THE TOP IN QUALITY
for all areas of healthcare

TOP INFUSION PUMP TOP-2500

THE NEW STANDARD

Specifications

Name	TOP Infusion Pump	
Model	TOP-2500 / TOP-2500W	
Power Supply	AC adapter	AC power supply : 100 ~ 240 V ±10 % 50/60 Hz
	Internal battery	Rechargeable, DC 12 V 1800 mAh Ni-MH (Type: BP-23)
		Battery life: Approx. 4 hours (New battery, Full charge, 25 mL/h)
Input Current	AC power supply : 0.3 A	
Applicable Infusion Sets	Designated TOP Solution Infusion Set	
	General Infusion Set 20 drops/mL, 60 drops/mL	
Flow Rate Range	mL/h	1 ~ 1200 mL/h (Designated 20 drops IV set)
		1 ~ 150 mL/h (Designated 60 drops IV set)
		1 ~ 360 mL/h (General 20 drops IV set)
		1 ~ 150 mL/h (General 60 drops IV set)
	mL/h (Micro mode)	0.1 ~ 99.9 mL/h (Designated 20, 60 drops IV set)
	Drops/min.	1 ~ 120 drops/min. (General 20 drops IV set)
		1 ~ 150 drops/min. (General 60 drops IV set)
Purge Flow Rate	Maximum flow in each Flow Rate Setting Range	
KVO Flow Rate Range	1 ~ 10 mL/h (1 mL/h steps)	
Volume Limit Range	1 ~ 9999 mL (1 mL steps)	
Total Volume Range	0 ~ 9999 mL (1 mL steps)	
Accuracy	mL/h	Designated Infusion Set: ±5 %
		General Infusion Set: ±10 %
	Drops/min.	±2 % (≧ 300 drops)
Downstream Occlusion Detection	4 steps selection (When Designated Infusion Set is selected)	
	PrdE 3: High Under 150 kPa / PrdE 2: Medium Under 120 kPa PrdE 1: Low Under 80 kPa / PrdE 0: Lowest Under 40 kPa	
	2 steps selection (When General Infusion Set is selected)	
	PrST 1: High Under 150 kPa / PrST0 : Low Under 80 kPa	
Upstream Occlusion Detection	1 step selection (When Designated Infusion Set is selected / For TOP-2500W only)	
	Under -20 kPa	
Air-in-line Detection Sensitivity	3 steps selection	
	Air0 : High Approx. 50 µL Air1 : Medium Approx. 0.1 mL / 15 minutes Air2 : Low Approx. 1 mL / 15 minutes	
Alarms	High priority alarm	Air-in-line, Empty Container, Flow Error (Over Drop, Under Drop), Free Flow, Downstream Occlusion, Upstream Occlusion, Auto Power OFF, Door Open, Drop Sensor, Infusion Complete, Power Loss, System Error
	Low priority alarm	Battery Alarm, Flow Rate Is Not Set, Check the Set Value, Prior End of Infusion, No Action with the Pump
	Information signals	Door Sensor Check, Switching Power, Maintenance Timer, Stand-by End, Battery Malfunction
Special features	History	Up to 300 items can be viewed in the Operation history.
	Key-Lock	Disables all Key operations except the Power Key during Infusion.
	KVO	After reaching the Infusion Volume Limit, continue Infusion at the KVO Flow Rate to prevent thrombosis.
	Nurse Call Signal	Connecting an External Communication Cable to the unit allows an Alarm Signal to be output when an alarm occurs.
	Auto Power OFF	When running on the Internal Battery, the power is turned off automatically if the unit is left for about 3 minutes after a No Action with the Pump Alarm occurs
	Key Light	The Keys light when operated. (For TOP-2500W only)
	Door Light	The door light turns on when the door is open.
	Maintenance Timer	The Maintenance Timer lamp lights when the set number of days is exceeded.
	Battery Refresh	Performs Refresh Charging to maintain the performance of the Internal Battery.
	Infusion Set Limit	Limits the types of Infusion Sets that can be selected.
	Stand-by	Temporarily extends the time until the No Action with the Pump Alarm is generated.
	Maintenance Mode	Makes it easy to check the Infusion accuracy and the status of various sensors.
	Buzzer Tone Setting	Sets the Buzzer Volume in 3 steps.
	Buzzer Setting	Select whether the Wait Tone and Key Operation Tones are heard.
	External Communication	Connecting the unit to a computer with an External Communication Cable allows data to be output from the pump.
	Anti Bolus	Reverses the motor direction when a downstream Occlusion Alarm occurs to reduce the temporary Bolus Volume due to the Occlusion. (When Designated is set)
	Repeat alarm	Sounds the Alarm tone again if the unit is left for more than 2 minutes without canceling the Alarm after the Alarm tone is silenced.

Operating conditions	Ambient temperature : 5 ~ 40 ℃ (During charging the internal battery: 5-30℃) Relative humidity : 20 ~ 90 % (No condensation) Atmospheric pressure : 70 ~ 106 kPa	
Transportation and Storage condition	Ambient temperature : -10 ~ 45 ℃ Relative humidity : 10 ~ 90 % (No condensation) Atmospheric pressure : 50 ~ 106 kPa	
Service life	6 years (Based on self certification using TOP corporation data)	
Classification	Class II ⊡ and Internally powered equipment, Type CF ♥, IP32	
Detentions	92(W) x 181(H) x 189(D) mm	
Weight	Approx. 1.9 kg	
Accessories	AC power cable x1, Drop sensor x1, Operation guide x1, Administrator Manual x1	
Material used	Case	ABS resin
	Door handle	Glass fiber-reinforced Nylon
	Clamp lever	Glass fiber-reinforced Nylon
	Operation panel	Polyester film
Options	Pole clamp, Infusion stand	

Manufacturer : **TOP Corporation** 19-10 Senju Nakai-cho, Adachi-ku, Tokyo 120-0035, Japan
Auth. Rep. : **MEDITOP CORPORATION (MALAYSIA) SDN. BHD.** [BRN: 198901006508 (183811-X)]
No.3, Persiaran Usahawan, Taman IKS, Seksyen 9, Bandar Baru Bangi, 43650 Selangor Darul Ehsan, Malaysia
Tel: +603-89240999 / Email: sales@meditop.com.my
Ref. No. 2022-08
"Registered under Act 737" / MDA Reg. No. GC8845621-53275

ASAL
ORIGINAL

PIHAK BERKUASA
PERANTI PERUBATAN

MEDICAL DEVICE
AUTHORITY

PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY
AKTA PERANTI PERUBATAN 2012 (AKTA 737)
MEDICAL DEVICE ACT 2012 (ACT 737)
SIJIL PENDAFTARAN PERANTI PERUBATAN
MEDICAL DEVICE REGISTRATION CERTIFICATE
Seksyen 5(1) Akta 737
Section 5(1) of Act 737

No. Pendaftaran: **GC8845621-53275**
Registration No.:

Tarikh Sah Pendaftaran: **13/01/2026 - 12/01/2031**
Registration Validity Date:

Sijil ini adalah dengan ini diberi kepada: **MEDITOP CORPORATION (MALAYSIA) SDN. BHD.**
This certificate is hereby issued to:

yang beralamat di:
which is located at:

NO. 3, PERSIARAN USAHAWAN, TAMAN IKS,
SEKSYEN 9, ,
43650 BANDAR BARU BANGI
SELANGOR DARUL EHSAN

Peranan establismen
Role of establishment

Wakil Diberi Kuasa
Authorized Representative

bagi mengesahkan peranti perubatan seperti yang dinyatakan dalam Lampiran 1 adalah berdaftar di bawah Seksyen 5(1) Akta 737.
to confirm that the medical device as detailed out in Attachment 1 is registered under Section 5(1) of Act 737.

Pendaftaran ini diberikan tertakluk kepada peruntukan-peruntukan di bawah Akta 737 dan peraturan-peraturan yang dibuat dibawahnya serta syarat-syarat seperti di Lampiran 2.
This registration is granted subject to the provisions under Act 737 and its subsidiary legislations and the conditions as in Attachment 2.

MURALITHARAN PARAMASUA
KETUA EKSEKUTIF
CHIEF EXECUTIVE
PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY

LAMPIRAN 1
Attachment 1

No. Pendaftaran: **GC8845621-53275**
Registration No.:

Tarikh Sah Pendaftaran: **13/01/2026 - 12/01/2031**
Registration Validity Date:

Butir-butir peranti perubatan yang didaftarkan
Particulars of the registered medical device

Nama Peranti Perubatan **INFUSION PUMP**
Medical Device Name

Kelas **CLASS C**
Class

Jenama **TOP INFUSION PUMP**
Brand

Kelompok **FAMILY**
Group

Nama dan alamat pembuat: **TOP CORPORATION 19-10 SENJU NAKAI-CHO, ADACHI-KU, TOKYO 120-0035, JAPAN , 120-0035 JAPAN**
Name and address of manufacturer

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	TOP INFUSION PUMP	TOP-2500	An active device used to administer medical agent into patient. In additionm this device is available on transfusion by use of the dedicated transfusion set.
2	TOP INFUSION PUMP	TOP-2500W	An active device used to administer medical agent into patient. In additionm this device is available on transfusion by use of the dedicated transfusion set.
"End Of Product List"			

SYARAT – SYARAT PENDAFTARAN PERANTI PERUBATAN
MEDICAL DEVICE REGISTRATION CONDITIONS

1.0 SYARAT AM
GENERAL CONDITIONS

1.1 Syarat-syarat pendaftaran peranti perubatan ini dibuat adalah berdasarkan kepada Seksyen 7 (1), Akta Peranti Perubatan 2012 (Akta 737). Kelulusan ini diberi berdasarkan maklumat-maklumat yang telah diterima.
Medical device registration conditions are prescribed in accordance to Section 7(1) of Medical Device Act (Act 737). Approval is granted based on information received.

1.2 Establismen hendaklah mematuhi segala arahan yang dikeluarkan oleh Pihak Berkuasa dari semasa ke semasa.
Establishment must comply with all instructions issued by the Authority from time to time.

1.3 Pihak Berkuasa berhak untuk meminda syarat-syarat pendaftaran dari semasa ke semasa.
The Authority reserves the rights to amend the registration conditions from time to time.

1.4 Pihak Berkuasa berhak menjalankan pemeriksaan ke atas establismen pada bila-bila masa tanpa dimaklumkan terlebih dahulu.
The Authority reserves the right to conduct inspection at any time without prior notice.

1.5 Pihak Berkuasa boleh membatalkan Pendaftaran Peranti Perubatan atau mengambil tindakan undang-undang sekiranya Establismen gagal mematuhi mana-mana syarat Pendaftaran Peranti Perubatan.
The Authority may cancel the Medical Device Registration or take legal action if the Establishment fails to comply with any medical device registration conditions.

1.6 Sijil Pendaftaran Peranti Perubatan yang dikeluarkan oleh Pihak Berkuasa tidak boleh dipindah milik.
Medical Device Registration Certificate issued by the Authority shall not be transferable or assignable.

1.7 Sijil Pendaftaran Peranti Perubatan hendaklah dikemukakan sekiranya diminta oleh mana-mana pegawai yang diberi kuasa.
Medical Device Registration Certificate must be presented upon request by any authorized officer.

1.8 Establismen tidak boleh membenarkan Sijil Pendaftaran Peranti Perubatan disalahgunakan oleh individu/syarikat lain dalam apa-apa cara.
Establishment shall not permit the Medical Device Registration Certificate to be abused in any way by any individual / another party.

1.9 Tempoh sahlaku Sijil Pendaftaran Peranti Perubatan adalah lima (5) tahun dari tarikh pendaftaran melainkan jika pendaftaran itu dibatalkan oleh Pihak Berkuasa sebelum habis tempohnya.
The validity of the Medical Device Registration Certificate is five (5) years from the date of registration unless the registration is cancelled by the Authority before its expiry.

1.10 Sijil ini tidak mengecualikan mana-mana keperluan perundangan lain yang terpakai untuk sesuatu peranti perubatan (contoh: Peranti Perubatan yang mengandungi racun berjadual tertakluk kepada Akta Racun 1952; peranti perubatan menggunakan sinaran mengion adalah tertakluk kepada Akta Perlesenan Tenaga Atom 1984.)
This certificate does not exempt any other regulatory requirements applicable to the medical device (for examples: Medical Device containing scheduled poison is subjected to the Poisons Act 1952; medical devices using ionizing radiation is subjected to the Atomic Energy Licensing Act 1984) .

1.11 Establismen hendaklah melaporkan insiden melibatkan peranti perubatan yang didaftarkan kepada Pihak Berkuasa seperti tertakluk di bawah Seksyen 40 Akta 737.
Establishment shall report any incidents involving registered medical device to the Authority as prescribed in Section 40 of Act 737.

1.12 Peranti perubatan yang diniatkan bagi kegunaan professional hanya boleh dibekalkan untuk kegunaan professional perubatan sahaja dan tidak boleh diletakkan dipasaran bagi kegunaan orang awam.
Medical device intended for professional use may only be supplied for use by medical professionals only and shall not be placed in the market for general public.

2.0 PINDAAN PENDAFTARAN PERANTI PERUBATAN
AMENDMENT OF MEDICAL DEVICE REGISTRATION

2.1 Sebarang pindaan kepada maklumat yang berkaitan peranti perubatan yang berdaftar hendaklah dimaklumkan kepada Pihak Berkuasa secara rasmi mengikut garis panduan yang ditetapkan oleh Pihak Berkuasa. Pihak Berkuasa berhak memberikan kelulusan atau menolak permohonan pindaan tersebut.
Any amendments to the information concerning registered medical device shall be notified to the Authority in accordance to the guidelines set by the Authority. The Authority reserves the right to grant approval or reject the application for such amendments.

3.0 PEMBATALAN SIJIL PENDAFTARAN PERANTI PERUBATAN
CANCELLATION OF MEDICAL DEVICE REGISTRATION CERTIFICATE

3.1 Sijil Pendaftaran Peranti Perubatan boleh dibatalkan seperti yang dinyatakan dalam Seksyen 9, Akta 737.
Medical Device Registration certificate may be cancelled as prescribed in Section 9 of Act 737.

3.2 Mana-mana peranti perubatan yang dibatalkan Sijil Pendaftarannya, tidak boleh diimport, dieksport atau diletakkan dalam pasaran.
Any Medical Device which the registration certificate has been cancelled shall not be imported, exported or placed in the market.

3.3 Sijil Pendaftaran Peranti Perubatan boleh dibatalkan jika Wakil Diberi Kuasa ditamatkan lantikan oleh pembuat.
Medical Device Registration Certificate may be cancelled if Authorized Representative appoinment is terminated by the manufacturer.

4.0 HAK PIHAK BERKUASA
THE AUTHORITY OWNERSHIP

4.1 Sijil Pendaftaran Peranti Perubatan yang dikeluarkan fizikal atau maya adalah **Hak Milik Pihak Berkuasa**.
The Authority retains the ownership of every Medical Device Registration Certificate issued by any means.

4.2 Sekiranya berlaku kehilangan atau kerosakan Sijil Pendaftaran Peranti Perubatan, hendaklah dimaklumkan kepada Pihak Berkuasa dan setiap penggantian sijil akan dikenakan caj perkhidmatan.
Any loss or damage to the Medical Device Registration Certificate shall be notified to the Authority and every replacement of certificate shall be liable with service charge rendered.

5.0 TUGAS DAN TANGGUNGJAWAB
ROLES AND RESPONSIBILITIES

5.1 Establismen hendaklah mematuhi Akta 737, peraturan-peraturan di bawah Akta dan syarat-syarat Pendaftaran Peranti Perubatan.
Establishment shall comply with Act 737, its subsidiary regulations and registration Condition.