUTION: DO NOT operate the unit if the readout is defective.**

g. HOLD force (7) and Hold timer setting (8)

By dialing the HOLD knob to select the intended Hold force that indicated by 3 highlight green LED as traction readout as mentioned above.

The setting value of Hold force is from 4 - 200 lb (2 - 91 kg).



The Hold time selected by pushing Up ▲ and Down ▼ buttons beside HOLD dialing knob.

Basically, Hold timer can be set from 00 - 99 seconds, it is adjustable in steps by 1 second of setting HOLD time.

After increasing setting to “99” seconds and by pushing UP ▲ button, the Hold time can be set as “--” as in unlimited condition. It’s “Static” therapy mode that set and controlled by therapist or doctor.

h. RELAX force (9) and Relax timer setting (10)

By dialing the RELAX knob to select the intended Relax force that indicated by 3 highlight green LED as traction readout as mentioned above.

The setting value of Relax force is from 0 - 197 lb (0 - 90 kg)



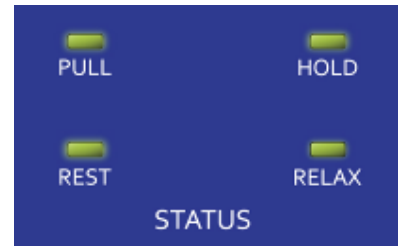
The Relax time selected by pushing Up ▲ and Down ▼ buttons beside RELAX dialing knob.

Relax timer can be set from 00 - 99 seconds, it is adjustable in steps by 1 second of setting Relax time.



i. Status indication lamps (11)

Four highlight green LED indicate the different mode of traction conditions during therapy period mentioned as below:

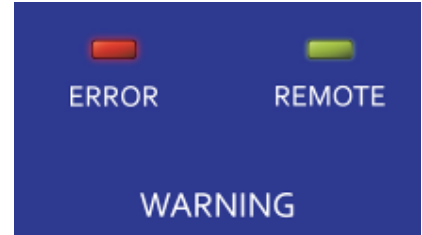


- (1) PULL mode: the traction force increases from the "REST" mode to the "HOLD" mode. Unit is under increasing traction force.
- (2) HOLD mode: The HOLD LED lights up, while the traction force is to setting HOLD force and holding following Hold time
- (3) RELAX mode : the traction force decreases from the "HOLD" mode to the "REST" mode. Unit is under decreasing traction force.
- (4) REST mode: The REST LED lights up, while the traction force is to setting RELAX force and holding following Relax time

j. Warning indication lamps (12)

One highlight green LED indicator as REMOTE lights up, while the remote controller be pushed, and the unit will be interrupted.

The indicator and condition can be cancelled till to push the RESET button.



One highlight red LED indicator as ERROR lights up, while the abnormal (error) conditions mentioned as below:

- (1) System malfunction
- (2) Setting values as  $RELAX > HOLD$  :  
When "RELAX" dial selected value is exceeded or  
Over "HOLD" dial selected value. The beeper (speaker) keeps  
Alarm till the operator to push RESET button.
- (3) OVERLOAD: Holding force is larger than selected, that means the machine is out of control.

k. SPEED control (14)

The dialing knob of SPEED is to adjust the traction speed of PULL and RELAX.

The variable speed can be adjusted continuously

The min. speed is around 20~30 of max. speed.



l. kg /lb switch(17)

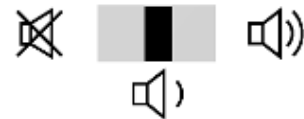
Operator can select the unit of traction force by kg or lb by adjust the slide switch on back setting panel election button for lb and kg unit.



m. Cervical / Lumbar switch (18)

Operator can select the therapy mode as “Cervical” (neck) type or “Lumbar” (low back) Type by adjust the slide switch on back setting panel.

It is a protection setting: when selecting button on “Cervical” mode, the max. traction force will not over 40lb/18kg and selecting button on “Lumbar mode, the max. traction force is 200lb /91kg.

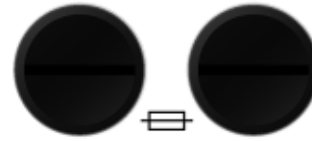


n. Speaker volume switch(16)

The volume of speaker can be set by slide switch of Speaker volume switch. There are total 3 sections of settings as mute, middle and max. volumes.

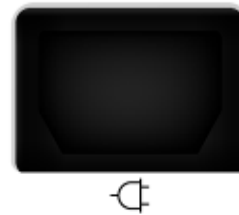
o. FUSES (23)

Two fuse holder sets on rear side of unit, engineer can replace and change new fuses as specified in TECHNICAL DATA by using suitable flat-blade screwdriver to open the cover of fuse holder set.



p. Power socket (19)

One power socket on rear side of unit. Before operating the unit, operator need to connect the specified suitable power cable with plug provided by manufacturer to the mains power supply as specified in TECHNICAL DATA.



q. Traction pulley (20)

The traction pulley link to a D-shape fast hook by traction cord for connecting the traction garments (cervical garment or belt garment).

The pulley can be rotated in any desired position or direction following the intended therapy modes or requests.



r. Traction cord (21)

The traction cord is from pulley to D-shape fast traction hook to connect the traction garments (cervical garment or belt garment). Its' length is around 120cm and the material is Nylon.

s. Traction hook (22)

The D-shape hook is intended to link traction garment and cord easily.

During operating, please settle the hook at the position of artwork (Fig 3.3) as shown.

The traction hook needs to be mounted like the bold circle, shown as below.

***CAUTION: Scale adjustment must be calibrated by an authorized technician.***

***CAUTION: The traction cord must be replaced by an authorized technician at least once a year.***

### 3.3 CONFIGURATION

It is envisioned the traction unit can be used in 4 different treatment configurations. As shown below. With the four configurations, different accessory packages can be selected.

Item	Description	-IA	-I	-II	-III
1.	<b>Main unit with:</b> -Remote stop controller x 1 -Hand screw x 4 -Power cord x 1	-	-	-	-
2.	Traction table			-	-
3.	Mounting stand (for cervical traction)		-		
4.	Flexion chair (for cervical traction)		-		
5.	Mounting bracket (for cervical traction)	-			
6.	Pelvic spreader bar			-	-
7.	Flexion stool			-	-
8.	Cervical traction garment, Velcro-type	-	-		-
9.	Pelvic Traction garment, Velcro-type			-	-
10.	Cervical spreader bar	-	-		-
11.	Cervical roll			-	-
12.	Double-sectioned fastening strap			-	-

Note: Please refer the accessories list from your local distributor.

## 4. OPERATING INSTRUCTIONS

### **CAUTION:**



Check the unit is operating normally before start of treatment !

### 4.1 INTRODUCTION

This section contains detailed procedures for use of the traction unit. It is designed to familiarize experienced users with the operation and function of the unit. Read this section thoroughly before operating this unit.

### **CAUTION:**



***The device must be installed only by authorized person.***

***Do not install the device by yourself.***

### 4.2 OPERATING PROCEDURE

- a. Connect the unit to AC power outlet or as indicated on the nameplate affixed to the back of the machine.
- b. Connect the remote switch plug of controller to the Remote Stop connector.

***CAUTION: Please assure the Remote Stop is set to normal before using.***

***Confirm the remote stop is being held by the patient before pushing the START button. Whenever the Remote Stop pushed, the device will stop running immediately.***

- c. Turn Power switch ON
  
- d. Set required Treatment time. HOLD time, RELAX time, HOLD force, RELAX force.  
(IT IS NECESSARY TO PRESET "HOLD" FORCE WHENEVER "RELAX" FORCE IS SELECTED. OTHERWISE, THE MACHINE WILL NOT OPERATE.)
  
- e. Press START button to begin treatment. If beeper (speaker) sounds, be sure RELAX force must be set lower than HOLD force. Press RESET button to reset alarm and indicator lamps. Repeat items "d" and "e".

***CAUTION: Ensure the traction cord is releasable and has a smooth action before starting treatment.***

- f. Adjust HOLD/RELAX forces after machine has started working :
  - (1) In Intermittent mode :  
Set the knob to new value then press START button. Machine will change to this new force in the next period.
  
  - (2) In Static mode :  
Machine doesn't accept any change until in RESET mode.
  
  - (3) In Harmonic mode:  
Machine doesn't accept any change until in RESET mode.

### 4.3 FAULT CONDITION

In the case of a sudden power shut or if the device runs abnormally or the patient feels uncomfortable during treatment, turn the power off immediately and undo the belt in order to release the patient from the device. Call the authorized service department as soon as possible.

- a. The following figures indicate how to release patient from the easy unlocked Traction-garment ! (See Fig.4.1)
- b. The operation method of cervical garment is completely same as that of Pelvic garment.
- c. The suitable Traction garments are with Velcro. (See Fig. 4.2)



Fig. 4.1

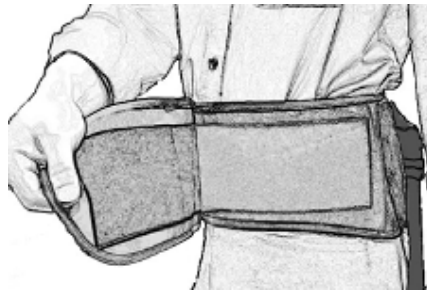


Fig. 4.2



#### 4.4 ACCESSORY

The Traction garment can purchased through our authorized representative as shown as below.

- a. Traction lumbar garment (Fig.4.3)



Fig. 4.3

- b. Traction cervical garment (Fig. 4.4)



Fig. 4.4

- c. Final installation:

Traction unit can link with traction garment and installed to specific traction table or chair as final treatment system as shown as below (Fig. 4.5, Fig. 4.6)



Fig. 4.5



Fig. 4.6

***CAUTION: The traction lumbar and cervical garments provided by Everyway, the material that will contact to patient's skins complied with all the requirements of biocompatibility (ISO 10993 standards).***

***CAUTION: Everyway did not provide the other traction equipments as traction table and traction chair. Please contact authorized distributors.***

## 4.5 MODES

### a. Intermittent program:

- (1) Press RESET button
- (2) Set HOLD and RELAX seconds as treatment time
- (3) Set HOLD and RELAX force
- (4) Set SPEED of motor
- (5) Press START button

### b. Static program:

- (1) Press RESET button
- (2) Set HOLD seconds to "--" as treatment time (only Hold force)
- (3) Set HOLD and RELAX force
- (4) Set SPEED of motor
- (5) Press START button

### c. Harmonic program:

- (1) Press RESET button
- (2) Set HOLD seconds to "00" as treatment time
- (3) Set RELAX seconds to "00" as treatment time
- (4) Set HOLD and RELAX force
- (5) Set SPEED of motor to min.
- (6) Press START button

## 5. MAINTENANCE INSTRUCTIONS

Preventive inspection and maintenance please notify distributor locally.

### 5.1 AUTHORIZED REPRESENTATIVE IN THE UNITED STATES

STONEHAVEN MEDICAL, INC.

22607 LA PALMA AVE., SUITE 408

YORBA LINDA, CA 92887

TELEPHONE

NUMBER (714)692-9800, (888)215-4205

FAX

NUMBER (714)692-9800



## 5.2 HOW TO CLEAN THE UNIT

Please clean the unit with a longhair brush or dry cloth. Never use alcoholic liquid or solvent liquid.

**The users should contact the nearest licensed recycling firms, according to the Directives of ISO-14000, to properly handle the products or/and related accessories whenever these materials to be disposed. Otherwise the users may consult the vendors for further assistance.**

### 5.3 CALIBRATION OF TRACTION FORCE

**CAUTION:** Calibrate regularly suggest calibrate annually.

**CAUTION:** Only a certified technician is allowed to calibrate the traction system.

**CAUTION:** Measurement equipment used for maintenance, calibration and inspection shall meet the direct or in direct approval of national laboratories with proper certificates.

**CAUTION:** The maintenance and calibration specifies the proper parts with parts number, no substitution is authorized. The distributor shall reorder the parts if it runs short.

Calibration procedure (See Fig.5.1)

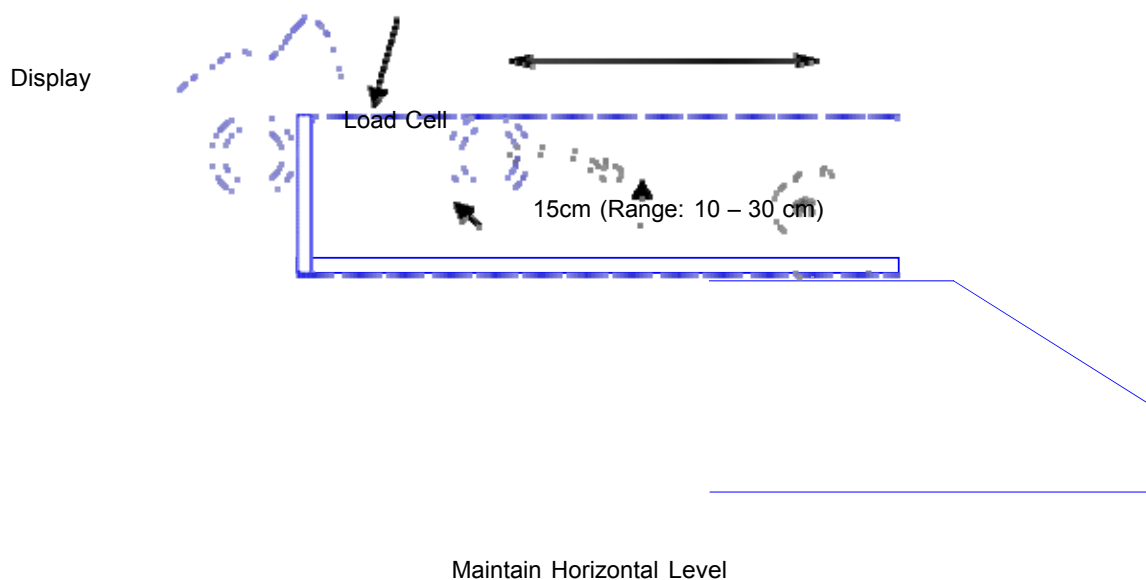


Fig. 5.1

- a. Fixed the Traction Unit
- b. Length of Traction cord : 15cm(Range : 10\_30cm)
- c. Fixed the Load Cell along with Traction cord.
- d. Maintain the Load Cell and Traction cord on Horizontal level.
- e. Setting
  - (1) Set HOLD time as "02" (sec.)
  - (2) Set RELAX time as "02" (sec.)
  - (3) Adjust the SPEED CONTROL at extreme fast (max.).
  - (4) Record HOLD\_The Max. data for display of load Cell.
  - (5) Record RELAX\_The Min .data for display of Load Cell
- f. Clockwise: Increase the traction force
- g. Acceptable criteria
  - Tolerance of traction force:
    - (1) HOLD Force  $\pm 4$  lb. (2kg)
    - (2) RELAX Force  $\pm 4$  lb. (2k)