THE TOP IN QUALITY
for all areas of healthcare

TOP SYRINGE PUMP TOP-5530/5530RS

On-site Clinical capabilities

A syringe pump with outstanding capabilities
and ease of use in the clinical setting,
whether on general ward or
when administering an anesthetic.

Specifications

Name	TOP Syringe Pump
Model	TOP-5530, TOP-5530RS
Power supply	AC power supply : 100 ~ 127 V±10 % 50/60 Hz (for 100 V area) 200 ~ 240 V±10 % 50/60 Hz (for 200 V area) DC power supply : 12 V±10 % (Type: ST55-4) Internal battery : DC 3.6 V 150 0mAh Ni-MH (Type: BP-55) Battery life is approx. 12hours. (At 5 mL/h set using a new battery is fully charged.) Alkaline battery : LR6 type, AA size alkaline battery DC6V x 4 pcs. Battery life is approx. 24hours. (At 5mL/h set using new batteries)
Input current	AC Power supply : 0.1 A (for 100V area), 0.05 A (for 200V area) DC power source : 0.4 A
Applicable Syringe	TOP, B.Braun, TERUMO, B-D, NIPRO, JMS and MONOJECT syringes, Plus one additional syringe registered by user per syringe size 10 mL, 20 mL, 30 mL and 50 mL, 1% Diprivan Injection-kit 20/50 mL
Flow rate range	mL/h (0.1 mL/h steps) 0.1 ~ 300.0 mL/h (10 mL syringe) 0.1 ~ 400.0 mL/h (20 mL syringe) 0.1 ~ 500.0 mL/h (30 mL syringe) 0.1 ~ 1200.0 mL/h (50 mL syringe, 1% Diprivan Injeciton-kit 20/50 mL)
Agent range	0.1 ~ 1000.0 mg
Solution range	0.1 ~ 1000.0 mL
Weight range	0.1 ~ 300.0 kg
KVO rate range	0.01 ~ 99.99 µg/kg/min 0.01 ~ 99.99 mg/kg/h 0.1 ~ 5.0 mL/h (0.1mL/h steps)
Bolus rate	300.0 mL/h (10 mL syringe) 400.0 mL/h (20 mL syringe) 500.0 mL/h (30 mL syringe) 1200.0 mL/h (50 mL syringe, 1% Diprivan Injeciton-kit 20/50 mL)
Bolus volume	mL : 0.1 ~ 50.0 mL (0.1 mL steps) µg : 0.1 ~ 50000.0 µg (0.1 µg steps) mg : 0.1 ~ 5000.0 mg (0.1 mg steps)
Purging	Approx. 330 mL/h (10 mL syringe) Approx. 620 mL/h (20 mL syringe) Approx. 740 mL/h (30 mL syringe) Approx. 1200 mL/h (50 mL syringe)
Volume limit setting	0.1 ~ 1000.0 mL
Total volume display range	0.0 ~ 1000.0 mL
Infusion accuracy	Mechanical accuracy : ± 1 % Accuracy including syringe : ± 3 %
Occlusion detection	4 steps selection High : 93± 33 kPa (700±250 mmHg / 0.95±0.34 kgf/cm2) Medium : 67± 27 kPa (500±200 mmHg / 0.68±0.27 kgf/cm2) Low : 40± 20 kPa (300±150 mmHg / 0.41±0.20 kgf/cm2) Very low : 20±10 kPa (150± 75 mmHg / 0.20±0.10 kgf/cm2) When using TOP Syringe (50 mL) for TOP syringe pump
Overload detection	Approx. 20N (2.0 kgf) or more (10 mL syringe) Approx. 40N (4.0 kgf) or more (20 mL syringe) Approx. 55N (5.5 kgf) or more (30 mL syringe) Approx. 80N (8.0 kgf) or more (50 mL syringe)
Alarm / Warning	High priority alarm: Occlusion, Overload, Infusion completion, Battery OFF, Power OFF, Power loss, Malfunction, Syringe barrel, Plunger clamp, Barrel flange, Volume limit completion Low priority alarm: Low volume, No battery, Low battery, Low alkaline battery, Operation reminder, No rate, No volume limit, No setting value, Sett value check, Prior to volume limit completion Information signal (Warning): Sensor check, Maintenance timer, Standby mode, Power supply switch, Hard limit, Soft limit, Bolus cancel
Special features	Power supply switched: The system has entered the build in battery operation mode when power is no longer supplied from the AC/DC power source. History: The system stores up to 600items of operation or operating-state data. ON/OFF selection: Limits selectable syringe brands or display/hide dose unit, volume limit

Functions	Auto Power OFF	During battery operation, when pump is left for 3minutes with infusion stopped or in alarm state, the buzzer sounds. When the buzzer has been left sounding for 3minutes, the power shuts off automatically.
	Reminder	Unless the cause of alarm is collected within 2 minutes after operator presses the Silence key, alarm will sound again to remind the operator of the problem.
	Power supply switch alarm	Alarm will should when AC power supply has stopped and the unit has switched over to battery operation.
	KVO function	After the volume limit is reached, infusion is performed at the set KVO rate for thrombus prevention.
	Standby function	Reminder alarm can be temporarily reset.
	Buzzer setting	Presence/Absence of wait tone and operation tone can be specified.
	History function	History of Infusion start/stop, alarm, change of flow rate while infusion is under way, power on/off ban be checked.
	Key lock function	During infusion, places the system is Key lock state. In Key lock state, all keys except the power, light and Silence keys are disabled.
	Syringe brand limit function	Selectable syringe brands can be limited.
	Volume limit display Switching function	Whether volume limit is displayed can be specified.
	Battery refresh function	Performs refresh operation in order to maintain the battery performance.
	Maintenance timer function	When the preset timing has been reached, a screen to prompt regular inspection is displayed.
	Flow rate upper limit value setting function	Flow rate upper limit value can be set.
	User syringe registration function	A syringe not registered to this machine can be registered.
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 : -20 to 45 ℃ Relative humidity : 10 to 95 % (Noncondensing) Atmospheric pressure : 50 to 106 kPa	
Service life	6years (Based on self certification using TOP corporation data)	
Classification	Class II ⊡ and Internally powered equipment, Type CF ♥, IPX2 (Drip proof)	
Fuse	T0.2AL (for 100 V area), T0.1AL (for 200 V area)	
Detentions	320(W) x 90(H) x 160(D) mm	
Weight	Approx. 2.0 kg	
Accessories	AC power cable x1 Operation guide x1, Administrator Manual x1	
Material used	Case: ABS (Acrylonitrile Butadiene Styrene) Syringe barrel clamp: Glass fiber-reinforced Polycarbonate (30%) Syringe plunger slider: Glass fiber-reinforced Polycarbonate (30%) Operation panel: Polyester film LED cover: Methyl methacrylate polymer	
Options	Pole clamp, Multiple pump mount, 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)]
Tel: +603-89240999 / Email: sales@meditop.com.my

Ref. No. 2022-01

"registered under Act 737" / MDA Reg. No. GC4581638216

No. Siri: 041038
Serial No.:

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: **GC4581638216**
Registration No.:

Tarikh Sah Pendaftaran: **14/07/2021 - 13/07/2026**
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

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.

AHMAD SHARIFF BIN HAMBALI
KETUA EKSEKUTIF
CHIEF EXECUTIVE
PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY

LAMPIRAN 1
Attachment 1

No. Pendaftaran: **GC4581638216**
Registration No.:

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

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

Kelas **CLASS C** Jenama **TOP**
Class *Brand*

Kelompok **FAMILY**
Group

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

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	TOP SYRINGE PUMP	TOP-5520RS	These are a micro-continuous infusion pump for parenteral nutrition and blood transfusion to immature infants and neonates, infusion of chemotherapeutic agents such as antineoplastic, oxytocic, anticoagulant, and anesthetic agents in the Intensive Care Unit / Critical Care Unit.
2	TOP SYRINGE PUMP	TOP-5530	These are a micro-continuous infusion pump for parenteral nutrition and blood transfusion to immature infants and neonates, infusion of chemotherapeutic agents such as antineoplastic, oxytocic, anticoagulant, and anesthetic agents in the Intensive Care Unit / Critical Care Unit.

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
3	TOP SYRINGE PUMP	TOP-5530RS	These are a micro-continuous infusion pump for parenteral nutrition and blood transfusion to immature infants and neonates, infusion of chemotherapeutic agents such as antineoplastic, oxytocic, anticoagulant, and anesthetic agents in the Intensive Care Unit / Critical Care Unit.
"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 untuk membuat lawatan atau pemeriksaan ke atas establismen pada bila-bila masa tanpa dimaklumkan terlebih dahulu.
The Authority reserves the right to conduct visit or 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 Pengiklanan peranti perubatan hendaklah tidak mengandungi apa-apa kenyataan yang boleh membawa maksud, sama ada secara langsung atau tidak langsung bahawa penggunaan peranti perubatan adalah dicadangkan, dipromosikan atau disahkan oleh Pihak Berkuasa atau mana-mana pihak yang berkaitan.
Advertising of medical device shall not contain any statement, whether directly or indirectly that the use of that medical device is suggested, promoted or endorsed by the Authority or another related party.

1.11 Tujuan yang diniatkan bagi peranti perubatan hendaklah dinyatakan dengan jelas dalam iklan produk, termasuk brosur, risalah dan lain-lain, dan tidak boleh merujuk kepada mana-mana 20 jenis penyakit yang tidak boleh diiklankan seperti yang tertakluk kepada Seksyen 3(1) Akta Ubat (Iklan Dan Penjualan) 1956.
Intended purpose of medical device shall be clearly stated in the advertisement of products, including brochures, pamphlets, and etc., and shall not refer to any 20 types of diseases that cannot be advertised as prescribed in Section 3 (1) of the Medicines (Advertisement and Sale) Act 1956.

1.12 Ia adalah menjadi tanggungjawab Establishmen untuk memastikan peranti perubatan mematuhi mana-mana keperluan undang-undang lain yang berkaitan. Sijil ini tidak mengecualikan mana-mana keperluan peraturan yang terpakai untuk peranti perubatan tersebut. (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.)
It is the responsibility of the Establishment to ensure that medical device complies with any other requirements of the law. This certificate does not exclude any regulatory requirements applicable to 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) .

1.13 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.

1.14 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 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.

4.0 HAK PIHAK BERKUASA
THE AUTHORITY OWNERSHIP

4.1 Sijil Pendaftaran Peranti Perubatan yang dikeluarkan secara manual atau elektronik 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 conditions.