

Micro Torque MT5000

Surgical Drill System



OPERATING INSTRUCTION MANUAL

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APPENDIX 1

EMC Information

Special instructions regarding electromagnetic compatibility

Electromagnetic instructions

Electromagnetic immunity

APPENDIX 2

EMC and Safety Certificates

SAFETY PRECAUTIONS

- **READ** this manual and familiarise yourself fully with this equipment before use.
- The unit must be at **REST** when attaching or replacing cutting burs.
- **NEVER** touch the cutting bur when 'Micro Motor' is in motion.
- Handpieces must only be fitted or replaced when 'Micro Motor' is **NOT** running.
- **DO NOT** allow any modifications on the Micro Torque System.
- If the 'Micro Motor' emits an unusual noise during operation **STOP** using immediately.
- Pay particular attention to the operating temperature of the Handpiece if the over heating is suspected **STOP** using immediately as this can be hazardous to the patient.
- Only use **COMPATIBLE** Handpieces on the 'Micro Motor' complying to DIN13940/ISO 3964.
- Should only be used by staff with the required knowledge and training for surgical procedures.
- To avoid the risk of electric shock this equipment must be connected to a mains supply with a protective earth.
- Risks of reciprocal interference posed by medical equipment during specific investigations or treatments.
- To safely terminate use of unit - switch off with mains switch on rear of unit.
- Do not touch the front contacts and the patient at the same time.
- There are no potential hazards when disposing of this equipment other than when disposing of any electronic equipment.

Environmental exclusions;

- This equipment is only to be used in a professional healthcare environment.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm/12" to any part of the MT5000 including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

1 INTRODUCTION

The MT5000 system provides highly efficient and reliable operation and is manufactured to the highest quality standards. The high performance self ventilating brushless DC 'Micro Motor' drives precision surgical Handpieces at the optimum speed for the procedure being undertaken.

The 'Micro Motor' speed is set on the easy to use Control Console in increments up to a maximum speed of 40,000 rpm. Forward and reverse operation of the 'Micro Motor' is also selectable on the Console.

The Control Console drives a peristaltic irrigation pump. The pump delivers a sterile water flow through an external sterile tubing direct to the cutting bur. Simple to operate controls for setting pump flow rate in increments up to 100% are provided on the Console.

The Control Console has 2 selectable 'Programmes' and a dedicated 'Set up' function button. There is also a memory feature that stores the last setting before the machine is switched off and recalls these final settings when switched back on again.

The 'Micro Motor' is operated by the Foot Control. Depressing the central pedal controls the 'Micro Motor' speed (up to the maximum figure set on the Console). There are two switches; one selects forward and reverse operation of the 'Micro Motor' and the other toggles the irrigation pump ON and OFF.

The maximum delivery of torque is delivered in the highest speed range. The highest torque can be obtained by running the 'Micro Motor' at the highest speed when fitted with compatible Handpiece attachments that have integral reduction gears. This combination will reduce the operating speed of the instrument but maintain the optimal torque.

The 'Micro Motor' and Cable are designed to be sterilised in an autoclave at 134°C. See page 17 for details of Lubrication, Disinfection and Cleaning procedures.

Refer to the relevant sections of these operating instructions for detailed operating information. A technical specification is provided on page 20 of these instructions.

1.1 Operating Conditions

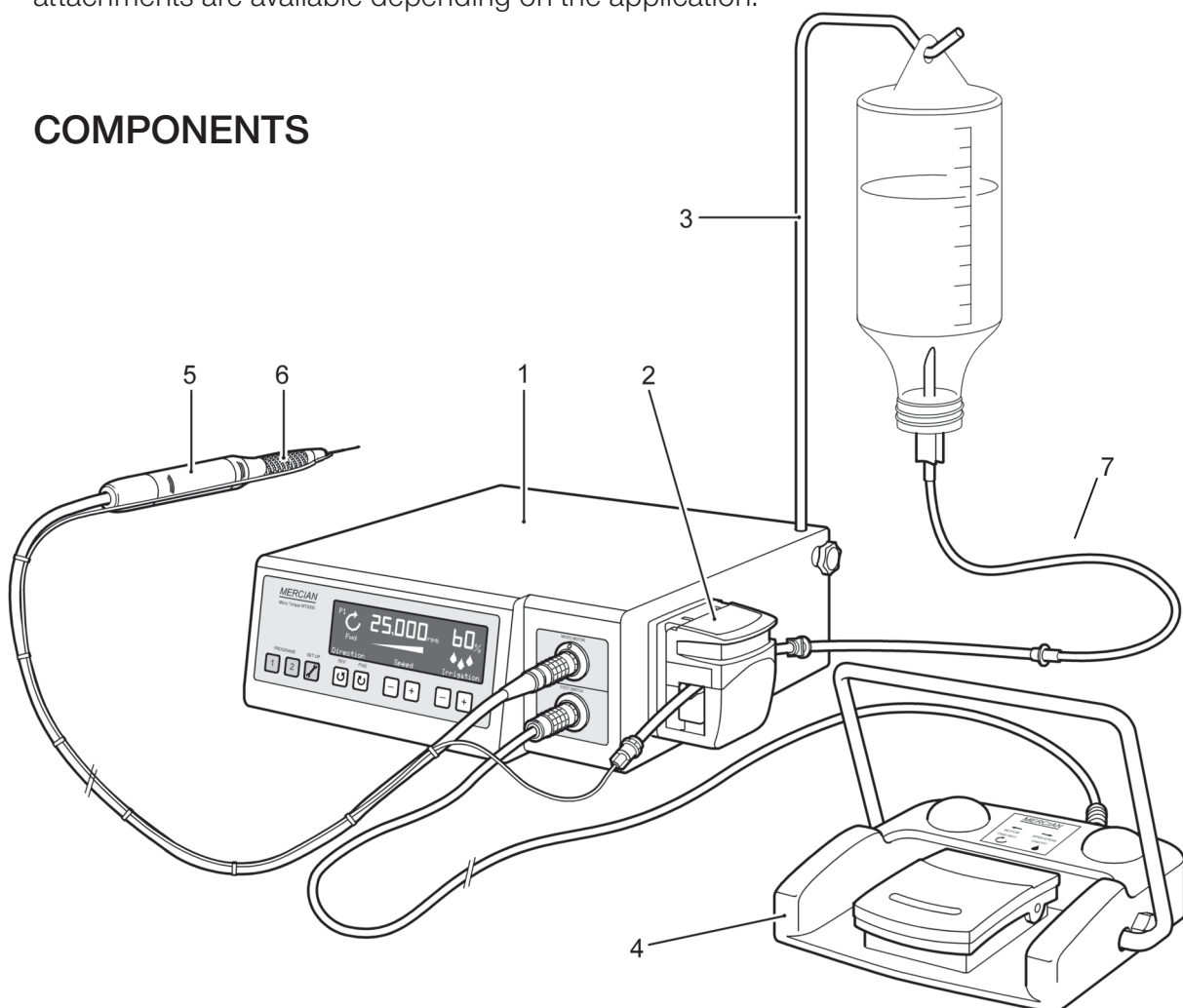
- Room Temperature: 10 to 25°C / 50 to 77°F
- Relative Air Humidity: 50 to 70%
- Relative Air Pressure: 900 to 1200 hPa
- Storage and Transport Conditions: -10 to 40°C / 14 to 104°F

1.2 Intended Use

The Micro Torque System is used in small bone surgery: oral surgery for drilling and cutting of the small bones around the facial and jaw area, for sectioning teeth during oral surgery, drilling and polishing bone or enamel, sawing bones, trephining bone and for ENT surgery drilling of the mastoid bone behind the ear. The irrigation pump delivers sterile water into the cutting bur, which aids in reducing the temperature of the bur, which may affect the surrounding bone during drilling.

The intra coupling used on the Micro Torque MT5000 motor system is designed for use with hand held surgical Handpiece attachments that comply with DIN 13940/ISO 3964. Different attachments are available depending on the application.

2 COMPONENTS

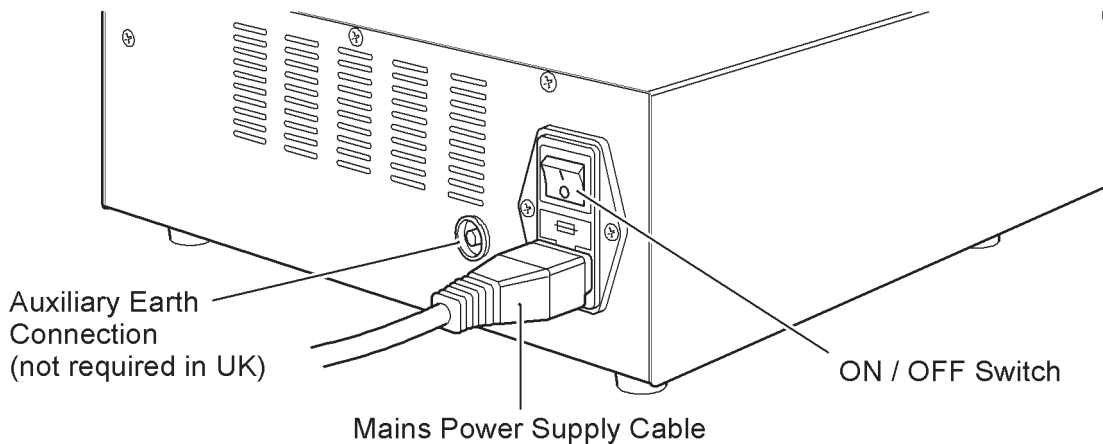


ITEM	CODE	DESCRIPTION	ITEM	CODE	DESCRIPTION
1	MT5010-00	Electronic Console Unit	5	MT5012-00	'Micro Motor' and Cable
2	MT5018-00	Irrigation Pump Unit	6	MT1124-00	Surgical Handpiece
3	MT5015-00	Irrigation Support	7	MT5243-00	Irrigation Tubing
4	MT5011-00	Footswitch Control			

NOTE: For a full list of accessories used with the system, refer to the Mercian Micro Torque and Bur brochure.

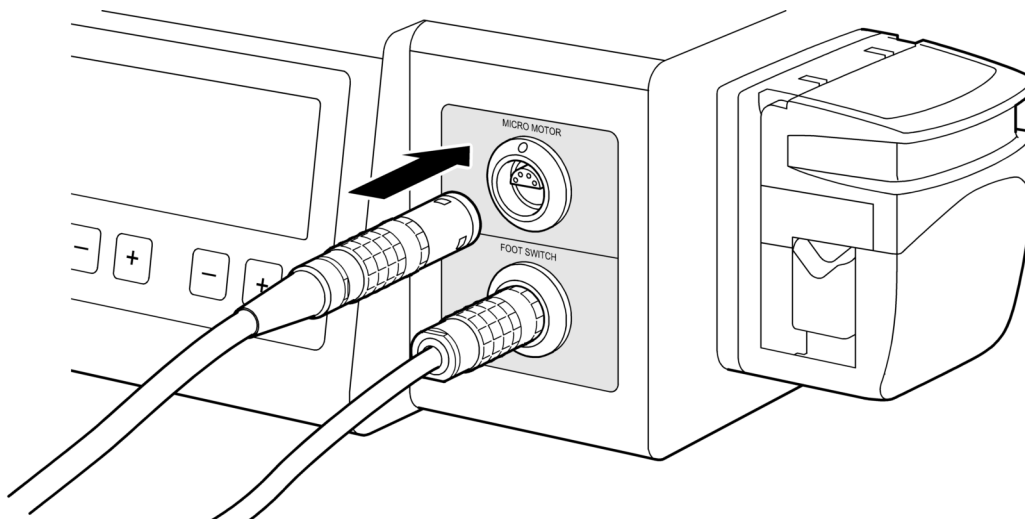
3 PREPARING FOR USE

1. Connect the mains power supply cable to the socket at rear of the Console.

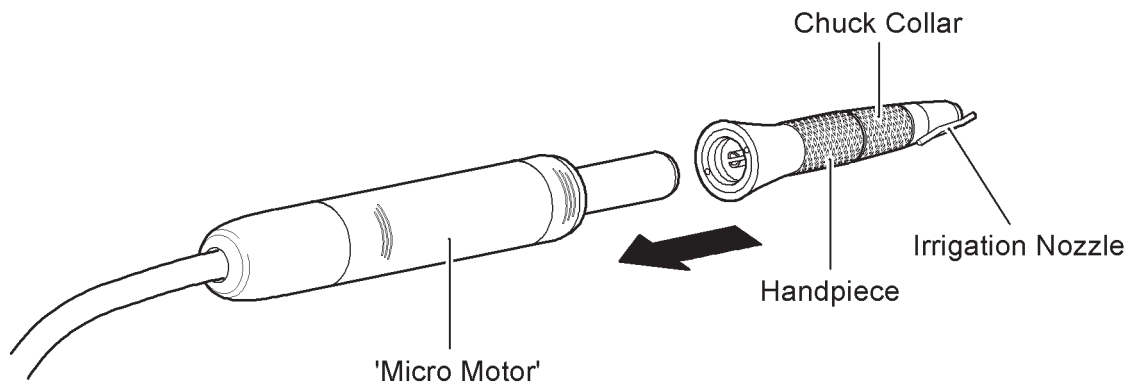


2. Locate the irrigation bag support in the hole at back of the Console. Position the upright to suit and secure with the thumb wheel.
3. Insert the 'Micro Motor' connector into the Console.
4. Insert the Foot Control connector into the Console.

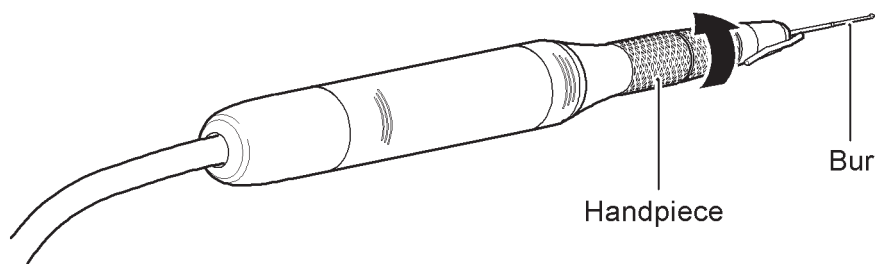
NOTE: Take care when locating the connectors in the Console. The connectors are industry standard 'Lemo' plugs and will only fit in one position. Orientate the connector so that it locates in the socket and push in (when fitted correctly the connector will click and lock in position). The connector has a spring loaded sleeve, the initial outward pressure applied when removing the connector will release the locking mechanism.



5. Attach a compatible Handpiece in to 'Micro Motor' and make sure that it is fitted securely.



6. Place a Sterile Bur in to the Handpiece and turn the collar anti-clockwise until you feel the 'click' of the chuck to secure the bur.

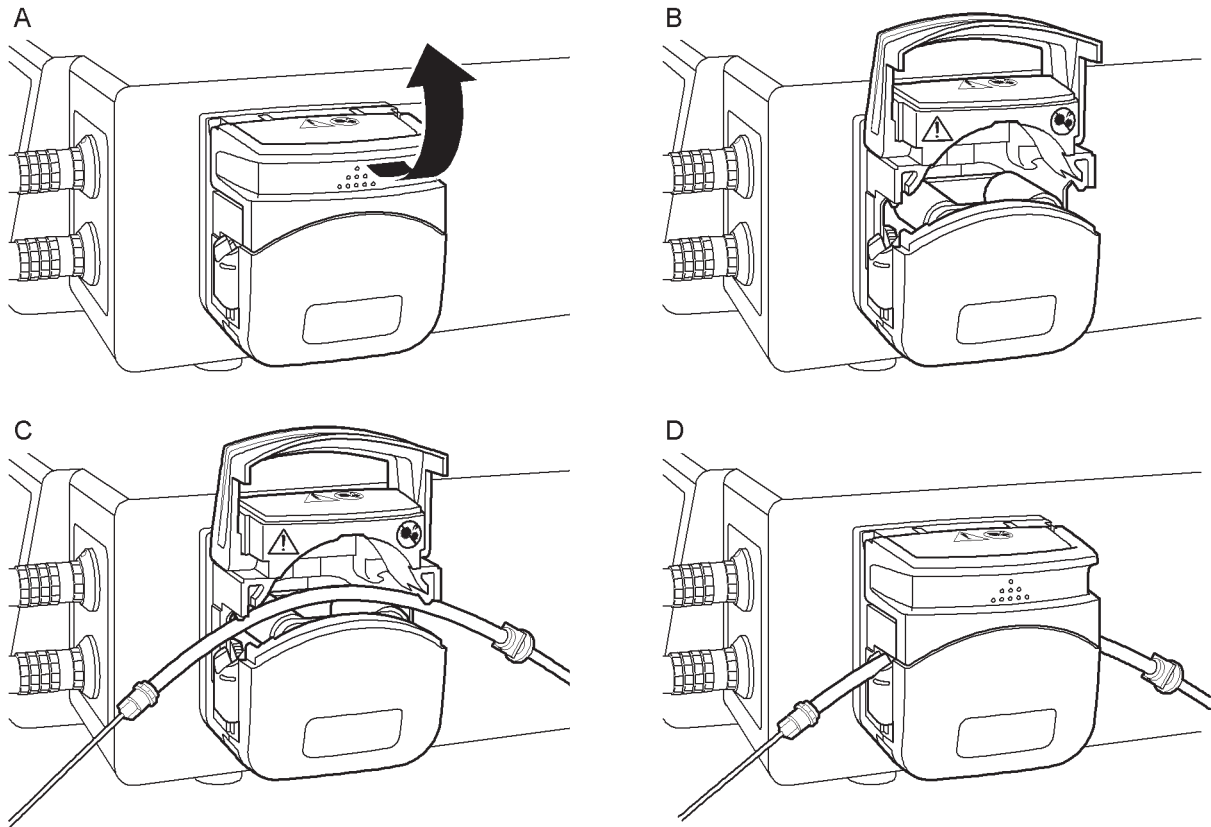


7. Switch **ON** the Console at the switch at the rear of the unit.

WARNING: *Always handle with care when the Console is switched ON and prepared for use. Inadvertent operation of the foot pedal can cause personal injury to the user or other persons nearby.*

WARNING: *Make sure that you feel the 'click' of the chuck closing onto the bur to ensure the locking mechanism is fully closed. There is a danger of the Handpiece overheating if it is run with the chuck not completely closed. This can result in lip burn to the patient.*

4 INSTALLING THE STERILE IRRIGATION TUBING IN TO THE PUMP UNIT ON THE CONSOLE



1. Hang the bag of sterile water on the upright. (Sterile water is recommended for use rather than saline)
2. Insert the spike of the sterile irrigation tubing into the sterile water bottle.

NOTE: Only use original Mercian irrigation sterile tubing.

3. Open the pump lid.
4. Place the larger bore irrigation tubing centrally on the pump rollers and close the lid on to the tubing.

NOTE: The action of closing the pump lid will centralise and clamp the tube on the rollers. The pump is designed for use with 3.2mm bore tube and requires no adjustment by the user.

5. Secure the micro bore irrigation tubing at convenient intervals to the 'Micro Motor' cable with the tubing clips and finally attach to the spray nozzle tube on the Handpiece.

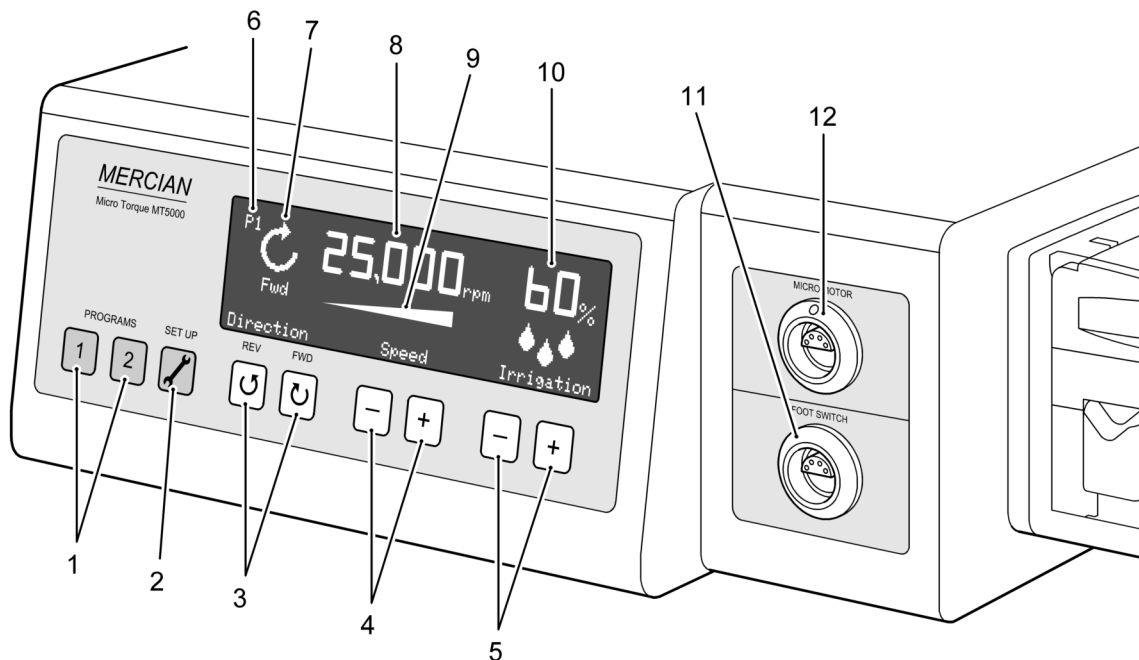


Read instructions before use



Do not put fingers in rollers!

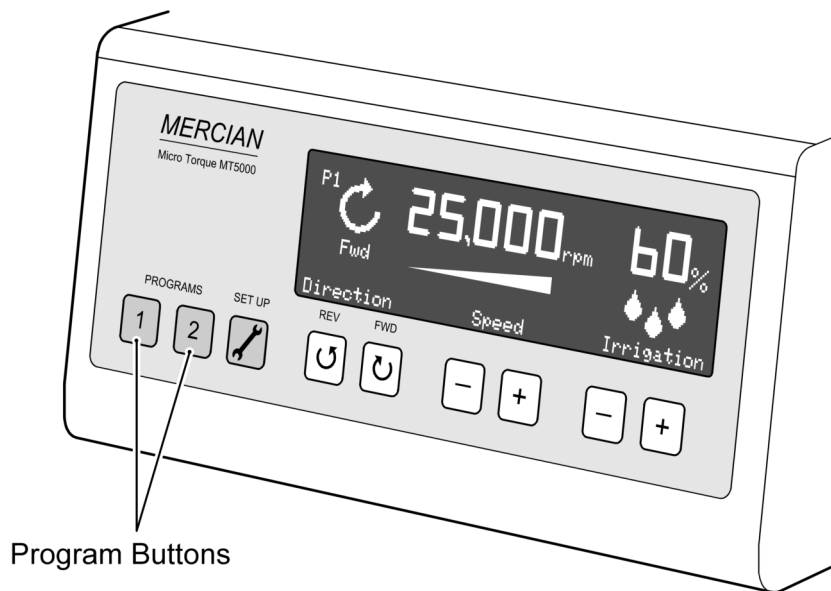
5 CONTROL UNIT FUNCTION AND DISPLAY



1. Buttons to select the 'Pre-Set' program settings 1 and 2.
2. Button to enter the 'Set up' menu.
3. Buttons to select FORWARD or REVERSE operation of the 'Micro Motor'.
4. Buttons to INCREASE (+) and DECREASE (-) the speed of the 'Micro Motor'.
5. Buttons to INCREASE (+) and DECREASE (-) the pump speed to control the water irrigation flow rate.
6. 'Pre-Set' program selected indicator (P1 or P2).
7. 'Micro Motor' operation FORWARD or REVERSE indicator.
8. 'Micro Motor' speed display in rpm (revolutions per minute). Shows the set maximum or the actual operating speed when the 'Micro Motor' is in use. (The accuracy is +/- 5%)
9. Bar display indicating the actual operating speed relative to the maximum speed set when the 'Micro Motor' is in use.
10. Irrigation flow rate display as a % of the maximum.
11. Socket for Foot Control connector.
12. Socket for 'Micro Motor' connector.

6 USING THE CONSOLE UNIT FUNCTIONS

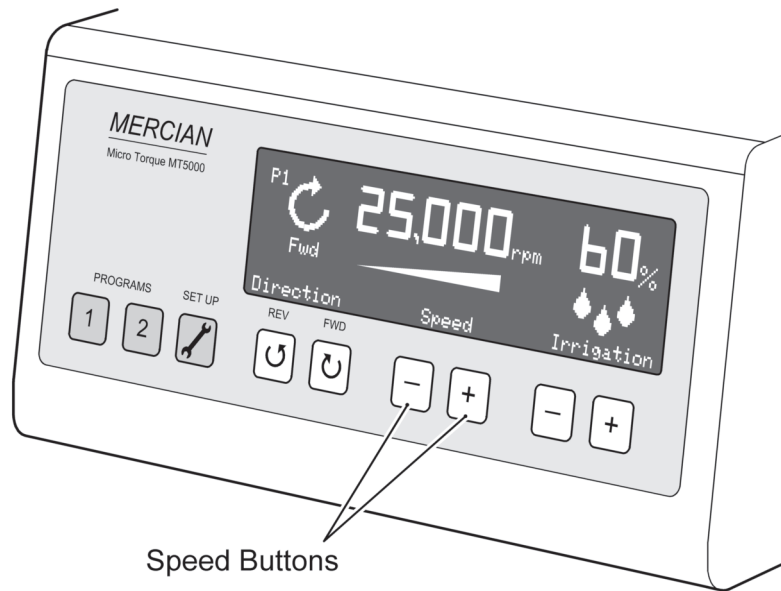
6.1 Using and Setting the 'Pre Set' Function



Commonly used program settings can be allocated and stored to the 2 quick set up buttons according to the user's needs.

The displayed 'Micro Motor' maximum speed and pump flow rate will be stored by holding down one of the 2 program buttons for a few seconds until a beep is heard. The settings will be stored against that program button and can be retrieved at any time by pressing the relevant button. The Console will retain these settings until the 'Pre Set' button is set again.

6.2 Adjusting the Speed of the 'Micro Motor'



Use the + or - buttons on the Console to set the required maximum speed of the 'Micro Motor'. The motor speed (rpm) is 'stepped' in increments there are 16 available speeds, these are shown below:

1,000	2,000	3,000	4,000	5,000	6,000	8,000	10,000
12,500	15,000	17,500	20,000	25,000	30,000	35,000	40,000

Figures show rpm (revolutions per minute)

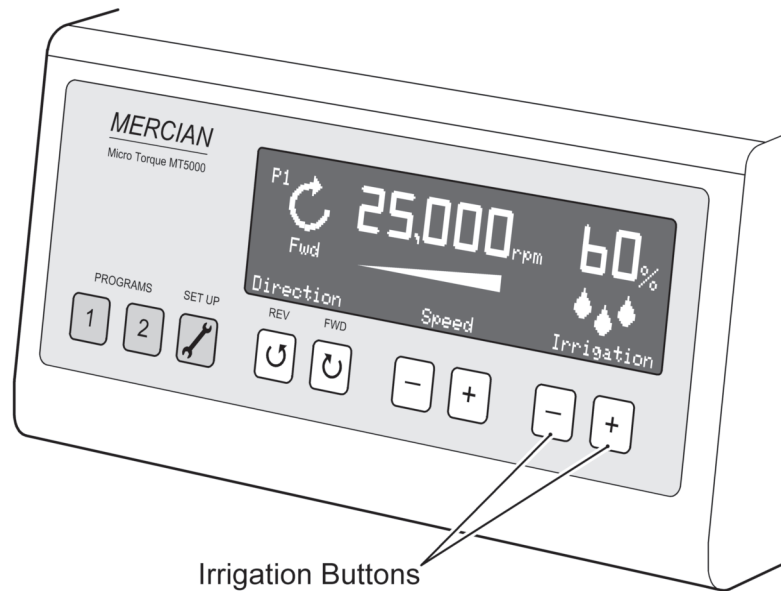
Pressing either the + or - button will move to the next speed in the range - higher or lower as applicable.

At the end of the speed setting sequence the micro motor will revert to **OFF** setting.

The Console has an 'built-in' memory. When the unit is powered down the last speed setting used will be recalled when the unit is switched back on again.

NOTE: The Console software will stop the 'Micro Motor' instantly the operating pedal on the Foot Control is released. This is a safety feature of the MT5000 to prevent the bur from running on.

6.3 Setting the Irrigation Functions on the Display



Use the irrigation adjustment + or - buttons on the Console to set the Irrigation flow rate. Again, the flow rate is adjusted in increments. there are 15 available flow rates these are given as a % of the maximum pump flow rate. The flow rates available are shown below.

5	10	15	20	25	30	35	40	45	50	60	70	80	90	100
---	----	----	----	----	----	----	----	----	----	----	----	----	----	-----

Figures % of maximum flow rate

Pressing either the + or - button will move to the next available flow rate in the range.

At the bottom end of the flow rate sequence the pump will revert to **OFF** setting.

The Console's memory will recall the last flow rate setting used when the unit is switched back on again.

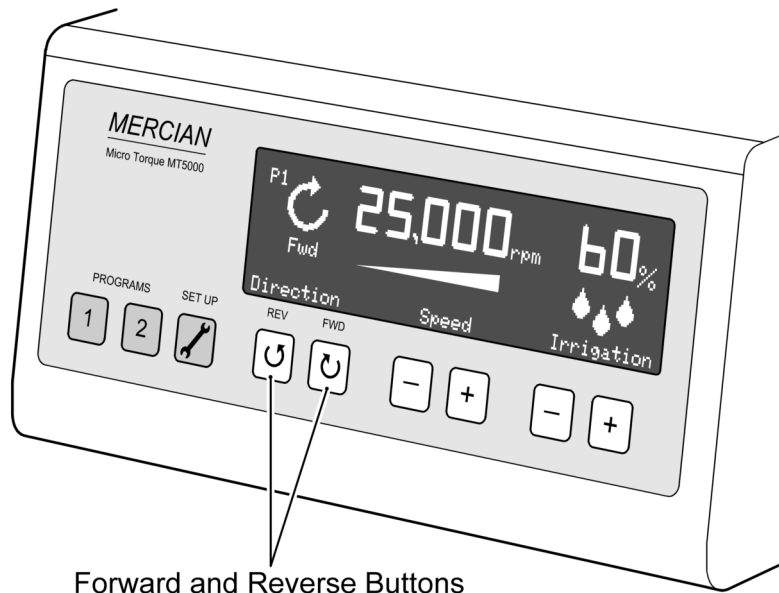
In operation the irrigation function can be toggled between **ON** (to the set Flow rate) or **OFF** with the right hand button on the Foot Control.

NOTE: When the pump is halted by the button on the Foot Control, the pump will cycle back half a turn before stopping. This is a design feature of the pump that prevents the 'run-on' of the irrigation fluid after the pump is switched off.

Maximum or 100% flow rate delivers 100 ml of water per minute.

When the pump is not operative  is indicated on the display.

6.4 Forward and Reverse Settings on the Display



The 'Micro Motor' rotation can be switched between **FORWARD** and **REVERSE** by using the buttons on the front of the Console. A beep will sound to warn the user when the direction of rotation has been changed.

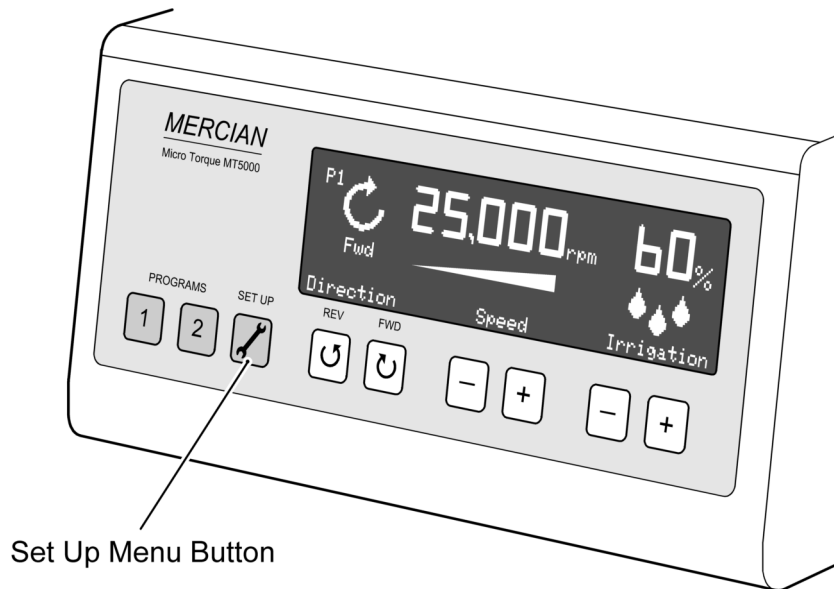
The direction of rotation will be shown on the display by the applicable symbol.



In operation **FORWARD** and **REVERSE** can be selected with the left hand button on the Foot Control.

This function is **NOT** stored in the pre-set function or recalled by the memory when the unit is switched **ON**. The unit will always display the **FORWARD** position by default when the unit is switched **ON**. The selected position will not change until the opposite direction is selected on the Console or with the button on the Foot Control.

6.5 Set up Menu function



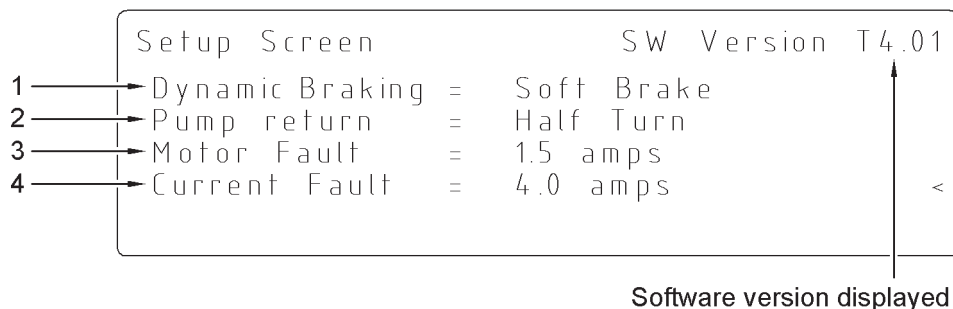
To enter the menu press the **set up** button to display and then use the + & - buttons to navigate and select from the following options;

- 1. Brake options** = selected Motor Brake operation from 3 options:
 - No brake Will allow the motor to slow down without any braking.
 - Soft brake Will allow the motor to brake but without any kick (Default Setting).
 - Hard brake Will allow motor will halt the motor immediately.
- 2. Pump return** = selection of the amount of backward rotation of the Pump after motor is stopped:
 - Half Turn Pump reverses half a return after motor stopped.
 - Full Turn Pump reverses a full return after motor stopped (Default Setting).
 - No return Pump does not reverse when the motor is stopped.

3. **Motor fault** will detect any difference in the currents between the 3 windings in the Micro Motor. When a Hand Piece or Motor stall occurs there is a difference in the current drawn by one winding against another, this compares the difference between the current on one winding against another and if it exceeds the settings selected below it cuts out to protect the Hand Piece and Motor.
- 1.5 amps Lower setting compares lower level of amps before cutting off.
 - 2.0 amps Medium setting compares medium level of amps before cutting off.
 - 2.5 amps Higher setting compares maximum level of amps before cutting off (Default Setting - recommended).

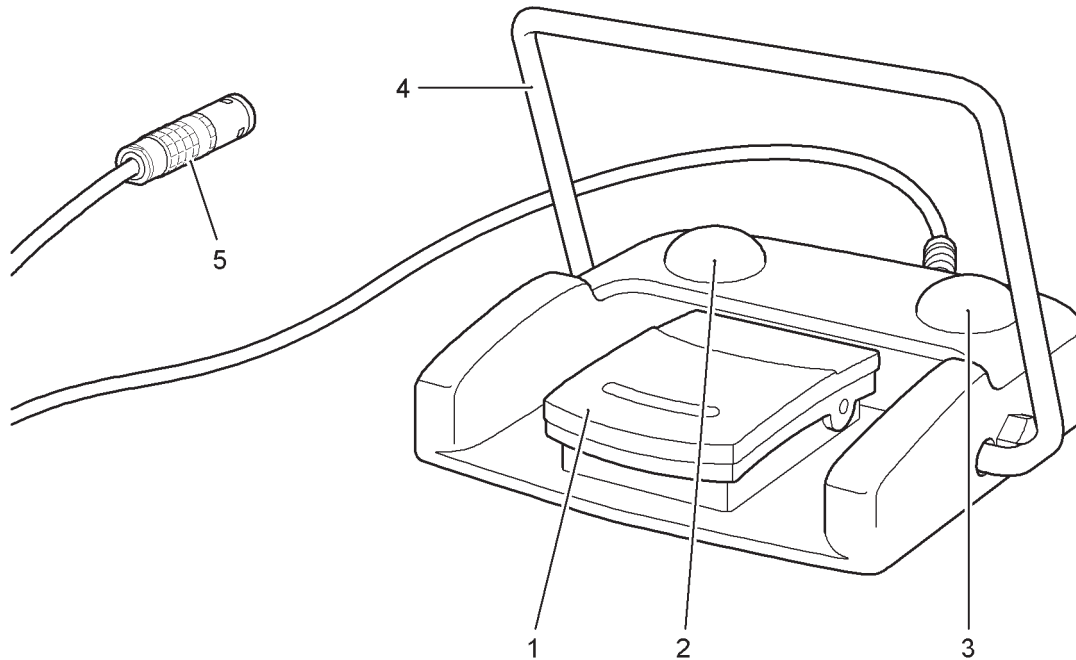
4. **Current fault** measures the total draw of current when the Motor/Hand Piece is put under load, therefore as the Surgeon exerts more pressure on the Bur the Motor will require to draw more current from the board to drive the Motor;
- 4 amps Lower setting.
 - 4.5 amps Medium setting.
 - 5 amps Higher setting for hard use (Default Setting – recommended).

The maximum recommended current drawn for the Micro Motor is 5 amps; anything exceeding this during heavy use can cause the Motor to overheat.



To exit the menu screen display press the Set up Menu button.

7 FUNCTIONS AND OPERATION OF THE FOOT CONTROL



- | | |
|--------------------------------------|--|
| 1. 'Micro Motor' speed control pedal | 4. Handle for moving pedal around |
| 2. Forward or reverse button | 5. Connector for Foot Control into Console |
| 3. Irrigation pump ON/OFF button | |

WARNING: *Always handle with care when the unit is switched ON and prepared for use. Inadvertent operation of the foot pedal can cause personal injury to the user or other persons nearby.*

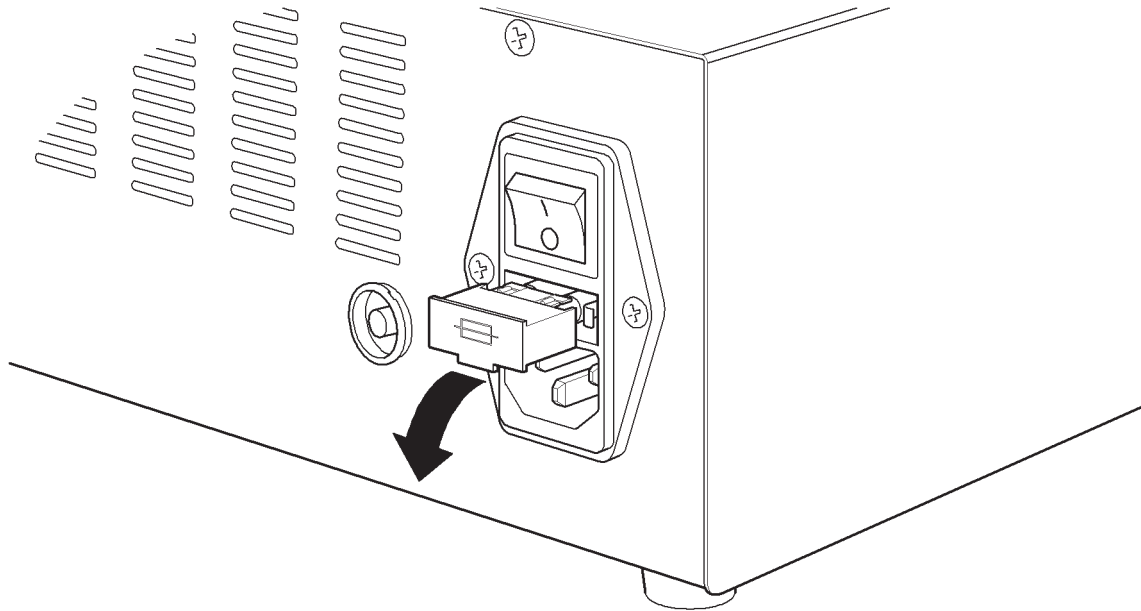
Applying gradual pressure to the pedal (1) will increase the 'Micro Motor' speed up to the full 'Pre-Set' speed shown on the Console display.

The right hand button (3) on the Foot Control will toggle the irrigation pump between **OFF** and **ON**.

FORWARD and **REVERSE** can be selected with the left hand button (2) on the Foot Control. A beep will sound to warn the user when the direction of rotation has been changed.

The handle (4) allows the operator to manoeuvre the Foot Control with their foot to suit. The handle can be positioned raised or lowered as required.

8 REPLACING FUSES ON THE UNIT



There are two fuses in the carrier they should be checked and replaced as necessary.

WARNING: *Make sure the unit is switched OFF and the power cable is removed from the MAINS supply before withdrawing the fuses.*

NOTE: *The fuses are installed in a fuse holder above the power connector located at the rear of the control unit. The mains cable must be removed from the power socket to access the tab on the fuse carrier.*

To remove the fuse carrier, place the finger nail or a small screwdriver under the tab and pull to release. Fully withdraw the carrier and rotate downwards to access the fuses.

Replacement 2.5 Amp fuses must be used.

9 SERVICE AND REPAIRS

No servicing or repairs should be undertaken by any agent other than Mercian Surgical technicians or technicians trained by Mercian Surgical.

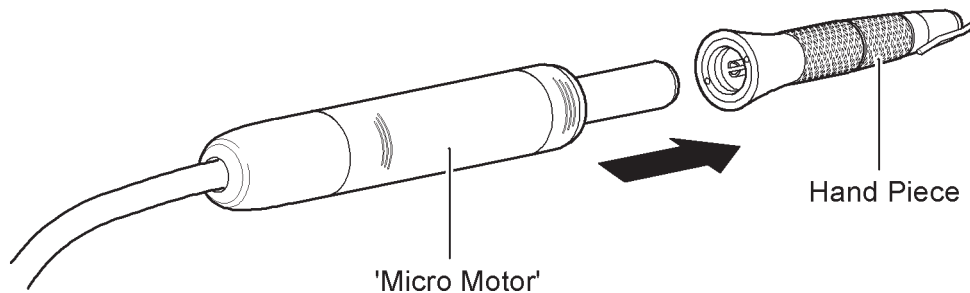
Liability cannot be assumed if repairs are undertaken by third parties without authorisation or the required training.

10 DISCONNECTING THE 'MICRO MOTOR' FROM THE HANDPIECE

The Handpiece can be pulled apart from the 'Micro Motor' easily as shown.

WARNING: Only use **COMPATIBLE** Handpieces on the 'Micro Motor' complying to **DIN13940/ISO 3964**.

The Micro Motor and Handpiece are applied parts of the system.



11 LUBRICATION, DISINFECTION AND CLEANING

11.1 Console Unit

The Console unit can be wiped down using a proprietary medical surface disinfection wipe.

11.2 Foot Control

The Foot Control can be wiped down with a surface disinfectant solution.

11.3 Maintenance Procedure 'Micro Motor' and Handpieces

11.3.1 Manual cleaning of Handpieces

Clean and disinfect the exterior of the Handpiece with a clean damp cloth and suitable disinfection solution.

Note: Products containing acetone, chlorine, and bleach are not recommended as disinfectants.

Visually inspect the Handpiece and Micro Motor for any remaining debris and damage.

Note: Handpieces are not suitable for cleaning in an ultrasonic bath.



Indicates that the Micro Motor can be processed in a washer-disinfector for thermal disinfection.



Sterilisable in a steam sterilizer at temperature specified.

11.3.2 Automatic cleaning of Handpieces in a washer disinfector

- 1) Place the Handpieces in the appropriate basket.
- 2) Pre rinse with cold mains water.
- 3) Wash with mains water up to 95°C with alkaline detergent giving a pH of between 8.0-11.00 in dilution.
- 4) Rinse with warm mains water at 50°C.
- 5) Post rinse with warm mains water at 50°C.
- 6) Final rinse with reverse osmosis water at 90°C.
- 7) Hot air drying.

Remove the instruments immediately from the Washer/Disinfector and lubricate prior to sterilisation.

As per HTM 01-01 Part D: Washer Disinfectors.

Caution: *Failure to lubricate immediately may lead to internal corrosion of the instrument and its subsequent failure.*

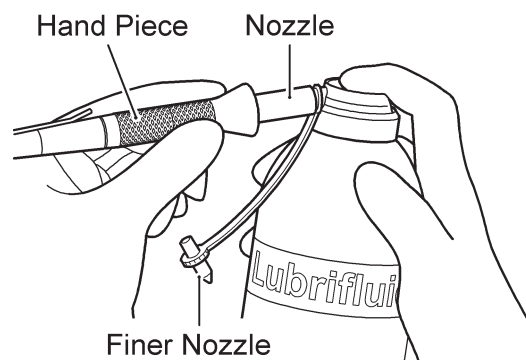
11.3.3 Lubrication of Handpieces and Micro Motor

Always Lubricate before each sterilisation.

Always use Mercian Lubrifluid oil spray order code; **1600064-006.**

Procedure for Lubricating Hand Pieces

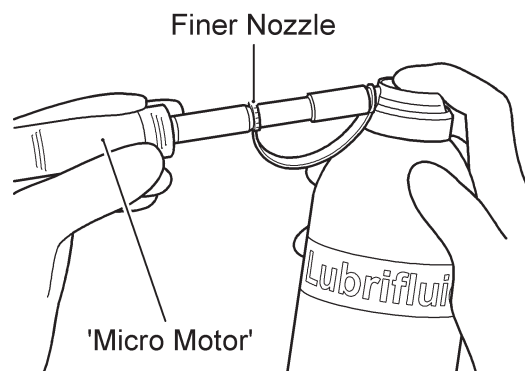
- 1) Remove Bur from instrument.
- 2) Open Chuck up.
- 3) Hold the Handpiece in a cloth to catch any debris and foreign matter expelled by the jet.
- 4) Remove the protective cap from the can, and insert nozzle into the back of the Handpiece sleeve.
- 5) Spray for about 1 second.



Note: *After lubrication, always stand the Handpiece upright for 5 minutes.*

Procedure for Lubricating Micro Motor

- 1) Use the Lubrifluid pointed finer nozzle.
- 2) Hold the Micro Motor in a cloth.
- 3) Remove the protective cap from the can, and insert nozzle into the open end of the Micro Motor.
- 4) Spray for less than 1 second.



11.3.4 Sterilisation

High temperature steam autoclave at 134 °C to 137 °C for 3 minutes.

or

Vacuum autoclave 134 °C to 137 °C for 3 minutes.

Drying cycle max 137 °C for maximum 30 minutes.

As per HTM 01-01 Part C: Steam sterilisation.

12 TECHNICAL DATA

12.1 Control Unit

Housing Dimensions	290 x 300 x 110 mm
Weight	5.2 kg
Voltage	100 - 240 V AC
Input Frequency	50 - 60 Hz
Fuses	Anti surge, 2.5A
Pump Capacity	100 ml of fluid per minute at 100% flow rate

12.2 Foot Control

Dimensions	201 x 187 mm
Weight	1.8 kg
Cable Length	2.9 m
Anaesthetic Test Class	AP

12.3 'Micro Motor'

Dimensions	Length with coupling 120mm. Diameter 20mm.
Weight	120 g
Mechanical Power	45W at 20,000 rpm
Classification	Ila
Unloaded Speed	40,000 rpm
Maximum torque	4 Ncm
Noise Level	Max 65 dBA

NOTE: The 'Micro Motor' is sterilised with the cable connected where applicable.

*NOTE: Recommended method of sterilisation is steam sterilisation
134°C / 1bar at an exposure time of at least 15 minutes.*

12.4 Motor Cable

Length	2.9 m
Weight	285 g
Classification	Ila

*NOTE: As above, the recommended method of sterilisation is steam sterilisation
134°C / 1bar at an exposure time of at least 15 minutes*

13 TROUBLE SHOOTING

Condition	Cause	Action
Control unit does not light up.	Mains switch off.	Switch mains supply ON.
	No power supply to Console.	Check power supply cable.
	Power supply cable defective.	Replace power supply cable.
	Fuses defective.	Fit new fuses.
Pump will not run.	Pump not engaged.	Switch pump ON, on Foot Control switch.
	Flow rate set at OFF	Set desired flow rate.
	'Micro Motor' not operating.	Pump only operates when 'Micro Motor' is running.
Foot Control is not working.	Connector is incorrectly inserted into Console.	Check connector is correctly inserted into Console.
'Micro Motor' will not operate.	Connector is incorrectly inserted into Console.	Check connector is correctly inserted into Console.
	'Micro Motor' connection to Cable faulty.	Check connection between cable and 'Micro Motor'.
	'Micro Motor' or cable defective.	Replace 'Micro Motor' or Cable and return to Mercian for repair.
'Micro Motor' is 'over heating'.	Prolonged peak load usage.	Refer to manufacturer's instructions.
	Bearings defective.	Stop use and replace 'Micro Motor'.
Handpiece rotates on the 'Micro Motor'.	Handpiece Chuck is not closed	Close Handpiece Chuck correctly.
Bur in Handpiece rotates intermittently or not at all.	Handpiece defective.	Replace Handpiece and return to Mercian for repair.
Bur not cutting efficiently.	Direction of 'Micro Motor' set in reverse.	Change direction of 'Micro Motor'.
	Bur worn and blunt.	Change Bur.

If the fault cannot be attributed to one of the following causes described above or rectified by one of the specified courses of action the component should be returned to Mercian Surgical for examination and if necessary repair.

Repairs should only be carried out by Mercian personnel.

Unauthorized repairs or attempted repairs release Mercian from any liability whatsoever.

14 GUARANTEE CONDITIONS

Our products are guaranteed for a period of One Year from the date of delivery of the System.

Claims under guarantee will only be considered provided the guarantee card has been returned to Mercian.

The Micro Torque Unit will be repaired free of charges if the defects can be attributed to faulty material and workmanship. Any other claims particularly for compensation are excluded.





If any modification or repairs are undertaken by third parties the guarantee will be rendered null and void.

Components should only be replaced 'like for like'.

Annual Service is recommended to ensure the safe and reliable operation of the Micro Torque System.

Upon request we will supply appropriate technical documents to allow service and repair of medical equipment to suitably qualified service personnel.

15 INFORMATION LABEL

Serial No	
Ref No	MT5000
Voltage 100-240V~ Frequency 50-60Hz Rated Input 40VA	
 1639 	 Type B  2016-03
MERCIAN SURGICAL SUPPLY CO LTD 10 Topaz Business Park, Topaz Way, Bromsgrove, B61 0GD, United Kingdom. Tel: +44 (0) 844 879 1133 Email: info@merciansurgical.com	

Key to Symbols

 1639



In conformity with the Council Directive 93/42/EEC of June 14, 1993 concerning medical devices.

Symbol indicating a Type B Appliance.
A Type B appliance classification is the least stringent classification and is used for applied parts that are generally not conductive and can be immediately released from the patient.
Type B applied parts may be connected to earth.

CAUTION.
Refer to the accompanying documentation.

Symbol indicating the date that the product was manufactured, expressed as four digits for the year and two digits for the month.

Symbol confirming the manufacturer's name and address.

APPENDIX 1
EMC INFORMATION

Special Instructions / Notes regarding the MT5000 and Electromagnetic compatibility (EMC) testing to EN60601-1-2:2015+A1:2021

The MT5000 has been tested regarding its ability to operate in an environment containing other electrical/electronic equipment (including other medical devices).

The purpose of this testing is to ensure the MT5000 is not likely to adversely affect the normal operation of other such equipment and that other such equipment is not likely to adversely affect the normal operation of the MT5000.

Despite the testing of the MT5000 that has been undertaken, normal operation of the MT5000 can be affected by other electrical/electronic equipment and portable and mobile RF communications equipment.

As the MT5000 is medical equipment, special precautions are needed regarding EMC (electromagnetic compatibility).

It is important that the MT5000 is configured and installed/put into service, in accordance with the instructions/guidance provided herein and is used only in the configuration as supplied.

The MT5000 has been tested (and should be used only with) the cables and micro motor provided.

If the MT5000 is used with cables or a micro motor other than those supplied, this may result in increased emissions or decreased immunity of the MT5000 in relation to EMC performance.

It should be noted that neither the cables nor the micro motor provided with the MT5000 should be used on other equipment. To do so may result in increased emissions or decreased immunity of the other equipment in relation to EMC performance.

The MT5000 should not be used adjacent to or stacked with other equipment. If adjacent or stacked use with other equipment is necessary, the MT5000 and the other equipment should be observed/monitored, to verify normal operation in the configuration in which it will be used.

The MT5000 essential performance during the emc immunity tests was that in run mode the micro motor speed shall not vary by more than +/-10% and the irrigation pump shall continue to operate, and in standby mode the micro motor or irrigation pump must not unintentionally operate.

Electromagnetic Compatibility Requirements - Emissions

Required Test	Compliance	Comments
RF emissions	Group 1	For use in a professional healthcare facility environment only
CISPR 11	Class A	
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC61000-3-3	Complied	

Electromagnetic Compatibility Requirements - Immunity

Required Test	60601 test level for equipment used in a professional healthcare facility only	Compliance level
Electrostatic discharge (ESD) IEC61000-4-2	± 8 kV contact ± 2, 4, 8, 15 kV air	± 8 kV contact ± 2, 4, 8, 15 kV air
Radiated RF EM Fields IEC61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz
Proximity fields from RF wireless communications IEC61000-4-3	385MHz - 27 V/m 450, 810, 870, 930MHz - 28 V/m 1.72, 1.845, 1.97, 2.45GHz - 28 V/m 710, 745, 780MHz - 9 V/m 5.24, 5.5, 5.875GHz - 9 V/m	385MHz - 27 V/m 450, 810, 870, 930MHz - 28 V/m 1.72, 1.845, 1.97, 2.45GHz - 28 V/m 710, 745, 780MHz - 9 V/m 5.24, 5.5, 5.875GHz - 9 V/m
Electrical fast transient / burst IEC61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	± 2 kV for power supply lines
Surge IEC61000-4-5	± 0.5, 1, 2 kV line(s) to earth, ± 0.5, 1 kV line(s) to line(s) for power supply lines	± 0.5, 1, 2 kV line(s) to earth, ± 0.5, 1 kV line(s) to line(s) for power supply lines
	± 2 kV line(s) to earth for input / output lines	
Conducted RF IEC61000-4-6	3 V - 150 kHz to 80 MHz 6V - ISM bands between 150 kHz to 80 MHz	3 V - 150 kHz to 80 MHz 6V - ISM bands between 150 kHz to 80 MHz

<p>Voltage dips, short interruptions and voltage variations on power</p>	<p>0% U_T (100 % dip in U_T) For 0.5 cycle supply input lines IEC61000-4-11</p> <p>0% U_T (100 % dip in U_T) For 1 cycle</p> <p>70% U_T (30 % dip in U_T) For 25/30 cycles</p> <p>0% U_T (100 % dip in U_T) For 250/300 cycles</p>	<p>0% U_T (100 % dip in U_T) For 0.5 cycle</p> <p>0% U_T (100 % dip in U_T) For 1 cycle</p> <p>70% U_T (30 % dip in U_T) For 25/30 cycles</p> <p>0% U_T (100 % dip in U_T) For 250/300 cycles</p>
<p>Power frequency (50/60Hz) Magnetic field IEC61000-4-8</p>	<p>30A/m</p>	<p>N/A</p>

APPENDIX 2
EMC AND SAFETY CERTIFICATES

Client: Mercian Surgical Supply Co Ltd.
Unit 10, Topaz Business Park,
Topaz Way, Bromsgrove.
Worcestershire
B61 OGD

Certificate of Test

Electromagnetic Compatibility for Micro Torque Surgical Drill System

Date of issue: 8th February 2018

SGS Reference: EMC248851/1

Details of sample: Model No.: MT5000
Serial No.: MT5010-00-208

Date of Receipt: 5th January 2018

Date(s) of Test: 17th January 2018 to 6th February 2018

Test(s) Required: EN 60601-1-2: 2015
Group 1 Class A limits

Conclusion: In the configuration tested the sample meets the requirements of the standards detailed above.

Issue Number: 1



Authorised Signatory

Geoff Hann
Automotive Manager

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Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 28 days only.

Mercian Surgical Supply Co. Ltd.
 10 Topaz Business Park
 Topas Way
 Bromsgrove
 B61 0DG
 United Kingdom

Page 1 of 1

Certificate of Test

Electrical Safety for Medical Drill

Date of Issue: 23rd March 2018

SGS Reference: ELS248851/2/C/MC/18

Details of Sample: Model: Micro Torque MT5000
 Rated: 100 – 240 V, 50/60Hz, 29-40VA
 S/No: 209 and 222

Date of Receipt: 22/10/2010 and 05/01/2018

Date of Test: 12/01/2011 to 13/05/2011, and
 11/01/2018 to 22/03/2018

Test Specification: BSEN 60601-1: 2006, incorporating amendments
 *A11: 2012, *A1: 2013, and *A12: 2014
*(Excluding Biocompatibility, PEMS, EMC, Risk Assessment, Usability
 and Sterilisation.)*

Medical Electrical Equipment – Part 1 – General
 requirements for basic safety and essential performance

Conclusion: The sample tested was found to comply with the Test
 Specification.



Test Engineer
 M Carter



Authorised Signatory
 A Nicholson

All enquires relating to this certificate must be directed to the Test Engineer

END OF TEST CERTIFICATE

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Unless otherwise stated the results shown in this test certificate refer only to the sample(s) tested and such sample(s) are retained for 28 days only.

Tests marked (*) are not UKAS accredited, in addition any opinions or interpretations expressed herein are outside the scope of the UKAS accreditation.

Declaration of Conformity


for Micro Torque Surgical Drill System

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states.

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Micro Torque Surgical Drill System
Legal Manufacturer:	Mercian Surgical Supply Co Limited, 10 Topaz Business Park, Topaz Way, Bromsgrove, Worcestershire, B61 0GD. UK
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	Maxillo Facial and Small Bone Surgery
MDD Classification:	Class II(a)
Notified Body:	SGS Belgium 1639
CE Certificate Reference:	GB19/964481
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	EC Declaration of Conformity in accordance with Annex VII of the Medical Device Directive coupled with Production Quality Assurance outlined in Annex V

Name John Duffy **Position** MD

Signed  **Date** 10/05/2021

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
EN ISO 14971:2019	Medical Devices - Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
BS EN 60601-1:2006+A12:2014	Medical electrical equipment - General requirements for basic safety and essential performance
BS EN 60601-1-2:2015+A1:2021	Medical electrical equipment - General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic disturbances. Requirements and tests

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
MT5010-00	Micro Torque Electronic Console	45572
MT5011-00	Footswitch Control	45572
MT5012-00	Micro Motor Complete with Cable	45572

Version History

Version	Compiled by	Date	Description
1.0	John Duffy	18/11/2020	First issue.
2.0	Hayley Claridge	10/05/2021	Revision of ISO 14971:2012 to ISO 14971:2019 and included 60601-1

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Surgical Instruments of Excellence

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www.merciansurgical.com