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TEST REPORT

Test Report No: RZ12030011

Test object: Syringe Pump

Manufacturer: Sino Medical-Device Technology Co., Ltd.

Applicant: Sino Medical-Device Technology Co., Ltd.

Test Type: Registration ( )

Registered Supplement ( )

Others (√) Certification Test

Digitally signed by Maxim Victor
Date: 2021.06.26 11:57:47 EEST
Reason: MoldSign Signature
Location: Moldova

Guangzhou Medical Instruments Quality Surveillance and Inspection Center of State Food and Drug Administration

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6. If any objection occurs, it should be submitted in written way to the test organization in 15 days from the day that this test report had been received.
7. This test report is responsible for the test samples only.

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Guangzhou Medical Instruments Quality Surveillance and Inspection Center of State Food and Drug Administration

Initial Page of Test Report

Name of Samples	Syringe Pump Send-off (√) Spot check ( )	Samples' Serial №	RZ12030011
Trademark	SINO MDT	Model / Type	SN-50T66R
Client	Sino Medical-Device Technology Co., Ltd.	Test Type	Certification Test
Client's Address	6th Floor, Building15, Majialong Industry Zone, Nanshan District, Shenzhen, P.R.China	Products' № / Lot №	/
Manufacturer	Sino Medical-Device Technology Co., Ltd.	Sampling Bill №	/
Corporation ing inspected	Sino Medical-Device Technology Co., Ltd.	Producing date	/
Sampled by	/	Samples' Quantity	1 set
ampled Place	/	Cardinal Number of Samples	/
ampled Date	/	Test Place	Self-laboratory
Samples' ccepting Date	2012.04.25	Test Date	2012.04.25~2012.08.13
Test Items	The whole items(with the exception of electromagnetic compatibility)		
st According to	IEC 60601-2-24:1998		
Test Conclusion	All the test items of this product are in accordance with the requirements of IEC 60601-2-24:1998. Conclusion: Pass. (Stamps of Test Organization) Issued Date: YY MM DD		
Remarks	1. / means blank. 2.By information and sample inspecting, the models SN-50F66、SN-50F66R、SN-50T66、SN-50C66、SN-50C66R、SN-50C66T、SN-50C66TR and SN-50T66R are in accord in principle, structure of circuit, they differ only in appearance and some auxiliary functions. So the model SN-50T66R can cover the models SN-50F66、SN-50F66R、SN-50T66、SN-50C66、SN-50C66R、SN-50C66T、SN-50C66TR.		

pproved by: Reviewed by: Tested by:

eadship:

GENERAL INFORMATION	
Test item particulars (see also clause 5):	
Classification of installation and use ..... :	Portable
Supply connection .....:	Detachable power supply cord Internally powered
Accessories and detachables parts included in the evaluation .....:	User Manual
Options included .....:	User Manual
Possible test case verdicts:	
- test case does not apply to the test object .....:N / A	
- test object does meet the requirement.....:P	
- test object does not meet the requirement .....:F	
Abbreviations used in the report:	
- normal condition.....:N.C.	- single fault condition .....:S.F.C.
- operational insulation .....:OP	- basic insulation .....:BI
- basic insulation between parts of opposite polarity .:BOP	- supplementary insulation.....:SI
- double insulation .....:DI	- reinforced insulation.....:RI

General remarks:

"(see Attachment #)" refers to additional information appended to the report.
"(see appended table)" refers to a table appended to the report.
Throughout this report a point is used as the decimal separator.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Summary of contents provided on the last page of this report.

General product information and considerations:

Syringe pump is a drug-injection equipment, which is intended for applications requiring accurate administration dosage, stable flow rate, low dose rate or long-time constant dose rate. The syringe pump is widely used in injection treatment of diseases, such as for children, patients with heart disease, chemotherapy of cancer, treatment in ICU, patients with diabetes, and so on.

Exclusions:

Clauses 36(EMC) was not part of the Manufacturers order and this testing.

Clause 52.1 with appliance of IEC60601-1-4 was excluded from testing.

IEC 60601-2-24：1998			
Clause	Requirement – Test	Result	Verdict
6	**IDENTIFICATION, MARKING AND DOCUMENTS**		
6.1	MARKING ON OUTSIDE OF EQUIPMENT OR EQUIPMENT PARTS		P
	aa) For detachable liquid reservoirs or PATIENT LINE(S) of specific sizes or brands, or containing specific concentrations of drugs to be used to maintain safe NORMAL USE of the EQUIPMENT, the relevant markings are fixed on the EQUIPMENT		N/A
	q) Symbol for physiological effect(s):		P
	- The body of the EQUIPMENT marked with the symbol No. 14 of appendix D of the General Standard or a statement to refer the OPERATOR to the ACCOMPANYING DOCUMENTS	⚠	P
	- An arrow or other appropriate symbol indicating the correct direction of flow marked on the EQUIPMENT if the ADMINISTRATION SET can be incorrectly loaded		P
	- EQUIPMENT as defined in 2.103 and 2.106 marked: "Caution: this equipment controls the drip rate not the volume delivered."		N/A
6.1.201	Sub-clause 6.1.201 of the Collateral Standard, IEC 60601-1-2 checked by inspection	Not evaluated in this report	/
6.8	ACCOMPANYING DOCUMENTS		P
6.8.2	Instructions For Use include the required information		P
	1) A list of the recommended ADMINISTRATION SET(S) to be used		P
	2) A warning of the consequences of the use of unsuitable ADMINISTRATION SET(S)		P
	3) A list of particular ACCESSORIES recommended by the manufacturer for use with the EQUIPMENT		P
	4) Permitted EQUIPMENT orientation and methods and precautions concerning this mounting, for example, stability on a pole		P

IEC 60601-2-24：1998			
Clause	Requirement – Test	Result	Verdict
	5) Instructions regarding loading, priming, changing and reloading THE ADMINISTRATION SET(S), and the ADMINISTRATION SET CHANGE INTERVAL to maintain the specified performance		P
	6) Instructions regarding the use of clamps on an ADMINISTRATION SET, the avoidance of FREE FLOW conditions and the procedure to be followed when changing liquid containers		N/A
	7) Where gravity is relevant to performance, the acceptable height range of the liquid container above the PATIENT'S heart		N/A
	8) The means provided to protect the PATIENT from air infusion		P
	9) The MAXIMUM INFUSION PRESSURE generated and the OCCLUSION ALARM THRESHOLD/ PRESSURE(S) of the EQUIPMENT		P
	10) The maximum time for activation of the occlusion alarm when EQUIPMENT is operating at the MINIMUM RATE, the INTERMEDIATE RATE and at the min./max. selectable OCCLUSION ALARM THRESHOLD/ PRESSURE(S)		P
	11) The BOLUS volume generated as a result of the EQUIPMENT operating at the INTERMEDIATE RATE and reaching the minimum and maximum OCCLUSION ALARM THRESHOLD/ PRESSURE(S)		P
	12) The means provided (if any) to manage the BOLUS before occlusion release		P
	13) A statement to indicate to the OPERATOR if the EQUIPMENT cannot be used as PORTABLE EQUIPMENT		N/A
	14) Precautions required with drop detectors, with respect to placement, cleanliness, liquid level, ambient light and others		N/A
	15) Recommendations on any specific method of cleaning and maintaining the EQUIPMENT		P

IEC 60601-2-24：1998			
Clause	Requirement – Test	Result	Verdict
	16) The typical operating time when the EQUIPMENT is operating from the INTERNAL ELECTRICAL POWER SOURCE at INTERMEDIATE RATE		P
	17) A statement of KEEP OPEN RATE(S), and when initiated		P
	18) A list of alarms and their operating conditions		P
	19) A warning that the specified accuracy may not be maintained under certain circumstances		P
	20) Reference to a guide on the SAFETY HAZARDS associated with the interconnection of other infusion systems or ACCESSORIES to the PATIENT LINE		P
	21) The rate obtained when the prime/purge or BOLUS control is operated, and a statement of any alarm disabled		P
	22) A warning on the possible SAFETY HAZARDS associated with external radio-frequency interference (RFI) or electromagnetic radiation which may affect safe operation of EQUIPMENT		P
	23) The selectable rate range and the increments of selection		P
	24) Guidance on tests to permit the OPERATOR to check the correct functioning of alarm(s) and the operational safety of the EQUIPMENT		P
	25) Data as evaluated by the test methods of 50.101 to 50.108 at the rates indicated in Table 102, including an explanation for the OPERATOR of the data presentation		P
	26) The time for which the electronic memory is retained following switch-off		N/A
	27) For SPECIAL USE EQUIPMENT, the conversion factor(s) for volume divided by unit of time		N/A
	28) The maximum volume that may be infused under SINGLE FAULT CONDITIONS		P

IEC 60601-2-24：1998			
Clause	Requirement – Test	Result	Verdict
	29) Guidance on the safe operation of the EQUIPMENT if it is connected operationally to a REMOTE CONTROL DEVICE		N/A
	30) Information concerning type(s) of battery to be used and where available		N/A
	31) A statement of the meaning of claimed IP-classification		P
6.8.3	TECHNICAL DESCRIPTION		P
	aa) Information on the sensitivity of the air detector, if included to comply with 51.9, over the specified range of rates for a single bubble		N/A
	bb) The units of measurement used for calibration of the EQUIPMENT		P
	cc) A description of any battery charging system		P
	dd) A functional description of the means provided to protect the PATIENT from EQUIPMENT error resulting in over-infusion and, where applicable, in under-infusion		P
	ee) Manufacturer's disclosure about the ADMINISTRATION SET(S) used for all the tests		P
10	ENVIRONMENTAL CONDITIONS		
10.2.1a	Ambient temperature between +5 °C and +40 °C		P
10.2.1b	A relative humidity between 20% and 90%		P
14	REQUIREMENTS RELATED TO CLASSIFICATION		
14.6b	EQUIPMENT is of Type BF or CF	Type CF	P
14.6d	EQUIPMENT intended for DIRECT CARDIAC APPLICATION having one or more APPLIED PARTS of TYPE CF may have one or more additional APPLIED PARTS of TYPE BF which may be applied simultaneously if the requirements of 6.1 l) and 19.3 for such EQUIPMENT have been met		N/A

IEC 60601-2-24：1998			
Clause	Requirement – Test	Result	Verdict
19	CONTINUOUS LEAKAGE CURRENTS AND PATIENT AUXILIARY CURRENTS		
19.4d	3) Measurement of the PATIENT LEAKAGE CURRENT made from the APPLIED PART with the PATIENT LINE filled with saline solution (0.9% NaCl) and with the PATIENT connection immersed in saline solution (0.9% NaCl)		P
21	MECHANICAL STRENGTH		
21.1	PORTABLE EQUIPMENT does not present a SAFETY HAZARD to the PATIENT as a result of external vibration		P
	Vibration Test		P
21.4	Remote parts including MAINS OPERATED adapters and parts not specified in 21.5 present no SAFETY HAZARD as a result of a free fall from a height of 1 m onto a hard surface		N/A
	- subsequent to the fall when the EQUIPMENT is turned on for use it ceases delivery and activates an alarm		N/A
	- subsequent to the fall, when the EQUIPMENT is turned on for use, it functions normally		N/A
	DIELECTRIC STRENGTH and LEAKAGE CURRENT Tests after the Free Fall Test		N/A
	FUNCTIONAL TESTES at the INTERMEDIATE RATE after the Free Fall Test		N/A
21.6	INFUSION PUMPS FOR AMBULATORY USE do not present a SAFETY HAZARD as a result of a free fall from a height of 1 m onto a hard surface		N/A
36	ELECTROMAGNETIC COMPATIBILITY		
	Equipment complies with IEC 601-1-2 except as specified in this standard	Not evaluated in this report	/
36.202	IMMUNITY		/

IEC 60601-2-24：1998			
Clause	Requirement – Test	Result	Verdict
	The safe functioning of the EQUIPMENT not impaired by any of the immunity tests or the EQUIPMENT fails as a result of these tests but without creating a SAFETY HAZARD	Not evaluated in this report	/
	The (non-hazardous) failure mode and the failure level to worst case per manufacturer's specification	Not evaluated in this report	/
36.202.1	ELECTROSTATIC DISCHARGE		/
	A level of 8 kV applies for contact discharge and a level of 15 kV applies for air discharge	Not evaluated in this report	/
36.202.2	RADIATED RADIO FREQUENCY ELECTROMAGNETIC FIELD		/
36.202.2.1	a) The applicable level is 10 V/m.	Not evaluated in this report	/
36.202.6	Magnetic Fields Level: 400 A/m	Not evaluated in this report	/
44	OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION AND DISINFECTION		
44.3	In the event of spillage (accidental wetting) no liquid is retained within the ENCLOSURE and the EQUIPMENT either continues to function normally or ceases delivery and activates an alarm		N/A
	Spillage Test according to this standard (if an IPX1-classification or better is not claimed)		N/A
44.4	Liquid which might leak from containers, tubing, couplings does not impair the safe functioning of the equipment nor wet uninsulated live parts or electrical insulation which is liable to be adversely affected by such a liquid.		P
	Pipette Drip Test	See appended Table 44	P
44.6	Ingress of Liquids Test (if an IPX1-classification is claimed) carried out with the equipment in the carrying pouch if the pouch is specified by the manufacturer as forming part of the protection against ingress of liquids		N/A

IEC 60601-2-24：1998			
Clause	Requirement – Test	Result	Verdict
49	INTERRUPTION OF THE POWER SUPPLY		
49.2	equipment powered from the supply mains gives an audible alarm in the event of an accidental disconnection or a supply mains failure		N/A
	The audible alarm maintained for at least 3 min or until power is restored		N/A
	EQUIPMENT which utilizes an INTERNAL ELECTRICAL POWER SOURCE either as a primary or standby supply gives a continuous visible and an intermittent audible warning 30 min before delivery ceases due to battery exhaustion	＞30 min	P
	At least 3 min before the end of the battery life the EQUIPMENT gives an audible and visible alarm and ceases delivery	＞3 min	P
	The alarm is maintained for the duration of the remaining battery lifetime		P
50	ACCURACY OF OPERATING DATA		
50.101	The equipment maintains the manufacturer's stated accuracy or better over the recommended administration set change interval		P
50.102	Accuracy tests for volumetric infusion controllers, volumetric infusion pumps and syringe pumps	See appended Table 50.102	P
50.103	Accuracy testes for drip-rate infusion controllers and drip-rate infusion pumps	Not such devices	N/A
50.104	Accuracy tests for infusion pumps for ambulatory use type 1	Not such devices	N/A

IEC 60601-2-24：1998			
Clause	Requirement – Test	Result	Verdict
50.105	Accuracy tests for infusion pumps for ambulatory use type 2	Not such devices	N/A
50.106	Accuracy tests for pumps type 3	Not such devices	N/A
50.107	Accuracy tests for pumps type 4	Not such devices	N/A
50.108	Accuracy tests for pumps type 5	Not such devices	N/A
51	PROTECTION AGAINST HAZARDOUS OUTPUT		
51.5	INCORRECT OUTPUT		P
	a) Means are provided to prevent over-infusion under SINGLE FAULT CONDITIONS		P
	An audible alarm is initiated in the event of over-infusion and the EQUIPMENT ceases delivery of infusion liquid or reduces the delivery rate to the KEEP OPEN RATE or less		P
	b) Means are provided to protect the patient from over-infusion as a result of free flow conditions		P
	Free Flow Condition Tests		P
51.101a	The equipment does not produce a maximum infusion pressure capable of causing a rupture or a leak in the administration set		P
51.101b	Means are provided to protect the patient from bolus and under-infusion resulting from occlusion following activation of the occlusion alarm		P
	Test to determine the occlusion alarm threshold (pressure) and bolus volumes - (conducted only on infusion pumps, volumetric infusion pumps, drip-rate infusion pumps, special use equipment and syringe pumps)		P
	Test results in accordance with the requirements of sub-clauses 51.5a and 51.5b		P

IEC 60601-2-24：1998			
Clause	Requirement – Test	Result	Verdict
	Test to determine the occlusion alarm threshold (pressure) and bolus volumes – (conducted only on infusion pumps for ambulatory use)		P
	Test results in accordance with the requirements of sub-clauses 51.101a and 51.101b		P
51.102	During normal use and/or single fault condition of the equipment, continuous reverse delivery, which may cause a safety hazard is not possible		P
51.103	Safe operation of the equipment is not affected by the mispositioning or removal of a drop sensor		N/A
	Safe operation of the EQUIPMENT is not affected by operating the EQUIPMENT with a tilted, removed or incorrectly positioned or filled drip chamber		N/A
	Under these conditions the EQUIPMENT either maintains the accuracy of delivery, or stops the flow and generates an audible alarm		N/A
51.104	The EQUIPMENT protects the PATIENT from air infusion which may cause a SAFETY HAZARD due to air embolism		N/A
	After the initiation of an air detection alarm it is not be possible to start again liquid delivery by a single action		N/A
51.105	Automatic means are provided or manual action(s) are necessary to prevent incorrect output in case of the use of a range of ADMINISTRATION SETS with different operational characteristics		P
51.106	Audible and visual alarms (except for INFUSION PUMPS FOR AMBULATORY USE)		P
	The alarms required by this Particular Standard are so arranged that an audible alarm occurs in all alarm situations		P

IEC 60601-2-24：1998			
Clause	Requirement – Test	Result	Verdict
51.107	a) The audible alarm is able to produce a sound-pressure level (if adjustable a maximum level) of at least 65 dB(A) at 1 m and it cannot be externally adjusted by the OPERATOR below 45 dB(A) at 1 m	66dB(A) not adjustable	P
	b) The audible alarm silence period of the EQUIPMENT in stand-alone operation does not exceed 2 minutes	2min	P
	c) The visual alarm continues to operate during the audible alarm silence period		P
	d) Means are provided to enable the OPERATOR to check the operation of audible/visual alarms		P
	- A-Weighted Sound Pressure Level Measurement Test (measured dB(A) at 1 m) :		P
51.108	INFUSION PUMPS FOR AMBULATORY USE include an alarm that occurs if the EQUIPMENT is switched to a standby mode for more than 1 h		N/A
51.109	Alarms required by Sub-clauses 51.108, 51.110 and 49.2 comply with this standard		P
	-the audible alarm produces a sound pressure level of at least 50 dB(A) at 1 m	66 dB(A)	P
	- the audible alarm is not adjustable without either the use of a TOOL or by special means (e.g. pressing a sequence of switches)		P
	- means are provided to enable the OPERATOR to check the operation of the alarms		P
	- A-Weighted Sound Pressure Level Measurement Test (measured dB(A) at 1 m)		P
51.110	Audible means are provided to indicate to the OPERATOR the end of infusion (except for INFUSION PUMPS FOR AMBULATORY USE)		P
51.111	An audible warning is provided prior to the end of the infusion alarm for SYRINGE PUMPS		P

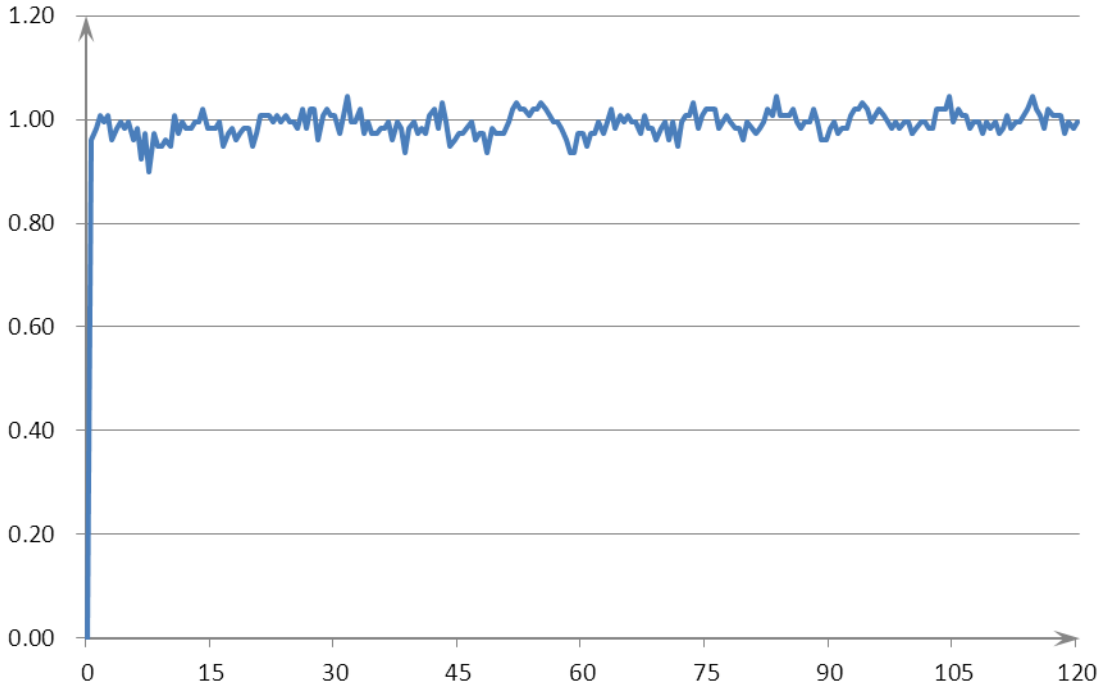
IEC 60601-2-24：1998			
Clause	Requirement – Test	Result	Verdict
54	CONSTRUCTIONAL REQUIREMENTS		
54.3	INADVERTENT CHANGING OF SETTINGS		P
	Means provided to prevent accidental or unintended changes in rate settings		P
	Manual means for priming/purging do not initiate priming/purging through a single action by the OPERATOR		P
54.101	FITTING OF THE SYRINGE		N/A
	Means provided to ensure correct clamping and location of a syringe barrel and plunger in the SYRINGE PUMP		N/A
	In the event of incorrect location of the plunger the SYRINGE PUMP does not start		N/A
	Means provided to prevent siphoning under SINGLE FAULT CONDITIONS		N/A
	An alarm is activated when removing the SYRINGE while the SYRINGE PUMP is running		N/A
	EQUIPMENT is so designed that no SAFETY HAZARD to the PATIENT can occur due to pulling force on the PATIENT LINE		N/A
54.102	FITTING OF THE ADMINISTRATION SET		N/A
	Means are provided to ensure correct fitting of the ADMINISTRATION SET into the EQUIPMENT		N/A
	An alarm is activated, if an attempt is made to remove the ADMINISTRATION SET while the pump is running		N/A
	EQUIPMENT is so designed that no SAFETY HAZARD to the PATIENT can occur due to pulling force on the PATIENT LINE		N/A
54.103	HUMAN ERRORS		P
	At least two distinctive and separate actions are required before FREE FLOW can occur in NORMAL USE		P

IEC 60601-2-24：1998			
Clause	Requirement – Test	Result	Verdict
	The first action stops the flow and initiates an audible alarm (except for SYRINGE PUMPS and INFUSION PUMPS FOR AMBULATORY USE with syringes)		P
54.104	EQUIPMENT is so designed that, if it is accidentally switched off and then switched on again by means of a functional control, the safety of the PATIENT is maintained		P
56	COMPONENTS AND GENERAL ASSEMBLY		
56.8	INDICATORS		P
	An indicator lamp or means other than marking provided to indicate that the SUPPLY MAINS is on		P

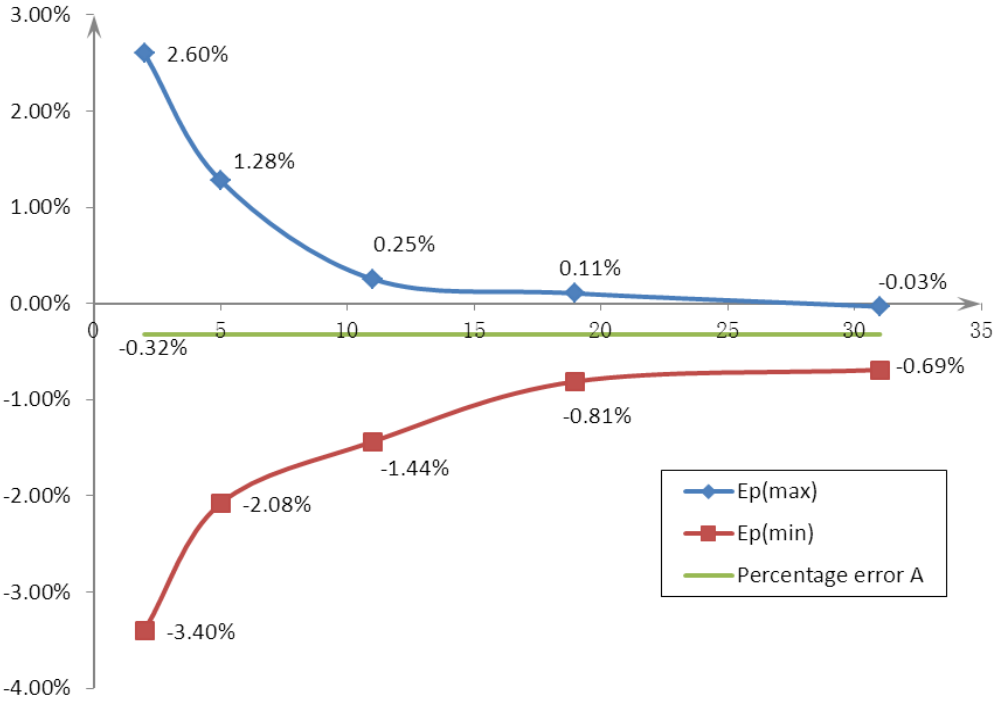
44	TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, desinfection	P

Test type and condition	Part under test	Remarks
Leakage test Humidity preconditioning Cleaning	The whole device	No damage

50.102	TABLE: Accuracy tests for VOLUMETRIC INFUSION CONTROLLERS, VOLUMETRIC INFUSION PUMPS and SYRINGE PUMPS (Fig. 104a and 104b)			P
Set rates..... :	Minimum: 1ml/h		Intermediate: 5ml/h	—
Bolus ..... :	Minimum: N/A		Maximum: N/A	—
Sample interval	S (minutes) = 30			—
Test period (T)	T (minutes) = 120			—
Analysis period (min)	Calculated flow rate Q_I (ml/h)	Calculated overall mean percentage flow error A (%)	Calculated overall mean percentage flow error B (%)	Remarks
60	1	-1.08%～1.20%	N/A	P
60	25	-1.71%～1.80%	N/A	P
Supplementary information: ±5%				

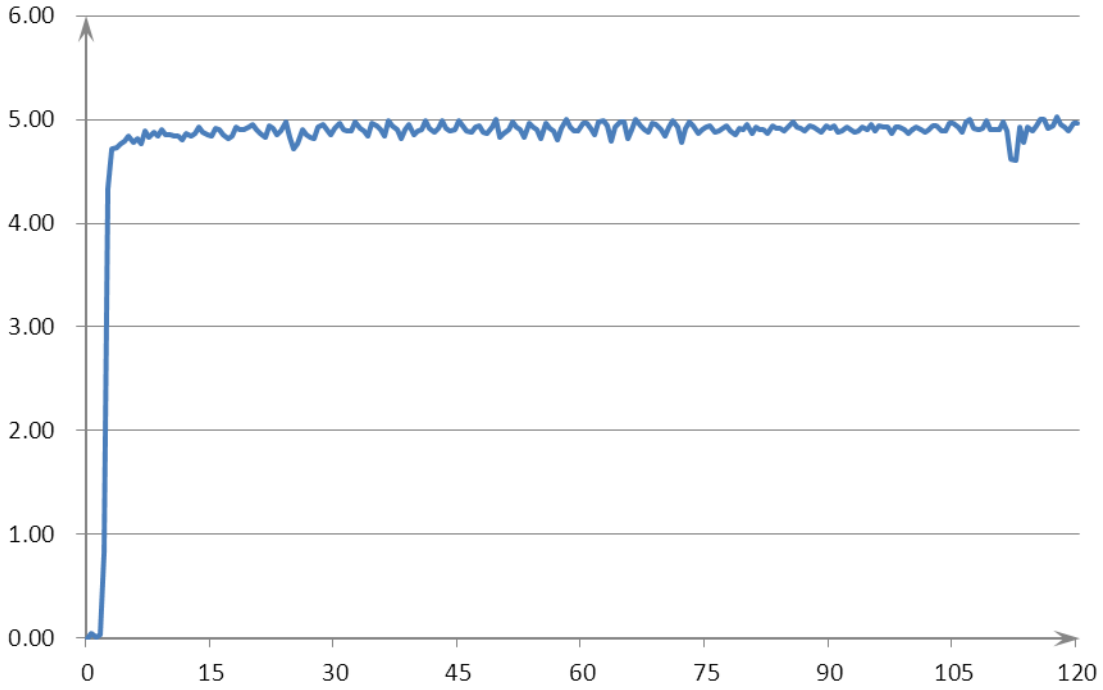


Graph 1 Start-up graph: Flow Q_I (ml/h)against time (min) plotted from data gathered during the first 2 h of the test period（Minimum）（10ml syringe）

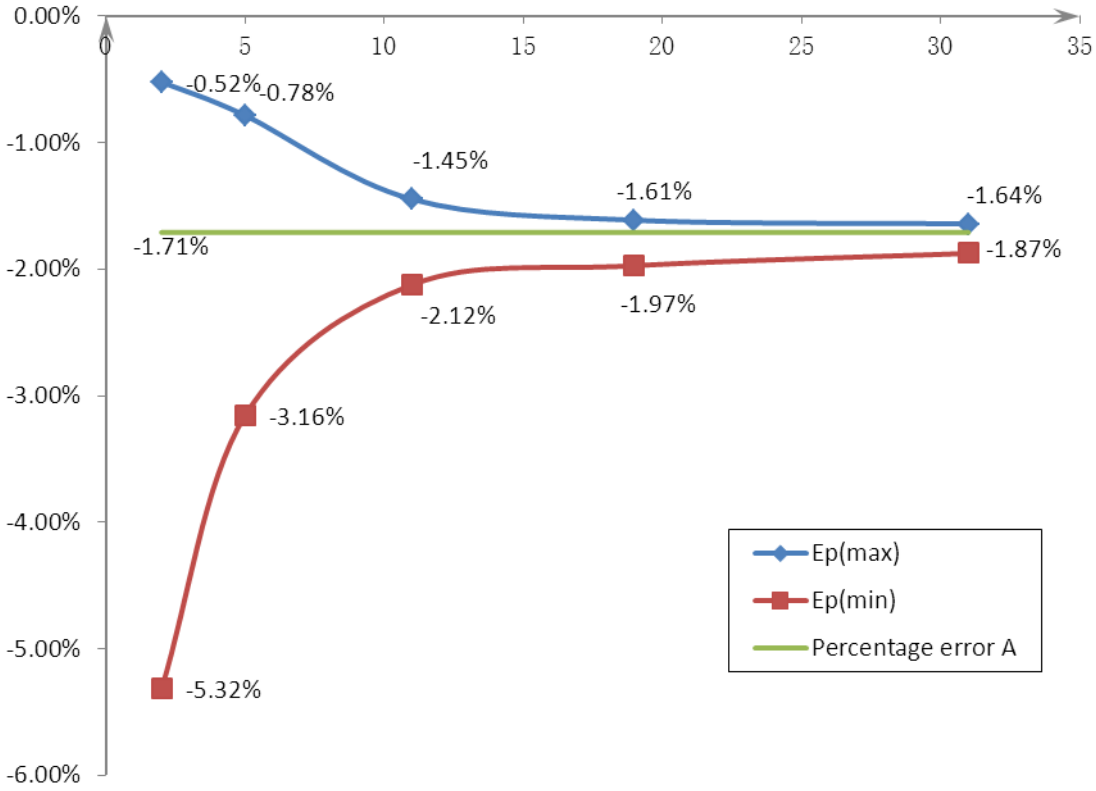


Graph 2 Trumpet curve: Percentage variation E_p against observation window duration P (min) and the

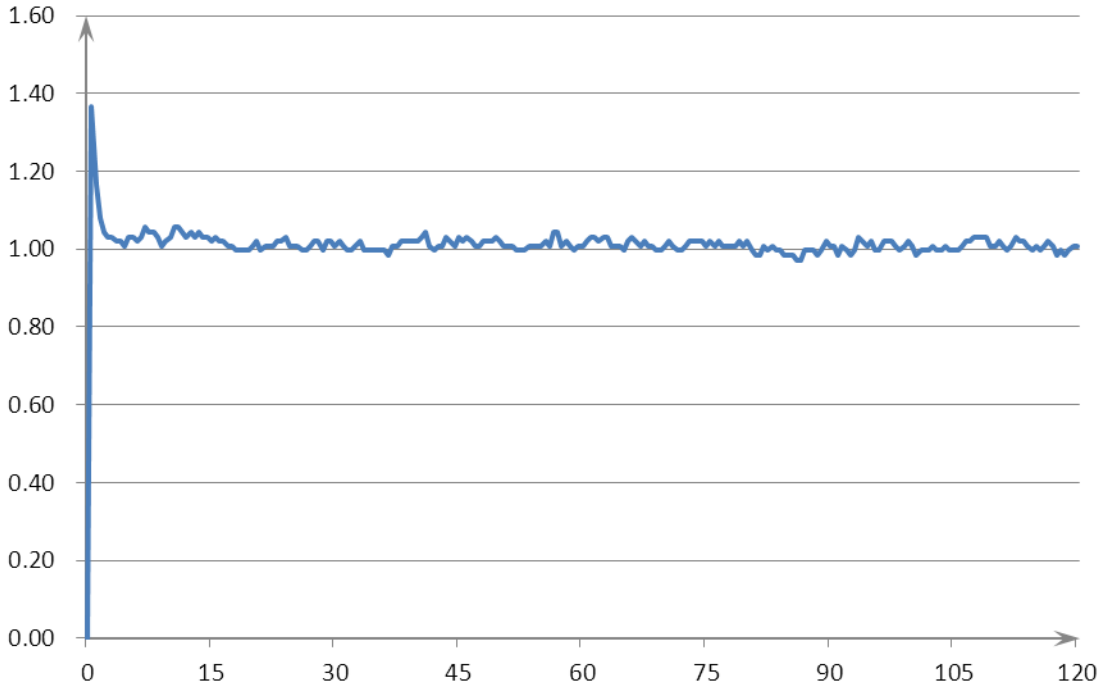
overall mean percentage error A plotted from data gathered during the second hour of the test period （Minimum）（10ml syringe）



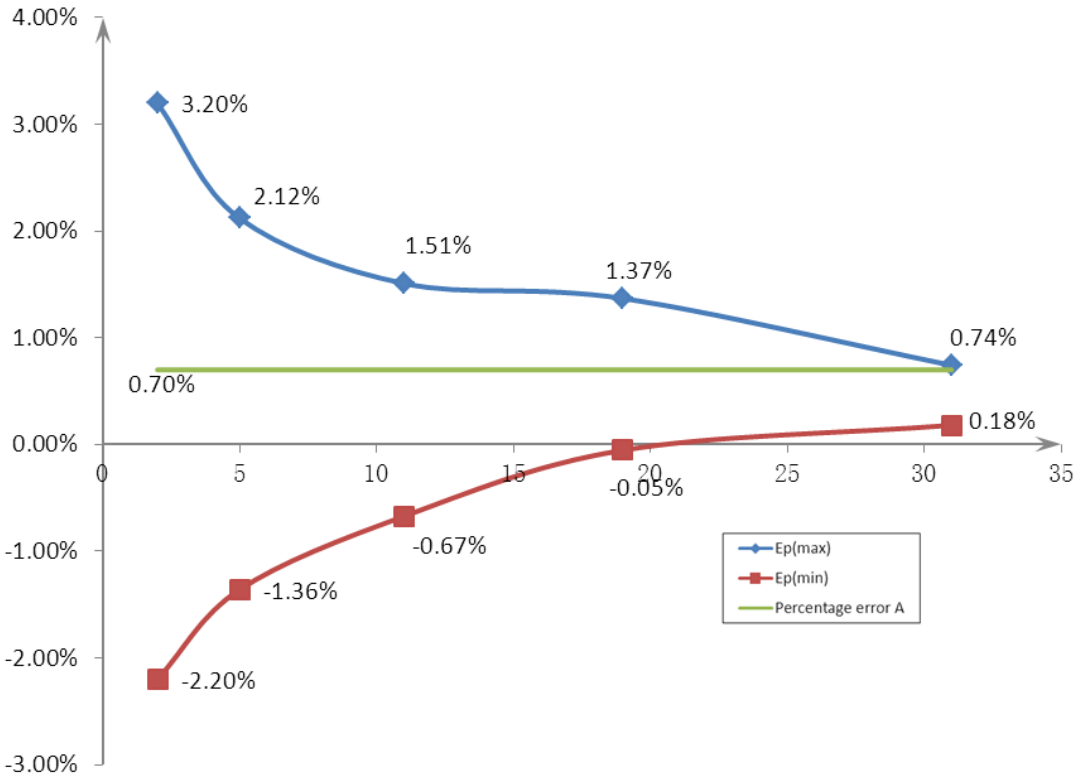
Graph3 Start-up graph: Flow Q_I (ml/h)against time (min) plotted from data gathered during the first 2 h of the test period（Intermediate）（10ml syringe）



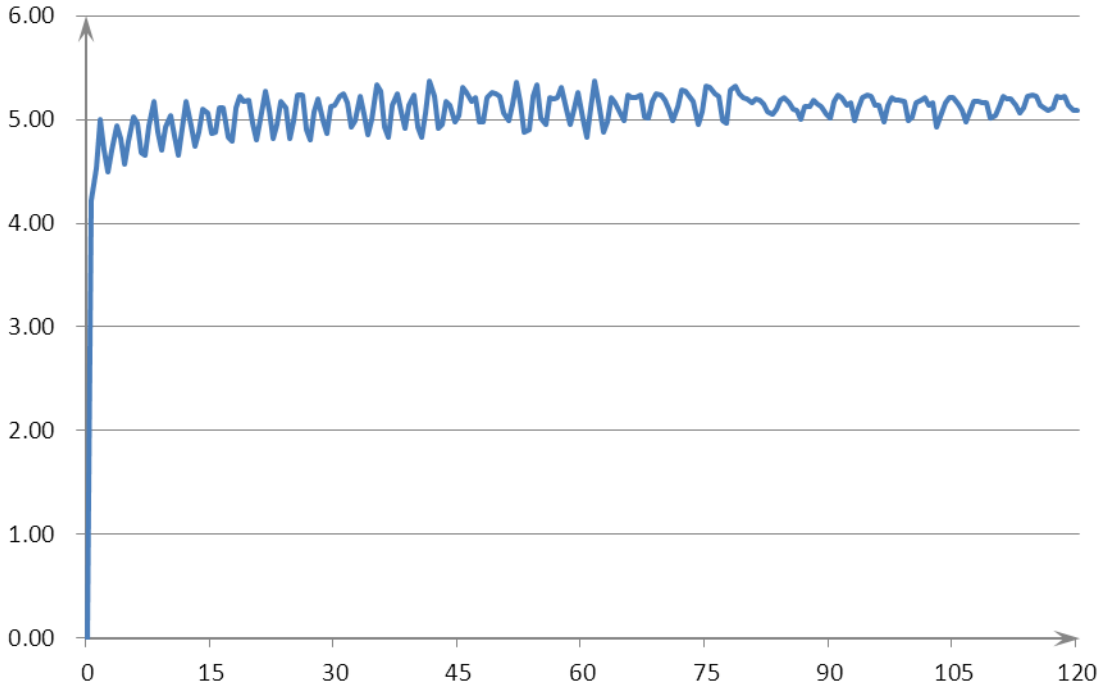
Graph 4 Trumpet curve: Percentage variation E_p against observation window duration P (min) and the overall mean percentage error A plotted from data gathered during the second hour of the test period （Intermediate）（10ml syringe）



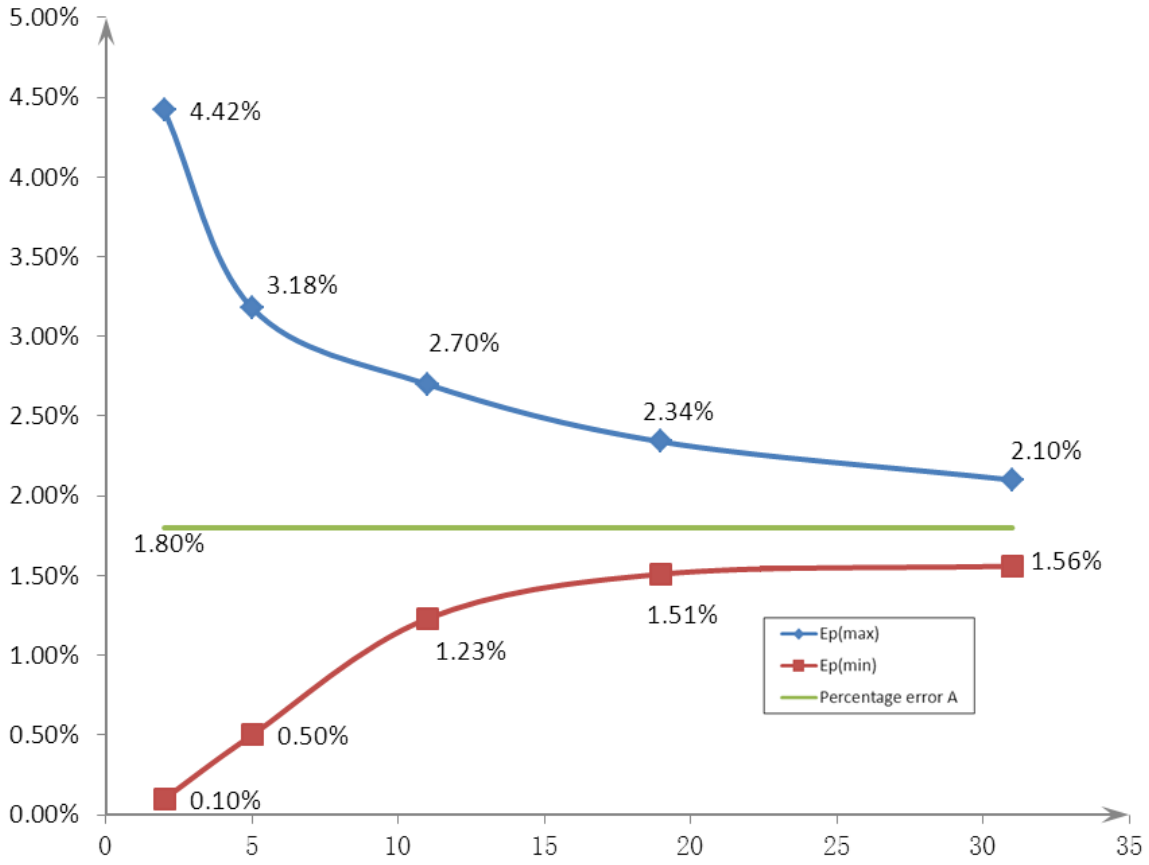
Graph 5 Start-up graph: Flow Q_I (ml/h)against time (min) plotted from data gathered during the first 2 h of the test period（Minimum）(20ml syringe)



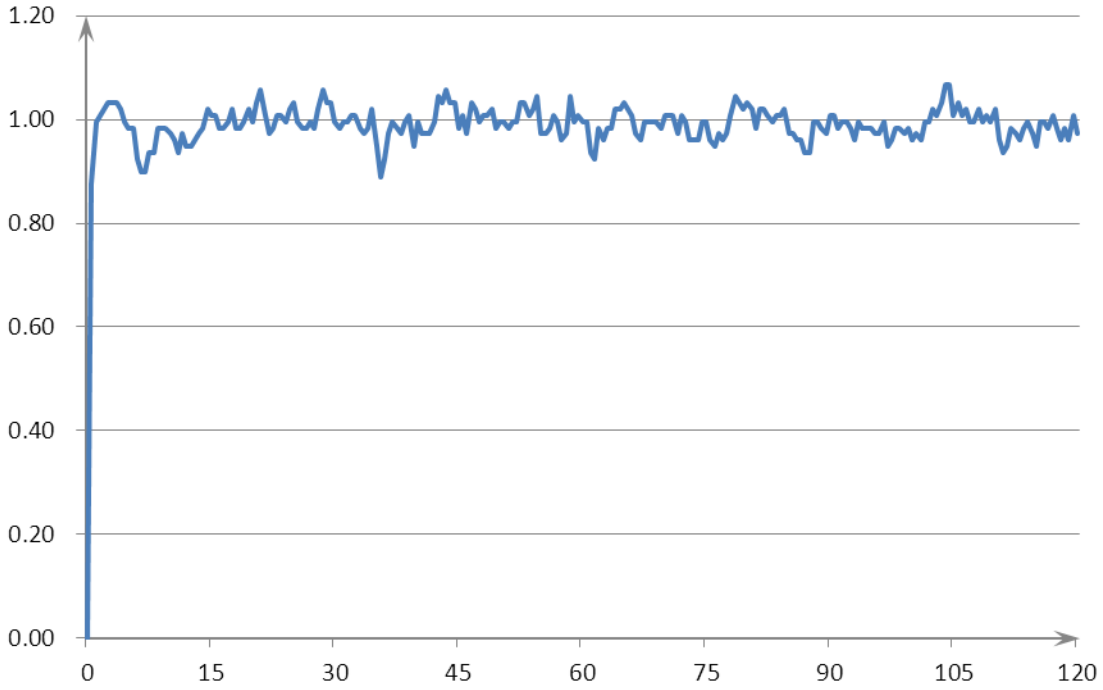
Graph 6 Trumpet curve: Percentage variation E_p against observation window duration P (min) and the overall mean percentage error A plotted from data gathered during the second hour of the test period （Minimum）（20ml syringe）



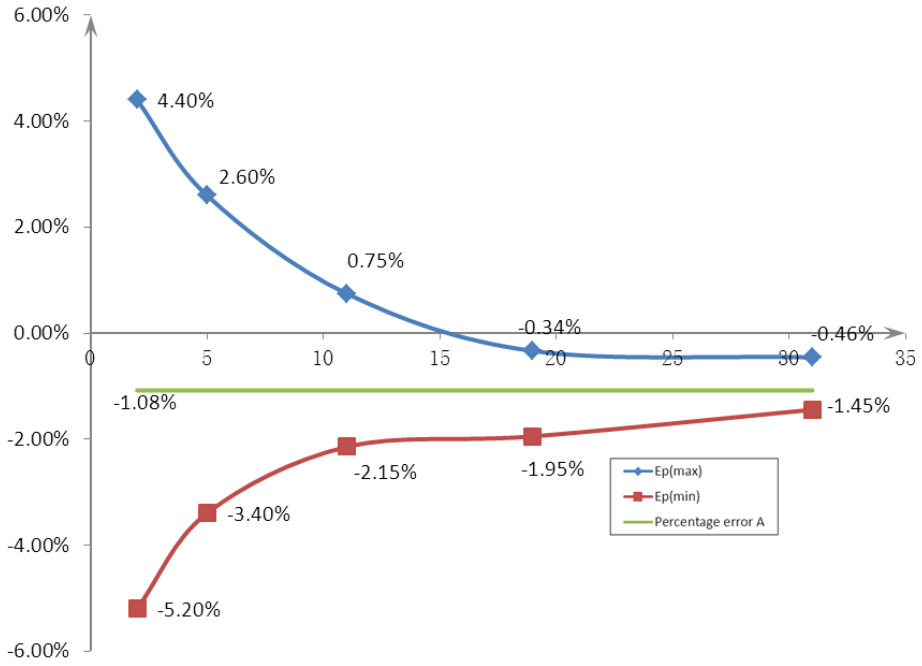
Graph 7 Start-up graph: Flow Q_I (ml/h)against time (min) plotted from data gathered during the first 2 h of the test period（Intermediate）（20ml syringe）



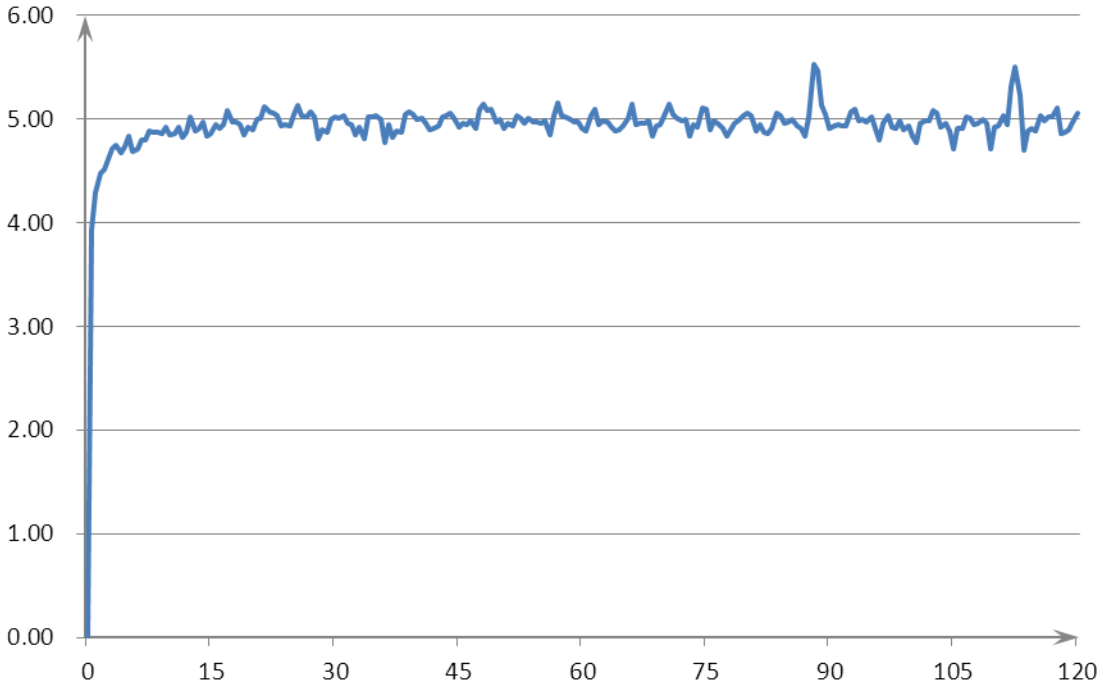
Graph 8 Trumpet curve: Percentage variation E_p against observation window duration P (min) and the overall mean percentage error A plotted from data gathered during the second hour of the test period （Intermediate）（20ml syringe）



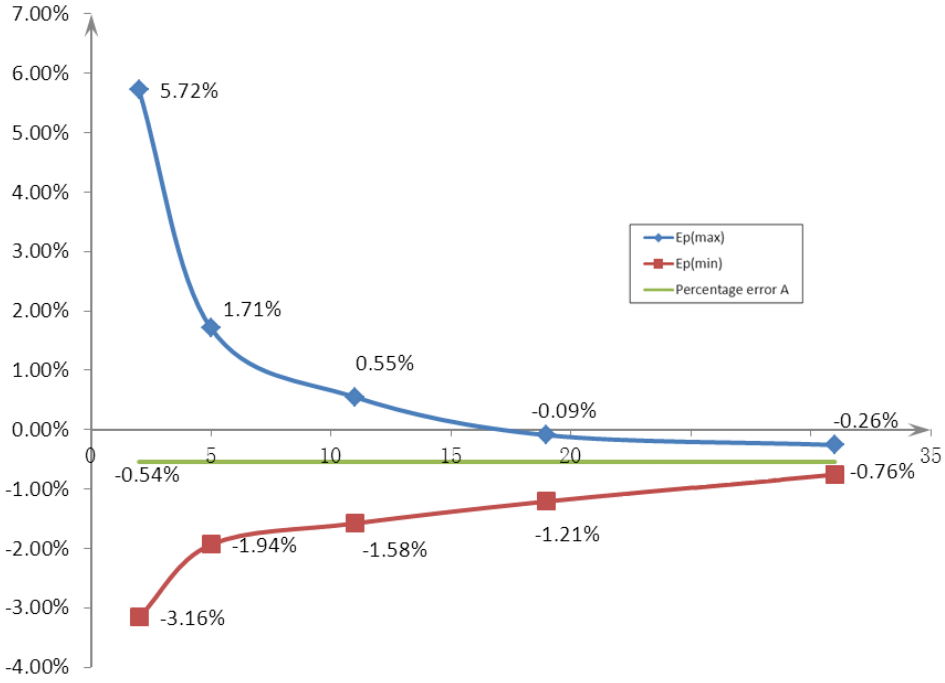
Graph 9 Start-up graph: Flow Q_I (ml/h)against time (min) plotted from data gathered during the first 2 h of the test period （Minimum）（30ml syringe）



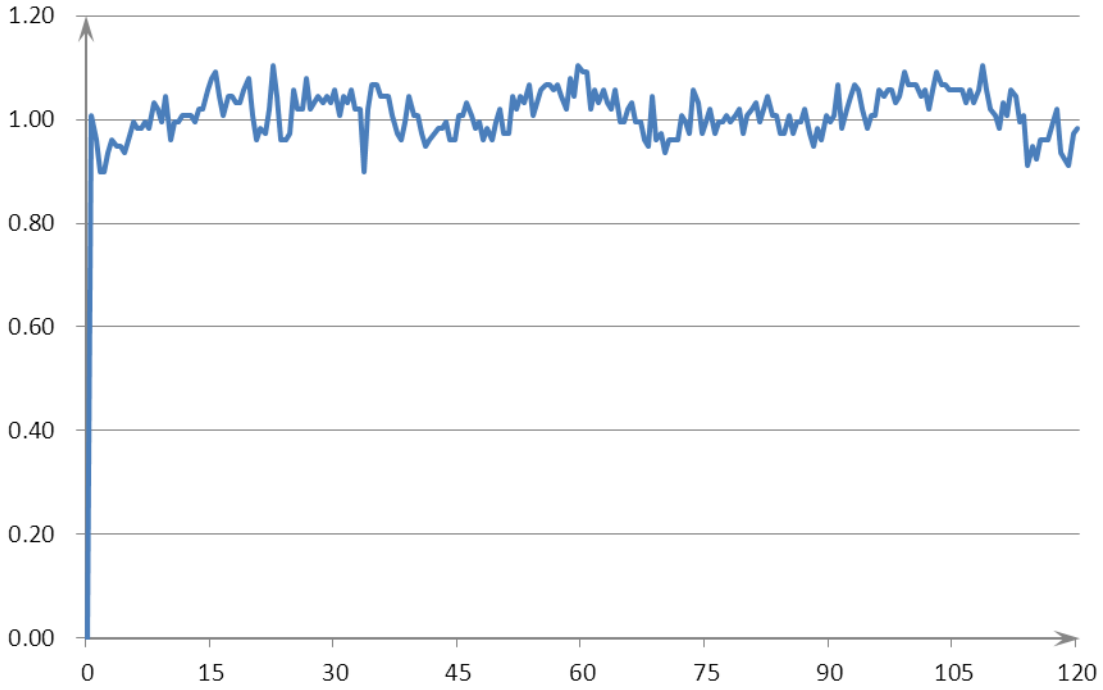
Graph 10 Trumpet curve: Percentage variation E_p against observation window duration P (min) and the overall mean percentage error A plotted from data gathered during the second hour of the test period （Minimum）（30ml syringe）



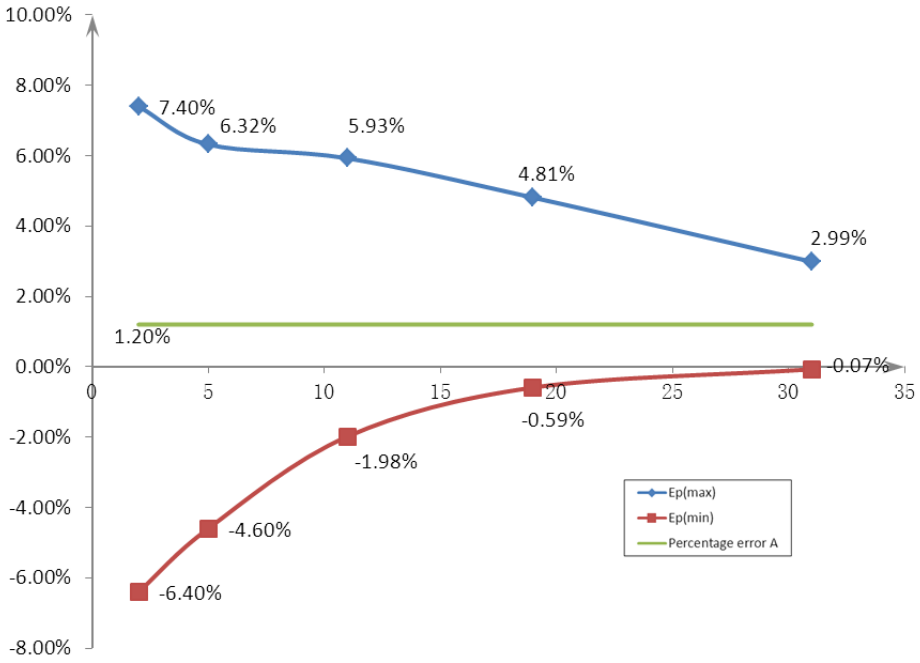
Graph 11 Start-up graph: Flow Q_I (ml/h)against time (min) plotted from data gathered during the first 2 h of the test period（Intermediate）（30ml syringe）



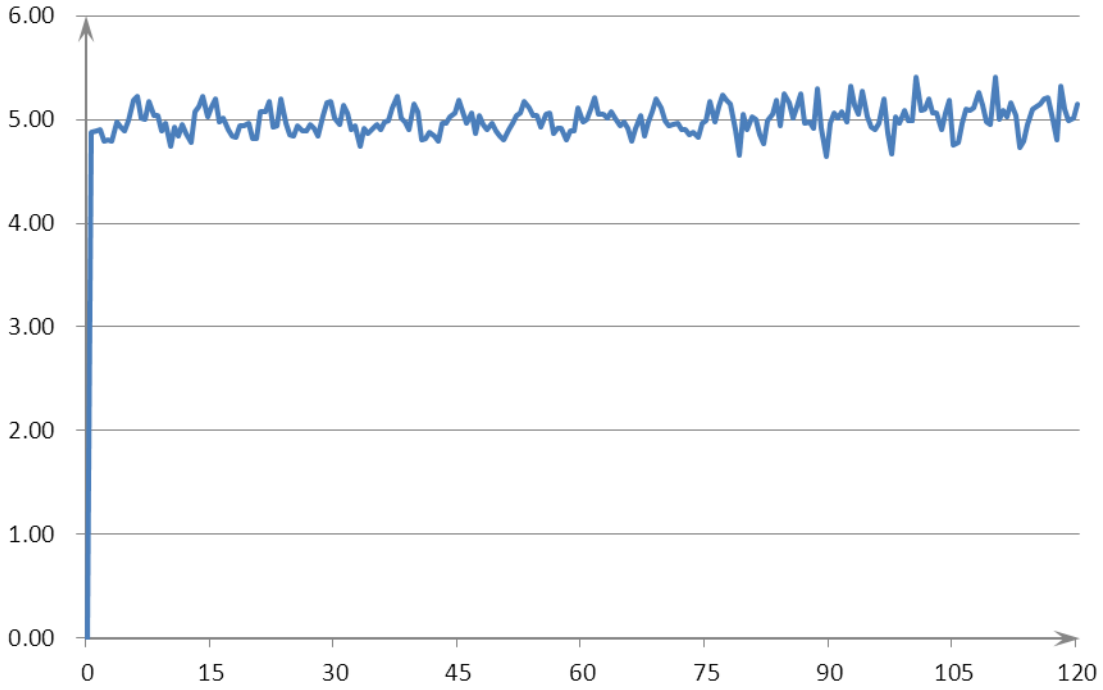
Graph 12 Trumpet curve: Percentage variation E_p against observation window duration P (min) and the overall mean percentage error A plotted from data gathered during the second hour of the test period（Intermediate）（30ml syringe）



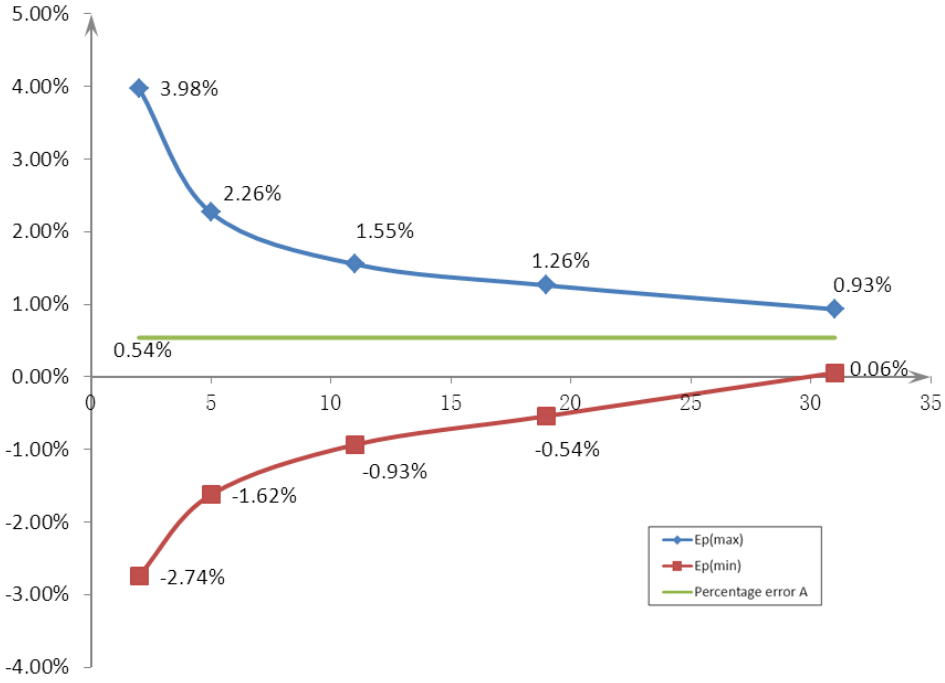
Graph 13 Start-up graph: Flow Q_I (ml/h)against time (min) plotted from data gathered during the first 2 h of the test period （Minimum）（50ml syringe）



Graph 14 Trumpet curve: Percentage variation E_p against observation window duration P (min) and the overall mean percentage error A plotted from data gathered during the second hour of the test period （Minimum）（50ml syringe）



Graph 15 Start-up graph: Flow Q_I (ml/h)against time (min) plotted from data gathered during the first 2 h of the test period（Intermediate）（50ml syringe）



Graph 16 Trumpet curve: Percentage variation E_p against observation window duration P (min) and the overall mean percentage error A plotted from data gathered during the second hour of the test period（Intermediate）（50ml syringe）

50.103	TABLE: Accuracy tests for drip-rate infusion controllers and drip-rate infusion pumps (Fig. 108)			N/A
Set rates:	Minimum:		Intermediate:	—
Sample interval	S (minutes) =			—
Test period (T)	T (minutes)=			—
Analysis period (min)	Calculated drip rate Q_I(drops/min)	Calculated overall mean percentage flow error A (%)	Calculated overall mean percentage flow error B (%)	Remarks
Supplementary information:				

50.104	TABLE: Accuracy tests for INFUSION PUMPS FOR AMBULATORY USE type 1 and for PUMPS type 4 and 5 (Fig. 104b)					N/A
Set rates..... :	Minimum:			Intermediate:		—
Sample interval	S (minutes) =					—
Test period (T)	T_1 (minutes) =			T_2 (minutes) =		—
Analysis period (min)	Calculated mean flow Q_i (μl/h)	Calculated E_p (%) maximum	Calculated E_p (%) minimum	Mass of infusate W_I (mg)	Calculated overall mean percentage flow error A (%)	Remarks
See attached graphs: No. 1 – Start-up graph (Flow Q_i (μl/h) against time (min) over the stabilization period T_1 at 30 min increments) No. 2 – Trumpet curve: Percentage variation E_p against observation window duration over the analysis period T_2 and the overall mean percentage error A						
Supplementary information:						

50.105	TABLE: Accuracy tests for INFUSION PUMPS FOR AMBULATORY USE type 2 and for PUMPS type 4 (Fig. 104b)		N/A
Set rates..... :	Minimum:	Intermediate:	—
Shot cycle ..... :	I (min) =		—
Sample interval	S (minutes) =		—

Analysis period (min)	Calculated mean flw Q_i (μl/h)	Calculated E_p (%)		Mass of infusate W_I (mg)	Calculated overall mean percentage flow error A (%)	Remarks
		maximum	minimum			
T_1=						
T_2=						

Supplementary information:

50.106	TABLE: Accuracy tests for PUMPS type 3, 4 and 5, and for VOLUMETRIC INFUSION PUMPS and SYRINGE PUMPS (Fig. 104a, 104b, or 108)		N/A
Set rates..... :	Minimum:	Intermediate:	—
Bolus ..... :	Minimum:	Maximum:	—

Bolus setting	Weight of 25 successive bolus deliveries	Calculated mean deviation from the set value	Calculated percentage deviation from the set value	Remarks
Minimum:2ml				
Maximum:N/A				

Test Report Photo

Photos and Explanations

Figure 1 The whole view

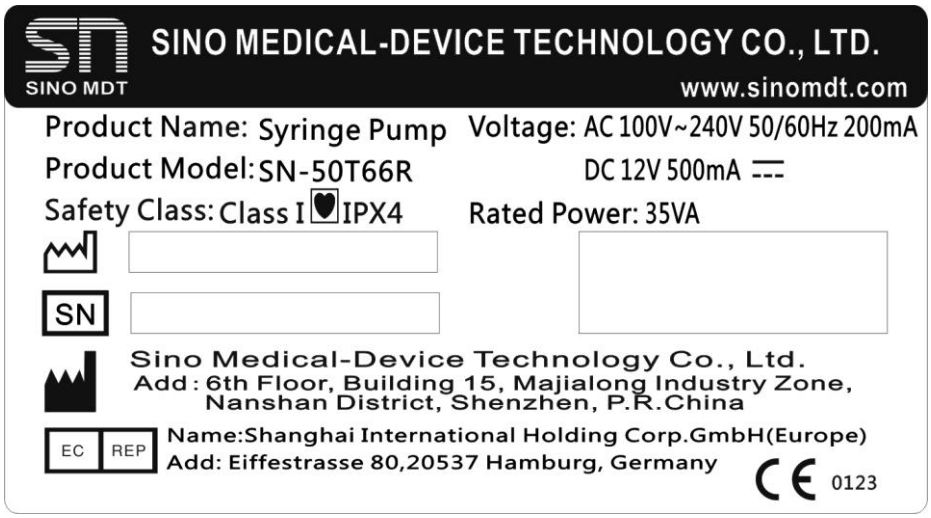


Figure 2 The label

Test Report Photo

Photos and Explanations

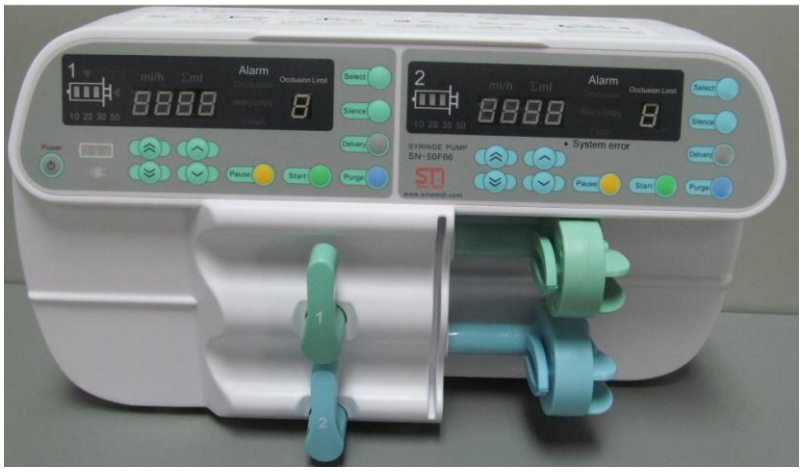


Figure 3 SN-50F66 Syringe Pump

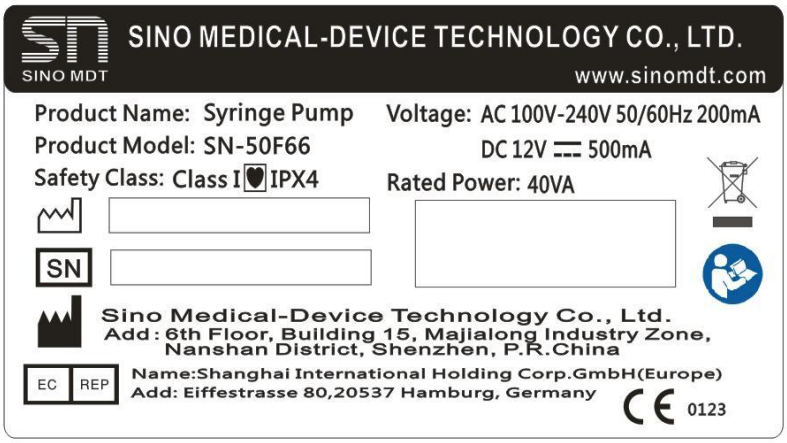


Figure 4 The label of SN-50F66 Syringe Pump

Test Report Photo

Photos and Explanations

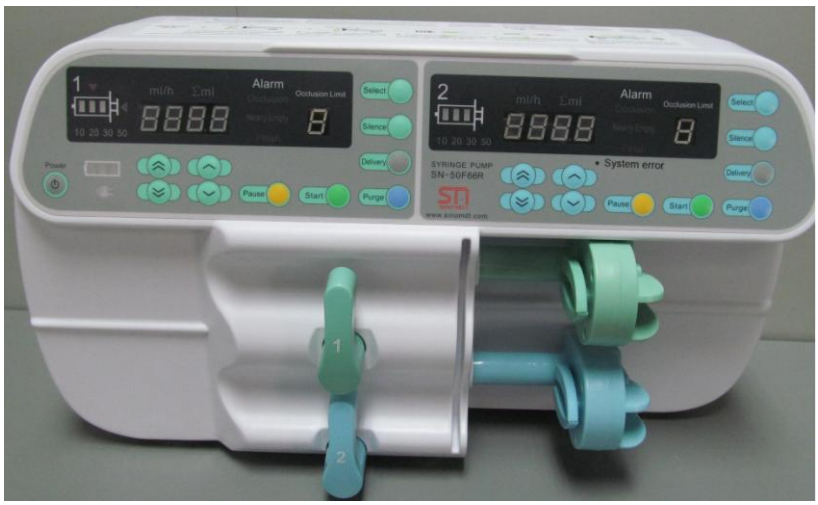


Figure 5 SN-50F66R Syringe Pump

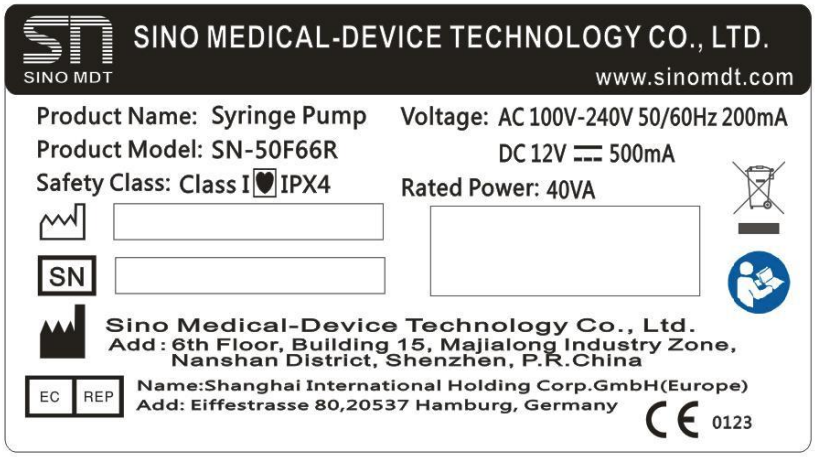


Figure 6 The label of SN-50F66R Syringe Pump

Test Report Photo

Photos and Explanations

Figure7 SN-50T66 Syringe Pump

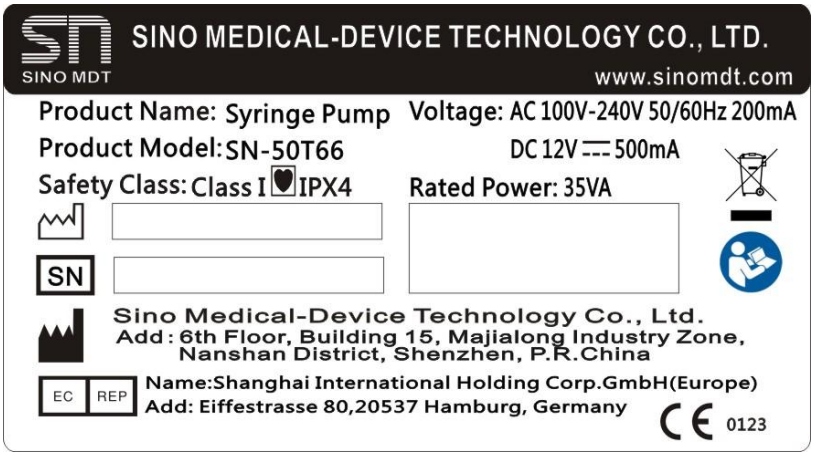


Figure 8 The label of SN-50T66 Syringe Pump

Test Report Photo

Photos and Explanations

Figure 9 SN-50C66 Syringe Pump

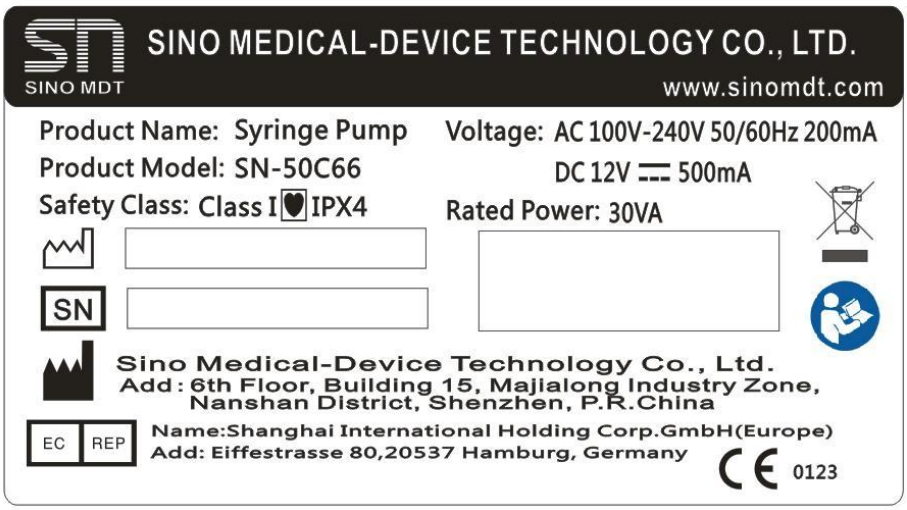


Figure 10 The label of SN-50C66 Syringe Pump

Test Report Photo

Photos and Explanations

Figure 11 SN-50C66R Syringe Pump

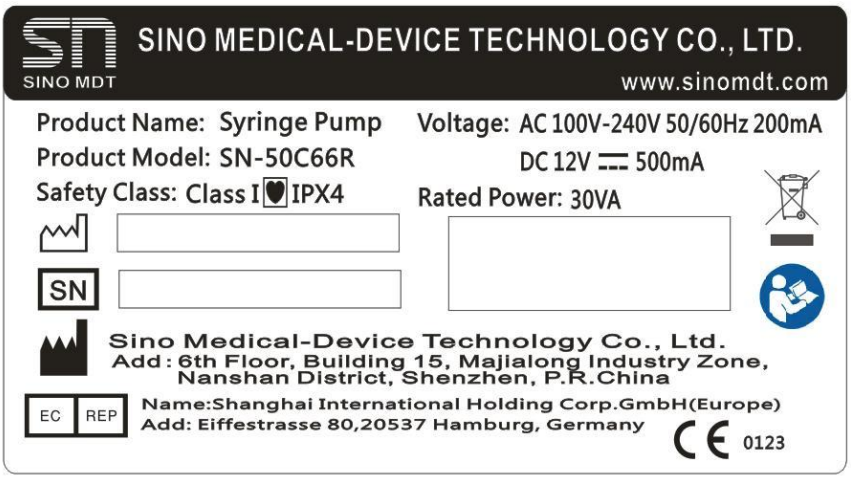


Figure 12 The label of SN-50C66R Syringe Pump

Test Report Photo

Photos and Explanations

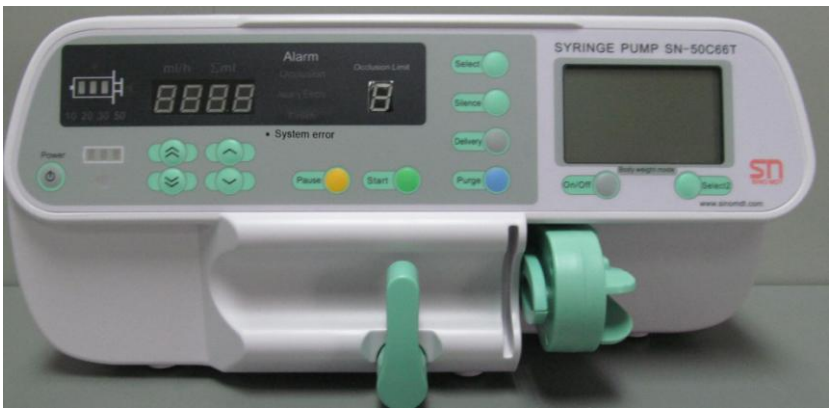


Figure 13 SN-50C66T Syringe Pump

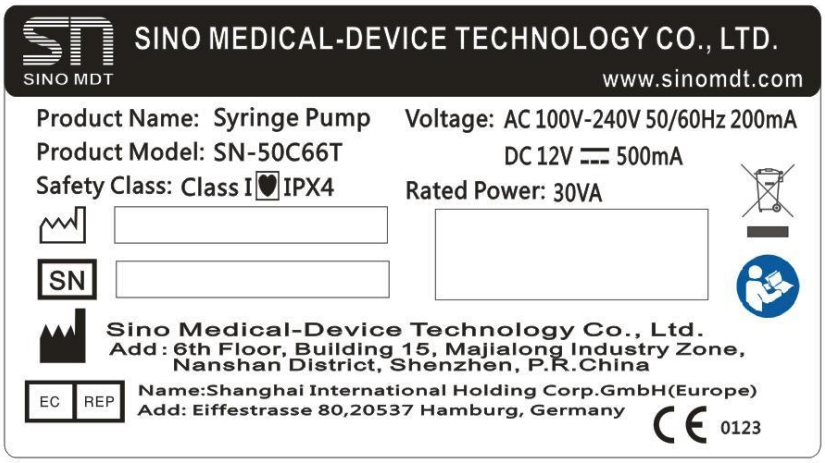


Figure 14 The label of SN-50C66T Syringe Pump

Test Report Photo

Photos and Explanations

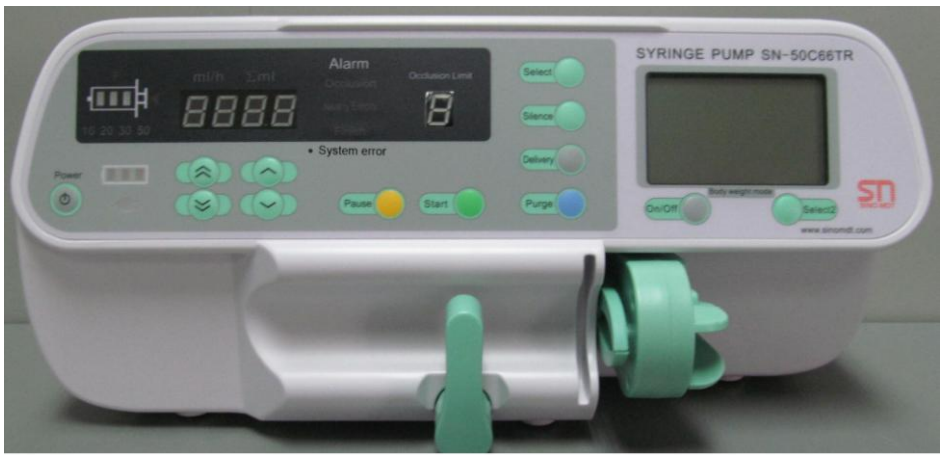


Figure 15 SN-50C66TR Syringe Pump

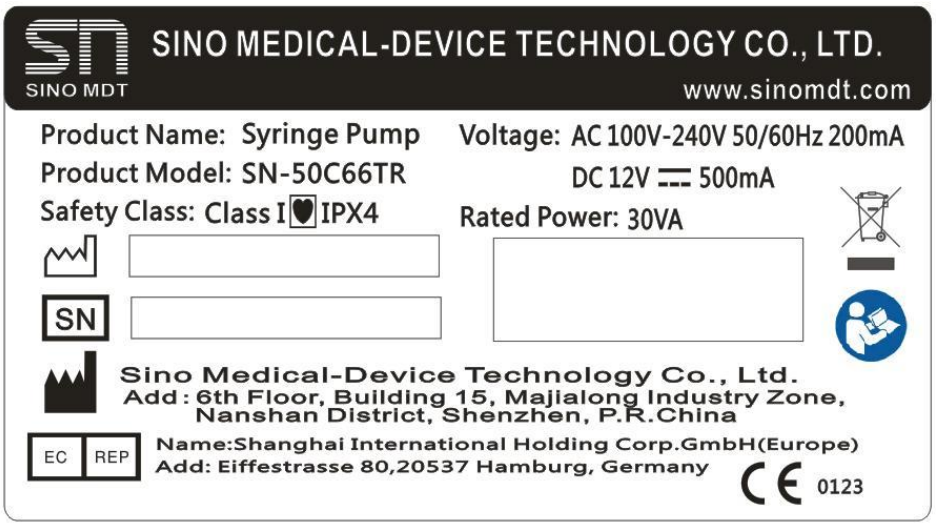


Figure 16 The label of SN-50C66TR Syringe Pump

Test Report Addendum

Samples' Descriptions
Syringe Pump is a series of products with high injection accuracy and stable flow rate, developed by Sino Medical-Device Technology Co., Ltd. It's composed of motor & actuator, lead screw, pusher head and syringe clamping device.
Types and Specifications or Other Explanations
By information and sample inspecting, the type SN-50F66、SN-50F66R、SN-50T66、SN-50C66、SN-50C66R、SN-50C66T、SN-50C66TR and SN-50T66R are in accord in principle, structure of circuit, they differ only in appearance and some auxiliary functions. So the type SN-50T66R can cover the type SN-50F66、SN-50F66R、SN-50T66、SN-50C66、SN-50C66R、SN-50C66T、SN-50C66TR.