GE Healthcare

T2100-ST1
Treadmill, 110V

T2100-ST2
Treadmill, 220V

Operator's Manual

2097937-001 Rev J

T2100-ST1 Treadmill, 110V / **T2100-ST2** Treadmill, 220V
English
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Publication Information

The information in this manual applies only to T2100-ST1 Treadmill, and T2100-ST2 Treadmill. It does not apply to earlier versions. Due to continuing product innovation, specifications in this manual are subject to change without notice.

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This product complies with the regulatory requirements concerning medical devices from the following bodies:

CE

Date of first CE mark – 2012.

T2100-ST1 and T2100-ST2 treadmills meet the following safety and regulatory standards for FDA Class 1 motor operated physical medicine machines. They have been tested by Intertek Testing Services N.A Inc., and are listed by Engineering Testing Laboratories (ETL). However, the ultimate conformance to IEC 6060-1 2005-3rd edition is the responsibility of the system integrator when combined with other equipment. Additionally, all motorized equipment is potentially dangerous if used incorrectly. Before using the T2100-ST1 or T2100-ST2 treadmill, follow all precautions listed in this manual and read the entire Operator's Manual thoroughly. Use the T2100-ST1 and T2100-ST2 treadmills only as described.

Revision History

The document part number and revision appear at the bottom of each page. The revision identifies the document's update level. The revision history of this document is summarized in the following table.

Revision	Publication Date	Description
A	20 August 2016	Internal release
B	9 September 2016	Initial public release
C	18 November 2016	Power cord configuration
D	30 March 2017	Authorized Representative Address Change
E	12 June 2017	Added power cord configuration
F	27 June 2018	Revised regulatory and safety conformance
G	03 January 2019	Added EMC Declaration section
H	25 February 2021	Added MDR Labeling & Reprocessing Instructions
J	17 February 2022	Implementation of New Motor and Drive Combination, 3 Wire Hall Effect Speed Sensor and Harness, Magnetic Pull Tether Clip with STOP Behavior Information

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1

Introduction

This document describes the T2100-ST1 and T2100-ST2 treadmills also referred to as the “system”, “device”, or “product”. The document is intended to be used by clinical professionals.

This chapter provides general information required for the proper use of the system and this manual. Familiarize yourself with this information before using the system.

Intended User

This manual is geared for clinical professionals. Clinical professionals are expected to have working knowledge of medical procedures, practices, and terminology as required for completing these examinations.

Indications for Use

The T2100-ST1 and T2100-ST2 treadmills are designed for cardiac stress testing.

Prescription Device Statement

CAUTION:

United States federal law restricts this device to sale by, or on the order of, a physician.

Regulatory and Safety Information

This section provides information about the safe use and regulatory compliance of this system. Familiarize yourself with this information, and read and understand all instructions before attempting to use this system. The system was designed and manufactured to the appropriate medical regulations and controls.

NOTE:

Disregarding the safety information provided in this manual is considered abnormal use of this system and could result in injury, loss of data, and void any existing product warranties.

Safety Conventions

A **Hazard** is a source of potential injury to a person, property, or the system.

This manual uses the terms DANGER, WARNING, CAUTION, and NOTICE to point out hazards and to designate a degree or level of seriousness. Familiarize yourself with the following definitions and their significance.

Definition of Safety Conventions

Convention	Definition
DANGER	Indicates an imminent hazard, which, if not avoided, will result in death or serious injury.
WARNING	Indicates a potential hazard or unsafe practice, which, if not avoided, could result in death or serious injury.
CAUTION	Indicates a potential hazard or unsafe practice, which, if not avoided, could result in moderate or minor injury.
NOTICE	Indicates a potential hazard or unsafe practice, which, if not avoided, could result in loss or destruction of property or data.

Safety Hazards

The following messages apply to the system as a whole. Specific messages may also appear elsewhere in the manual.

WARNING:

The T2100-ST1 and T2100-ST2 treadmills are manufactured to exacting standards both in physical form and in component selection. The components used in our products have been selected with performance and medical safety in mind. The treadmills have been engineered and certified to conform to the list of medical and safety regulatory standards which appear on the next page. Modification or part substitution of any kind is strictly forbidden. Any deviation in component replacement, physical or electrical modification will result in loss of medical safety certification and warranty of this product. Modifications to this equipment may put the patient at risk of electrical shock or hardware malfunction.

Contact GE Healthcare Service department for all your repair part needs.

WARNING:

The T2100-ST1 and T2100-ST2 treadmills must be grounded to reduce the risk of electrical shock. If a malfunction occurs, grounding provides a path of least resistance for an electric current. Ungrounded connections must not be used.

No other equipment may be used on the electrical circuit with the treadmills. Do not use extension cords. Using a shared or unreliable circuit can also cause the treadmills to unexpectedly shut off, potentially resulting in injury to the patient.

Ensure the master power switch is in the off position before plugging in the T2100-ST1 or T2100-ST2. A power surge could damage the sophisticated electronic system of the treadmills.

WARNING:

Before permitting anyone to use the T2100-ST Series, do the following:

- Warn each user about the risk of falling while the belt is in motion.
- Stress the need for caution.
- Demonstrate the proper mounting and dismounting methods.
- Show each user how to use the T2100-ST Series as described in this manual.
- Ask each user to perform a supervised "test usage" at minimum belt speed to review and practice usage techniques.
- Observe all the precautions listed under “Responsibility of the Customer” on page 17 to reduce the possibility of serious injury as a result of falls or loss of balance.

WARNING:

Serious injury or death could result from electrical shock. To reduce the possibility of electrical shock, carefully observe the following precautions.

- To disconnect the treadmill, set the power switch to the OFF position, and remove the plug from the outlet. When the power is off, the green light on the power switch is dark.
- Never operate the unit with a damaged power cord or plug.
- Power cord should be routed through frame mounted clamp and kept clear of the elevation mechanism.
- Keep the power cord out of traffic areas and away from heated surfaces.
- Never use extension cords.
- Never operate the unit when it is wet.
- Never operate the unit if it is not operating properly.
- Always unplug the machine before service or maintenance is performed.
- Treadmill should be serviced by authorized technicians only.
- Operator should report any electrical shock when touching the treadmill and discontinue use immediately.
- Never use the treadmill outdoors.
- Immediately discontinue use and unplug the treadmill if you smell the distinctive odor of hot electrical components.

WARNING:

Serious injury or death could result from electrical shock occurring during defibrillation. Never allow patient or operators near treadmill during defibrillation.

WARNING:

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the T2100-ST Series, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING:

Consult your physician prior to using this appliance to determine the patient's physical readiness and capabilities. Stop exercising immediately and seek medical attention if the patient experience chest pain, dizziness or shortness of breath or if you experience symptoms of overexertion.

WARNING:

Serious injury or death could result from operating the treadmill in the presence of explosive or flammable vapors and antiseptics.

WARNING:

The potential for foot crush injury at frontal end of treadmill at lift mechanism (landing gear) when treadmill is descending. Keep feet and hands away from this area at all times.

Potential foot crush injury at rearward side rail, rear of side rail and rear roller exists when treadmill approaches full elevation. Keep feet and hands away from this area at all times.

Classification of Medical Device

This device is classified as follows, according to IEC 60601-1:

Medical Device Classification

Category	Classification
Type of protection against electrical shock	Class I motor operated physical medicine machine.
Degree of protection against electrical shocks	Type B external application applied part.
Degree of protection against harmful ingress or water	Ordinary equipment (enclosed equipment without protection against ingress of water).
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or with nitrous oxide	Equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or with nitrous oxide.
Method(s) of sterilization or disinfection recommended by the manufacturer	Not applicable
Mode of operation	Continuous operation.

Regulatory and Safety Conformance

T2100-ST1 and T2100-ST2 treadmills meet the safety and regulatory standards for FDA Class 1 motor-operated physical medicine machines. They have been tested by Intertek Testing Services N.A Inc., and are listed by Engineering Testing Laboratories (ETL). However, the ultimate conformance to IEC 60601-1 is the responsibility of the system integrator when combined with other equipment. Additionally, all motorized equipment is potentially dangerous if used incorrectly. Before using the T2100-ST1 or T2100-ST2 treadmill, follow all precautions listed in this manual and read

the entire Operator's Manual thoroughly. Use the T2100-ST1 and T2100-ST2 treadmills only as described.

NOTE:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at owner's expense.

Table 1: Guidance and Manufacturer's Declaration - Emissions

The T2100-ST Series is intended for use in the electromagnetic environment specified below. The customer or user of the T2100-ST Series should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	**Group 1**	The T2100-ST Series 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**	The T2100-ST Series is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	**Class A**	
Flicker IEC 61000-3-3	**Complies**	

Table 2: Guidance and Manufacturer's Declaration – Immunity All ME Equipment and ME Systems

The T2100-ST Series is intended for use in the electromagnetic environment specified below. The customer or user of the T2100-ST Series should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD IEC 61000-4-2	**±8kV Contact** **±15kV Air**	±8kV Contact ±15kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
EFT IEC 61000-4-4	**±2kV Mains** **±1kV I/Os**	±2kV Mains ±1kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	**±1kV Differential** **±2kV Common**	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	**>95% Dip for** **0.5 Cycle** **60% Dip for** **5 Cycles** **30% Dip for** **25 Cycles** **>95% Dip for** **5 Seconds**	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the T2100-ST Series requires continued operation during power mains interruptions, it is recommended that the T2100-ST Series be powered from an uninterruptible power supply or battery.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	**30 A/m**	30 A/m, 50/60Hz	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Table 3: Guidance and Manufacturer's Declaration – Immunity ME Equipment and ME Systems that is NOT Life-supporting

The T2100-ST Series is intended for use in the electromagnetic environment specified below. The customer or user of the T2100-ST Series should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	**3 Vrms** **150 kHz to 80 MHz** **3 V/m** **80 MHz to 2.7 GHz**	3V, 6V at ISM + (Amateur Frequencies 3 V/m at 80 - 2,700MHz, AM Modulation 9-28V/m, 385 - 6,000MHz, FM or Digital Modulation	Portable and mobile communications equipment should be separated from the T2100-ST Series by no less than the distances calculated/listed below: D = (3.5/V1) (Sqrt P) 150kHz to 80MHz D (3.5/E1) (Sqrt P) 80 to 800 MHz D = (7/E1) (Sqrt P) 800 MHz to 2.5 GHz where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.

Table 4: Recommended Separation Distances between portable and mobile RF Communications equipment and the T2100-ST Series ME Equipment and ME Systems that is NOT Life-supporting

The T2100-ST Series is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the T2100-ST Series can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the T2100-ST Series as recommended below, according to the maximum output power of the communications equipment.

Max Output Power (Watts)	**Separation (m) 150kHz to 80MHz** **D=(3.5/V1)(Sqrt P)**	**Separation (m) 80 to 800MHz** **D=(3.5/E1)(Sqrt P)**	**Separation (m) 800MHz to 2.5GHz** **D=(7/E1)(Sqrt P)**
0.01	0.11667	0.11667	0.23333
0.1	0.36894	0.36894	0.73785
1	1.1667	1.1667	2.3333
10	3.6894	3.6894	7.3785
100	11.667	11.667	23.333

Responsibility of the Manufacturer

Full-Vision Inc. is responsible for the effects of safety, reliability, and performance of the treadmill only if the following conditions are met:

- Assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized GE Healthcare.
- The electrical installation of the relevant room complies with the requirements of the appropriate local, state, and other government regulations.
- The equipment is used in accordance with the instructions for use.

Responsibility of the Customer

The customer is responsible for providing appropriate desks, chairs, electrical wall outlets, network connections, and analog phone lines, and for locating any of the system components described in this manual in compliance with all local, state, and national codes.

The customer is solely responsible for the training, instruction, supervision and safety of all users of the **T2100-ST Series treadmill**, and to use it as intended by the manufacturer. This device is intended to be used as a motion appliance to facilitate cardiac or VO_2 medical evaluation.

- Read this Operator's Manual before operating the **T2100-ST Series Treadmill**.
- Assist in off-loading the patient in the event of abnormal or unexpected operation of the treadmill.
- If the treadmill is not responding properly, stop the treadmill, assist in removing the patient off the running belt, unplug the treadmill power supply, and seek factory authorized repair before attempting to restart the treadmill.
- Never allow children or pets near the machine without qualified adult supervision.
- Note the location of stop and/or emergency stop controls and their operation before starting a test or workout.
- This device is not intended for use by persons with reduced physical, sensory or mental capabilities, or lack of experience and knowledge unless they have been given supervision or instruction concerning use of the appliance by a person responsible for their safety.
- Verify the Patient and Operator both know how to stop the machine in the event of malfunction or emergency.
- Patient should not wear loose fitting nylon material when exercising on this treadmill to avoid generating Electrostatic Discharge.
- Never attempt to remove any article of clothing while the running belt is moving.
- All persons on and around the treadmill must wear enclosed, protective footwear. Shoelaces must be tight and not drape as to cause a trip or catch hazard. Sandals, flip flops, slippers and the like are not considered enclosed, protective footwear.
- Walk in the center of the running belt. Contact with the side rail and the moving belt could cause injury.

- The Patient must always wear the Stop Tether lanyard wrist strap while operating the **T2100-ST Series Treadmill**.
- Place the treadmill on a hard, level and unobstructed surface. See Chapter 3“Assembly and Setup“ of this manual.
- Check input power cord connection and location for hazardous pinch points before use.
- Check input communications cord connection (if equipped) for proper interface with all equipment.
- Keep all cords clear of patient to avoid trip hazards.
- Never attempt to remove the motor pan hood or do electrical repairs yourself. Repairs should only be done by a factory authorized repair provider.
- Always unplug the **T2100-ST Series Treadmill** when servicing, inspecting or cleaning the treadmill.
- Routinely inspect the treadmill for loose parts.
- Inspect handrails and ensure they will support the patient properly.
- Always start the running belt at its slowest speed before starting the patient test.
- Do not step onto belt when it is moving.
- Always slow the running belt to its minimum speed before stopping.
- Keep hands, feet, and clothing away from any moving parts.
- Verify no one is near the elevation mechanism before operating. Never put any part of the body under any part of a running treadmill.
- Never drop or insert objects into any opening.
- Never drape garments, hook-up leads, or other equipment over the side rails or drop objects on the belt while the **T2100-ST Series Treadmill** is running.
- Do not allow moisture or oils to accumulate on equipment, creating a slip hazard.

Product and Package Information

This section describes the location of the labels used on your device and its packaging. It also describes the symbols used on the labels.

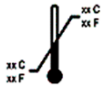
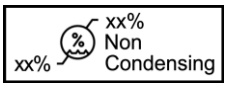
Symbols

The following symbols may appear on the device or its packaging. Familiarity with these symbols assists in the safe use and disposal of the equipment. For equipment symbols not shown, refer to the original equipment manufacturers (OEM) manuals.

Symbols are used to convey warnings, cautions, prohibitions, mandatory actions, or information. Any hazard symbols on your device or packaging with markings in color indicates there is certain danger and is a warning. Any hazard symbols on your device or packaging that is in black and white indicates a potential hazard and is a caution.

Symbols

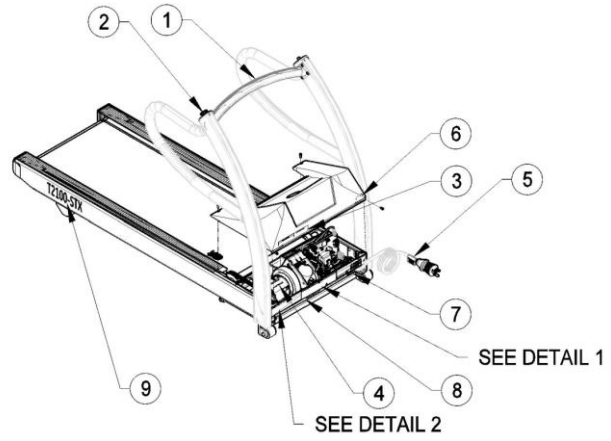
Symbol	Description
	**Catalog or Orderable Part Number** Indicates the manufacturer's catalog or part number.
	**Serial Number** Indicates the manufacturer's serial number.
	**Date of Manufacture (Year-Month)** Indicates the original manufacture date for this device.
	**Manufacturer Name and Address** Indicates the name and address for the manufacturer of this device.
	**CAUTION:** CONSULT ACCOMPANYING DOCUMENTS - There may be specific warnings or precautions associated with the device that are not otherwise found on the label. Consult the accompanying documentation for more information about safely using this device.
	**CAUTION:** ELECTRIC SHOCK - Indicates the presence of hazardous energy circuits or electric shock hazards. To reduce the risk of electric shock hazards, do not open this enclosure. Refer servicing to qualified personnel.
	**Reading of the Owner's Manual is mandatory.**
	**Upper Temperature Limit** Indicates the maximum temperature for transportation and handling of this package.

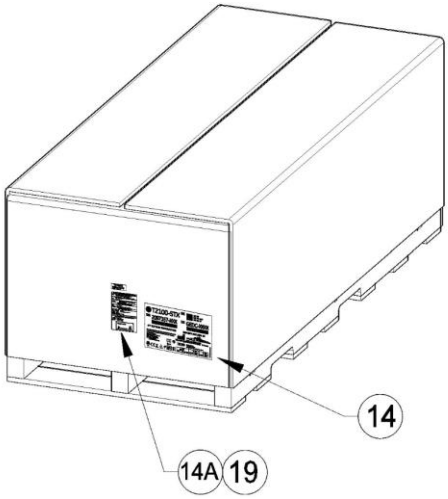
Symbol	Description
	**Temperature Limits** Indicates the upper and lower temperature limitations for the transportation and handling of this package.
	**Humidity Limits** Indicates the upper and lower Non-Condensing Humidity limitations for the transportation and handling of this package.
	**European Union Disposal Requirements** This equipment complies with the EU WEEE marking requirement for proper disposal of electrical and electronic waste in accordance with the European Directive. This directive calls for separation and recovery or reuse of used electrical or electronic equipment upon end-of-life EEE disposal. The T2100 must not be disposed of as unsorted municipal waste. Electrical or electronic components must be collected separately and disposed of in accordance with your local requirements and sources. The EEE program minimizes any potential effects on the environment and user health by eliminating the potential presence of hazardous substances in the waste stream. Customers should contact their local authorities or T2100 Distributor for guidance in complying with the directive.
	**Keep Dry** Indicates that you need to keep the container away from rain and other sources of moisture.
	**CE Mark** Indicates the device or product conforms with applicable EU (European Union) directives.
	**Eurasian Conformity mark** Conformity to applicable technical regulations of Customs Union.
	**Electrical Testing Laboratories** Indicates the device or product has been tested by an accredited third-party testing laboratory and meets applicable safety standards for sale and distribution within North America.

Symbol	Description
	**PCT (GOST-R) Mark** Indicates the device or product conforms with applicable Russian Gost standard technical and safety standards.
	Protective earth (ground).
	Alternating current.
	Device is suitable for the external application of the type “B” applied parts.
UDI	Unique Device Identification is a unique marking of the medical device
	Follow operating instructions
MD	Medical device
EC REP	Authorized Representative In European Union (Regulatory affairs only).
Rx ONLY	Federal law restricts this device to sale by or on the order of a physician.

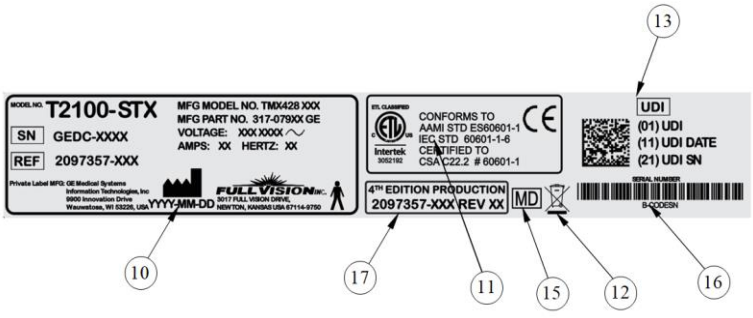
Label Locations

This section identifies the labels and their locations on the product and packaging.

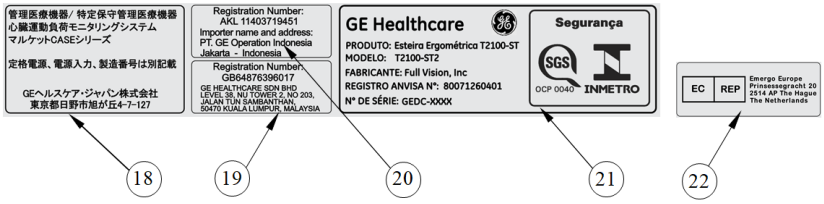




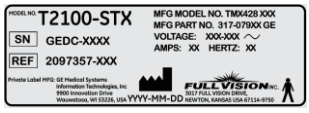
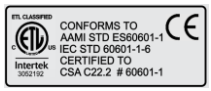
DETAIL 1

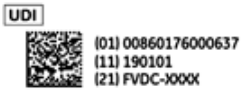


Detail 2



Refer to the previous illustrations for the locations of the labels identified in the following table. For detailed descriptions of the symbols that appear on the labels, refer to “Symbols” on page 19.

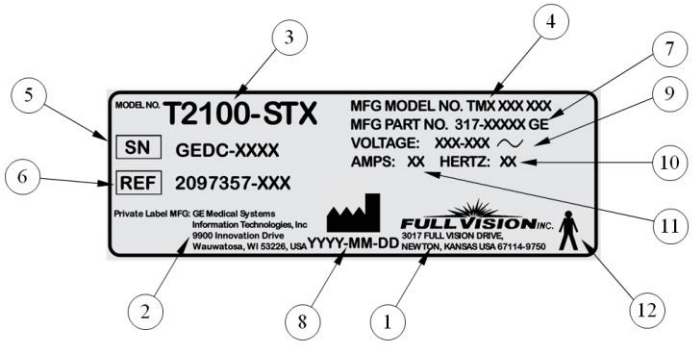
Item	Label	Location	Description
1		TMX428 on center handrail TMX428CP center console	Identifies Reading of the Owner's Manual
2		Stop on RH or LH end cap on handrail	Identifies E-Stop
3		Front of the device on the hood	Identifies the Caution Electrical shock hazard
4		On the motor	Identifies the Caution Electrical shock hazard
5		On the Power Cord	Identifies DC Hi-Pot Caution
6		Front of the device on the hood	Identifies Master Power switch.
7		Front of the device	Identifies Power Off (disconnection form mains) and Power On (connection to the mains)
8		Front of the device	Identifies the location for the RS232 & USB connection point.
9	Decal T2100-STX	On side channel Right & Left position above rear foot.	Identifies GE Model T2100-STX
10		Front of device	Identifies the product model.
11		Front of device	Identifies Listing Standards

12		Front of device	Contains the European Union disposal requirements
13		Front of the device on motor pan & on Shipping label.	Identifies Unique Device Identifier • (01) GTIN Number • (11) Manufacture Date • (21) Serial Number
14		On shipping container.	Identifies the following information for shipping: • Customer • Model Number • Serial Number • Storage conditions • Regulatory Compliance • Country of origin • EC Representative information
14A		On shipping container T2100-ST2 Only.	Identifies Brazil shipping registration information
15		Front of device	Identifies Medical Device
16		Front of device	Identifies FSE Barcode for service information requested by GE Healthcare

17	4TH EDITION PRODUCTION 2097357-XXX REV XX	Front of device	Identifies 4TH Edition Production and Revision level
18	管理医療機器/ 特定保守管理医療機器 心臓運動負荷モニタリングシステム マルケットCASEシリーズ 定格電源、電源入力、製造番号は別記載 GEヘルスケア・ジャパン株式会社 東京都日野市旭が丘4-7-127	Front of device	Identifies Japan registration information
19	Registration Number: AKL 11403719451 Importer name and address: PT. GE Operation Indonesia Jakarta - Indonesia	Front of device & On shipping container T2100-ST2 Only.	Identifies Indonesia registration information
20	Registration Number: GB6487639601 7 GE HEALTHCARE SDN BHD LEVEL 38, NU TOWER 2, NO 203, JALAN TUN SAMBANTHAN, 50470 KUALA LUMPUR, MALAYSIA	Front of device	Identifies Malaysia registration information
21	GE Healthcare PRODUTO: Esteira Ergométrica T2100-ST MODELO: T2100-ST2 FABRICANTE: Full Vision, Inc REGISTRO ANVISA Nº: 80071260401 Nº DE SÉRIE: GEDC-XXXX Segurança SGS OCP 0040 INMETRO	Front of device	Identifies Brazil registration information
22	EC REP Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	Front of device	Identifies EC REP information

Equipment Identification

Product Label



Product Label Format

Item	Name	Description
1	Manufacturer	Full Vision Inc.
2	Private Label Manufacturer	GE Medical Systems Information Technologies, Inc.
3	Model Number	Identifies model of treadmill
4	Manufacturer Model Number	Identifies manufacturing model of treadmill

Item	Name	Description
5	Serial Number	Manufacturer assigned serial number
6	REF	GE Medical Systems reference part number
7	Manufacturer Part Number	Manufacturing part number
8	Manufacturer Date	Manufacturing date code
9	Voltage	Specifies operating voltage of treadmill
10	Hertz	Specifies the electrical hertz of treadmill
11	Amps	Specifies amperage of treadmill
12	Type B Equipment	Device is suitable for the external application of type “B” applied parts

Service Information

This section provides information pertaining to the maintenance and servicing of the system. Familiarize yourself with this information before requesting service from GE Healthcare or its authorized representatives.

Service Requirements

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 safety hazards.

Regular maintenance, irrespective of usage, is essential to ensure that the components of this system are always functional when required.

Warranty Information

This device is considered GE Healthcare-supplied hardware. Only authorized GE Healthcare service personnel should service the device. Any unauthorized attempt to repair equipment under warranty voids that warranty. It is the user's responsibility to report the need for service to GE Healthcare or to one of their authorized agents.

Additional Assistance

GE Healthcare maintains a trained staff of application and technical experts to answer questions and respond to issues and problems that may arise during the installation, maintenance, and use of this system.

Contact your local GE Healthcare representative to request additional assistance.

Reporting of serious incidents

Any serious incident related to the use of this GE Healthcare device, should be reported to both the manufacturer and the health authority/competent authority where the device is installed.

- To report to manufacturer:

  FULL VISION INC.
  Email: tmservice@full-vision.com

- Please provide the following information:
  - The catalogue number or the model designation of the device as stated on its identification plate affixed on the device
  - The SystemID/serial number/lot number of the device
  - Date of incident
  - Description of incident, including any patient or user impact/injury
  - Your contact information (facility, address, contact name, title, and telephone number)'

Manual Information

This section provides information for the correct use of this manual.

Keep this manual with the equipment at all times and periodically review it. You should request training assistance from GE Healthcare, if needed.

Manual Purpose

This manual provides information necessary for the configuration and safe operation of this equipment in accordance with its function and intended use. It is not intended as a replacement for, but a supplement to, thorough product training. Keep it with the equipment at all times. Additional manuals may be ordered by contacting GE Healthcare.

Refer to the service manual for technical information related to the maintenance and repair of the equipment.

Document Conventions

This document uses the following conventions.

Typographical Conventions

The following table identifies the typographical conventions used in both this document and GE Healthcare Diagnostic Cardiology product documents.

Convention	Description
Bold Text	Indicates keys on the keyboard, text to enter, or hardware items such as buttons or switches on the equipment
Italicized Bold Text	Indicates software terms that identify menu items, buttons, or options in various windows.
KEY1+KEY2	Indicates a keyboard operation. A plus (+) sign between the names of two keys indicates that while holding the first key, you should press and release the second key. For example, Press CTRL+ESC means to press and hold the CTRL key and then press and release the ESC key.
<space>	Indicates that you must press the spacebar. When instructions are given for typing a precise text string with one or more spaces, the point where you must press the spacebar is indicated as: <space>. This ensures that the correct number of spaces are inserted in the correct positions within the literal text string. The purpose of the <> brackets is to distinguish the command from the literal text within the string.
Enter	Indicates that you must press the **Enter** or **Return** key on the keyboard. Do not type **Enter**.

Convention	Description
>	The greater than symbol, or right-angle bracket, is a concise method to indicate a sequence of menu selections. For example, the statement “From the main menu, select ***System***>***Setup***>***Options*** to open the ***Option Activation*** window” replaces the following: 1. From the main menu, select ***System*** to open the ***System*** menu. 2. From the ***System*** menu, select ***Setup*** to open the ***Setup*** menu. 3. From the ***Setup*** menu, select ***Options*** to open the ***Option Activation*** window.

Illustrations

All illustrations in the document are provided as examples only.

Notes

Notes provide tips or additional information that, while useful, are not essential to the correct operation of the tools. They are called out from the body text through a flag word and indentation, as follows:

NOTE:

The tip or additional information appears indented below the **NOTE** flag word.

Related Documents

The following documents are referenced in this manual and provide additional information that may be helpful in the installation, configuration, maintenance, and use of this product.

Part Number	Title
2097937-002	T2100-ST1 /T2100-ST2 Field Service Manual

Training

This manual is intended as a supplement to, not a substitute for, thorough product training. If you have not received training on the use of the system, you should request training assistance from GE Healthcare.

To see available training, go to the GE Healthcare training Web site (http://www.gehealthcare.com/usen/education/index.html). Under the Technical Service Education section, select Diagnostic Cardiology.

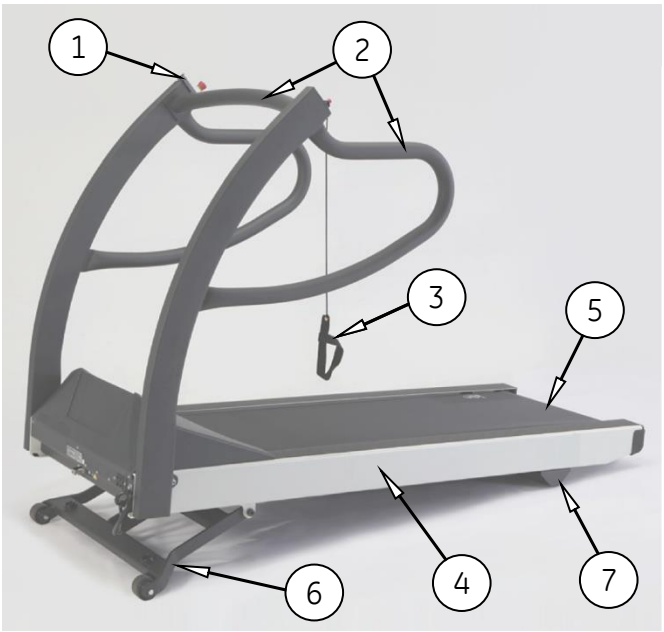
For more self-paced course offerings, tools, and reference guides you may find useful, please visit the GE Healthcare Education Store at www.gehealthcare.com/educationstore.

2

Product Overview

The T2100-ST1 and T2100-ST2 treadmills are designed and built to withstand the extraordinary demands of medical devices and are compatible with CASE, CardioSoft/CS, MAC 5500, and MAC 2000.

References to left, right, front, and rear are based on the assumption that you are standing on the treadmill, facing the handrails. All parts listed below are considered Patient Applied Parts except where noted.



Item	Description
1	Emergency Stop Button
2	Patient Grab Handles
3	Pull Tether Switch / Magnetic Tether
4	Side Rail
5	Running Belt
6	Elevation Landing Gear (Non-Applied Part)

Item	Description
7	Rear Foot (Non-Applied Part)

Safety Systems

- Dual comparative speed sensors
- Auto runaway shutdown
- Auto communication loss shutdown
- Manual twist lock Emergency Stop button
- Manual Stop Tether
- Braking system for safe patient off-loading
- Fire-rated motor pan hood enclosure

Treadmill

- Patient weight capacity 500 lb., 227 kg
- All steel construction with powder-coat finish
- Treadmill net weight: 425 lb., 193 kg

Drive System

- Heavy-duty 4- hp. brushless, DC servo motor
- T2100-ST1 110-120VAC, 1-phase, 60 Hz, 20-amp power supply
- T2100-ST2 200-240VAC, 1-phase, 50-60 Hz, 15-amp power supply

Speed Range

0.1 to 15.0 mph, 0.2 to 24.0km/h, self-calibrating and adjustable in 0.1 mph 0.1 km/h increments.

NOTE:

The T2100-ST2 maximum speed (15.0 mph) will deteriorate at lower voltages (210VAC or below).

Incline Range

0 to 25%, 0.5% incremental movements, self-calibrating.

Running Surface

- 22 in. x 63 in., 56cm x 160cm
- MasterTrack® running belt tracking system
- Cushioned running deck absorbs shock of foot falls
- Self-lubricated and reversible running deck
- Step-up height (7 in., 18cm from floor)

Communication Ports

- RS232 Female Serial port
- USB 1.0 “B” port

Floor Surface Footprint

33.0 in. x 78.5 in., 84cm x 200cm level surface. (See “Location” on page 42.)

Operating and Storage Condition Recommendations

- Operating Temperature Range: 4.5° to +38° C (+40° to +85° F)
- Storage Temperature Range: -40° to +70° C (-40° to +158° F)
- Operating and Storage Relative Humidity Range: 10% - 90%, non-condensing
- Altitude: -50 to 9,842 feet (-15m to 3000m); derate performance by 5% per each additional 500 feet (152m) above 5,280 feet (152m)

Power Requirements

The T2100-ST1 is designed to operate on a dedicated 110-120 VAC 20-amp power supply and the T2100-ST2 is designed to operate on a dedicated 200-240 VAC 15-amp. Make sure that the treadmill is connected to an outlet that looks like the following illustration.

This product is equipped with a three-wire grounding-type plug. The plug will only fit into a grounding-type outlet. This safety feature must not be disabled. Contact a qualified electrician if you are unable to insert the plug into your outlet, or uncertain if the outlet meets local electrical codes. Polarized outlets such as NEMA 5-20 and CEE7/7 must be verified for proper polarity configuration before plugging in the T2100-ST2. Incorrect polarization of the outlet could cause failure of onboard electrical components or cause electrical shock. Proper grounding is necessary for the equipment to meet acceptable current leakage standards consistent with the standards to which it was certified.



110-120 VAC
NEMA 5-20R
Single Phase



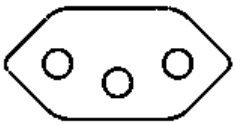
220/240 VAC
NEMA 6-15R
Split Phase



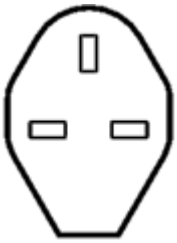
230 VAC
AS/NZS 3112



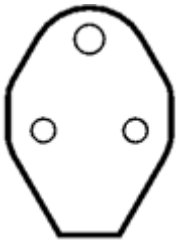
220/240 VAC
CEE 7/7 EURO



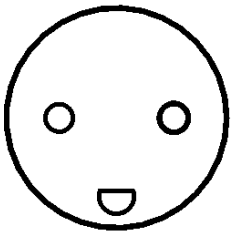
250 VAC
Type N BRAZIL



230 VAC
BS1363



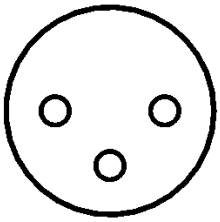
240 VAC
BS546 3 PIN



250 VAC
Type K DANISH



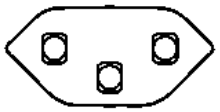
240 VAC
GB 1002



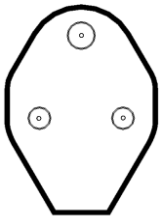
250 VAC
Type H ISREAL



250 VAC
Type L ITALY



250 VAC
Type J SWISS



250VAC
BS546 INDIAN



250 VAC
NEMA 6-20P
Single Phase

WARNING:

The T2100-ST1 and T2100-ST2 treadmills must be grounded to reduce the risk of electrical shock. If a malfunction occurs, grounding provides a path of least resistance for an electric current. Ungrounded connections must not be used.

No other equipment may be used on the electrical circuit with the treadmills. Do not use extension cords. Using a shared or unreliable circuit can also cause the treadmills to

unexpectedly shut off, potentially resulting in injury to the patient.

Ensure the master power switch is in the off position before plugging in the T2100-ST1 or T2100-ST2. A power surge could damage the sophisticated electronic system of the treadmills.

NOTE:

The T2100-ST1 and T2100-ST2 Treadmills must have their own dedicated power outlet. Maximum length of power cord should not exceed 10 Feet or 3.05 Meters. Replacement Power Cords need to be ordered through the manufacturer of the operating equipment.

WARNING:

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING:

Only use accessories, transducers, and cables provided by the manufacturer of the equipment. Using supplies and accessories not recommended by GE Healthcare could result in increased electromagnetic emissions or decreased electromagnetic immunity of the equipment and could result in improper operation.

3

Assembly and Setup

The T2100-ST1 and T2100-ST2 treadmills are shipped fully assembled and packaged in a knock down condition. They are designed to pass through a standard 36" door opening measuring at least 35½". It will be necessary to remove the door from the jamb in most cases if the door is not capable of opening fully parallel to door opening. After you have unpacked the treadmill and secured the handrail assembly to the frame, move the treadmill to the area by rolling it on its front wheels. If your treadmill must pass through a door opening less than 36" wide, additional disassembly will be required. This task should be performed by an authorized service provider to ensure that the T2100-ST1 and T2100-ST2 are properly reassembled and functioning correctly.

Safe Handling Guidelines

- Do not attempt to move the treadmill with the handrails in the shipping position due to the possibility of cutting the internal wiring. You must either fully secure the handrails in their proper position or secure handrails with 3/8-16 bolt in the folded position.
- Lift the end of the bed assembly to a comfortable height, keeping knees bent and back straight as you lift.
- Rotate the treadmill in the direction you want to go (the treadmill will pivot on its wheels) and push forward.
- When you have maneuvered the treadmill into its location, gently lower the end of the bed assembly to the floor.



WARNING

The T2100-ST1 and T2100-ST2 treadmills each weigh 425 lbs. When lifting the rear of the treadmill and rolling it on its front wheels, you are moving 132 lbs. This can be accomplished by one person, but each installer must evaluate whether he or she can move this amount of weight without causing strain or injury. If in doubt, a second person should be recruited to assist.

If you are moving the treadmill over rough surface, such as pavement, use a dolly under front of the treadmill to prevent damage to the wheels and lift mechanism.

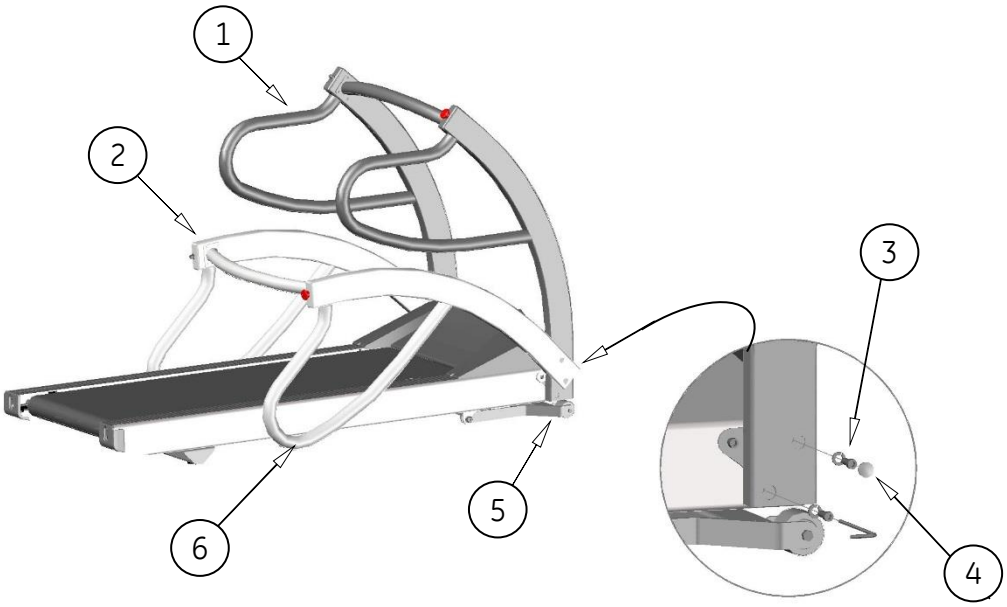
Initial Setup

Tools required for assembly

- 5/16 Allen wrench (supplied)

The treadmill is shipped with the handrails loose, straddling the treadmill frame. It is advised that you secure the handrails in their proper location before removing the treadmill from the base of the crate. This prevents the internal wires running down the handrail mount to the motor pan from being cut.

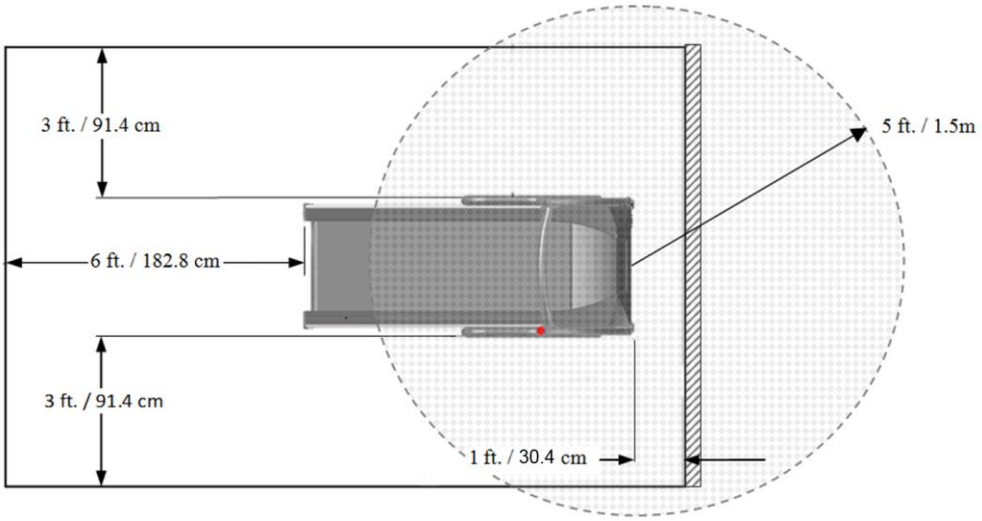
1. Swing the handrail assembly into the operating position and insert (2) 3/8-16 bolts and 3/8 lock washer each side and tighten securely.
2. Install (2) plastic caps each side for a finished look.



Item	Description
1	Operating Position
2	Shipping Position
3	Insert (2) washer and bolts each side
4	Insert (2) caps each side
5	Pivot Point
6	When folding handrails apply cardboard between frame and handrail to prevent handrail damage.

Location

Place the T2100-ST1 or T2100-ST2 on a firm and level hard surface that is free of tile grout lines. The illustration below shows the minimum recommended clearances from the treadmill edges to any obstruction for dismount and safety purposes. Observe that the operator should be stationed by the E-Stop.



WARNING:

The T2100-ST1 and T2100-ST2 treadmills conform to FCC class B rating for electromagnetic emissions. It is recommended not to place the treadmill closer than 5ft. (1.5m) from sensitive electronic devices within the room or in an adjacent room. If an interference problem occurs, move the treadmill farther away from the sensitive device or relocate either device to another area, or consult with an EMI specialist for ways to shield the room from electromagnetic radiation.

Do not place it on thick or long-pile carpeting. Such carpeting could cause instability or static build-up, and carpet fibers could get caught in the belt and damage the unit.

Ensure that power cords do not cross traffic areas. Exposed power cords can cause a fall, resulting in injury.

Keep it away from sources of moisture, such as spas or fountains. Moisture can cause the electronic circuitry to malfunction.

Final Setup - Running Belt Tracking Adjustment

NOTE:

Because this adjustment is not covered under your warranty, it is important that you review these instructions thoroughly before proceeding. Uneven floors accelerate belt misalignment. This situation may require more frequent adjustment to prevent belt damage.

The patented MasterTrack® Belt Tracking System significantly reduces the need to adjust the belt on your T2100-ST1 or T2100-ST2 treadmill. However, when you operate your treadmill for the first time, you may need to adjust the tracking of the belt to conform to your floor.

You may also need to adjust the tracking if you move the machine to another location. (See “Running Belt Tracking Adjustment” on page 59 for details.)

Final Setup - Running Belt Tension Adjustment

Your T2100® running belt has been pre-tensioned at the factory and run for 16 hours prior to shipment. It may, however, be necessary to adjust the belt tension when the treadmill is run in its final location. A loose belt tends to hesitate or stick with a heavy foot plant. If your belt needs tensioning, the adjustment procedure can be found in “Running Belt Tension Adjustment” on page 60.

NOTE:

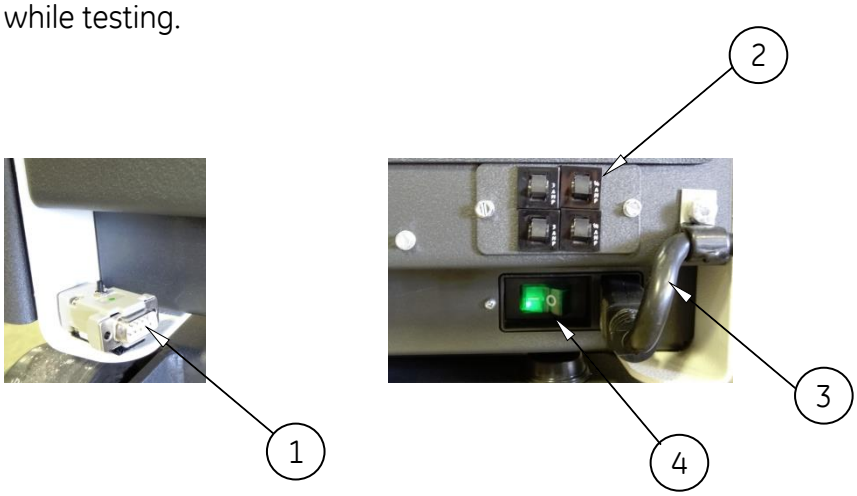
Improper adjustment could cause the treadmill to hesitate and cause a trip and fall hazard. Because this adjustment is not covered under your warranty, it is important that you review these instructions thoroughly before proceeding.

Final Setup - Drive Belt Tension Adjustment

The drive belt tension has been pre-set at the factory to minimize maintenance. If there are indications that the drive belt has stretched and become loose, refer to "Drive Belt Tension Adjustment" in the Preventive Maintenance chapter of the T2100-ST1 / T2100-ST2 Field Service Manual. Symptoms of a stretched drive belt could include increased noise.

Final Setup - Test Plug Procedure

Each T2100-ST1 and T2100-ST2 treadmill includes an RS-232 test plug that enables you to test the operation of the treadmill without the ECG unit attached. The plug is located on the left side of the treadmill secured to the frame by Velcro®. The plug is to be used only for testing the treadmill. Do not stand on or use the treadmill while testing.



Item	Description
1	Test Plug Location on Left
2	Circuit Breaker Array
3	Incoming Power Cord
4	Main Power Switch

Using the Test Plug

1. Turn the power "OFF" at the treadmill.
2. Disconnect the RS232 or USB interface cable from the treadmill and plug in the test connector.
3. Press and hold the button on the test connector and turn the treadmill power "ON". Continue holding until the treadmill begins to elevate.
4. When the treadmill begins to raise, repeatedly press the button to cycle through the different phases of the test.
    - Once the treadmill begins to rise, each press of the button should raise it in 5% increments.
    - Once the treadmill reaches a 20% elevation, the next press of the button should start the treadmill running belt.
    - Once the treadmill running belt starts, each press of the button should increase the speed by 2.5 mph (4 km/h).

- Once the treadmill reaches 10 mph (16 km/h), each press of the button should decrease the speed by 2.5 mph (4 km/h) and lower the elevation in 5% increments.
- Once the treadmill reaches the minimum speed and elevation, the next press of the button should stop the treadmill running belt.

NOTE:
Successful completion of the preceding testing procedure ensures that the treadmill is fully functional and responsive to command signals.

NOTE:
Unsuccessful completion of the preceding testing procedure indicates a problem with the setup. Call GE Medical Systems *Information Technologies* to trouble shoot failure of test plug procedure.

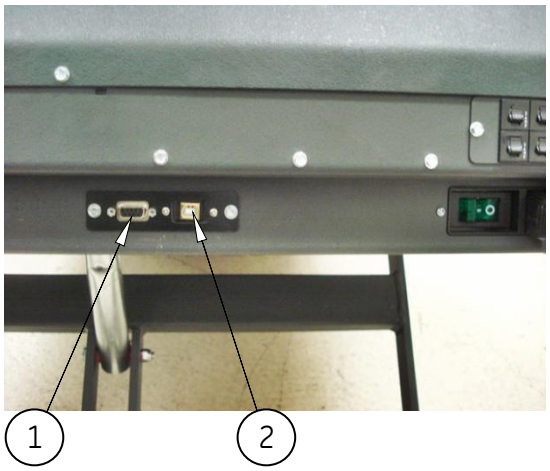
5. Remove the test connector.
6. Reconnect the RS232 or USB interface cable from the host computer. You are ready to begin the set-up procedure prescribed by your medical test equipment supplier.

Communication Access Location

The communication ports are located at the very front of the treadmill near the center of the unit.

Two ports are offered with equal communication capability. The standard female RS232 port and a USB Type B port offer connectivity diversification.

To communicate to the T2100-ST1 or T2100-ST2 treadmill using the USB port, you will need to install the appropriate USB driver software on your host computer. The USB driver is supplied on the provided flash drive. When connecting to the USB port, ensure port configuration is congruent with your software port identification.



Item	Description
1	RS232 Port “Female”
2	USB “B” Port

4

Operating Instructions

Before operating the T2100-ST1 or T2100-ST2, familiarize yourself with the following control safety features of the treadmills.

Electrical Safety Tests

The electrical safety of this installation is the responsibility of the customer, not GE Medical Systems *Information Technologies*. In hospitals, contact your in-house biomedical technician, electrician, or technically qualified personnel. Outside of hospital, contact your hospital affiliation of these services. Otherwise, contact GE Medical Systems *Information Technologies and open a customer-billable service call.*

Before using the treadmill, have qualified personnel perform the test listed below:

- AC line voltage test to verify the power outlet is properly wired.
- Ground continuity test to verify all exposed metal is properly grounded.
- Leakage test to verify the equipment passes all applicable leakage tests.

Your in-house biomedical technician, electrician, or technically qualified personnel can find instruction for performing these tests in the T2100-ST1/T2100-ST2 Treadmill Service Manual shipped with your system.

Operating Controls

The treadmill has three operating controls: the power switch, emergency stop switch, and pull tether. The power switch is located on the rear panel, the emergency stop is located on the right-hand rail, and the pull tether is located on the left handrail.

Controlling the Treadmill

- Turn the power switch ON (I).
- Use the controlling equipment to start the treadmill, adjust the treadmill speed and grade, proceed through exercise phases, terminate the exercise session, and turn off the treadmill. Refer to the appropriate controlling equipment Operator Manual for instructions.

Power Switch

The power switch controls the AC power to the treadmill. The ON position (I) applies power. The Off position (0) removes power.

Emergency Stop Switch

The Emergency Stop switch is a safety device for use in emergency situations to stop the treadmill. Press the STOP push-button and the treadmill will coast to a stop.

To release the Emergency Stop switch, turn the push button ¼-turn in counterclockwise direction. The treadmill will return to 0.0% elevation.

Emergency Stop Switch Check

NOTE:

Verify proper operation of the stop switch assembly every month.

- With the belt moving at a relatively high speed, press the emergency stop switch. The treadmill will coast to a stop. To release the Emergency Stop switch, turn the push button ¼-turn in counterclockwise direction. The treadmill will return to 0.0% elevation.
- Use the controlling equipment to terminate the exercise session and turn off the treadmill.

Pull Tether Switch/Magnetic Tether

The pull tether switch is a safety device for patient safety use in emergency situations to stop the treadmill. Pull the pull tether strap, the treadmill will have a controlled stop.

To reattach the Wrist Strap Tether, attach clip to the original position on the switch. The treadmill will return to 0.0% elevation.



To reattach the Magnetic Tether, place the Magnet Tether to the original position on the switch. The treadmill will return to 0.0% elevation.



Pull Tether Switch/Magnetic Tether Check

NOTE:

Verify proper operation of the tether switch assembly every month.

- With the belt moving at a relatively high speed, pull the wrist strap to activate. The treadmill will have a controlled stop to 0.0 speeds. The running belt will have resistance preventing the free movement of the running surface.
- Use the controlling equipment to terminate the exercise session and turn off the treadmill.

Treadmill Behavior under Different STOP Scenarios

Following are the various STOP scenarios frequently observed in the Treadmill:

- Treadmill Emergency STOP Button (ESB)
- Treadmill Safety Tether Clip/Magnetic Switch
- Host System - Single press of STOP Button

- Host System - Double Press (or depressed for > 2secs) of STOP Button
- Host system – Test End
- Loss of Communication with the Host System
- Loss of Communication due to Timeout

Treadmill Power Up Sequence Mode

The treadmill enters into “Power Up Sequence” mode while recovering from certain Stop scenarios.

During this mode the treadmill performs an internal check while returning to its parking position, i.e., zero-elevation point. Ensure NOT to press the “Start tmill” button until the treadmill completes its Power Up Sequence.

Treadmill Emergency STOP Button (ESB)

When the treadmill is in motion and you press the Emergency Stop Button (ESB) on the treadmill, the treadmill speed gradually reduces until it is stopped. The elevation is maintained, and the belt remains unlocked. The power is cut-off from the internal motor drive circuit, which results in communication loss with the Host. Hence there will be “communication loss” message displayed on the Host system.



After releasing or resetting the ESB, allow the treadmill to complete its “Power Up Sequence”. Until 0% elevation is achieved, communication loss will appear. Press the “Start tmill” button on the Host system. Exercise test cycle will restart (belt starts moving) at the speed and elevation as commanded by the Host system.

NOTE:

Allow the treadmill to complete its “Power Up Sequence”. If you press the “Start tmill” button on the Host system before the treadmill reaches zero elevation, the treadmill will reject the start command and will enter into an error mode. In this error mode, the treadmill will be non-responsive to all start commands. You may observe the elevation to change but belt will not start. You need to perform a main power cycle on the treadmill to come out of the error mode. During the “Power Up Sequence”, there could be a maximum delay of 45 seconds. Pressing the ESB or Pull Tether activation will also serve the purpose of entering the “Power Up Sequence”. Alternatively,

you may recover from a reject start command error mode by pressing the “STOP tmill” followed by “Start tmill” button.

Treadmill Safety Tether Clip/Magnetic Switch

Wrist Strap Tether Clip Detachment

When the treadmill is in motion and you pull the wrist strap tether clip, the treadmill speed gradually reduces at 2.5 mph/sec to “0” mph. The elevation is maintained, and belt will be locked for 3 minutes.

Wrist Strap Tether Clip Attached



Wrist Strap Tether Clip Detached



Wrist Strap Tether Clip Reattachment

To initiate the start-up sequence, re-attach the Wrist Strap Tether Clip to the original position on the switch. The treadmill will return to 0.0% elevation. The treadmill enters into a “Power-Up Sequence” mode where it goes to the parking position. Wait until the treadmill reaches the parking position and returns to its previous elevation. Press the “Start tmill” button on the Host system. Exercise test cycle will restart (belt starts moving) at the speed and elevation as commanded by the Host system.

NOTE:

When resetting the Wrist Strap Tether Clip or Magnetic Tether, there may or may not be a break in communication between the host system and treadmill.

NOTE:

Allow the treadmill to complete its “Power Up Sequence”. If you press the “Start tmill” button on the Host system before the treadmill reaches zero elevation, the treadmill will reject the start command and will enter into an error mode. In this error mode, the treadmill will be non-responsive to all start commands. You may observe the elevation to change but belt will not start. You need to perform a main power cycle on the treadmill to come out of the error mode. During the “Power Up Sequence”, there could be a maximum delay of 45 seconds. Pressing the ESB or Pull Tether activation will also serve the purpose of entering the “Power Up Sequence”. Alternatively, you may recover from a reject start command error mode by pressing the “STOP tmill” followed by “Start tmill” button.

Activation by Pressing Red Cap Safety Tether Version

The RED cap on the safety tether can also be activated by pressing down the button for greater than 3/4 seconds. This will simulate the activation of the safety tether. The treadmill speed gradually reduces at 2.5 mph/sec to “0” mph. The treadmill enters into “Power Up Sequence” mode where it goes to the parking position. Wait until the treadmill reaches the parking position and return to its previous elevation. Press the “Start tmill” button on the Host system. Exercise test cycle will restart (belt starts moving) at the speed and elevation as commanded by the Host system.

NOTE:

Allow the treadmill to complete its “Power Up Sequence”. If you press the “Start tmill” button on the Host system before the treadmill reaches zero elevation, the treadmill will reject the start command and will enter into an error mode. In this error mode, the treadmill will be non-responsive to all start commands. You may observe the elevation to change but belt will not start. You need to perform a main power cycle on the treadmill to come out of the error mode. During the “Power Up Sequence”, there could be a maximum delay of 45 seconds. Pressing the ESB or Pull Tether activation will also serve the purpose of entering the “Power Up Sequence”. Alternatively, you may recover from a reject start command error mode by pressing the “STOP tmill” followed by “Start tmill” button.

During Safety Tether activation, treadmill communication is maintained with the Host System.

Activate by pressing down the button for more than 3/4 seconds.





NOTE:

The momentary activation of the red button, for example, if the red button is pressed between 0.2 seconds to 3 seconds the treadmill will hold elevation and belt will decelerate to 0 mph and maintain position for 3 minutes. Allow the treadmill to complete its “Power Up Sequence”. Until 0% elevation is achieved, communication loss will appear. Pressing the ESB or Pull Tether activation will also serve the purpose. Exercise test cycle will restart (belt starts moving) at the speed and elevation as commanded by the Host system.

- T2100-ST Series with firmware 1.19.XX onwards will not enter into “Power Up Sequence” by means of the momentary activation as stated above.

Magnetic Tether Detachment

When the treadmill is in motion and you pull the magnetic tether, the treadmill speed gradually reduces at 2.5 mph/sec to “0” mph. The elevation is maintained, and belt will be locked for 3 minutes.

Magnetic Tether Attached *Magnetic Tether Detached*





Magnetic Tether Reattachment

To initiate the start-up sequence, re-attach the Magnetic Tether to the original position on the switch. The treadmill will return to 0.0% elevation. The treadmill enters into a “Power-Up Sequence” mode where it goes to the parking position. Wait until the treadmill reaches the parking position and returns to its previous elevation. Press the “Start tmill” button on the Host system. Exercise test cycle will restart (belt starts moving) at the speed and elevation as commanded by the Host system.

NOTE:

When resetting the Wrist Strap Tether Clip or Magnetic Tether, there may or may not be a break in communication between the host system and treadmill.

NOTE:

Allow the treadmill to complete its “Power Up Sequence”. If you press the “Start tmill” button on the Host system before the treadmill reaches zero elevation, the treadmill will reject the start command and enters into an error mode. In this

error mode, the treadmill will be non-responsive to all start commands. You may observe the elevation to change but belt will not start. You need to perform a main power cycle on the treadmill to come out of the error mode. During the “Power Up Sequence”, there could be a maximum delay of 45 seconds. Pressing the ESB or Pull Tether activation will also serve the purpose of entering the “Power Up Sequence”. Alternatively, you may recover from a reject start command error mode by pressing the “STOP tmill” followed by “Start tmill” button.

Host System - Single press of STOP Button

When the treadmill is running and pressing the “**STOP tmill”** button on the Host system will result in gradual deceleration of the treadmill at 0.5 mph to “0” mph. The elevation is maintained, and belt remains locked for 3 mins. The communication is maintained with the Host System throughout the stop condition.

Pressing the “Start tmill” button on the Host system will restart the Exercise test cycle (belt starts moving) at the speed and elevation as commanded by the Host system.

NOTE:

Both the elevation and speed reduce to “0” while connected to the Host system MAC5500-ST. You can press “Start Tmill” before it reaches “0” elevation or speed. No communication loss is found.

Host System - Double Press (or depressed for > 2secs) of STOP Button

When the treadmill is running and you press the “STOP tmill” button on the Host system twice to represent an emergency stop condition invoked through the Host system, the treadmill speed will rapidly decrease at 2.5 mph/sec until stopped. The elevation is maintained and belt remains locked for 3 mins. There will be momentarily disruption of communication between the Host and the treadmill.

Press the “Start tmill” button on the Host system to resume the Exercise test cycle at the speed and elevation as commanded by the Host system.

To resume operation, press “Start tmill” on the Host system. Exercise test cycle will restart (belt starts moving) at the speed and elevation as commanded by the Host system.

NOTE:

Both the elevation and speed reduce to “0” while connected to the Host system MAC5500-ST. You can press “Start Tmill” before it reaches “0” elevation or speed. No communication loss is found.

Host system – Test End

When an exercise cycle is active and the treadmill is in running condition, pressing the “Test End” button on the Host system will terminate the exercise test. the treadmill speed will gradually decrease at 0.5 mph/sec to “0” mph. Treadmill elevation will reach its parking position and belt remains locked for 3 minutes.

Select a new exercise test and press pretest > exercise > “Start tmill” on the Host system to start a new exercise test cycle, Follow the Host system manual for instructions on how to setup and perform an Exercise test.

Loss of Communication with the Host System

The treadmill is equipped with a RS232 or USB port to provide communication with the Stress Host system. Communication with the treadmill can be lost due to multiple factors like interface cable or connector damage, loose connection, cable pinching or entanglement etc. If there is a communication loss while the treadmill is running, the treadmill will gradually decelerate at 0.5mph/sec until stopped. The elevation is maintained, and belt remains locked for 3 mins. The communication between the Host and treadmill is lost and hence an error message will be displayed on the Host system indicating communication loss to the treadmill.

Perform a check on the communication cable, if damaged or fallen lose from its position. Restoring the cable connection will establish communication with the Host system and the error message on the Host will disappear. Press the “Start tmill” button on the Host system to resume the Exercise test cycle at the speed and elevation as commanded by the Host system.

Loss of Communication due to Timeout

A “Communication timeout” may occur if communication is lost for 2.5 seconds between the Host system and the treadmill. If a communication timeout occurs while the treadmill is running, the treadmill will gradually decelerate at 0.5mph/sec until stopped. The elevation is maintained, and belt remains locked for 3 mins. The Host system may display “No Communication” momentarily, then reestablish communication. Press the “Start tmill” button on the Host system to resume the Exercise test cycle at the speed and elevation as commanded by the Host system.

If following the above does not restart the test cycle, you need to end the test and start a new exercise test. The elevation will go to the parking position. Press **pretest > exercise > “Start tmill”** on the Host system. Exercise test cycle will start (belt starts moving) at the speed and elevation as commanded by the Host system.

If you encounter intermittent stops which is not attributed to any of the stop conditions above, or if the resumption of exercise test cycle is not possible even after following the above instructions, please contact your authorized GE representative for troubleshooting.

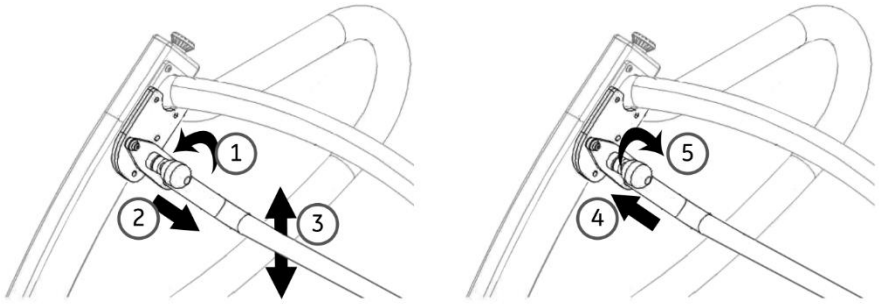
Adjustable Handrail Option

The adjustable handrail is an optional feature that allows you to change its position to accommodate patients of various heights. If this option is installed on the T2100-ST series treadmill, use the following procedure to adjust its position.

CAUTION

POTENTIAL BODILY INJURY – Attempting to reposition the adjustable handrail while the running belt is operating could result in bodily injury.

Make sure the running belt is off before performing the following procedure.



1. Turn the adjustment knob counterclockwise twice to unlock the handrail.
2. Pull out the adjustment knob to release the handrail.
3. Adjust the handrail to the desired height.
4. Release the adjustment knob to secure the handrail in the current position.
5. Turn the adjustment knob clockwise twice to lock the handrail.

5

Preventive Maintenance

Regular cleaning and maintenance is essential to keep your T2100-ST1 and T2100-ST2 treadmills operating at their best for many years. We recommend that you record all maintenance and service in a log (as shown in Appendix A).

CAUTION



Before cleaning the T2100-ST1 and T2100-ST2 treadmills, turn the main power switch to OFF, and disconnect the treadmill from its power outlet. Never use wet cleaning materials near a power source: Since there is a risk of electrical shock, this should be a Caution.

To preserve the condition of your warranty, make sure that all repair procedures (other than normal maintenance) are performed by an authorized and qualified service provider. Contact your local GE customer support representative.

Use only authorized replacement parts. Using other parts may void your warranty and may cause your T2100-ST1 or T2100-ST2 treadmill to malfunction.

NOTE:

Replacement Parts need to be ordered through the manufacturer of all operating equipment to ensure BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES for the EXPECTED SERVICE LIFE.

Reprocessing Instructions

To reprocess the treadmill between each patient use, follow the reprocessing instructions in Appendix B.

Daily Maintenance

- Ensure that the treadmill is functioning properly.
- Visual inspection of treadmill and walking belt for damage and wear.

Weekly Maintenance

- Vacuum around and under the treadmill. Clean all exposed surfaces with a vacuum cleaner. Avoid moving the treadmill from its original position as moving it will compromise the original belt tracking setting.
- Check running belt tension.
- Observe running belt tracking and correct as required.

Monthly Maintenance

Inspect and clean the belt.

Semi-annual Maintenance

- Evaluate the condition of the deck and belt.
- Adjust the belt to assure proper alignment.
- Check the running belt adjustment.
- Check the drive belt tension adjustment.
- Clean and lubricate the treadmill elevation screw.
- Clean the interior of the motor electrical enclosure as needed.

Belt Cleaning and Inspection

1. Turn the treadmill main power switch ON.
2. Start treadmill at 0.5 mph (0.8 km/h).
3. With a damp small towel wipe excessive dirt from running belt keeping the towel in the center of the length of the treadmill. Avoid getting the towel near the rear roller.
4. When belt is clean, stop the treadmill.
5. Inspect the running belt for tears or nicks. If damaged, replace the belt.
6. Perform the Running Belt Tracking Adjustment and Belt Tension Adjustment.

Running Belt Tracking Adjustment

This procedure requires the following tool:

¼" Allen wrench

NOTE:

Because this adjustment is not covered under your warranty, it is important that you review these instructions thoroughly before proceeding.

The patented MasterTrack® Belt Tracking System significantly reduces the need to adjust the belt on your T2100-ST1 or T2100-ST2 treadmill. However, when you operate your T2100-ST1 or T2100-ST2 treadmill for the first time, you may need to adjust the tracking of the belt to conform to your floor. You may also need to adjust the tracking if you move the machine to another location.

Your running belt should remain centered, although a slight amount of movement to the left or right is normal during use. Do not allow the running belt to travel all the way to either side.

To adjust the belt tracking, do the following:

1. Turn the treadmill's power switch to ON.
2. Increase the speed to 3 mph (4.8 km/h)
3. Observe the left side of the running belt as it travels over the rear roller. If the belt runs to the right side of the roller, turn the right bolt 1/8 turn clockwise, and turn the left bolt 1/16 turn counterclockwise.

   NOTE:

   When tightening one side of the belt, always loosen the opposite side one-half as much. This procedure provides finer control, with a smaller impact on the belt tension.

   Check the belt after 2 minutes, with the treadmill running at approximately 7 mph (11.3 km/h). If the belt does not correct itself, continue with slight turns until the belt is in the center of the rear roller. If the belt runs toward the left side of the roller, reverse the adjustments.

   NOTE:

   Uneven floors accelerate belt misalignment. This situation may require more frequent adjustment to prevent belt damage.

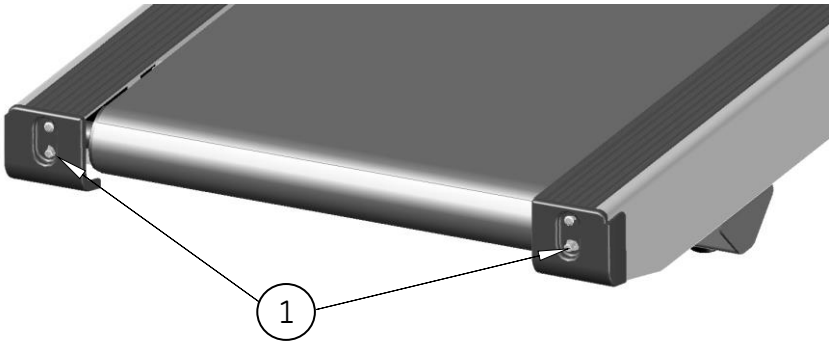
Running Belt Tension Adjustment

The running belt may stretch and loosen with regular use. This looseness is noticeable when the belt tends to hesitate or stick. Adjust the tension on the belt by following the procedure and referring to the illustration below.

1. Turn the treadmill's power switch to ON.
2. Start the treadmill and increase to 1 mph (1.6 km/h).
3. Start walking on the treadmill, grabbing side handrail and applying pressure with your foot to create resistance on the running belt.
4. If the running belt hesitates or slips on the front drive roller, tighten both tension bolts ½ turn (clockwise).
5. Repeat steps 2 thru 4 until the running belt stops slipping.

NOTE:

When the running belt is too tight, the edge of belt will curl, causing premature running belt failure.



Item	Description
1	Adjustment Bolts

NOTE:

Operating the treadmill at a high-speed application may cause hesitation or slippage of the running belt with each foot plant. This could be a sign of the backing of the running belt breaking down causing a premature failure.

Drive Belt Tension Adjustment

NOTE:

Because this adjustment is not covered under your warranty, refer to "Drive Belt Tension Adjustment" in the Preventive Maintenance chapter of the T2100-ST1 / T2100-ST2 Field Service Manual.

NOTE:

If there are indications that the drive belt has stretched and become loose, contact your in-house biomedical technician, or contact GE Medical Systems Information Technologies and open a customer-billable service call.

Exterior Care

The powder-coat finish on your T2100-ST1 or T2100-ST2 treadmill is an extremely durable finish and requires minimal care. Do not allow perspiration to build up on your treadmill. Wipe the unit daily.

- Use a moist cloth to wipe the surface clean; do not allow liquids to enter the system. All cleaning agents and disinfectants used in hospitals and containing up to 70% alcohol are suitable. If liquids have entered the system, notify service to have the system inspected for damage before it is used again.
- DO NOT use disinfection with a phenol base or peroxide compound to disinfect the external surface.

Elevation Screw Lubrication

The Elevation Screw must be cleaned and lubricated every 6 months to maintain proper operation of the treadmill. Failure to perform this maintenance function will result in premature wear and ultimate failure of the lift mechanism.

This procedure requires the following tools:

- Service Grease, GE part number 2097829-072
- Clean, lint-free cloth
- Small paint brush

1. Raise the treadmill to its maximum elevation.
2. Turn the main power switch to the OFF position and unplug the treadmill from its outlet.
3. Using a lint-free cloth, remove the old lubricant and accumulated dust from the elevation screw.
4. Use a small brush to reapply a thin coat of grease to the threads of the elevation screw. Do not use too much grease—

the excess could squeeze onto the floor and create a slip-and-fall hazard.

5. Return the unit to service.

Running Deck Maintenance

The treadmill's running deck is maintenance–free and offers two running deck surfaces for double the life of ordinary treadmills.

NOTE:

Do not use any silicone or lubricating sprays to wax your treadmill deck. Using such sprays may void the warranty. Using such sprays can bring about surface changes that may result in hesitation or excessive belt slip.

Prolonged use in high-speed running may cause hesitation or slippage on each foot plant. Inspect the running deck for factory lubrication on running surface.

If the running deck surface becomes grooved due to wear, it can be renewed by flipping the deck to the opposite side, in the Preventive Maintenance chapter of the T2100-ST1 / T2100-ST2 Field Service Manual. Your in-house biomedical technician or contact GE Medical Systems *Information Technologies and open a customer-billable service call.*

6

Troubleshooting

Your in-house biomedical technician or technically qualified personnel can perform basic troubleshooting. Advanced troubleshooting may be found in the *T2100-ST1/T2100-ST2 Service Manual* shipped with your system, or contact GE Medical Systems *Information Technologies*, Inc., and open a customer-billable service call.

Power Switch Will Not Illuminate

This procedure requires the use of a meter that is capable of reading at least 250 VAC.

1. Turn the treadmill's main power switch to OFF and unplug the treadmill's power cable from the wall receptacle.
2. Measure the voltage at the wall outlet for the correct voltage level.

   If the voltage is not correct, reset the circuit breaker. If the voltage is still not correct, refer the problem to your local electrician.

   If the voltage is correct, proceed to step 3.
3. Plug the treadmill's power cable into the wall receptacle and turn the treadmill's main power switch to ON.
4. Observe whether the power switch LED lights up, indicating the treadmill is receiving power.

NOTE:

Contact GE Medical Systems *Information Technologies*, Inc., for additional troubleshooting if the power switch will not illuminate.

Facility Circuit Breaker Trips when Powering Up

If the main circuit breaker trips when the treadmill is first turned on, the main circuit that the treadmill is on may be overloaded. This will happen even if the treadmill is on a proper, dedicated line. Refer this problem to your local electrician and check that the service panel circuit breaker is a high magnetic breaker.

Treadmill Will Not Start

1. Make sure the Emergency Stop Button is released.
2. Make sure the Safety Lanyard clip is connected to the switch.

Running Belt Slips When in Use

Over a period, the treadmill running belt will stretch and allow slippage when used by a heavy person. See “Final Setup - Running Belt Tension Adjustment” on page 43 to adjust.

Running Belt Is Off-Center

Occasionally the treadmill running belt will become off-center. See “Final Setup - Running Belt Tracking Adjustment” on page 43 to adjust.

Running Belt Hesitation or Slippage in High-Speed Application

When operating the treadmill in prolonged excessive speed, (high speed running) may cause hesitation on each foot plant.

NOTE:

It is recommended to release the tension on the running belt, Inspect the running deck for factory lubrication on running surface and the backing fabric of the running belt.

Contact GE Medical Systems *Information Technologies*, Inc., for more information regarding Running Belt Hesitation/Slippage.

Internal Circuit Breaker Location and Resetting

All circuit breakers are located at the front of the treadmill and below the hood.

- 2 ea. Power Supply / Relay Board (1/4 amp)
- 2 ea. Elevation Motor (3 amp [110v or 220v])

To reset a breaker, push the button.

NOTE:

Contact GE Medical Systems *Information Technologies*, Inc., for information on possible causes of tripped circuit breakers.

A

Maintenance Log

Serial # _____ Date Purchased_____

DATE	HOURS	SERVICE COMPLETED	COST

B

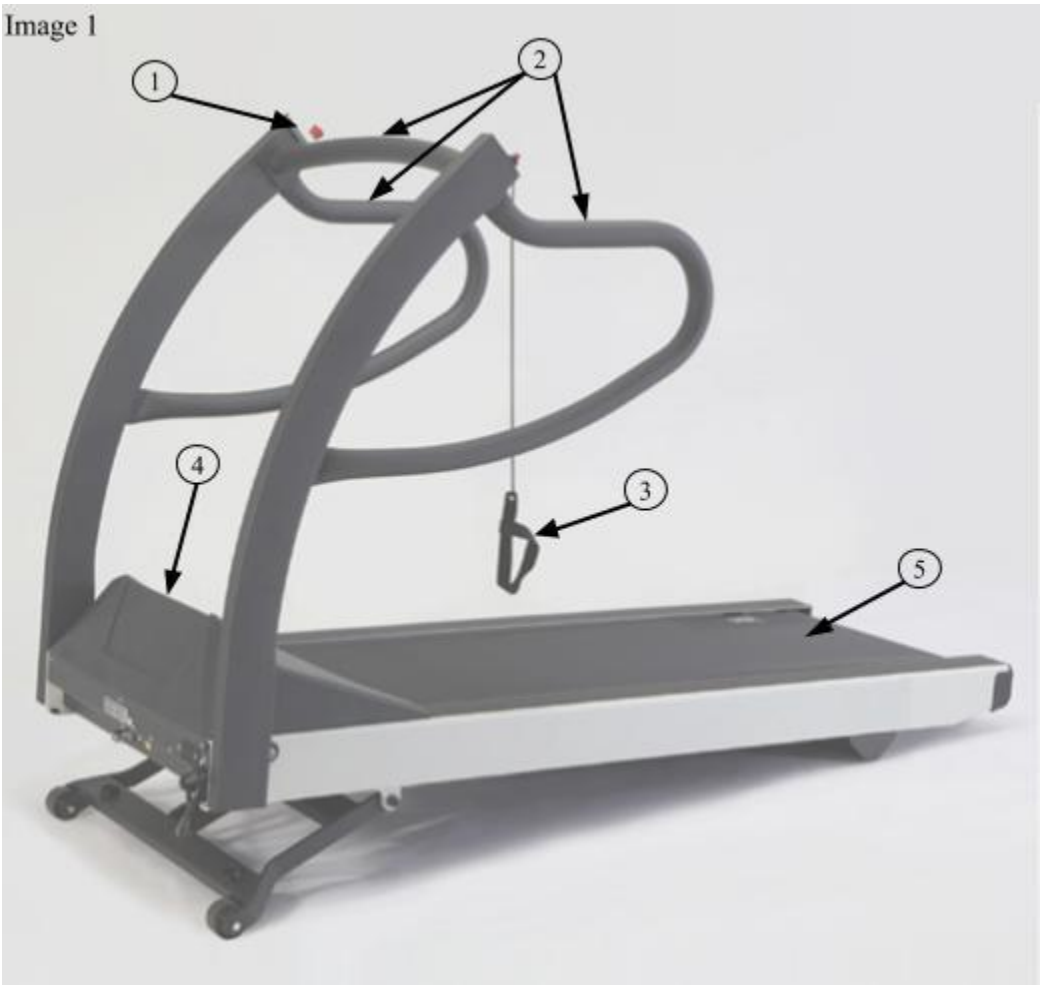
Reprocessing Instructions

The following reprocessing instructions apply to all treadmills. The treadmill is neither sterile nor can it be sterilized.

Manufacturer:	Full Vision Inc	Symbol: 
Device(s):	Treadmills	
WARNINGS	Before cleaning the device, turn the main power switch to OFF and disconnect the treadmill from its power outlet. Never use wet cleaning materials near a power source: you could suffer an electrical shock. Do not improperly clean the device ○ During cleaning, do not allow fluid to enter the motor pan assembly area. ○ Always wear appropriate PPE when cleaning. ○ Do not use abrasive brushes or abrasive cleaners. This could damage the paint and plastic surfaces. ○ Do not use sharp tools (e.g. knife, metal scraper) or aggressive cleaning solvents for cleaning ○ Alcohols are flammable and should only be used in well ventilated spaces	
Limitations on Processing	Not Applicable	

INSTRUCTIONS	
Initial Treatment at the Point of Use	Use a soft, clean, lint-free cloth / paper towel dampened (not wet) with tap water and mild detergent to wipe all treadmill surfaces to remove excess soil, moisture, and perspiration.
Preparation Before Cleaning	All cleaning solutions should be prepared at the dilution and temperature recommended by the manufacturer.
Cleaning: Automated	Not applicable
Cleaning: Manual	Step 1 – Turn the main power switch to OFF and disconnect the treadmill from its power outlet. Step 2 – Use 20 mL (0.68 oz) of an alkaline cleaner or similar mild, non-abrasive detergent (ex. Spray 409) on a soft, clean, lint-free 25 x 25 cm (9.8 x 9.8 in) size cloth / paper towel and manually clean item 1, 2. Reference Image 1 for corresponding items. **Note:** Do not spray cleaning chemical directly on the device Step 3 – Use an appropriately sized soft-bristled brush (e.g. standard toothbrush) dampened with 5 mL (0.17 oz) of mild soapy tap water (or similar mild, non-abrasive detergent) to clean item 3 and hard to reach spots. Reference Image 1 for corresponding items. Step 4 – Wipe all surfaces 1-5 (reference Image 1) with a soft, clean, lint-free 25 x 25 cm (9.8 x 9.8 in) size cloth / paper towel dampened with 20 mL (0.68 oz) (not wet) of lukewarm tap water 27°C to 44°C (80°F to 111°F) for a minimum of 30 seconds. Step 5 – Dispose of all cleaning materials according to your institutions established procedure.
Disinfection	If necessary, to disinfect the treadmill, follow these steps. Step 1 – Turn the main power switch to OFF and disconnect the treadmill from its power outlet. Step 2 – Prepare 20 mL (0.68 oz) of 70% or greater isopropyl alcohol disinfectant solution according to the manufacturer's directions. Step 3 – Use a soft, clean, lint-free 25 x 25 cm (9.8 x 9.8 in) size cloth / paper towel or gauze that is saturated with 20 mL (0.68 oz) of the disinfection solution and manually disinfect all contaminated surfaces of the device for a minimum of 15

	minutes. Step 4 – Use an appropriately sized soft-bristled brush (e.g. standard toothbrush) dampened with 5 mL (0.17 oz) of the disinfectant solution to clean item 3 and hard to reach spots. (Reference Image 1 for corresponding items) Surface must remain wet for a minimum of 15 minutes. Step 5 – Wipe all contaminated surfaces 1-5 (reference Image 1) with a soft, clean, lint-free 25 x 25 cm (9.8 x 9.8 in) size cloth / paper towel or gauze dampened with 20 mL (0.68 oz) of purified water 27°C to 44°C (80°F to 111°F) for a minimum of 30 seconds. Step 6 – Dispose of all cleaning materials according to your institutions established procedure.
Drying	Dry the device with a soft, clean, lint-free cloth/paper towel 25 x 25 cm (9.8 x 9.8 in).
Maintenance, Inspection and Testing	Visually examine each device for cleanliness. If visible soil remains, repeat cleaning procedure until the device is thoroughly clean.
Packaging	Not applicable
Sterilization	Not applicable
Storage	
Additional Information	No additional requirements
Manufacturer Contact	Full Vision Inc. Email: tmservice@full-vision.com



Item	Description
1	Emergency Stop Button
2	Patient Grab Handrails
3	Pull Tether Switch / Magnetic Tether
4	Hood
5	Running Belt

The instructions provided have been validated by the manufacturer of the medical device as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the DESIRED result. This requires verification and/or validation and routine monitoring of the process.

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Distributor World Headquarters:



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GE Medical Systems Information Technologies, Inc., a General Electric Company, going to market as GE Healthcare.

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