THE TOP IN QUALITY
for all areas of healthcare

TOP SYRINGE PUMP TOP-S500

THE NEW STANDARD

Specifications

Name	TOP Syringe Pump	
Model	TOP-S500	
Power supply	AC power supply : 100 ~ 240 V 50/60 Hz Internal battery : Li-ion battery, Rechargeable, DC 3.6 V 3250 mAh (Type: BP-A6LG) Battery life is approx. 10 hours. (At 5 mL/h set using new battery is fully charged) Alkaline battery : AA size Alkaline battery x 4 pcs Battery life is approx. 10 hours (At 5 mL/h set using new batteries)	
Input current	0.3 A	
Use syringe	5, 10, 20, 30, 50 mL Syringe	
Syringe brand	TOP, B.Braun, TERUMO, B-D, NIPRO, JMS, 1% Diprivan Injection-kit 20/50 mL, User- registered syringe (One syringe)	
Flow rate range	0.10 ~ 150 mL/h (5mL syringe) 0.10 ~ 300 mL/h (10mL syringe) 0.10 ~ 400 mL/h (20mL syringe) 0.10 ~ 500 mL/h (30mL syringe) 0.10 ~ 1200 mL/h (50mL syringe, 1% Diprivan Injeciton-kit 20/50 mL)	
	0.10 ~ 99.99 mL/h: 0.01 mL/h steps, 100 ~ 1200 mL/h: 1 mL/h steps	
Infusion accuracy	Mechanical accuracy : ± 1 % Accuracy including syringe : ± 3 % (Accuracy after infusing for 1 hour or more at 1.0 mL/h or more setting)	
Volume limit range	No Setting, 0.1 ~ 999.9 mL (0.1 mL steps)	
Total volume range	0.0 ~ 999.9 mL (0.1 mL steps)	
Purge flow rate	150 mL/h (5mL syringe) 300 mL/h (10mL syringe) 400 mL/h (20mL syringe) 500 mL/h (30mL syringe) 1200 mL/h (50mL syringe, 1% Diprivan Injeciton-kit 20/50 mL)	
Bolus flow rate	150 mL/h (5mL syringe) 300 mL/h (10mL syringe) 400 mL/h (20mL syringe) 500 mL/h (30mL syringe) 1200 mL/h (50mL syringe, 1% Diprivan Injeciton-kit 20/50 mL)	
Bolus volume	0.1 ~ 5.0mL (5mL syringe) 0.1 ~ 10.0mL (10mL syringe) 0.1 ~ 20.0mL (20mL syringe) 0.1 ~ 30.0mL (30mL syringe) 0.1 ~ 50.0mL (50mL syringe, 1% Diprivan Injeciton-kit 20/50 mL) (0.1mL steps)	
Bolus accuracy	±3 % (± 0.1 mL at 0.1 - 3.3 mL setting)	
KVO rate range	0.1 ~ 5.0mL/h (0.1mL/h steps)	
Occlusion detection pressure	SL (Special low) : 30 ± 20 kPa (225 ± 150 mmHg / 0.30 ± 0.20 kgf/cm2) L (Low) : 50 ± 20 kPa (375 ± 150 mmHg / 0.51 ± 0.20 kgf/cm2) M (Medium) : 70 ± 30 kPa (525 ± 225 mmHg / 0.71 ± 0.30 kgf/cm2) H (High) : 90 ± 30 kPa (675 ± 225 mmHg / 0.92 ± 0.30 kgf/cm2)	
Alarm	High priority alarm	Occlusion, Syringe empty, Infusion complete, Battery empty, Power loss, Malfunction, Syringe barrel clamp, Syringe plunger clamp, Syringe barrel flange
	Low priority alarm	No Action, No battery, Low battery, Low volume, Infusion complete pre-alarm, No rate, No Volume limit, Flow rate＞Volume limit, Flow rate soft limit,
	Information signal (Warning)	Sensor check, Power supply switched, Maintenance timer, Shock detection
Special features	Auto power OFF	When running on internal battery, the power turns off automatically if the device is left for about 3 minutes after a No Action (low priority) is issued.
	Repeat alarm	Sounds the alarm tone again if the device is left for more than 2 minutes without canceling the alarm after the alarm tone is silenced.
	Standby	Temporarily disables No Action (low priority).
	Key-lock	Disables all key operations during infusion.
	KVO	After reaching the volume limit, perform infusion at the KVO flow rate to prevent blood clotting.
	Flow rate change during infusion	Allows the flow rate to be changed without stopping infusion.
	Bolus	Allows bolus injection during infusion.
	Maintenance timer	When the set period is reached, a screen prompting periodic maintenance is displayed.
	Automatic brightness switching	Automatically changes the display brightness according to the ambient brightness. (The display brightness reduces as the surroundings become darker.)
	Change syringe brand	Allows the syringe brand to be changed.

Special features	Changing second decimal place display	The second decimal place display can be changed for the flow rate.
	Operation history	Check the operation history (power ON / OFF, purging, start, stop, bolus, flow rate change, alarms). [Max. 800 items]
	Add purging volume setting	Sets the purging volume to add to the total volume.
	Forced priming	Sets whether or not to prevent infusion starting until purging is performed after mounting a syringe.
	Flow rate soft limit setting	Sets the flow rate soft limit for each syringe size (lower limit value to call attention to the set flow rate).
	Flow rate hard limit setting	Sets the flow rate hard limit for each syringe size (upper limit value of the set flow rate).
	Maintenance timer setting	Sets the number of days before the maintenance timer is issued.
	Syringe brand setting	Allows the syringe brand to be restricted.
	Flow rate soft/hard limit setting	1 ~ 150 mL/h (5mL syringe) 1 ~ 300 mL/h (10mL syringe) 1 ~ 400 mL/h (20mL syringe) 1 ~ 500 mL/h (30mL syringe) 1 ~ 1200 mL/h (50mL syringe, 1% Diprivan Injeciton-kit 20/50 mL) (0.1mL steps)
	Maintenance	The status of Lighting, Flow rate and Occlusion detection can be checked.
	Shock detection	Allows the date and time when a shock was detected to be checked and reset.
	User syringe registration	Registers a syringe that is not pre-registered in the device.
	External communication	Allows to monitor the operation history of the Device by USB cable.
Operating conditions	Ambient temperature : 5 to 40 ℃ (While charging the internal battery: 5-30℃) Relative humidity : 20 to 90 % (Noncondensing) Atmospheric pressure : 70 to 106 kPa	
Transportation and Storage condition	Ambient temperature : -10 to 45 ℃ Relative humidity : 10 to 90 % (Noncondensing) Atmospheric pressure : 50 to 106 kPa	
Service life	6 years (Based on self certification using TOP corporation data)	
Classification	Class II □ and Internally powered equipment, Type CF, IP34	
Detentions	360(W) x 110(H) x 135(D) mm	
Weight	Approx. 1.3 kg	
Accessories	AC power cable x1, Operation guide x1, Administrator Manual x1	
Material used	Case, Syringe plunger slider — ABS (Acrylonitrile Butadiene Styrene) Syringe plunger clamp, Syringe barrel clamp — POM (Polyacetal) resin Drive shaft — Stainless steel Syringe barrel detection switch — Silicone rubber Operation indicator — PC (Polycarbonate) resin Operation panel — Polyester film	
Options	Pole clamp, Infusino 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. GC8728721-54797

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: **GC8728721-54797**
Registration No.:

Tarikh Sah Pendaftaran: **01/02/2026 - 31/01/2031**
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: **GC8728721-54797**
Registration No.:

Tarikh Sah Pendaftaran: **01/02/2026 - 31/01/2031**
Registration Validity Date:

Butir-butir peranti perubatan yang didaftarkan

Particulars of the registered medical device

Nama Peranti Perubatan *Medical Device Name*	**SYRINGE PUMP**
Kelas *Class*	**CLASS C**
Jenama *Brand*	**TOP SYRINGE PUMP**
Kelompok *Group*	**SINGLE**
Produk Identifikasi *Product Identifier*	**TOP-S500**
Nama dan alamat pembuat: *Name and address of manufacturer*	**TOP CORPORATION** **19-10 SENJU NAKAI-CHO, ADACHI-KU, TOKYO, JAPAN, 120-0035** **JAPAN**

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.