2024

TSL-200 USER MANUAL

OPHTHALMIC INSTRUMENT TABLE

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VERSION	AUTHOR	DATE
2.0	JULIAN TAPP	

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1. Installation

Installation may only be performed by an engineer competent in servicing and installing medical devices. Adherence to EN 60601-1 is mandatory.

1.1. Remove all packaging. Always lift the table by the base, never lift the tables from the worktops. Doing so might damage the worktops and make the table unsafe to use. Follow the instructions in Table 1 depending on how the TSL-200 is packaged.

TSL-200U	• Remove the foam cover by cutting the plastic straps
TSL-200S	• Remove the foam cover and fit the equipment worktop (Figure 1) and finger guard (Figure 2). Please note It is critical that the earth wire is connected to the finger guard termination point as indicated by the protective earth symbol.
TSL-200I	• Undo the straps holding the carton to the pallet • Remove the outer carboard packaging • Lift table out of the carton. Table weighs 76kg and must be lifted only from the base, it is a 2-person operation. • Fit the equipment worktop (Figure 1) and finger guard (Figure 2). Please note It is critical that the earth wire is connected to the finger guard termination point as indicated by the protective earth symbol.

Table 1 Unpacking TSL-200

1.2. The TSL-200 is supplied with our lead C17009. This lead has a C13 and C14 end and is intended to take power from an Isolation Transformer (not supplied) to the table. A separate feed from the Isolation Transformer must power the equipment.

1.3. The table is intended for use with a mains supply as stated in Technical and Performance data.

1.4. The ON/OFF switch is in the computer cabinet. When powered the power light will be lit, next to the UP/DOWN buttons (Figure 3)

1.5. The table must be positioned such that mains plug is accessible, to enable the device to be isolated from the supply mains if necessary.

1.6. The TSL-200 must be installed on a level floor, the wheels should need to be braked to stop the table rolling while free standing.

1.7. Check the castors by making sure the table rolls freely. Then check the braked wheels operate correctly, locking both rotation and rolling of the castor. Each braked wheel must be checked independently.

1.8. When the table has been unpacked and equipment installed, with particular note that the earth tag is fitted to the finger guard, the system must be tested to EN 62353:2015.

2. Functional description and general use

The table is designed for Ophthalmic Instruments used for examination only and is contraindicated for use during treatment. Equipment must not exceed the stated weight limit

To raise or lower table use switch marked with UP/DOWN arrows located on the operators' side of the table (identified in Figure 3).

The table can raise the equipment worktop by 300mm. The column movement limit is controlled by internal micro switches top and bottom. The actuator is rated for intermittent use not continuous movement. After 1 minute's continuous movement the actuator will need 9 minutes cool down.

Before starting a patient observation, the brakes must be applied to ensure the table does not move and it stable. The patient must not use the table as aid to standing, only resting forearms on the table for comfort during an observation.

The patient must not wrap hands around the worktops. The clinician must be aware of the patent while raising or lowering the equipment worktop.

3. Disposal

This device must not be mixed with general waste but disposed of as Waste Electrical Electronic Equipment (WEEE). Disposing of this product correctly will save valuable resources and prevent any potential negative effects on human health and the environment. If you are unsure of your specific national requirements, contact your local authority for further information or directly to Base Design Ltd. Penalties may be applied for incorrect disposal of this device, in accordance with national legislation

4. Maintenance and care

4.1. The main adjustable column is maintenance free and does not require servicing.

4.2. The UP/DOWN can be worn after use. Replace when required (pt no STA01WV6000X100).

4.3. If required to prevent cross infection and maintain general hygiene the external surfaces may be disinfected using alcohol wipes or a cloth dampened with appropriate disinfectant for plastic surfaces and approved for medical devices, which has been diluted to the manufacturer's instructions. Avoid liquid, and do not let moisture ingress into the table and under no circumstances must Solvents, Corrosive or Abrasive agents be used.

4.4. The castors are maintenance free but must be inspected regularly.

4.5. Should the castors become worn and need replacing please follow the instructions illustrated in Figure 5. Please note the use of Loctite 242 on the castor thread and a final tightening torque of 50 Nm

4.6. If there are any changes in performance of the table stop using immediately and have it checked by a competent medical engineer.

5. Safety Inspection

The table must always be checked before use to ensure safe operation:

- Ensure the mains cable is positioned so that it is not a trip hazard.
- Check the mains cable to ensure there are no abrasions or frays.
- There is no damage to the table controls.
- The equipment worktop raises and lowers smoothly
- Ensure the ophthalmic equipment is securely fixed.
- Make sure the table rolls smoothly and there is no visible damage to the castors.
- Make sure all the braked castors work with both castor rolling and rotation stopped when braked.

Periodically electrical safety checks must be undertaken. At the same time the castors must be close inspected making sure the shaft is secure in the base.

6. Technical and Performance data

The table has been designed to be used only for Ophthalmological Instruments, in particular the Heidelberg SPECTRALIS OCT. The table is intended for use by trained medical professionals in doctor's surgeries, hospitals, clinics and universities.

Device type	Medical Class 1 as per EC 2017/745
Protection	Class 1 as per EN 60601-1
Power input	230V, 50Hz 6A, 1380W supply mains with protective earth conductor.
Mains lead	1m length, sheathed 3 core. Connector (A) IEC C13 moulded socket connector (B) C1 moulded socket, voltage rating 250V, current rating 10A (Cross section 1mm^2) Figure 4 is shows the IEC wiring. Replacement must only be performed by a competent person.
Castors	5 – 3 braked, 2 unbraked
Fuse	6.3A fast blow fuse fitted (F6.3A/H 240V 20mm). Replacement only by a competent person.
Environmental conditions:	
In use	Temperature: +10^{0}C to +40^{0}C Relative Humidity: 10% to 90%, non-condensing. Altitude: up to 3000 metres above sea level. Atmospheric pressure: 50 kPa to 107 kPa
Operating mode:	1 min ON / 9 min OFF

Ingress protection rating of casing	IPX0
Maximum height (Figure 3)	948 mm
Minimum height	648 mm
Raise or lower speed	10mm/second
Other dimensions	Width 1376mm, Depth 722 mm
Max weight supported on equipment worktop	30 kg
Total bare table mass (no instruments or isolation amplifier fitted)	76 kg
During use the patient and clinician sides of the table are indicated in Figure 3	

Table 2 Table Technical and Performance Data

7. Storage and Transport

When storing or transporting the table please adhere to the following:

Temperature:	-40^{0}C to +70^{0}C
Relative Humidity:	10% to 95%, non-condensing
If moving the table within the hospital or clinic after installation (see HAZARDS) always ensure the table is set to the lowest position. If moving to another building or over an internal uneven surface the instrument must be removed and handled separately.	
If moving on vehicle after unpacking, ensure table is at its lowest position and securely strapped down. Remove any instruments and transport separately.	
If sending the table by a carrier it must be adequately packed to avoid damage. Packaging designed for the purpose can be supplied by the manufacturer.	

Table 3 Table storage and transport requirements

8. Patient Restrictions

There are no restrictions to the patient population, and this device does not have any contraindications

9. Electromagnetic compatibility

This device has been tested to EN60601-1-2 EMC Standard for Medical Equipment and passed. The emission characteristics of this device (group 1 Class B) make it suitable for use in a professional ophthalmic environment.

When using this device with ophthalmic equipment, observe both the table and equipment to make sure they are operating correctly, and reorientate the table if necessary. Ensure that the power cable is separated from other cables.

10. Manufacturer's declaration

Complies to EN_60601_1;2006+A1+A12+A2+A13;2024 Safety of Electrical Medical Equipment

11. Hazards and Precautions

Hazards	
10.1 	Warning take care when lowering table, do not trap patients or operators' limbs. Details of potential crush or trap zones are indicated on Figure 3, they are: • Between the actuator upper and lower columns (crush). • Between actuator upper and lower columns (drawing in). • Between the tabletop and floor (crush). Between the frame (lowest part) and the metal compartments beneath the tabletop (crush)
10.2	The operator must be aware of the trapping zones and must monitor the patient while the tabletop is moved either up or down.
10.3	Do not sit or stand on the table
10.4	Table weighs 76kg and must be lifted only from the base, it is a 2-person operation
Precautions	
10.5	Do not attempt to access and electrical parts unless the unit is disconnected from the mains, and the work is carried out by a qualified engineer. If this is required circuit diagrams, and other relevant information is available upon request.
10.6	No maintenance or servicing shall be carried out when the device is being used on a patient
10.7	Do not attempt to access the adjustable column, in the event of the column failing, this must only be replaced by a competent medical engineer.
10.8	If the fuses require replacing, disconnect the unit from the mains, and ensure a Heidelberg engineer completes this work.
10.9	Only connect the Ophthalmic Instruments to the sockets within this table.
10.10	Keep table away from electrical heaters and or naked flames.
10.11	The table has only one moving part which is the vertical movement, please ensure that no limbs are trapped during this operation.
10.12	The table must not be moved outside the operational space.
10.13	Do not push table over threshold until all equipment is removed.
10.14	
10.15	Connecting electrical equipment to the IEC C13 connectors effectively leads to the creation of a medical electrical system, which can potentially result in a reduced level of safety. Users must refer to the requirements of EN 60601-1 in this case.
10.16	To avoid the risk of electric shock, this device must only be connected to a mains supply with protective earth.

10.17	No modification of this equipment is allowed
10.18	This device must not be used in an oxygen rich environment, or in the presence of flammable gases
10.19	With the power disconnected from the mains source. At no time must the operator touch both the table and the patient simultaneously.

Table 4 Hazards and Precautions

Any serious incident that has occurred in relation to the device must be reported to the manufacturer and within the EU/EEA/ NI to the competent authority of the Member State in which the user and/or patient is established.

12. Failure to work

- Ensure the main power plug is correctly fitted into floor or wall socket and switched on.
- Ensure mains lead is correctly fitted into inlet filter located under tabletop and the unit is switched to the "I" ON position.
- If unit has overheated due to continuous running allow to cool for 30 minutes. If the table still fails to move maintenance is required by a competent person.
- Fuses must be checked by a competent person only – Hazard 16
- **DO NOT ATTEPT TO EXPOSE INTERNAL WIRING OR GAIN ACCESS TO THE COLUMN, CONTACT THE MANUFACTURER**

13. Replacement parts

Part Description	Base Design Part number
Isolation transformer lead	C17009
Castor braked	C3502/409
Castor unbraked	C3504/409
Table switch	STA01WV6000X100
Equipment worktop	TSL-270/01
Cabinet worktop	TSL-200/02

Table 5 Replacement parts

14. General

The manufacturer reserves the right to modify the design of this product at any time which may affect the wording of these instructions.

15. Symbols glossary

	Attention – Consult accompanying documents
	Read instructions for use
IPX0	The device is not water resistant

CE	CE mark
MD	Indicates that the device is a medical device
UK	Country and date of manufacture (yyyy-mm)
	Manufacturer name and address
	Do not dispose of in normal waste. Please recycle where facilities exist. The WEEE directive applies as the device has been placed on the market after 2005.
	Power on
	Power off
EC REP	Authorised representative within the EU
REF	Reference or catalogue number
SN	Serial number
	Raise the surface of the table
	Lower the surface of the table
	Risk of crush or trapping.
	Hazard
	Type B applied Part

Table 6 Symbols

16. Diagrams

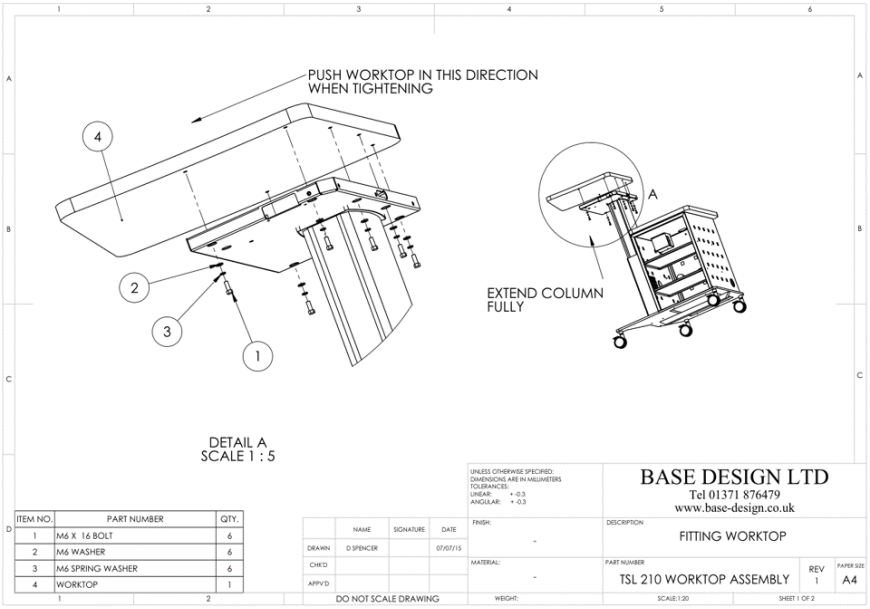

Figure 1 Fit the equipment worktop

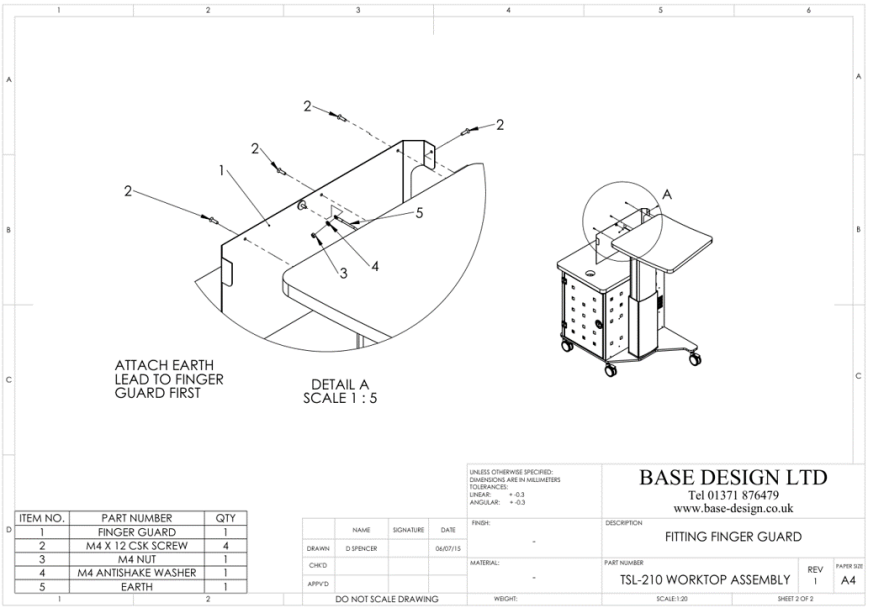

Figure 2 Fit the finger guard

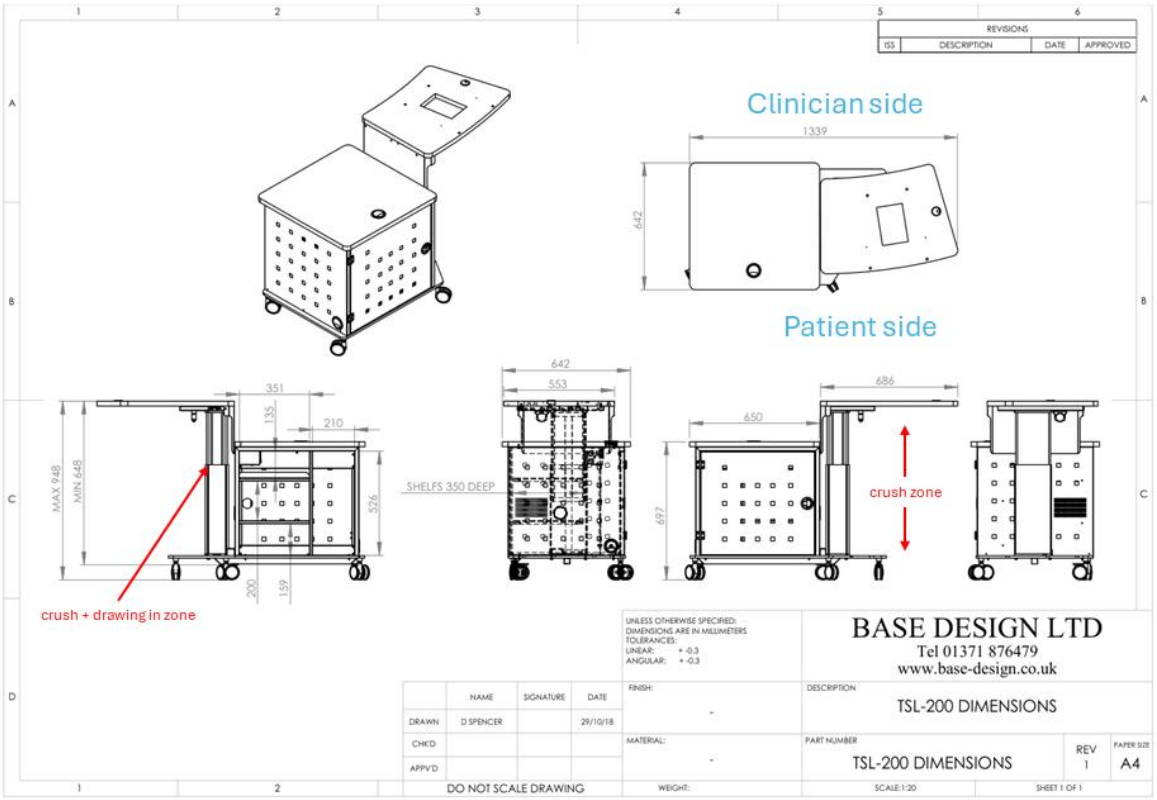

Figure 3 TSL-200 Dimensions and identified regions

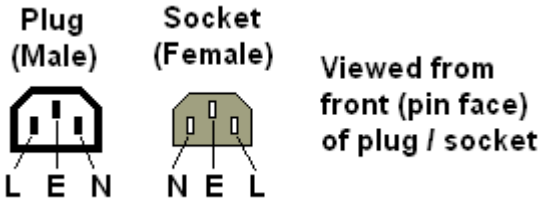

Figure 4 IEC wiring

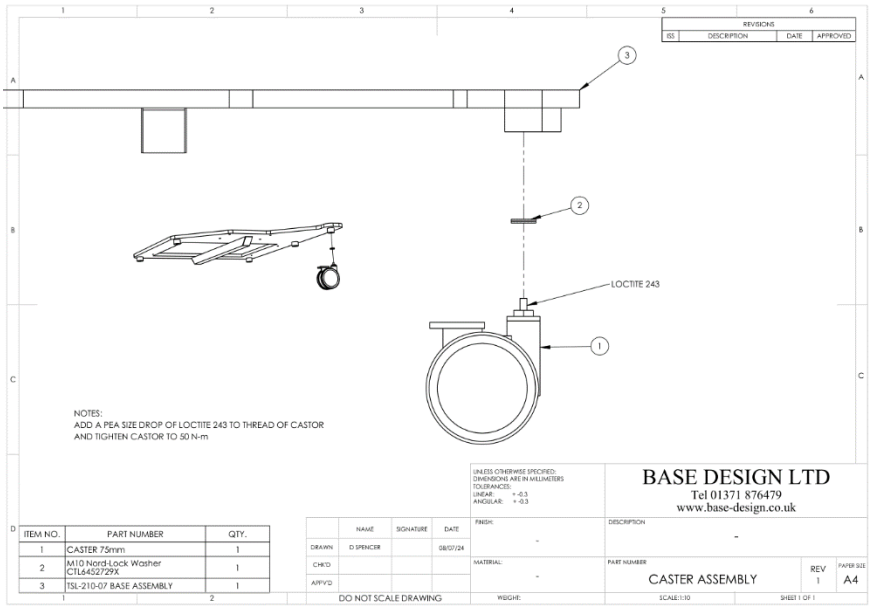

Figure 5 Castor fitting