Powered Traction Unit

# 7M-400





# CONTENTS

Symbols	
Safety precautions ····································	
Storage condition and period of service	
Handling precautions	5
Maintenance and inspections·····	6
Components ·····	
Main Unit and Standard Accessories	8
Optional Accessories	
Specifications·····	
Names of parts	
Operation panel ······	
Installation·····	
Operating procedures	·· 14
Preparations	
Operation After operation	
·	
Program setting window Saving program	20
Loading program	
Deleting program	23
Sorting program ·····	24
Configuration settings	26
Error codes ·····	
EMC	

# **Safety precautions**

#### • Symbol for "CAUTION"



• Symbol for "TEMPERATURE LIMIT"



 Symbol for "CONSULT INSTRUCTIONS FOR USE"



 Symbol for "HUMIDITY LIMITATION"



Symbol for "SERIAL NUMBER"



 Symbol for "ATMOSPHERIC PRESSURE LIMITATION"



 Symbol for "CATALOGUE NUMBER"



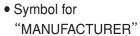
 Symbol for "Waste Electrical and Electronic Equipment (WEEE), Directive 2002/96/ EC"



 Symbol for "AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"



\* This symbol is only valid in European Union.





• Symbol for "TYPE B APPLIED PART"



• Symbol for "DATE OF MANUFACTURE"



 This mark is to be used for class IIa medical devices.
 MDD (93/42/EEC)



#### Read this manual and follow all instructions.

#### Note on operation manual

The operation manual constitutes an important part of this system. Before lending or transferring this system to another facility, be sure to attach this manual to provide the information (including precautions for use and operating procedures necessary for safe use.

This unit should be used by a licensed medical practitioner.

#### [Intended use]

Intended benefits applied by the use of TM-400.

- 1.Distraction or decreasing pressure of the vertebral bodies
- 2.Reduction of protruding nuclear disc materials
- 3. Stretching of soft tissues surrounding the vertebra
- 4. Muscle relaxation and so on

#### [Indications]

- 1.Herniated disc
- 2. Hypomobility of joints and muscles
- 3. Nerve root compression

#### [Contraindications]

Do not use this system with the individuals or on the areas listed below.

- 1. Rheumatoid arthritis
- 2. Marfan's syndrome
- 3. Down's syndrome
- 4. Sepsis
- 5. Hiatal hernia
- 6. Paget's disease
- 7. Metastatic malignant tumors
- 8. Osteoporosis
- 9. Atlas/axis subluxation
- 10. Areas where joint hypermobility are identified
- 11. Infection
- 12. Acute phase
- 13. Pregnancy
- 14. Claustrophobia

### [Contraindications for combined use]

- 1. Do not use this system with an electrocardiograph or other wearable medical electrical device.
- Do not use this system with any devices and accessories other than those specifically stated. When using this system in combination with another device, also check the contraindications and precautions for that device.

# **Safety precautions**

### Precautions for use

#### General precautions

- 1. Make sure that the patient is comfortably positioned so that he or she will be relaxed and comfortable during treatment.
- 2. Do not use parts from other therapy systems.
- 3. Do not operate this system within 2.5 m of a shortwave therapy system or microwave therapy system. Doing so may result in unstable operation
- 4. Follow the instructions given below when installing the system.
  - (1) Avoid locations where the system may be subject to splashing water.
  - (2) Avoid locations where the system may be exposed to variations in atmospheric pressure, excessive temperatures or humidity, direct sunlight, excessive dust, air containing salt or sulfur, or any other adverse factors.
  - (3) Be careful to protect the system from any adverse effects of sloping surfaces, vibrations, and shock (e.g., during transport). Make sure that the system is kept stable.
  - (4) Avoid locations with flammable gases: e.g., flammable anesthetic gas mixed with air, pure oxygen, nitrous oxide, or flammable disinfectant or cleanser vapors.
  - (5) Avoid locations where chemicals are stored or where gases may be generated.
  - (6) Do not install the system near flame sources. Doing so may result in deformation of the system or accidents.
  - (7) Note the system requirements for power supply frequency, voltage, and allowable current (or power consumption).
  - (8) Use an outlet devoted solely to system use.
- 5. To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

#### Precautions before use

- 1. Carefully review the patient's diagnosis and prescription for any special precautions or instructions.
- 2. Check whether a pacemaker or other metal device is implanted in the area to be treated.
- 3. Confirm that the patient is able to indicate unusual sensations of pressure, heat, or other discomfort or pain that may arise during treatment.
- 4. If the patient is an infant (aged 6 or under), an individual with senile dementia, or any other individual incapable of articulating volition, determining the appropriate treatment intensity will be difficult. Carefully consider possible consequences before deciding whether to use and extent of usage of this system with such patients.
- 5. Check the switches and keys to confirm that the system operates correctly.
- 6. Make sure that all cables are correctly and safely connected.
- 7. Make sure there are no problems with the traction harness and that the patient is wearing the harness in the correct fashion.

8. Never operate the system without drawing out the traction rope. Failure to do so may result in malfunction

#### Precautions during use

- 1. Make sure the treatment time and intensity are appropriate for the treatment purpose.
- 2. Monitor the system and patient to ensure that no problems arise. In the event of a problem, take adequate measures, including shutting down the system by a method safe for the patient. Then contact the distributor or manufacturer.
- 3. To prevent accidents, make sure that the patient and operator will not attempt to operate or touch the moving parts.

#### Precautions after use

- 1. Review the specified steps, and return all switches and controls to their original positions, then switch off power, and disconnect the Power Supply Cord from the outlet.
- 2. When disconnecting the Power Supply Cord from the outlet, make sure that the power switch is "off." Grasp the plug to disconnect cables. Do not pull on the cables.
- 3. Clean the system and accessories before storing as part of maintenance.

### Storage condition and period of service

- 1. To prevent malfunction, follow the instructions given below when storing the system.
- (1) Avoid locations where the system may be subject to splashing water.
- (2) Avoid locations where the system may be exposed to variations in atmospheric pressure, excessive temperatures or humidity, insufficient ventilation, direct sunlight, excessive dust, air containing salt or sulfur, or any other adverse factors
- (3) Be careful to protect the system from any adverse effects of sloping surfaces, vibrations, and shock (e.g., during transport). Make sure that the system is kept stable.
- (4) Avoid locations where chemicals are stored or where gases may be generated.
- 2. Be sure to disconnect the power plug from the output if the system is not to be used for extended periods.

# Handling precautions

- 1. Avoid subjecting the equipment to strong vibrations or sharp blows (through impact, overturning, dropping, etc.). Such may cause imperceptible damage, leading to later malfunction or accident.
- 2. To minimize environmental impact, follow local regulations when disposing of consumables, residue, or the system itself or accessories at the end of their service life.

# **Safety precautions**

# Maintenance and inspections

#### Precautions

- 1. In the event of a system malfunction, do not attempt to perform repairs yourself. Place an out-oforder notice on the system to prevent use and contact the distributor or manufacturer to obtain repairs.
- 2. WARNING: No modification of this equipment is allowed.
- 3. Never open the system.
- 4. When cleaning the system and accessories, avoid using thinners, gasoline, kerosene, benzene and other flammable liquids, polishing powders, hot water, and chemicals generally. These substances may result in discoloration and deterioration. Use a cloth moistened with alcohol, cold or lukewarm water, or neutral detergent.

#### User maintenance and inspections

- 1. Check the system and accessories with each use to confirm that they function properly.
- 2. If a problem or defect (e.g., scratch, crack in the covering of a cable, frayed wires, or connector contactfailure) is observed during a preliminary or regular inspection, contact the distributor or manufacturer.
- 3. Before using the system after an extended storage period, confirm that the system functions properly and safely.

### • Maintenance and inspection by the distributor

- 1. Ask your distributor for periodic (yearly) inspections to maintain system performance and to ensure safety and proper operation.
- 2. Replace consumables (including accessories) periodically to prevent hazards during use of the systemand accessories.

#### • Maintenance / inspection items

Item	Detail	Method
Appearance and indications	Check for visible damage, panel deformation, and flickering indicators.	Visual inspection
Operation	Turn on the power switch. Confirm that the system functions properly. Look for potential problems.	Check by operation
Accessories	Check for damage and for broken wires in any of the cables.	Visual inspection
Safety	Check for wear on the traction rope.	Visual inspection

#### Change parts and consumables

Description	Replacement method	Replacement time
Traction rope	Ask the distributor or manufacturer	Replace if found to be worn during inspections

# **Specifications**

# Main Unit and Standard Accessories





- ① Main Unit
- 2 010850 Patient Switch
- \* Hexagon Socket Head Bolt, 4×
- \* B180350 Power Supply Cord (220–240 V, Type F)
- \* B180290 Power Supply Cord (110–120 V, Type A)
- \* Spring Washer, 4×
- \* Plain Washer, 8×

### Optional Accessories

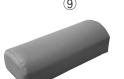














③ 011977	Cervical Harness
④ 012003	Spreader Bar
⑤ 011975	Triangular Flexion S

6 011990 Thoracic Harness
7 011978 Pelvic Harness

8 8005760 Armpit Holder, 2pcs/set9 011976 Pillow



10 8005700 Fixed Height Traction Table including 2 Armpit Holders, 600  $\times$  2500 mm

1 8005702 Electric Variable Height Traction Table,  $640 \times 2540 \ \text{mm}$ 

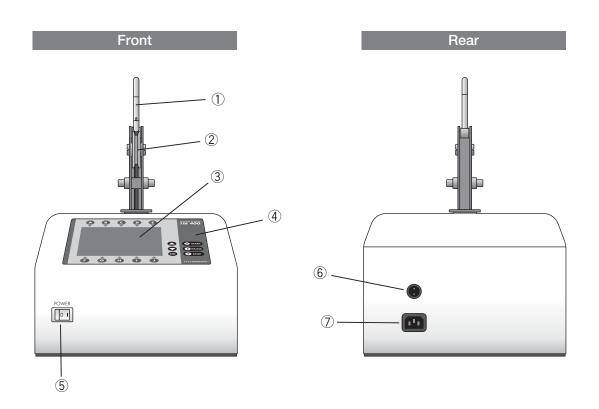
\*011843 Traction Rope Kit is not shown above.

\*The operator can not exchange a traction rope. When exchanging a traction rope, contact to manufacturer.

\*Optional Accessories except traction rope are not used in the area of the CE marking application.

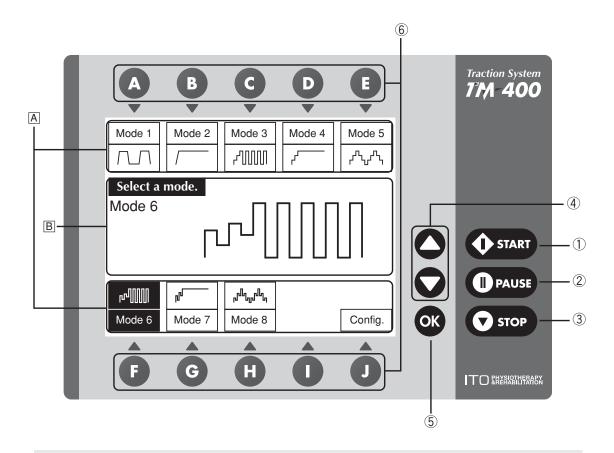
Power supply	100-240 VAC, 50 / 60Hz			
Rated power consumption	75VA			
High force range	1–90 kg (1–198 lbs) $\pm$ 3 kg			
Low force range	0−89 kg (0−197 lbs) ± 3 kg			
Traction speed	1:1 (15 sec.), 1:2 (30 sec.), 1:4 (60 sec.), 1:6 (90 sec.), 1:8 (120 sec.) *The figures in parentheses are the times required to reach 90kg of force when pulling with 90 kg of force.			
Hold time range	0-99 seconds			
Rest time range	0-99 seconds			
Number of ramp steps	<ul> <li>2-9 steps</li> <li>*The actual values from these ranges of values for any particular case will depend on the difference between the maximum and residual traction force. A minimum difference of 1 kg (1 lb) is required per step.</li> </ul>			
Pause time of each ramp step	2-20 seconds			
Timer	1-99 minutes ± 5%			
Free program memory	30			
Classification	Class I, Type B / (IEC) / Class IIa (MDD)			
Dimensions	260 (W) $\times$ 350 (D) $\times$ 295 (H) mm			
Weight	approx. 14kg			
		Ambient Temperature	Relative Humidity	Atmospheric Pressure
Environment conditions	Operating environment	10−40 ℃	30-75%	700-1060 hPa
Environment conditions	Storage environment	-10−60 °C	30-95%	700-1060 hPa
	Transport conditions	-10−60 °C	30-95%	700-1060 hPa

# **Operation panel**



- 1) Hook
- 2 Main unit pulley
- 3 LCD
- 4 Operation panel

- ⑤ Power switch
- 6 Patient switch cable inlet
- 7 Power inlet



3 Stop key [ Stop ] ..... Stop traction.

④ Parameter set keys [♠ / ♠] ······ Sets parameters.

⑤ OK key [🐼] ······ Confirms a parameter setting.

⑥ Function keys [♠ to ♠] ·········· Retrieves a setting window or changes setting items.

A ····· Displays items corresponding to function keys **(a)** to **(1)**. These differ from window to window.

 $\ensuremath{\mathbb{B}}$  ..... Displays the item selected by function key  $\ensuremath{\Delta}$  to  $\ensuremath{\mathbf{0}}$ .

# Installation

# ( CAUTION )

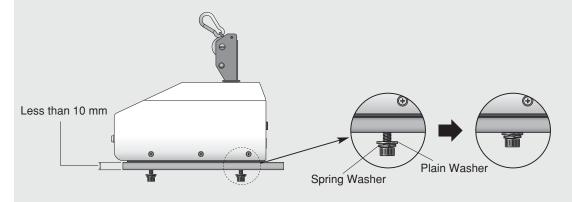
Follow the instructions given below when installing the system.

- Make sure the mounting plate is sturdy and level.
- Use the system in an environment that meets the specified operating conditions. \*For ambient conditions, see page 9.
- To prevent injury and damage to the system, use the supplied bolts and washers to secure the system to the traction table.
- 1. Align the screw holes in the bottom plate of the system with the holes in the mounting plate of the traction table. Securely screw the Hexagon Socket Head Bolts into the holes.
  - \*If the mounting plate is less than 10 mm thick, a Plain Washer and Spring Washer are required. Read the instructions given below.

### Thickness of mounting plate

The mounting plate is less than 10 mm thick.

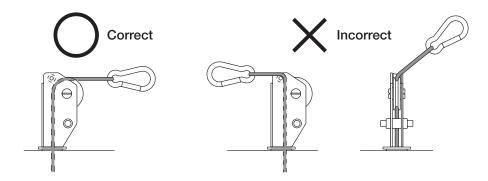
Use a Plain Washer and Spring Washer for each Hexagon Socket Head Bolt and screw in the bolts tightly.



\*If the thickness of the mounting plate is less than 5 mm, use two Plain Washers for each bolt.

#### 2. Set the traction rope.

Make sure the rope is set on the pulley in the correct direction, as shown below, and that the traction rope is not twisted or worn.



\*The small roller is provided to prevent damage to the traction rope in case the rope and pulley are set in the incorrect direction. Do not set the rope on the small roller.

# **Operating procedures**

Appoint an individual to be responsible for this system. This individual shall make sure that the system is operated by only those familiar with the system.

#### **Preparations**

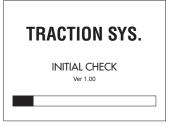
- 1. Make sure that the Main Unit is fastened securely to the mounting plate of the traction table. \* For installation, see page 12.
- 2. Confirm that the power switch for the Main Unit is "off."
- 3. Connect the Patient Switch cable to the Patient Switch cable inlet of the Main Unit.
- 4. Connect the Power Supply Cord to the power inlet at the rear of the Main Unit, then to the medical outlet.
- 5. Place the patient into a harness suitable for the treatment purpose.
- 6. Draw out the traction rope and attach the hook to the Spreader Bar or harness.
  - \* If the clutch has been activated accidentally during transport, the traction rope will be locked. If the traction rope cannot be drawn out, turn on the power switch to unlock the rope.

### Operation

1. Turn on the power switch.

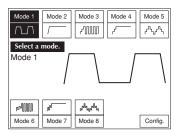
The initial check window appears, followed by the traction mode selection window.

\* After the system has been turned on for the first time, the parameter window of the previously used treatment mode (the last-finished treatment mode) will appear.





Initial check window

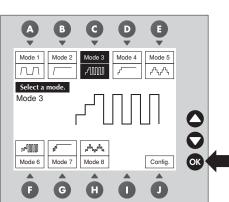


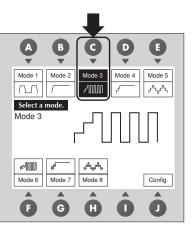
Traction mode selection window

2. In the traction mode selection window, pressing a function key (A) to (H) will highlight the corresponding traction mode and display an outline of the traction mode.

There are eight traction modes, as shown below.

- ⚠ Mode 1 [Intermittent mode] Alternately applies the maximum and residual traction
- Mode 2 [Static mode] Traction is performed continuously at maximum force.
- Mode 3 [Progressive / intermittent mode] The progressive mode is used for initial ramp-up. After the traction force has reached its maximum value, the maximum traction force and residual traction force alternate.
- Mode 4 [Progressive / static mode] The progressive mode is used for initial ramp-up. After the traction force has reached its maximum value, traction is performed continuously at maximum force.
- Mode 5 [Progressive / regressive mode] The progressive and regressive modes alternate between maximum and residual traction force.
- Mode 6 [Cyclic / intermittent mode] The cyclic mode is used for initial ramp-up. After the traction force has reached its maximum value, the maximum and residual traction force alternate.
- G Mode 7 [Cyclic / static mode] The cyclic mode is used for initial ramp-up. After the traction force has reached its maximum value, traction is performed continuously at maximum force.
- Mode 8 [Cyclic mode] Traction is performed in cyclic mode between the maximum and residual traction force.
- 3. Select a traction mode and press the ox key. This confirms the traction mode and opens the parameter selection window.

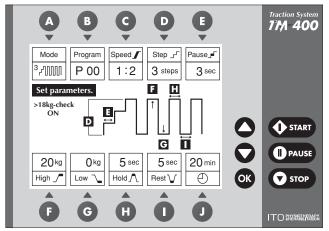




# **Operating procedures**

4. The parameter selection window displays detailed parameters for the selected traction mode.

To make changes in parameter settings, press a function key from (a) to (1) corresponding to the parameter you wish to edit. The setting window for the selected parameter will appear.



Parameter selection window

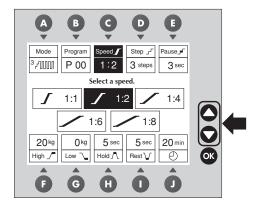
The function keys correspond to the parameters as shown below.

- **A** Mode ..... Displays the traction mode selection window.
  - \* For traction mode selection, see page 15.
- B Program ... Displays the program setting window.

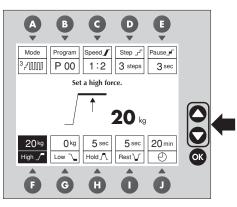
The window lets you save, load, and delete parameters.

- \* For program setting screen, see page 20 onward.
- **©** Speed ······ Sets the traction speed.
- **D** Step ...... Sets the number of ramp steps.
  - \*Selectable values within the range of all possible values may depend on the difference between the maximum and residual traction force. There must be a minimum difference of 1 kg (1 lb) per step.
- **B** Pause ..... Sets the ramp pause time.
- High ······ Sets the maximum traction force.
- **G** Low ...... Sets the residual traction force.
- Hold ······· Sets the traction hold time.
- Rest ······· Sets the traction rest time.
- Sets the treatment time.
- \*Some parameters may not be available, depending on traction mode.

Display the setting window of the parameter you wish to edit.
 Set the parameter using the ♠ / ♠ keys. Press ♠ key to return to the parameter selection window.



Traction speed setting window

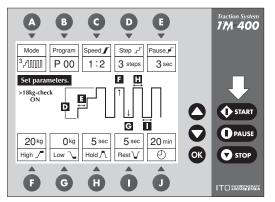


Maximum traction force setting window

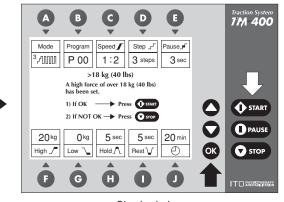
6. After completing the parameter settings, press the key to start treatment. If the traction force exceeds 18 kg (40 lbs), the check window will appear.

If the traction force is correct, press the Ostart key or ok key to start treatment.

To change the traction force, press the we key to return to the previous window and edit settings.





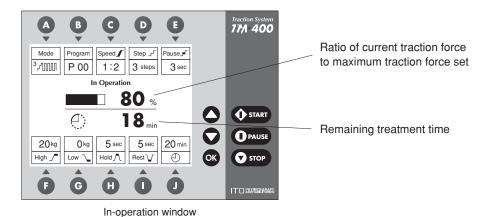


Check window

<sup>\*</sup>The 18 kg (40 lbs) check is turned on and off in the configuration window. For information on the configuration window, see page 26.

# **Operating procedures**

7. The in-operation window appears after treatment starts. This window displays in real-time the remaining treatment duration and the ratio of the current traction force to the maximum traction force set.



- 8. When the timer has counted down to zero, the buzzer will sound. The traction force returns to zero at a traction speed of 1:1, and the traction rope is released. The parameter selection window appears, and the timer reverts to the set value.
  - \* Immediately after the initial check is finished or treatment has been completed or canceled; it may take several seconds to begin traction when you press the key. This delay is attributable to the calibration procedure performed by the automatic calibration function.

### Editing parameters during operations

The parameters displayed in the in-operation window other than "Mode," "Program," and "Speed" can be edited during operations.

Press one of the function keys **①** to **①** corresponding to the parameter you wish to edit. The setting window of the selected parameter will appear. Edit the parameter using the **②** / **②** keys.

After the changes have been made, press the key or the edited parameter is confirmed, and you will be returned to the in-operation window.

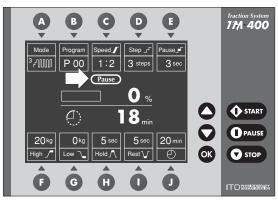
When "High" or "Low" setting has been edited, the change is reflected in real-time during operations. If "High" is edited during traction hold time or if "Low" is edited during traction rest time, the traction hold or rest time will restart when the setting is edited. Changes in other parameters are reflected in the next movement related to each parameter.

#### Pausing treatment

Press the PAUSE key during treatment to suspend treatment and return the traction force to zero at a traction speed of 1:1.

While treatment is interrupted, the screen will display "Pause," the entire screen will blink, and the timer will stop counting.

Press the start key to restart. Treatment resumes from the point at which it was suspended.



Interruption window

#### Canceling treatment

Press the Ostop key during treatment to terminate treatment, return the traction force to zero at a traction speed of 1:1, and release the traction rope.

When treatment has been canceled, the parameter selection window appears and the timer reverts to the set value.

### **Operation when Patient Switch is pressed**

If the Patient Switch is pressed during treatment, the alarm sounds and treatment ends. The traction force returns to zero at a traction speed of 1:1, and the traction rope is released.

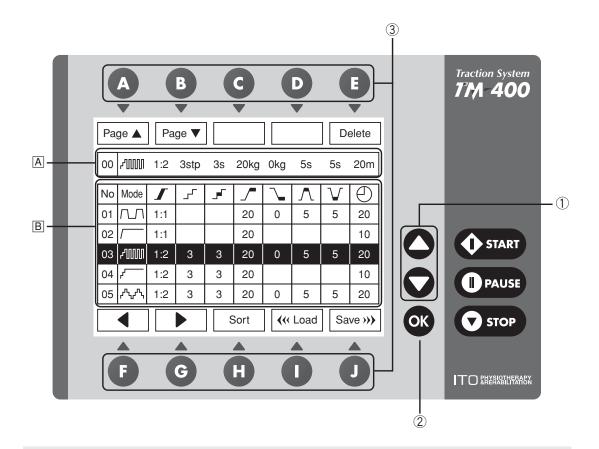
The screen displays the error code.

Press any key to cancel the error. You will be returned to the previous window.

### After operation

- 1. To end treatment, switch off the power switch and remove the harness.
- 2. Disconnect the Power Supply Cord from the wall outlet.
- 3. Clean the Main Unit and accessories before storing as part of maintenance. Make sure they are not exposed to dust in storage.

# **Program setting window**



#### A Current program area

Displays the traction mode and parameters currently set.

The parameters are displayed from left to right in the following order:

"Program No.," "Traction mode," "Traction speed,"

"Number of ramp steps (stp = step)," "Ramp pause time (s = sec.),"

"Maximum traction force (kg or lb)," "Residual traction force (kg or lb),"

"Traction hold time (s = sec.)," "Traction rest time (s = sec.),"

and "Treatment time (m = min.)."

If certain parameters are not available, the corresponding values will appear as blanks.

#### B Program list (max. 30)

Displays the contents of stored programs.

The parameters displayed and the setting units are the same as those of the current program area.

The currently selected program is highlighted. If all parameters other than "Program No." have blank values, no program is stored under that number.

- - A key ..... Selects the program directly above.
  - key ..... Selects the program directly below.

#### 2 OK key [0]

Returns to the parameter selection window.
Used to turn off the sort function when the sort function is on.

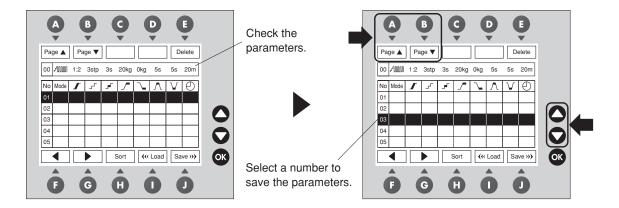
- 3 Function keys [ to ]
  - A Page ▲ ····· Scrolls up through the program list by five rows.
  - B Page ▼ ····· Scrolls down through the program list by five rows.
  - **G** and **D** ····· Not used.
  - **B** Delete ..... Deletes a stored program.

  - **⊙** ▶····· Selects a parameter to sort by (moves to the right).
  - Sort ..... Sorts the list by the selected parameter in ascending order.
    Press once again to sort in descending order.
    This key toggles between ascending and descending order.
  - Load ······ Loads the program for the selected "Program No."
  - Save ...... Saves the parameters displayed in the current program area (currently set parameters) under the selected "Program No." If parameters are already stored under the selected "Program No," they are overwritten.

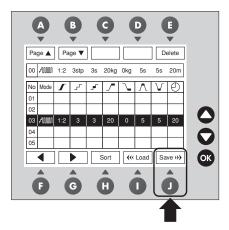
# **Program setting window**

### Saving program

- 1. In the parameter selection window (see page 16), press "Program (**B** key)" to display the program setting window.
- 2. Make sure that the parameters you want to save are displayed in the current program area. Select the "Program No." to save using the ♠ / ♠ keys and the "Page ♠ (♠ key)" and "Page ▼ (♠ key)." The selected Program No. is highlighted.

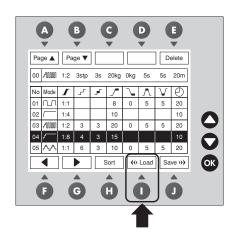


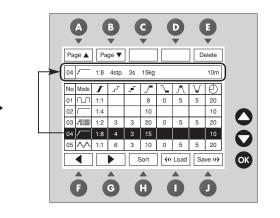
- 3. Press the "Save ( key)" to save the parameters under the selected "Program No."
  - \*If parameters are already stored under the selected "Program No," the stored parameters are overwritten.
  - \* Up to 30 programs can be stored.
- 4. Press the key to return to the parameter selection window.



### Loading program

- 1. Select a program you wish to load much as described for "Saving program."
- 2. Press the "Load ( key)" to load the contents of the selected program into the current program area.



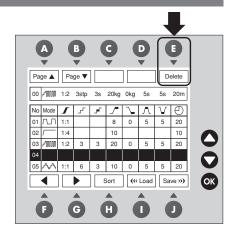


3. Press the key to return to the parameter selection window.

The parameter selection window displays the contents of the loaded program.

# Deleting program

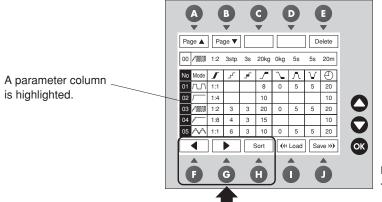
- Select a program you want to delete much as described for "Saving program."
- 2. Press the "Delete ( key)" to delete the contents of the selected program.
- 3. Press the key to return to the parameter selection window.



# **Program setting window**

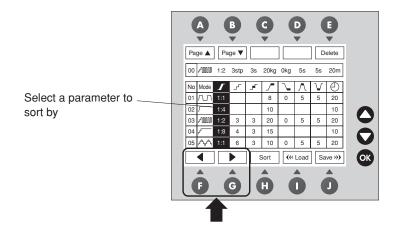
### Sorting program

1. In the program setting window, press "Sort (♠ key)," "◄ (♠ key)," or "▶ (♠ key)" to highlight a parameter column on the program list and enable the sort function.



Program setting window < Sort function is enabled >

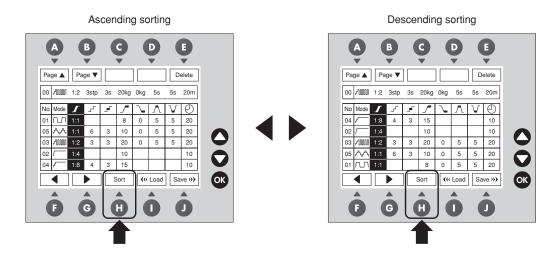
- 2. Select a parameter to sort by, using the "◀ (♠ key)" and "▶ (♠ key)." The programs can be sorted by any of the parameters.
  - \*While the sort function is enabled, "Delete (3 key)," "Save (1 key)," and "Load (1 key)" are disabled.



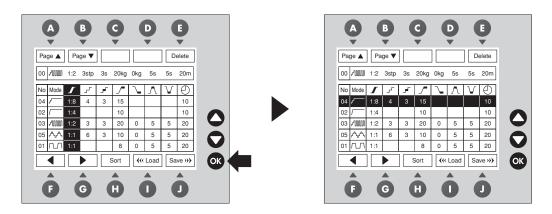
3. Press the "Sort (① key)" to sort programs by the selected parameter in ascending order.

Press the key once again to sort the programs in descending order.

Toggling the "Sort (① key)" alternates between ascending and descending order.

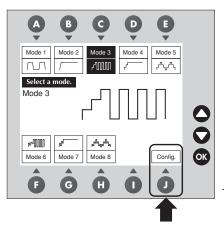


4. After sorting, press the key to turn off the sort function.



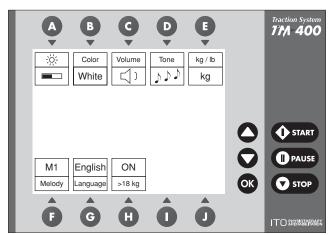
# **Configuration settings**

1. Press the "Config. ( key)" in the traction mode selection window to display the configuration window.



Traction mode selection window

2. Set the configuration using the function key (a) to (b) corresponding to the item you wish to edit.



Configuration window

Adjusts the brightness of the LCD screen.

Press lacktriangle to increase and lacktriangle to decrease brightness.

**B** Color ...... Sets the colors used on screen.

Toggling the (3) key alternates between "White: Blue letters on white background" and "Blue: White letters on blue background."

● Volume ······ Adjusts the sound volume.

Select from "×<: Mute," "1<: Min," "2<: Medium," and "3<: Max" using the ◆ / ◆ keys.

**• Tone** ········ Sets the touch key sound.
Select "♪♪♪: Sol-fa" or "♪♪♪: Monotone" using the ◆ / ◆ keys.

G Language ··· Sets the language for screen display.

Select from "English," "Deutsch," "Français," "Italiano," "Español," "Português,"

"Nederlands," "Svenska," "Dansk," and "中文" using the ♠ / ♠ keys.

• >18kg ······· Shows or hides the check window to be displayed if the traction force exceeds 18 kg (40 lbs).

Toggling the • key alternates between "ON: Show" and "OFF: Hide."

and • ····· Not used.

3. When the settings are complete, press the we key to return to the traction mode selection window.

# **Error codes**

If the system is not functioning properly or a problem occurs, an error code is displayed on the screen, and an alarm sounds.

#### Error 01

Error involving the Patient Switch. Take the relevant action below.

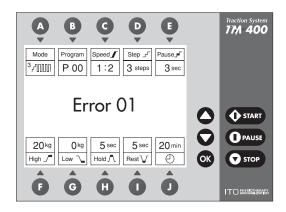
 The Patient Switch is not connected to the Main Unit.

Turn off the power switch and connect the Patient Switch.

 The Patient Switch is pressed during treatment.

Treatment ends. Press any key to cancel the error.

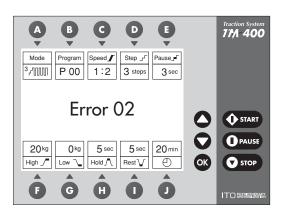
The Patient Switch malfunctions.
 Contact the distributor or manufacturer.



#### ●Error 02

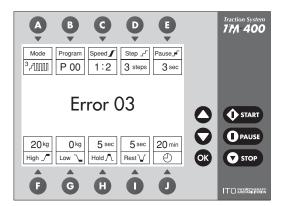
This code appears when the traction force is not accurate.

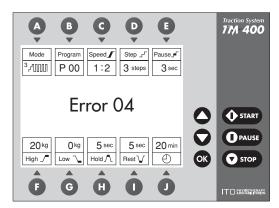
Contact the distributor or manufacturer.

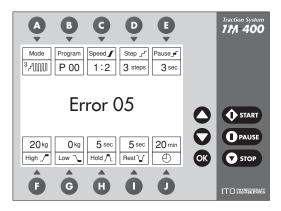


#### ●Error 03, Error 04 and Error 05

Press any key to cancel the error and power cycle the system.







Contact the distributor or manufacturer if an error code persists after you take the relevant action above.

- Medical electronic devices are designed to ensure electromagnetic compatibility (EMC).
   These devices must be installed and used in accordance with the EMC information provided in the attached document.
- Portable and mobile RF communications devices may affect medical electronic devices.
- Cable length
- Patient Switch: 2.67 m
   Power Supply Cord: 2.44 m
- If accessories other than those supplied as spare parts by the manufacturer are used, the emission of this instrument may increase and immunity may be reduced.
- Do not place this instrument next to or on top of another device when using it. If it has to be placed next to or on top of another device, check that this instrument and the device function properly before use.

### Guidance and manufacturer's declaration – electromagnetic emissions

This unit is intended for use in the electromagnetic environment specified below.

The customer or the user of this unit should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment — guidance
RF emissions CISPR 11	Group 1	This unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	This unit is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

### Guidance and manufacturer's declaration – electromagnetic immunity

This unit is intended for use in the electromagnetic environment specified below.

The customer or the user of this unit should assure that it is used in such an environment.

contact air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the	
	relative humidity should be at least 30%.	
± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.	
	Mains power quality should be that of a typical commercial or hospital environment.	
cycle (60% dip in $U$ T) rcles (30%dip in $U$ T) cycles (>95% dip in $U$ T)	Mains power quality should be that of a typical commercial or hospital environment. If the user of this unit requires continued operation during power mains interruptions, it is recommended that this unit be powered from an uninterruptible power	
	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.	
lin for lin / / / / / / / / / / / / / / / / / / /	lines power supply lines lines  / line (s) to line *(s) / line (s) to earth  / (>95% dip in UT) / (50% dip in UT) / (30% dip in UT) / (2008 dip in UT) / (30% dip in UT)	

NOTE  $U_T$  is the a.c. mains voltage prior to application of the test level.

### Guidance and manufacturer's declaration – electromagnetic immunity

This unit is intended for use in the electromagnetic environment specified below.

The customer or the user of this unit should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2 test level	compliance level	Electromagnetic environment — guidance
			Portable and mobile RF communications equipment should be used no closer to any part of this unit. including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Recommended separation distance d = $1.2 \sqrt{P}$ d = $1.2 \sqrt{P}$ 80 MHz to 800 MHz d = $2.3 \sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

- NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
- NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- <sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this unit is used exceeds the applicable RF compliance level above, this unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating this unit.
- Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

# Recommended separation distances between portable and mobile RF communications equipment and this unit

This unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this unit as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output	Separation distance according to frequency of transmitter m			
power of transmitter W	150 kHz to 80 MHz d = 1.2 $\sqrt{P}$	80 MHz to 800 MHz d = 1.2 $\sqrt{P}$	800 MHz to 2.5 GHz d = $2.3 \sqrt{P}$	
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

- NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.











EC REP "AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"