TERUMOBCT

TSCD®-II

TERUMO STERILE TUBING WELDER

OPERATING INSTRUCTIONS

Read this manual carefully before use. Use this instrument as instructed.

04/2016

CONTENTS

IMPORTANT SAFETY INFORMATION

The TSCD®-II Sterile Tubing Welder has been designed for use in the storage and handling of blood products. If the instrument or procedures are used for purpose over and above the capabilities specified herein, confirmation of their validity and suitability should be obtained; otherwise the manufacturer will not guarantee the results and assumes no obligation or liability. It is the user's responsibility to follow all procedures outlined in this manual.

NOTES, PRECAUTIONS or CAUTIONS and WARNINGS within the text of this manual are used to emphasize important and critical instructions.

NOTE

- Highlights essential information.

CAUTION

- Includes information regarding any special care to be exercised by the operator for the safe and effective use of the device.

WARNING

- Informs the operator of a hazard or an unsafe practice that could result in personal injury, affect the operator's health or contaminate the environment.

WARNINGS

- Failure to follow all operating instructions can result in leaking, non-sterile welds.
- Check each weld carefully. If, for any reason, the weld leaks, the sterility of your system may be compromised, resulting in contamination. Handle appropriately.
- The TSCD®-II is an electro-mechanical instrument designed for reliability. However, electrical or mechanical failures may occur which could result in leaking, non-sterile welds.
- Wafers can be used only once. Wafers cannot be reused. Be sure to dispose of all used wafers properly. Treat wafers that have been used on tubing containing blood products as biological waste, and handle according to proper infectious disposal procedures.
- Be careful not to spill any liquid into the TSCD®-II. Liquid inside the instrument can cause irregular operation and/or incomplete welds.

1 FEATURES AND SPECIFICATIONS

1.1 Features

The Terumo BCT TSCD®-II is a system for automatically connecting two sections of PVC tubing in a sterile manner.

- The TSCD®-II has a compact design and is portable.
- The system automatically connects two pieces of tubing in three easy steps.
- The system is able to connect two pieces of tubing empty or filled with solution such as blood or medicine.
- An LCD display indicates operating status, guidance for the operators and error messages.
- Wafers are automatically replaced. Used wafers are automatically disposed of into a disposal box without any external contact.
- Wafers are packed in cassettes, which assure easy replacement.

1.2 Specifications

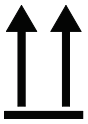
Name of product:	TERUMO STERILE TUBING WELDER TSCD®-II
Product code:	ME–SC203AH
Tubing material:	Polyvinyl chloride (PVC) Tubing associated with: Blood bags Leukocyte reduction filters Apheresis Kits AVF Needles
Tubing sizes:	Outside diameter: 3.9 - 4.5 mm Inside diameter: 2.9 - 3.1 mm
Wafer used:	TSCD® Wafer, model number SC*W017
Operating condition:	Ambient temperature 10°C to 40°C (50°F to 104°F) Relative humidity 10% to 80%, non-condensing Maximum Altitude 2000 m (6562 ft)
Storage condition:	Ambient temperature -10°C to 50°C (14°F to 122°F) Relative humidity 10% to 95%, non-condensing
Pollution degree:	2 (according to IEC 664-1)
Power supply:	AC 100V±10% to AC 240V±10% 50/60 Hz
Noise level:	< 65 dBA
External dimension:	W224 x H177 x D342 mm
Weight:	Approx. 6.5 kg (14.33 lbs)
Accessories with TSCD®-II:	AC power cable, 2 bag supports, 2 Fuses (250V 4.0A) Slow Blow cassette of TSCD® wafers, 1 air filter, 2 wafer jam repair tools, 2 surface fasteners (fit-in type), 2 surface fasteners (adhesive tape type), Operating Instructions, Warranty Card
Communication ports:	RS-232 for TOMEs (Terumo Operational Medical Equipment software)

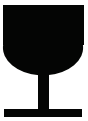
1.3 Symbols

Product code

Serial number

Stacking limit by 3


This way up


Handle with care


Keep dry


Attention, see instructions for use

EC representative


Separate collection for electrical and electronic equipment (European symbol)


Manufacturer

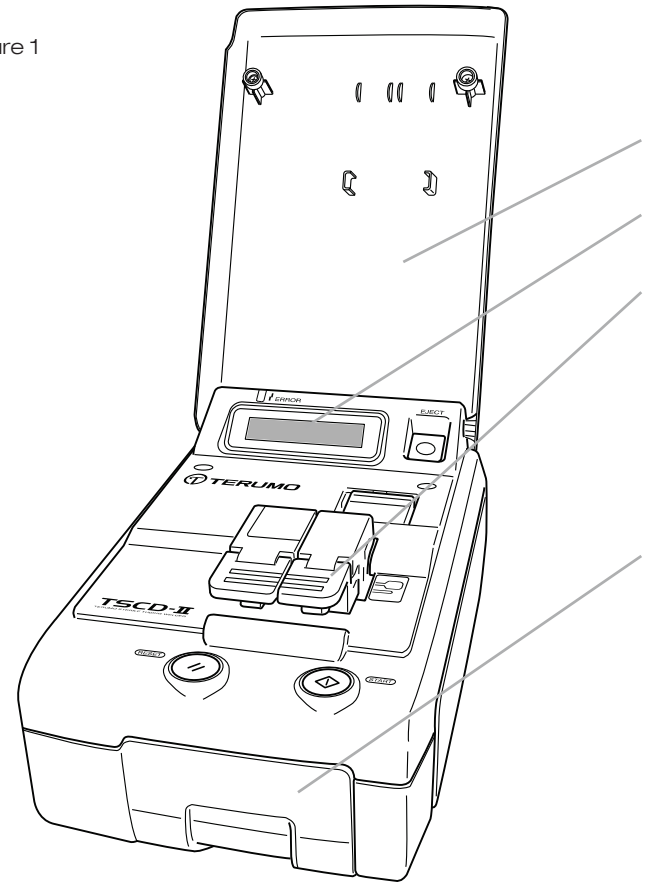

Keep away from heat and sunlight


We herewith declare that this product complies with the requirements of EC Directive 2004/108/EC or 2014/30/EU for electromagnetic compatibility in accordance with EN 61326-1, and those of EC Directive 2006/42/EC for machinery in accordance with EN 61010-1.

2 PHYSICAL DESCRIPTION

2.1 Front of TSCD®-II

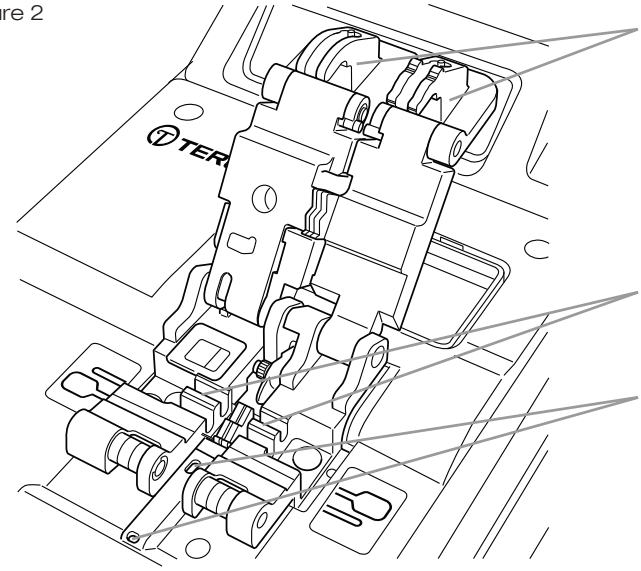
Figure 1



- Cover
- Display
- Clamps
- Disposal box
  Used TSCD® wafers are automatically discarded in this box.

2.2 Clamps

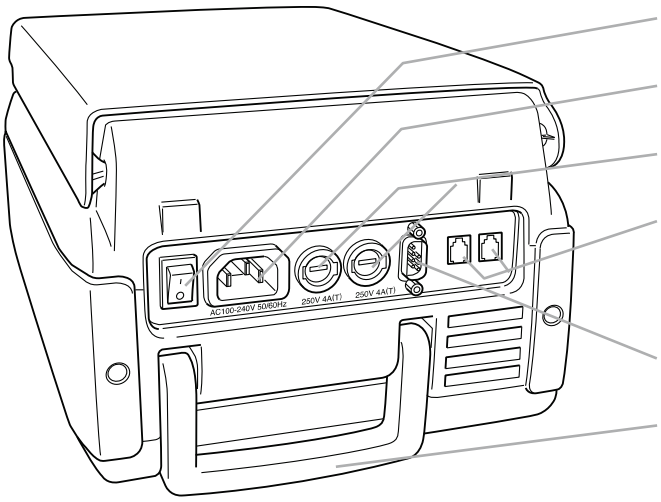
Figure 2



- Clamp covers
- Slots
  Tubing is placed in these slots.
- Wafer jam repair holes

2.3 Rear of TSCD®-II

Figure 3



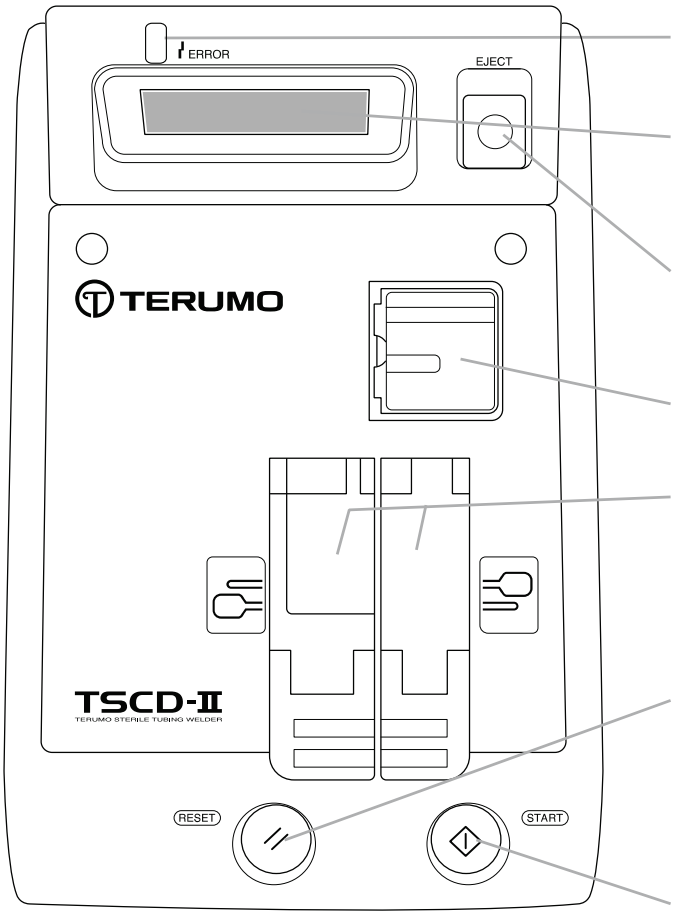
- Power switch
- AC inlet
- Fuse holders
- RS485 connectors
- RS232C Connector
- Handle

WARNINGS

- To avoid electric shock, protective grounding conductor in the power cord must be connected to the ground.
- Do not remove covers. Refer servicing to qualified personnel only.
- Disconnect input power before replacing fuse.
- To avoid fire hazard, replace only with specified type and rate fuse.

2.4 Control panel

Figure 4



- ALARM" indicator lamp
  Lightens when an alarm occurs.
- LCD DISPLAY
  Indicates Operating Status, Guidance and Error messages. Illuminates when power is on.
- "EJECT" button
  Press down this button and the wafer cassette will be released from its compartment.
- Wafer cassette compartment
  Compartment housing the wafer cassette.
- "CLAMPS"
  Set tubing in the front and rear slots and lock the jaws so that the weld cycle can begin. After the cycle is complete, the tubing in the left front slot is connected to the tubing in the right rear slot.
- "RESET" button
  Press this button to realign the clamps after a weld and to automatically replace a wafer. This button is also used to reset the machine when the alarm sounds.
- "START" button
  Press this button after the tubing has been locked in the clamps.

2.5 Accessories

- AC power cable
- Bag-support (2 pieces)
- Fuse 4.0A Slow Blow (2 pieces)
- TSCD® wafers (1 cassette)
- Air filter (1 sheet of filter material)
- Operating Instructions
- Warranty card
- Wafer jam repair tool (2 pieces)
- Surface fastener (fit-in type) (2 pieces)
- Surface fastener (adhesive tape type) (2 pieces)

2.6 Optional Accessories

TOMEs (Terumo Operational Medical Equipment software)
TOMEs is an information system which, when connected to the TSCD®-II, is able to store all information regarding the welding process and the items being welded.
In order to connect TSCD®-II to TOMEs, following items are needed:

- Accessory kit for TSCD®-II (2ME05TSC001): 1 needed per connected TSCD®-II.
- TOMEs hardware + software (2METOMES)
  or TOMEs software to install on customer server (2METOMESINST).
- TOMEs Stations license (2METOMESSTA): 1 per two stations.

3 OPERATION OF TSCD®-II

3.1 Principles of operation

In this system, two lines of tubing, set parallel to each other, are cut with a TSCD® wafer which has been heated to approximately 300°C (572°F). At this temperature one section of cut tubing is moved along the heated wafer until it reaches an equal plane with the other section of tubing. Once the two sections of tubing are directly opposite to each other, the wafer returns to its original position so that it is no longer between the two tubing sections. With the wafer lowered, the clamps press the ends of the tubing together and hold them in that position until the PVC has fused, and the joint has cooled enough to be handled.

1. A TSCD® wafer which has been heated to approximately 300°C (572°F), cuts two sections of tubing which are held in the clamps (see Figure 5A).

2. The tubing section held in clamp #1, is moved along the wafer until it is aligned directly across the tubing section held in clamp #2. At this point the wafer is lowered, the clamps are pushed together, and the two sections of tubing are butted up against each other so that the weld is completed (see Figure 5B).

Figure 5A

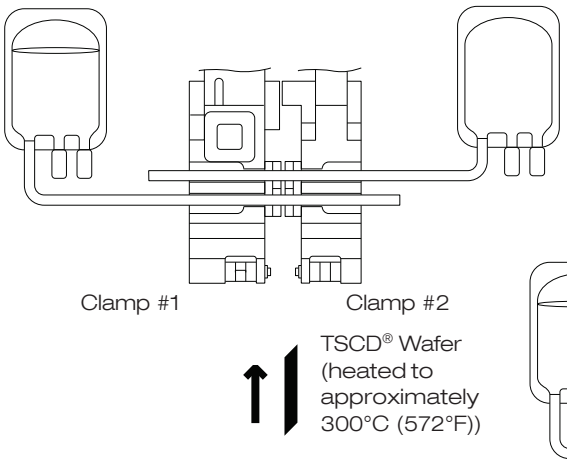
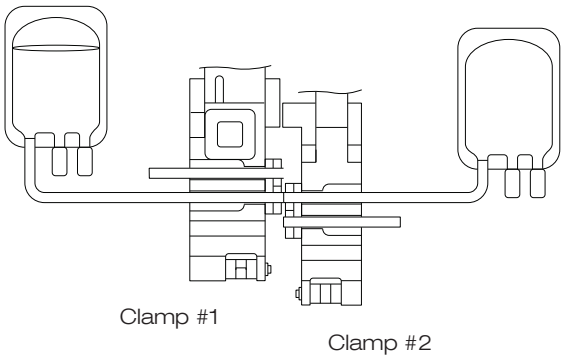


Figure 5B



4 GENERAL WARNINGS AND CAUTIONS

4.1 General warnings and cautions

WARNINGS

- Never use the system on tubing that is connected to a patient.
- Visually check each connection. If a leak is detected, consider the unit contaminated and handle appropriately.

CAUTIONS

- Do not use this system to connect tubing that does not fall within the ranges specified under section 1.2 “Specifications”.
- Do not use the TSCD®-II near a high frequency power source.
- Used wafers are considered as biohazard, dispose of them properly according your local disposal procedures.
- Wafers are designed for single use only. Wafers cannot be reused.
- A system failure can occur if any foreign matter (solid or liquid) comes in contact with the internal components of the TSCD®-II. If such a situation occurs, have the unit serviced by an authorised repair service before further use.
- The TSCD®-II is an electro-mechanical instrument designed for reliability. However, electrical or mechanical failures may occur if the TSCD®-II is dropped or handled roughly. PLEASE HANDLE WITH CARE.
- A part of a wafer may stick out of the wafer jam repair holes. Do not touch the wafer jam repair holes because a wafer can damage your fingers.
- A used wafer jam repair tool is considered as biohazard and must be disinfected using medical alcohol or a chlorhexidine gluconate solution of less than 0.5%.

4.2 Storage

CAUTIONS

- Avoid high temperature or humidity during storage. See section 1.2 “Specifications” storage condition.
- Do not store in areas that are subject to vibration, that are excessively dusty, or where the TSCD®-II could be exposed to corrosive gas.
- Long term exposure to ultra-violet radiation may cause the external surface to discolor.

4.3 Cleaning procedure

The TSCD®-II is designed for minimum care. Always keep the TSCD®-II clean. Surfaces of the instrument may be cleaned with a damp cloth and a neutral detergent.

WARNINGS

- Turn the power off and disconnect the TSCD®-II before cleaning.
- When cleaning the TSCD®-II, be careful not to spill any cleaning solutions inside the instrument. If this occurs, do not operate the instrument.
- Professional cleaning and service is required if any liquid (blood, blood product, cleaning solution or other fluid) is spilled into the internal components of the machine.

CAUTIONS

- Clean the surface of the TSCD®-II with soft clots saturated with medical alcohol, mild detergent or a chlorhexidine gluconate solution of less than 0.5%. Abrasive solutions or organic solvents shall not be used.
- Clean the clamps of the TSCD®-II with a cotton swab saturated with chlorhexidine gluconate solution of less than 0.5%.
- Clean the wafer jam repair holes with a cotton swab saturated with medical alcohol, mild detergent or a chlorhexidine gluconate solution of less than 0.5%. Abrasive solutions or organic solvents shall not be used.

4.4 Periodical maintenance

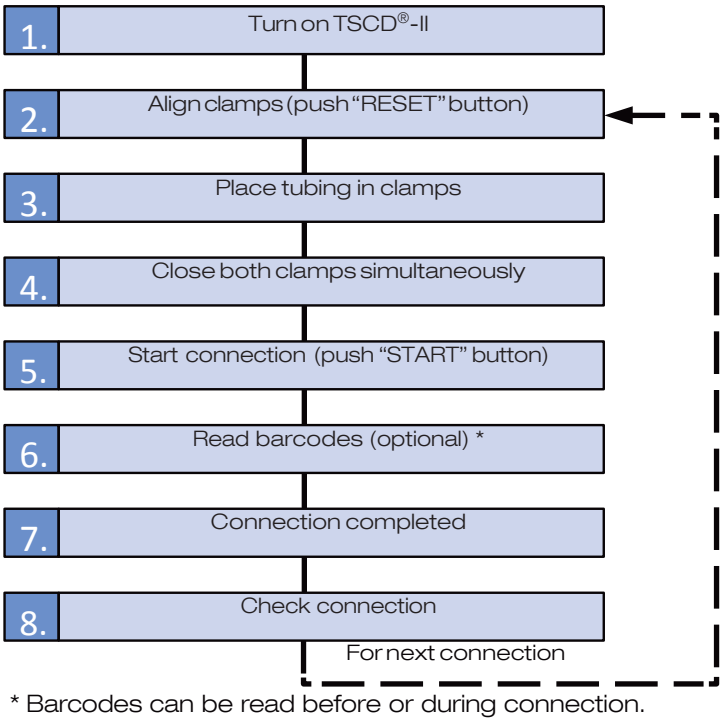
CAUTIONS

- To assure safe, trouble free service, please have your TSCD®-II serviced once every twelve (12) months or every 20,000 wafers used.
- If the TSCD®-II is dropped, service is recommended even if there is no outward sign of damage.
- For servicing, please call Terumo BCT.

5 PROCEDURE FOR USE

Please read « IMPORTANT SAFETY INFORMATION » and
« 4. GENERAL WARNINGS AND CAUTIONS » carefully before use.

5.1 Operational flow chart



* Barcodes can be read before or during connection.

5.1.1 System set-up

1. Connect the system to the power supply. Connect the AC power cable to the AC inlet at the back of the TSCD®-II, and then to the earthed AC socket.

2. For connection of TOMEs to the TSCD®-II, carefully read the Instructions for use of TOMEs.

3. Open the cover. The cover can be easily removed (See section 5.4 "Detachable Cover").

4. Turn the "POWER" switch on (See Figure 7).When the TSCD®-II is turned on, the LCD display illuminates, a self check starts and 3 beeps will sound when the instrument is operating properly. The fan starts. The wafer holder is warming up to 70°C to shorten the welding time (See Figure 8).

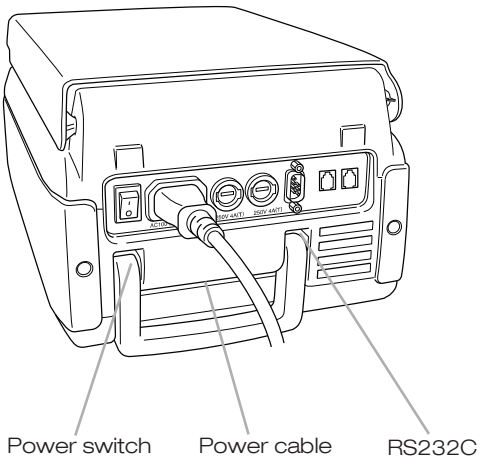


Figure 6

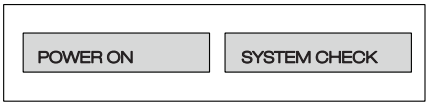


Figure 7

5. During warming up of the Wafer Holder portion, maintenance information appears on the display. Each message turns at 3-seconds interval.

6. After maintenance information, the display shows wafer holder temperature with increment of "*". When the wafer holder temperature reaches 70°C, a beep will sound and the TSCD®-II is ready for operation.

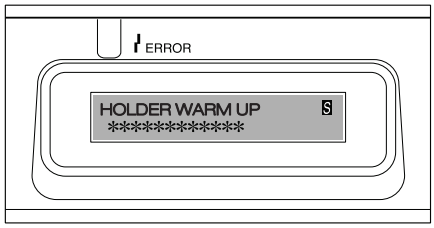


Figure 8

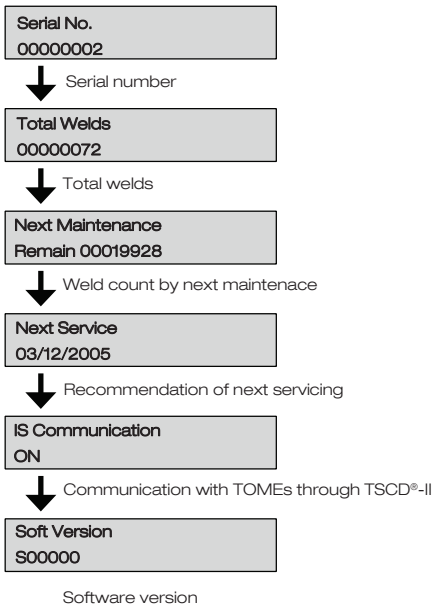
7. Place the wafer cassette. (See section 5.2 "Replacing the Wafer Cassette").

CAUTION

- Do not block the ventilator on the rear (See Figure 9).

NOTES

- If the LCD display does not illuminate, turn off the unit, unplug the AC power cable and check the fuses.
- A system failure is indicated if the alarm lamp is flashing or the buzzer is sounding continuously. Turn off the unit immediately and call Terumo BCT for servicing.
- If the wafer cassette in the holder is empty, press the "EJECT" button, pull out the old cassette and replace it with a new one (See section 5.2 "Replacing the Wafer Cassette").
- It takes approximately 3 minutes for warming up the Wafer Holder starting from room temperature.



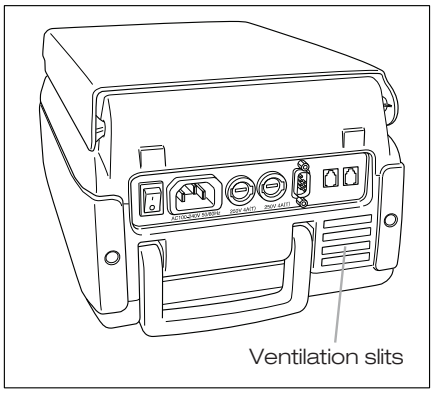


Figure 9

5.1.2 Clamp Alignment

1. Press the “RESET” button.

CAUTIONS

- The “RESET” button is not functioning when the wafer holder is warming up.
- The left clamp realigns with the right clamp. The wafer is replaced at the same time.
- The clamps shall not realign when they are already aligned.

NOTES

- Pressing the “RESET” button with both clamps locked, activates the buzzer and “OPEN CLAMP” is indicated on the display. The clamps will not realign until both clamps are opened and tubing is removed from the slots.
- Do not press the “RESET” button to align clamps when tubing is present in the slots.

5.1.3 Tube placement

1. Set the tubing in the slots.

NOTE

- **Tube size:** Outside diameter: 3.9 – 4.5 mm
  Inside diameter: 2.9 – 3.1 mm
  Material PVC (polyvinyl chloride)

CAUTIONS

- Only tubing with specifications mentioned above should be used.
- Do not use this system to connect two pieces of tubing, of which one, or both are too short. If the tubing placed in the clamp slots does not extend beyond the clamps or if the bag is in such a position as to obstruct the movement of the clamp, the connection may fail in weld strength or may leak.

2. Close clamp cover(s) completely until they are locked.

CAUTIONS

- Failure to lock the clamp covers may allow them to open during the welding process and may result in tubing welds of inadequate strength.
- Do not touch the indicated part with the fingers because it is hot (See Figure 10).

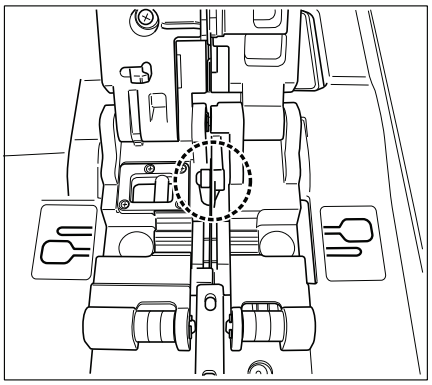


Figure 10

5.1.4 Starting the Weld cycle

1. Press the “START” button. After pressing the “START” button, the fan absorbing the smoke will start, and “HEATING WAFER” will be displayed on the LCD display. When the wafer reaches the setting temperature, “WELDING” will be displayed and the welding process starts. After a certain time “COOLING” is displayed, the buzzer sounds, the fan stops and the welding cycle is completed.

CAUTIONS

- Do not touch the clamps once the weld cycle has begun, as this might stop the welding process.
- After pressing the “START” button, the clamps are locked until the welding cycle is completed. Do not intentionally open the clamps during welding.
- Do not pull the tubing during welding.
- If “DEFECTIVE WAFER” is displayed after pressing the “START” button, press the “RESET” button to stop the alarm. Then press the “RESET” button again to replace the wafer.

2. Open the clamp covers. When “WELD COMPLETE” is displayed and the buzzer sounds, open the clamp covers and take out the tubing from both slots.

CAUTION

- Normally it takes 14 seconds to complete the weld cycle after pressing the “START” button.

5.1.5 Weld Alignment Inspection

1. To inspect the weld alignment, leave the weld sealed and rotate the welded tubing 360° and visually inspect how well the outer diameters of the two tubes are aligned at the connection (weld).

2. Compare your weld to those illustrated in Figure 11. Ideally, you should see no misalignment (VIEW A), but differences in the ACCEPTABLE outer diameters of the two sections of tubing may produce an apparent misalignment of the weld. This is acceptable. View B shows a misaligned weld that may be unacceptable. Repeated misalignment of welds (VIEW B) could indicate that service may be necessary.

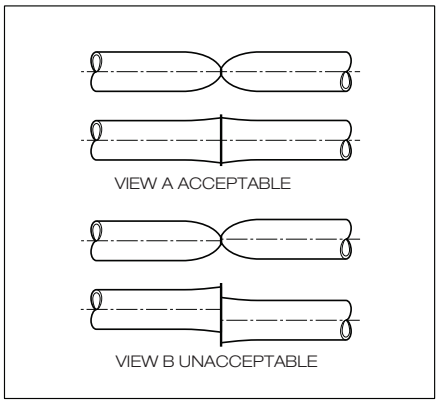


Figure 11

CAUTION

- Misaligned welds may not be complete. Consider that the blood product has been exposed to air and change the product expiration accordingly.

5.1.6 Opening the weld

Hold the welded tubing between your fingers with the flattened side of the weld facing up. Open the seal by pinching or rolling the tubing until the fluid pathway opens (See Figure 12).

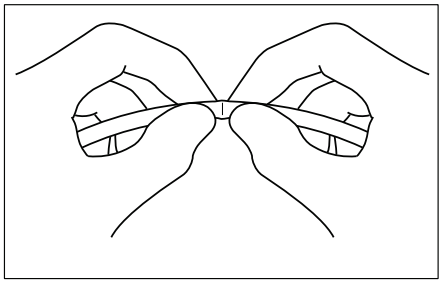


Figure 12

5.2 Replacing the wafer cassette

1. Confirm that the TSCD®-II is not replacing the wafer.
2. Press the “EJECT” button (See Figure 13). The far edge of the cassette will pop up so that it can be seized and pulled out of the compartment.
3. Position the new cassette so that the label is on top and facing the operator installing the cassette. Slide the cavity at the front edge of the cassette onto the metal tab at the front edge of the compartment.
4. Push the back edge of the cassette down until it snaps into place.

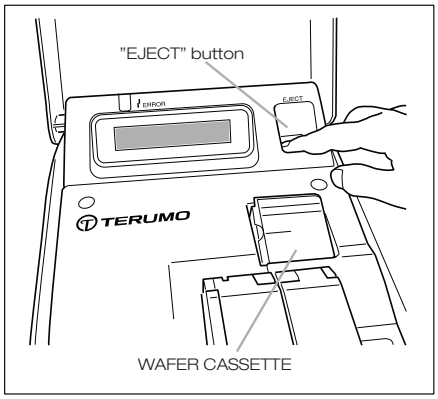


Figure 13

5.3 Snap on the blood bag support

1. The Blood Bag support has two tips, one on each end. Snap the tips carefully into the respective holders on the TSCD®-II (See Figure 14).

CAUTIONS

- DO NOT LIFT THE BAG SUPPORTS FOR CARRY.
- Do not transport the TSCD®-II with the mounted blood bag supports.
- Place the blood bag softly on the blood bag support. Do not drop it onto the blood bag support.
- Withstand load of each support is 20 N. For safety reason, bag support can be taken off when impact strikes.

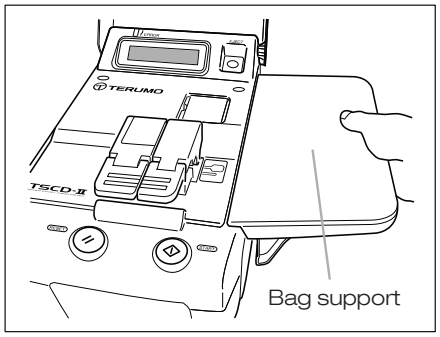


Figure 14

2. Pull up the blood bag support to remove it (See Figure 15).

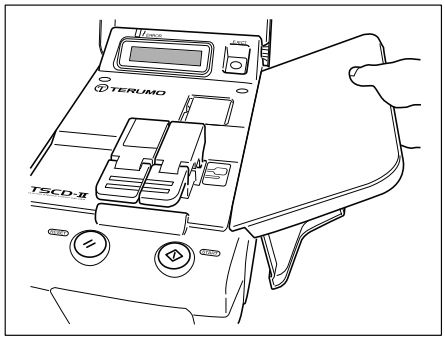


Figure 15

5.4 Detachable cover

1. After opening the cover, it can be detached by pushing it backwards (See Figure 16).

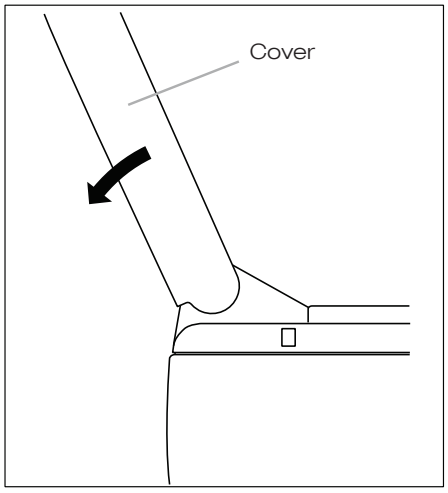


Figure 16

2. To re-attach the cover, hold it in vertical position and slide it down into the hinge sockets on the top at the rear side of the TSCD®-II (See Figure 17).

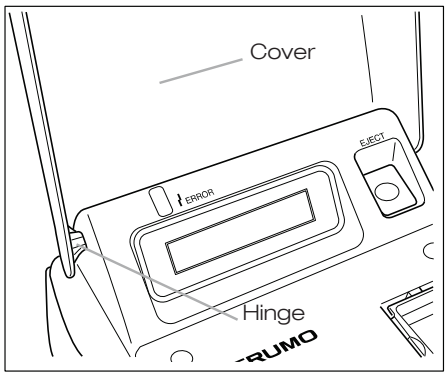


Figure 17

CAUTION

- Do not bring any magnetic sensitive equipment close to the parts on the TSCD®-II where the magnets are mounted (See Figure 18).

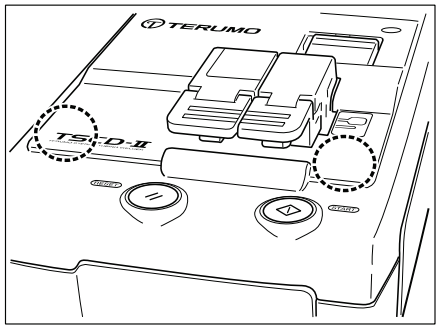


Figure 18

5.5 Wafer disposal

1. Remove the wafer disposal box from the TSCD®-II by drawing it backwards (See Figure 19).

CAUTIONS

- Remove the wafer disposal box immediately when the display indicates "DISPOSAL BOX FULL". Wafers cannot be replaced until full wafer disposal box has been emptied.
- The wafer disposal box can be removed any time even if not full. Check if the TSCD®-II is not replacing a wafer when removing a not completely filled wafer disposal box.

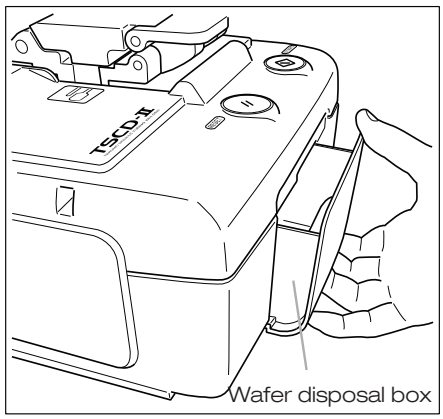


Figure 19

2. Dispose the used wafers by opening and emptying the wafer disposal box.

WARNINGS

- Follow proper biohazard handling procedures when disposing the used wafers. Treat all used wafers as potentially infectious.
- Wafers may not be reused.

3. Insert wafer disposal box

CAUTIONS

- The TSCD®-II has photo sensors on both sides of the wafer disposal box to detect the filling level of the box. Do not block the two holes on the wafer disposal box.
- Insert the wafer disposal box correctly into the TSCD®-II. If the wafer disposal box is incorrectly inserted, wafer jam or incorrect fill detection may occur.

5.6 Cleaning procedure

The TSCD®-II is designed for minimum care. Always keep the TSCD®-II clean. Surfaces of the instrument may be cleaned with a damp cloth and a neutral detergent or a disinfectant such as medical alcohol or an aqueous solution of chlorhexidine gluconate.

1. Turn off the "POWER" switch and unplug the AC power cable from the AC outlet.
2. Clean the surfaces of the instrument with a soft cloth saturated with a neutral detergent or medical alcohol or an aqueous solution of chlorhexidine gluconate of less than 0.5%.
3. Clean the clamps with a cotton swab saturated with medical alcohol or an aqueous solution of chlorhexidine gluconate of less than 0.5%.
4. Clean the wafer jam repair holes with a cotton swab saturated with medical alcohol, mild detergent or a chlorhexidine gluconate solution of less than 0.5%.

5.7 Replacing the air filter

Periodical replacement of the air filter is recommended and can be done as follows:

1. Pull out the filter case from the bottom of the TSCD®-II and take away present filter in the filter case (See Figure 20).

2. Set new air filter in the filter case. (See Figure 21)

CAUTION

- Set the new air filter carefully and do not bend it or let it slip out of the filter case.

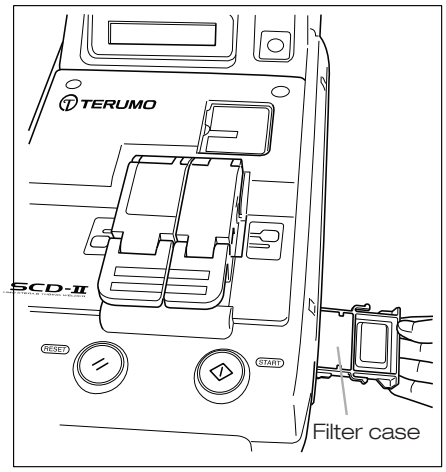


Figure 20

3. Insert the filter case in the TSCD®-II.

NOTES

- If excessive smoke comes out of the TSCD®-II during welding, replace the air filter.
- It is recommended to replace the air filter each 2000 welds or after 1 month.
- New air filters and/or more information on filter replacement is available from Terumo BCT's personnel.

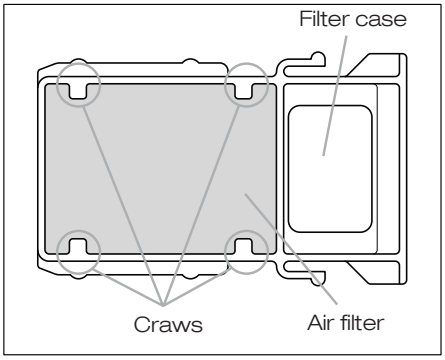


Figure 21

5.8 Parameter setting mode

When the “S” mark appears on the display, the parameter setting mode can be selected by pressing the “START” button for 2 seconds. Parameters are changed using the “START” and “RESET” buttons.

5.8.1 Language

Select language

1. Press the “RESET” button and “Language” is indicated on the display. The display indicates the current language.

2. Change the language by pressing the “START” button (English, French, German, Spanish, Italian, Dutch, Swedish, Danish, Norwegian, Finnish, Portuguese and Greek are available).

5.8.2 Buzzer volume

Buzzer volume can be selected from 8 levels.

1. Press “RESET” button till “Buzzer Volume” is indicated on the display. Display indicates current volume.

2. Change the volume by pressing the “START” button.

5.8.3 Date format

Select European or American date format.

1. Press “RESET” button till “Date Configuration” is indicated on the display. The display indicates current date format.

2. Change the date format by pressing the “START” button.

5.8.4 Information system activation

Select the activation of TOMEs connection.

1. Press “RESET” button till “IS connection” is indicated on the display. The display indicates the current status of the IS activation.

2. Change the IS activation status by pressing the “START” button.

NOTE

- When changing parameter of IS activation, Hardware must be reset. Turn the power off after exiting parameter setting mode and turn the power on again.

5.8.5 Weld counter

Check or reset the number of welds.

1. Press the "RESET" button till "Counter Reset" is indicated on the display. The display indicates the current weld count.

5. Counter Reset 00000019

2. Reset the weld count by pressing "START" button for 2 seconds.

5.8.6 Exit from parameter setting mode

1. Press "RESET" button, then "Exit SETTING MODE?" is shown on the display.

Exit SETTING MODE? Start: YES Reset: No

2. Press "START" button to save all parameters and exit from Parameter Setting Mode.

5.9 Installing the wafer jam repair tool

The wafer jam repair tool, a fit-in type surface fastener and an adhesive tape type surface fastener are included in the box with TSCD®-II (See Figure 22). Install the wafer jam repair tool to the TSCD®-II as described below (otherwise it may be lost).

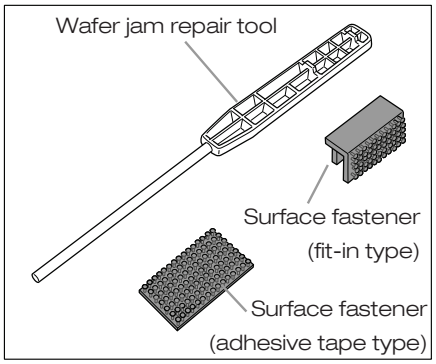


Figure 22

1. Put the fit-in type surface fastener into the wafer jam repair tool by inserting it between the projections of the tool (See Figure 23).

CAUTION

- Be sure the direction of the fastener is right against the tool, otherwise it cannot be attached to the tool.

2. Attach the adhesive tape type surface fastener on a place that does not obstruct you when using the TSCD®-II. Before attaching the adhesive tape type surface fastener, the surface must be wiped using medical alcohol and dried thoroughly. Attach firmly so that no clearance gap is made between adhesive surfaces of the fastener and TSCD®-II.

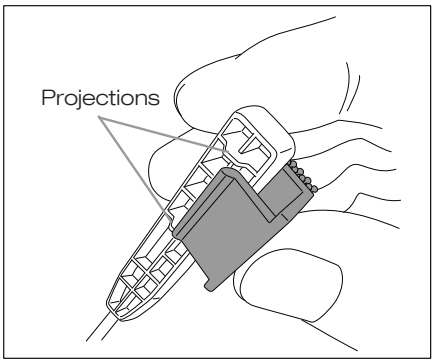


Figure 23

CAUTION

- Don't attach the fastener to the wafer disposal box, the clamps, the filter case, the "START" button, the "RESET" button, the "EJECT" button, the "ALARM" indicator lamp or to the back of TSCD®-II (See Figure 1~4 and 20).

3. Push the wafer jam repair tool (with surface fastener) on the surface fastener attached to the TSCD®-II.

6 TROUBLESHOOTING

6.1 Prompts on the display

The information in this section was compiled to serve as a reference for the operators during welding and troubleshooting of the TSCD®-II.
By following the prompts on the LCD the operators will know where in the welding process they are as well as be able to perform basic troubleshooting routines. If after following the recommended routines listed below the problem still persist, call Terumo BCT for servicing.

OPERATIONAL PROMPTS

Item No.	Message on display	Status	Action required
1	POWER ON	Power is turned on.	Wait till display change.
2	SYSTEM CHECK	The TSCD®-II is checked.	Wait till display change.
3	HOLDER WARM UP *****	The wafer holder is warming up.	Wait till display change.
4	ALIGN CLAMP OPEN CLAMP	Clamp is closed and not aligned.	Open the clamp and remove the tubes.
5	ALIGN CLAMP PRESS RESET	Clamp is not aligned.	Press “Reset” button to align the clamp.
6	CLAMP ALIGNING	Clamp is moving to home position.	Wait till display change.
7	ADVANCING WAFER	New Wafer is automatically advanced to welding position.	Wait till display change.
8	DISPOSAL BOX FULL DISCARD WAFERS	Wafer Disposal Box is full of Wafers.	Discard used Wafers and press “Reset” button.
9	CASSETTE EMPTY INSTALL CASSETTE	Wafer Cassette is either empty or not installed.	Install new Wafer Cassette.
10	PLACE TUBING OPEN CLAMP	Clamp is still closed and tubing has to be placed.	Open clamp and place tubing.
11	PLACE TUBING CLOSE CLAMP	Clamp is open and tubing has to be placed.	Place tubing and close clamp.
12	WELDING PRESS START	Ready to start welding process.	Press “Start” button to start welding process.
13	HEATING WAFER	Heating Wafer to welding temperature.	Wait till display change.
14	WELDING	Welding process occurs.	Wait till display change.
15	COOLING	The time allowed for the weld to cool down.	Wait till display change.
16	WELD COMPLETE OPEN CLAMP	Weld process is complete.	Open Clamp and remove welded tubing and segments from clamp.
17	OPERATING TEMP OUT OF RANGE	The TSCD®-II is unable to stabilize welding temperature because it is not within its recommended operating range.	Place the TSCD®-II into an environment that is within the recommended operating range of 10 - 40°C, 50 - 104°F.
18	WAFER JAM PRESS RESET	Wafer is jammed.	See section 6.3 “Procedure to repair a Wafer jam”

Item No.	Message on display	Status	Action required
19	DEFECTIVE WAFER 1 PRESS RESET	Welding with used Wafer.	Press “Reset” button once to clear error. Press “Reset” button again to replace used Wafer.
20	DEFECTIVE WAFER 2 PRESS RESET	Welding with incorrect Wafer not the TSCD® Wafer.	Press “Reset” button once to clear error. Install TSCD® Wafer Cassette into compartment and press “Reset” to replace SCD Wafer, two times.
21	DEFECTIVE WAFER 3 PRESS RESET	Wafer is wet during heating to welding temperature.	Press “Reset” button once to clear error. Press “Reset” button again to replace wet Wafer.
22	DEFECTIVE WAFER 4 PRESS RESET	Abnormal current through the wafer during heating process.	Press “Reset” button once to clear error. Press “Reset” button again to replace Wafer.
23	DEFECTIVE WAFER 5 PRESS RESET	Abnormal voltage during heating the wafer.	Press “Reset” button once to clear error. Press “Reset” button again to replace Wafer.
24	DEFECTIVE WAFER 6 PRESS RESET	Wafer initial resistance over range.	Press “Reset” button once to clear error. Press “Reset” button again to replace Wafer.
25	DEFECTIVE WAFER 7 PRESS RESET	Wafer heating power continuously high.	Press “Reset” button once to clear error. Press “Reset” button again to replace Wafer.
26	DEFECTIVE WAFER 8 PRESS RESET	Wafer breaking.	Press “Reset” button once to clear error. Press “Reset” button again to replace Wafer.
27	WAFER JAM REMOVE WAFER	Wafer is jammed at Clamp position.	See section 6.3 “Procedure to repair a Wafer jam”
28	INSTALLATION CLOSE CLAMP	Recovering from wafer jam.	Close the clamps and press “Reset” button after taking the wafer away from clamp portion.
29	ADVANCE WAFER PRESS RESET	No or used Wafer in welding position.	Press “Reset” button to advance new Wafer.
30	START RESTORING PRESS RESET	Turning the power on after shut down during welding operation.	Press “Reset” button to restart welding.
31	RESTOR COMPLETE OPEN CLAMP	Complete recovering from shut down process.	Open Clamp and remove welded tubing and segments from clamp.
32	Retry IS connection? START: yes Reset: no	Re-start Communication with IS.	Press “Start” to connect to TOMEs Stations. Press “Reset” to work offline.
33	IS connection now connecting	Re-try to send command.	Re-start communication.

RECOVERABLE ERROR

Following errors are recoverable by pressing the "RESET" button. If after following the recommendations in the following table, the problem still persists, call Terumo BCT for servicing.

Item No.	Message on display	Status	Action required
34	SENSOR ERR 0 PRESS RESET	Technical problem: clamp Solenoid Sensor is "On".	Press "Reset" to clear. If the problem still persists, call Terumo BCT for servicing.
35	SENSOR ERR 1 PRESS RESET	Technical problem: clamp Solenoid Sensor is "Off".	Press "Reset" to clear. If the problem still persists, call Terumo BCT for servicing.
36	SENSOR ERR 2 PRESS RESET	Technical problem: clamp Solenoid Sensor is "Off" while the Clamp Solenoid is "On".	Press "Reset" to clear. If the problem still persists, call Terumo BCT for servicing.
37	SENSOR ERR 3 PRESS RESET	Disposal box sensor facing to the sun.	Press "Reset" to clear. If the problem still persists, call Terumo BCT for servicing.
38	CAM ERR 0 PRESS RESET	Technical problem: Cam cannot find home position when rotation is initialized.	Press "Reset" to clear. If the problem still persists, call Terumo BCT for servicing.
39	CAM ERR 1 PRESS RESET	Technical problem: Cam cannot leave home position when rotation is initialized.	Press "Reset" to clear. If the problem still persists, call Terumo BCT for servicing.
40	CAM ERR 2 PRESS RESET	Technical problem: Cam cannot find welding position when rotation is initialized.	Press "Reset" to clear. If the problem still persists, call Terumo BCT for servicing.
41	CAM ERR 3 PRESS RESET	Technical problem: Cam cannot leave welding position when rotation is initialized.	Press "Reset" to clear. If the problem still persists, call Terumo BCT for servicing.
42	CAM ERR 4 PRESS RESET	Technical problem: Cam cannot find home position when rotation is initialized.	Press "Reset" to clear. If the problem still persists, call Terumo BCT for servicing.
43	CAM ERR 5 PRESS RESET	Technical problem: Cam cannot leave home position when rotation is initialized.	Press "Reset" to clear. If the problem still persists, call Terumo BCT for servicing.
44	CAM ERR 6 PRESS RESET	Technical problem: Cam cannot find welding position when rotation is initialized.	Press "Reset" to clear. If the problem still persists, call Terumo BCT for servicing.
45	CAM ERR 7 PRESS RESET	Wafer holder cannot reach to the upper limit.	Press "Reset" to clear. If the problem still persists, call Terumo BCT for servicing.
46	RESET JAM ERR PRESS RESET	Technical problem: Wafer Shuttle cannot return to home position because of Wafer jam.	Press "Reset" to clear. If the problem still persists, call Terumo BCT for servicing.
47	ENCODER ERR PRESS RESET	Technical problem: Stepper Motor and Encoder are not synchronized.	Press "Reset" to clear. If the problem still persists, call Terumo BCT for servicing.
48	REPL WF ERR 0 PRESS RESET	Technical problem: Home Sensor stays activated when Wafer Shuttle is in forward position.	Press "Reset" to clear. If the problem still persists, call Terumo BCT for servicing.

Item No.	Message on display	Status	Action required
49	REPL WF ERR 1 PRESS RESET	Technical problem: Forward Sensor does not activate when Wafer Shuttle is in forward position.	Press "Reset" to clear. If the problem still persists, call Terumo BCT for servicing.
50	REPL WF ERR 2 PRESS RESET	Technical problem: Forward Sensor stays activated when Wafer Shuttle is in home position.	Press "Reset" to clear. If the problem still persists, call Terumo BCT for servicing.
51	REPL WF ERR 3 PRESS RESET	Technical problem: Home Sensor does not activate when Wafer Shuttle is in home position.	Press "Reset" to clear. If the problem still persists, call Terumo BCT for servicing.

Following errors can only happen if the parameter 'Information System connection' is activated.

Item No.	Message on display	Status	Action required
52	COMM ERR 0 PRESS RESET	Communication problem: No Carriage Return.	Press "Reset" to clear. If the problem still persists, call Terumo BCT for servicing.
53	COMM ERR 1 PRESS RESET	Communication problem: No Carriage Command.	Press "Reset" to clear. If the problem still persists, call Terumo BCT for servicing.
54	COMM ERR 2 PRESS RESET	Communication problem: RX Command Data Length Error.	Press "Reset" to clear. If the problem still persists, call Terumo BCT for servicing.
55	COMM ERR 3 PRESS RESET	Communication problem: No Comma on RX.	Press "Reset" to clear. If the problem still persists, call Terumo BCT for servicing.
56	COMM ERR 4 PRESS RESET	Communication problem: RX Numeric Code Error.	Press "Reset" to clear. If the problem still persists, call Terumo BCT for servicing.
57	COMM ERR 5 PRESS RESET	Communication problem: Communication Error.	Press "Reset" to clear. If the problem still persists, call Terumo BCT for servicing.
58	COMM ERR 6 PRESS RESET	On TOMEs Stations, the user left a process after a Prepare Weld event was passed but before its Weld event was passed. This is not a problem.	Press "Reset" to clear. The connection should not be lost and the user can continue using TSCD®-II together with TOMEs.
		Communication problem: Communication Error.	Press "Reset" to clear. If the problem still persists, call Terumo BCT for servicing.
59	COMM ERR 7 PRESS RESET	Available communication receiving AB command.	Press "Reset" to clear. If the problem still persists, call Terumo BCT for servicing.
60	COMM ERR TIME OUT PRESS RESET	Communication problem.	Press "Reset" to clear. Please refer to the Instructions for Use of TOMEs.

If there are other kinds of phenomena out of above list, call Terumo BCT for servicing.

6.2 Troubleshooting table

The information in this section is compiled so that many common problems can be solved by the operator. If after following the recommendations in the following table, the problem still persists, call Terumo BCT for servicing.

Symptom	Probable Cause	Corrective Action
The display does not light up.	1. Instrument is turned off.	1. Turn the "POWER" switch ON.
	2. Instrument is unplugged.	2. Check power cord connection at wall outlet and back of instrument.
	3. The display light is broken.	3. Verify by testing that the left clamp will align with the right clamp after completing a weld although the display light is defective. Continue using the instrument, but call Terumo BCT for servicing.
	4. Fuses have blown.	4. Replace fuses. If the fuses break frequently, call Terumo BCT for servicing.
Continuous beep sounds.	Mechanical system is faulty.	Call Terumo BCT for servicing.
Excessive smoke is observed during the welding process.	Air filter is blocked.	Replace the Air Filter. See Section 5.7 "Replacing the Air Filter".
Solution leakage is observed in the welding part	Tubing being welded is incompatible.	CAUTION: Solution leakage suggests that the inside of the tubing may have been contaminated. Check size of tubing used. See Section 1.2 "Specifications".

6.3 Procedure to repair a wafer jam

When the display indicates "WAFER JAM REMOVE WAFER" or "WAFER JAM PRESS RESET" you have to repair the wafer jam with the help of the wafer jam repair tool. Do it as follows.

CAUTION

- Never insert the wafer jam repair tool into the wafer jam repair holes (both rear and front holes) towards the rear direction of the TSCD®-II (See Figure 24). Doing so could damage the parts inside the unit causing incomplete welds.

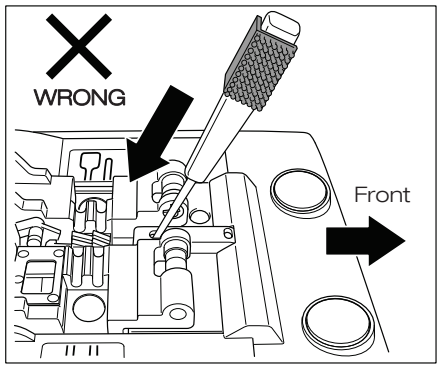


Figure 24

1. Remove the tube, if any, from the slots of the clamps.

2. Insert the wafer jam repair tool through the front wafer jam repair hole of the TSCD®-II and push the tool straightly down so that a wafer inside can be dropped into the wafer disposal box (See Figure 25).

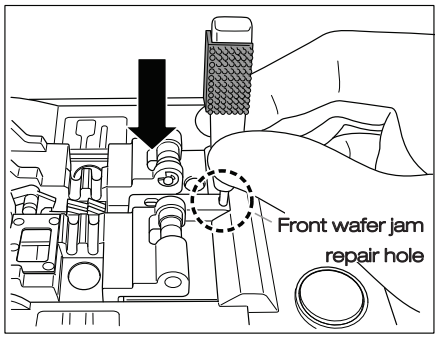


Figure 25

CAUTIONS

- For the front wafer jam repair hole, insert the wafer jam repair tool vertically.
- For the rear wafer jam repair hole, insert the wafer jam repair tool into the slantingly forward direction.

3. Similarly, insert the wafer jam repair tool through the rear wafer jam repair hole of the TSCD®-II and push the tool slantingly forward so that a wafer inside can be dropped into the wafer disposal box (See Figure 26).

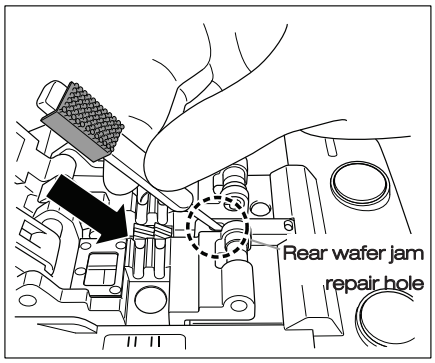


Figure 26

CAUTIONS

- A used wafer jam repair tool is considered as biohazard and must be disinfected using medical alcohol or a chlorhexidine gluconate solution of less than 0.5%. After disinfection, return the wafer jam repair tool to the original position to avoid losing it.
- For the front wafer jam repair hole, insert the wafer jam repair tool vertically.
- For the rear wafer jam repair hole, insert the wafer jam repair tool into the slantingly forward direction.
- Do not insert any items other than the wafer jam repair tool through the wafer jam repair holes.

CAUTIONS

- When inserting the wafer jam repair tool through the wafer jam repair holes, do not apply excessive force that could damage the wafer jam repair tool and the TSCD®-II.
- In the case of failure in dropping jammed wafers into the wafer disposal box, stop the procedure and call Terumo BCT for servicing.

4. In the case that the display indicates "WAFER JAM REMOVE WAFER" push the right clamp to the right to secure a clearance between the clamps. While pushing the right clamp to the right, remove the wafer between the clamps using tweezers or needle nose pliers (See Figure 27).

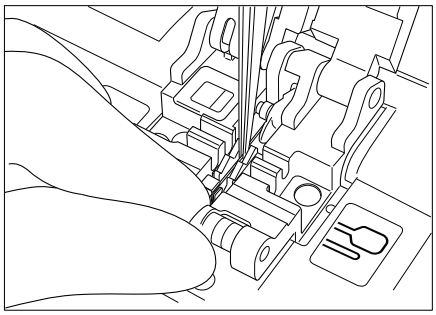


Figure 27

CAUTIONS

- When removing a wafer, care must be taken not to damage other parts inside of the TSCD®-II. It may cause incomplete welds.
- In the case of the failure to remove a wafer, stop the procedure and call Terumo BCT for servicing.

In the case that the display indicates "WAFER JAM PRESS RESET" the right clamp cannot be pushed to the right direction. In this case don't try to remove the wafer between the clamps in a forced manner.

5. Visually check that there are not jammed wafers inside through the wafer jam repair holes.

6. Remove the wafer disposal box and check visually that there are not jammed wafers inside from the front of TSCD®-II (See Figure 28). After confirming, return the wafer disposal box.

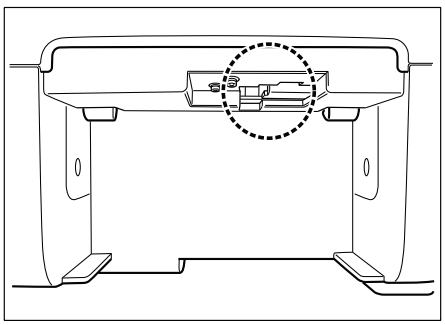


Figure 28

7. Remove the wafer cassette out of the TSCD®-II. In case this is not possible, re-insert the wafer cassette. Then,

press the “RESET” button according to the instructions on the display until the wafer is replaced with a new one. After the replacement, try to remove the wafer cassette again.

CAUTION

- In the case that a wafer has been replaced but the wafer cassette still cannot be removed, stop the procedure and call Terumo BCT for servicing.

8. Visually check whether a wafer still remains in the wafer cassette holder and confirm that the wafer in the wafer cassette is not damaged. In the case of a wafer remaining in the wafer cassette holder, remove it using tweezers or needle nose pliers (See Figure 29).

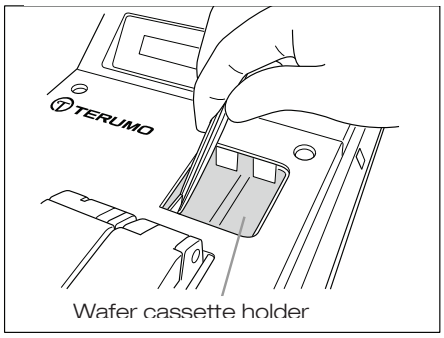


Figure 29

CAUTION

- In the case of failure to remove wafer from the wafer cassette holder, stop the procedure and call Terumo BCT for servicing.

In the case that the wafer cassette taken out from the unit is found damaged or cracked, don’ use it but replace it with a cassette without any damages. In the case that the wafer in the wafer cassette is found deformed or dislocated, don’t use it but replace it with a cassette without any damages (See Figure 30).

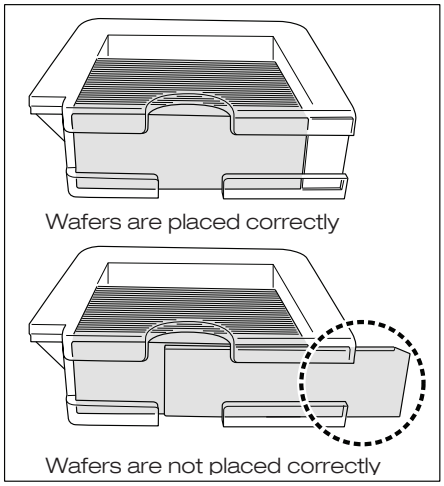


Figure 30

9. Re-insert the wafer cassette.

10. Press the “RESET” and/or “START” button according to the instructions on the display to continue the welding process.

CAUTION

- In the case of a wafer jam error recurring, discontinue removal of the jammed wafer and call Terumo BCT for servicing.

7 TECHNICAL SUPPORT

If you experience a system failure, call Terumo BCT for servicing. When calling for servicing, please be able to describe the problem and have the serial number available so that faster handling of the repair will be possible.
Do not attempt to dismantle or repair the unit on site. Only qualified personnel are authorized to service the unit and any attempt to repair the TSCD®-II by unqualified personnel will void the warranty and could increase the cost of the repair.
When sending the unit in for service, please include a completed decontamination certificate.

Technical support - Toll **free** number from:

A	0800-293711	B	0800-94410	DK	808-80701
SF	0800-115226	IRL	1800-553224	CH	0800-563594
F	0800-908793	I	800-785891	UK	0800-9179659
D	0800-1808183	NL	0800-0222810	N	0800-12270
GR	00800-3212721	E	900-963251	S	020-791373

Other countries call +32 16 39 14 00 at international rates
E-mail: meservice@terumobct.com

8 DISPOSAL (END OF LIFE)

Electrical and electronic equipment (EEE) and batteries contain materials, components and substances which can be dangerous to the environment and harmful to human health if waste electrical and electronic equipment (WEEE) and batteries are not disposed of correctly.

Waste electrical and electronic equipment and batteries must not be disposed of with the remainder of unseparated waste, but should instead be collected separately. In this way, the environmental impact associated with disposal of WEEE and batteries is reduced and there will be more opportunity for reusing, recycling and recovering WEEE and recycling batteries.

At end of life, please dispose of this equipment according to your local regulations. Contact your local distributor or municipality to know the available collection schemes. The embedded memory back-up CR2032 battery, collected together with this equipment at end of life as WEEE, is to be removed and treated by the recycling centre.

9 EU DECLARATION OF CONFORMITY

Legal Entity:	Terumo BCT, Inc.
Address of Legal Entity:	10811 West Collins Avenue Lakewood Colorado, 80215 USA
Authorized Representative established in the Community:	Terumo BCT Europe NV Ikaroslaan 41 1930 Zaventem Belgium Tel: +32.2.715.05.90 Fax: +32.2.721.07.70
Product Name:	**Terumo Sterile Tubing Welder (TSCD®-II)**
Product Class:	The TSCD®-II is classified as active laboratory equipment covered by the Machinery Directive, the Electromagnetic Compatibility Directives and the Directives on Electrical equipment designed for use within certain voltage limits.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

We hereby declare that the Terumo Sterile Tubing Welder (TSCD®-II) catalog number ME-SC203AH, complies with the following European Council Directives:

- European Council Directive 2006/42/EC concerning Machinery
- European Council Directive concerning Electromagnetic Compatibility
  - 2004/108/EC until 19 April 2016
  - 2014/30/EU on and after 20 April 2016
- European Council Directive concerning Electrical equipment designed for use within certain voltage limits
  - 2006/95/EC until 19 April 2016
  - 2014/35/EU on and after 20 April 2016

In addition to the following European Standards:

EN 61010-1:2001, Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General Requirements.

EN 61010-2-010:2003, Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-10: Particular requirements for laboratory equipment for the heating of materials.

EN 61326-1:2013, Electrical equipment for measurement, control and laboratory use - EMC requirements. General requirements.

FOR INFORMATION ABOUT TERUMO BCT PRODUCTS
A TERUMO BCT TERMÉKEKKEL KAPCSOLATOS TOVÁBBI INFORMÁCIÓKÉRT
POUR PLUS D'INFORMATIONS SUR LES PRODUITS TERUMO BCT
INFORMATIONEN ÜBER TERUMO BCT-PRODUKTE
PARA INFORMACION ACERCA DE LOS PRODUCTOS DE TERUMO BCT
PARA INFORMAÇÕES SOBRE PRODUTOS TERUMO BCT
PER INFORMAZIONI SUI PRODOTTI TERUMO BCT
VOOR INFORMATIE OVER TERUMO BCT PRODUCTEN
FÖR INFORMATION OM TERUMOS BCT PRODUKTER
FOR INFORMATION OM TERUMOS BCT PRODUKTER
FOR INFORMASJON OM PRODUKTER FRA TERUMO BCT
TIETOJA TERUMO BCT-TUOTTEISTA
ΓΙΑ ΠΛΗΡΦΟΡΙΕΣ ΣΧΕΤΙΚΑ ΜΕ ΤΑ ΠΡΟΪΟΝΤΑ ΤΗΣ TERUMO BCT
ДЛЯ ИНФОРМАЦИИ ОТНОСИТЕЛЬНО ИЗДЕЛИЙ TERUMO BCT
INFORMACJE NA TEMAT PRODUKTÓW FIRMY TERUMO BCT

- If this product should fail to perform as intended, immediately stop use and contact the nearest office of TERUMO BCT
- Amennyiben a termék nem a rendeltetésének megfelelően működik, hagyja abba a használatát és vegye fel a kapcsolatot a TERUMO BCT legközelebbi kirendeltségével.
- Si ce produit ne fonctionne pas comme prévu, ne pas l'utiliser et contacter immédiatement le bureau le plus proche de TERUMO BCT
- Falls sich dieses Produkt nicht wie beschrieben verhält darf es nicht weiter eingesetzt werden. Benachrichtigen Sie die nächste Vertretung von TERUMO BCT
- Si este producto no funcionara como se espera, suspenda su utilización de forma immediate y contáctese con la oficina de TERUMO BCT más cercana.
- Se este produto não realizar o desempenho pretendido, interromper imediatamente a sua utilização e contactar a dependência ou ponto de venda mais próximo de TERUMO BCT
- Se il prodotto in vostro possesso non funzionasse correttamente, interromperne immediatamente l'utilizzo e contattare la filiale TERUMO BCT piu vicina.
- Indien dit toestel niet meer volgens de specificaties functioneert, stop het gebruik onmiddellijk en neem contact op met het dichtsbijzijnde kantoor van TERUMO BCT
- Om denna produkt ej fungerar så som avsetts, avbryt omedelbart användningen och kontakta den lokala TERUMO BCT -representanten.
- Hvis dette produkt ikke virker efter hensigten, bør De afholde Dem fra at bruge det yderligere og omgående kontakte TERUMO BCTs nærmeste kontor.
- Hvis dette apparatet ikke fungerer som forutsatt, må man umiddelbart slutte å bruke det og kontakte nærmeste salgskontrol forTERUMO BCT
- Ellei tämä tuote toimi sille tarkoitetulle tavalla, lopeta sen käyttö heti ja ota yhteys lähimpään TERUMO BCT tytäryhtiöön tai myyntiliikkeeseen.
- Αν αυτό το προϊόν δεν καταφέρει να λειτουργήσει όπως προορίζεται, σταματήστε αμέσως τη χρήση και επικοινωνήστε με το κοντινότερο υποκατάστημα ή γραφείο πωλήσεων της TERUMO BCT
- Если данное изделие оказалось не в состоянии выполнять свое предназначение, прекратите немедленно его использование и свяжитесь с ближайшим офисом TERUMO BCT
- W przypadku nieprawidłowej pracy urządzenia należy natychmiast zaprzestać jego używania i skontaktować się z najbliższym oddziałem firmy TERUMO BCT

TERUMOBCT
Unlocking the Potential of Blood

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