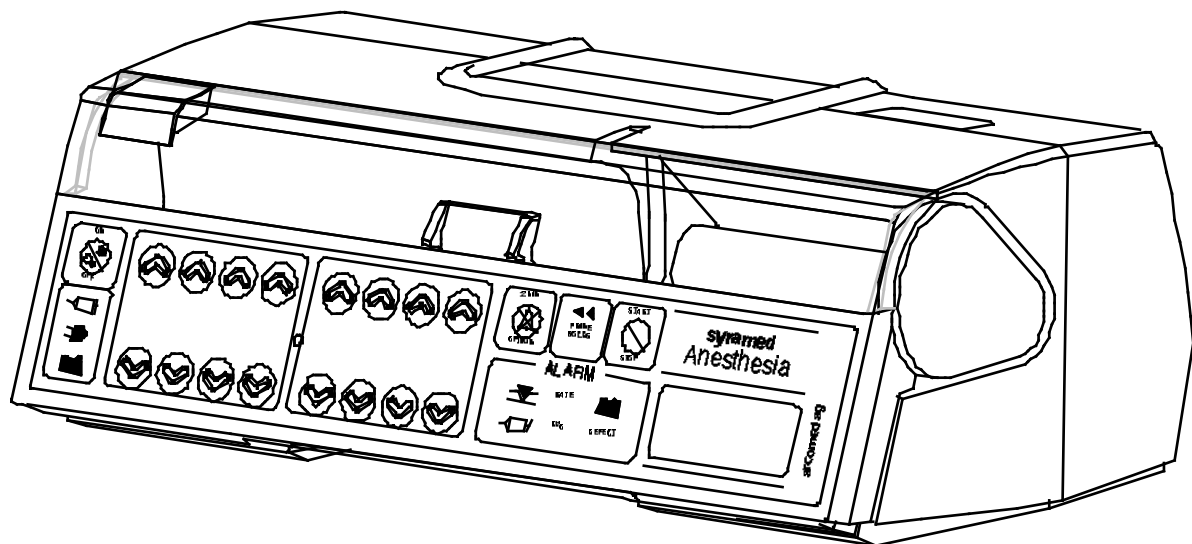


# Instructions for use

## syramed<sup>®</sup> $\mu$ SP6000 Anaesthesia syringe pump



CE 0123

Swiss Made

ARCOMED AG  
8105 Regensdorf / Zürich  
an ISO 9001 company

Edition 08/05 -VA-GA-6000-ANE-E

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# 1. Introduction

## 1.0 Introduction

The Syramed  $\mu$ SP6000-**Anesthesia** is a syringe pump using the latest technology. This microprocessor-controlled syringe pump operates by pumping the infusate in the syringe using a controlled single action pumping stroke. The sterility of the infusate is not affected. The pump is designed to infuse drugs or other infusates into the patient by controlled means under pressure.

The Syramed  $\mu$ SP6000-**Anesthesia** is a **specialist pump** and allows to **calculate the rate and dose** by the means of the **concentration** of the potent drug and **patient weight**. Also, the time can be configured in **hours or minutes**. Furthermore, **minimum** and **maximum limits** can be configured to achieve a maximum safety for the patient. With a **password** eight different programs can be saved including preset values, units and safety limits. These programs can be easily recalled later for various applications. During the infusion, the rate can be modified and confirmed in ml/h or the selected unit without interruption of the current infusion (**dynamic rate change**). The new rate setting is only applied after confirmation with the start key.

The Syramed  $\mu$ SP6000 meets the performance requirements of the MDA (UK) for neonatal and high risk infusions. It can be used in both stationary and transportable applications as it has a long battery life up to 12 hours duration. Applications include neonatology, intensive and cardiac care, paediatrics, gynaecology and obstetrics, surgery and general medicine. It can also be used in ambulances and air rescue. It is not recommended for blood infusion (unless the dose requirement is small) due to the limitations in syringe size accommodated (50/60ml maximum).

The Syramed  $\mu$ SP6000 meets the Medical Device Directive (MDD) requirements of the EC Guideline 93/42 EEC and is marked CE.

The manufacturer according to MDD is Arcomed AG, Althardstrasse 146, CH 8105 Regensdorf, Switzerland. Responsible for the EC is Arcomedical Infusion Ltd., West Horndon, Essex CM133XL, UK.

The Syramed  $\mu$ SP6000 may be operated only on mains power installed to DIN 57107 VDE 0107 or the appropriate national standards. If the integrity of the mains power supply protective earth system is in doubt, the pump should be operated on battery power. Mobile telephones should not be used anywhere near this equipment.

## 1.1 Mounting the pump

Check the pump and accompanying accessories for damage when unpacking. The pump must not be operated if damaged. Should the pump be damaged contact our Service Department.

Permitted mounting: positioned on a flat horizontal surface or pole mounted on an infusion stand or rail mounted.

The pump should normally be operated from a mains power supply. The internal batteries will automatically operate the pump in the event of a power failure.

**CAUTION:** This pump is not designed for use in areas where there is an explosion hazard. Environmental requirements as per IEC601-1-2 must be observed. Do not operate this pump in an environment with high levels of electromagnetic radiation such as surgical diathermy or mobile telephones. For further information contact the official distributor in your country or the Customer Service Department in Switzerland:

**Switzerland:** a r c o m e d a g, Althardstr. 146, CH-8105 Regensdorf  
Tel. ++41 (0) 43 388 90 30, Fax. ++41 (0) 43 388 90 40

**United Kingdom:** Arcomedical Infusion Ltd., 5j West Horndon Industrial  
Estate, West Horndon, Essex CM13 XL, UK  
Tel. ++44 (1) 277'81'04'32 Fax. ++44 (1) 277'81'19'67

### 1.2.1 Cleaning and disinfection

**CAUTION:** The pump must be switched off and disconnected from the mains power supply before cleaning and disinfecting.

The pump must be kept clean and dry. Remove any spillage immediately. The pump must not be placed in an autoclave.

The unit is disinfected by wiping over with a cloth which has been dampened slightly with an alcohol-based disinfectant. Take care when cleaning that no liquid enters the inside of the pump case. Wait at least 30 seconds after disinfecting before switching the pump on.







### 1.2.2 Annual safety check

Battery power is provided by a nickel metal hydride (NiMH) battery which must be checked annually. Battery condition is checked by connecting the pump to the mains power supply for 15 hours in a switched off condition so that the battery may be fully charged. Disconnect the mains power supply and switch the pump on using battery power. Determine the operating time when the low battery alarm activates. This should be at least 3 hours - if not the battery must be replaced. Repeated charging and discharging may in certain circumstances cause regeneration of the battery (memory effect).

Used batteries must be disposed of in an environmentally friendly manner or returned to the manufacturer. Safety checks (see chapter 6) may be performed only by qualified staff.

### 1.3. Key to symbols

The pictograms and symbols shown on the reverse of the pump have the following meanings or functions:

	Nurse call		CF (cardiac floating) part
	Interface RS232 (Infrared)		<b>CAUTION:</b> consult accompanying documents
			Drip-proof
			class II double insulated

## 2. Specifications

CE Marking	No. G5 01 08 13006 010
Classification	I Ib
Software revision	4.xx
Flow rate range (ml/h)	0.1 - 500 (750 max)
Flow rate increments (ml/h)	0.1
Volume range (ml)	0.1 - 999.9
Volume increments (ml)	0.1
Syringe size (ml)	5, 10, 20, 30, 50/60 (Automatic size recognition)
Syringe brands	B Braun, Fresenius, BD, Monoject, Terumo, Codan, other brands on request
Syringe nearly empty alarm	3 mins (adjustable)
Bolus volume after occlusion	Automatic bolus reduction (see also 3.9)
Overinfusion in case of electrical or mechanical defect	1.5 ml max.
Keep vein open rate (KVO)	0.3 ml/h, adjustable
Bolus rate, Prime rate	1500 ml/h (50/60 ml syringe), adjustable
Alarm pressure limit	0 - 999 mbar/mmHg
Battery operation time (1.85Ah)	3 - 12 hours (dependent on rate set)
Charging time	15 hours/20 hours
Supply voltage	230 VAC+10%-15%, 50/60 Hz
External power supply (optional)	12-15V AD/DC
Input power	8.5 VA
Mains fuse	T200 mA
Type of protection against electric shock	Class II
Protection against ingress of liquids	IPX 1, drip proof
Leakage current	< 40 $\mu$ A
Radio interference	CE-Class A
Nurse call, potential-free contact switch	24V/0.2A
Degree of protection against electric shock	CF (cardiac floating)
Dimensions	245x90x180 mm (WxHxD)
Housing	ABS plastic, UL listed
Weight	2.3 kg (approx.)
Max. storage period	3 months without charging
Permitted temperature range (operation/storage)	15°C - 35°C / 0°C- 40°C
Permitted relative humidity	20-90% max. (no vapor deposit)
Safety certification	DIN IEC 601 Part 1 EN55011 Radio interference IEC601-1-2 Susceptibility IEC601-2-24

## 2.2 Anesthesia specific settings:

Units and time:	ml/h, mg/h, $\mu$ g/h, un/h <sup>1</sup> , ml/min, mg/min, $\mu$ g/min, un/min
Concentration:	1 (Unit = ml), 0.1 mg/ml - 100.0 mg/ml, 1 - 1000 $\mu$ g/ml, 1 - 1000 un/ml
Patient Weight:	0.1 - 200.0 kg
Initial Bolus Dose:	0.1 ml - 100.0 ml/kg, 0.01 - 10.00 mg/kg, 0.1 - 100.0 $\mu$ g/kg, 0.1 - 100.0 un/kg
Initial Bolus Time:	Flash <sup>2</sup> or 1 - 100 min
Surgeon Bolus Dose:	0.1 ml - 100.0 ml/kg, 0.01 - 10.00 mg/kg, 0.1 - 100.0 $\mu$ g/kg, 0.1 - 100.0 un/kg
Surgeon Bolus Time:	Flash or 1 - 100 min
Maximum Bolus Rate:	1500 ml/h
Base-Rate:	0.1 ml/kg/h - 500.0 ml/kg/h (750. ml/kg/h), 0.01 mg/kg/h - 99.99 mg/kg/h, 0.1 $\mu$ g/kg/h - 999.9 $\mu$ g/kg/h 0.1 un/kg/h - 999.9 un/kg/h
Maximum Volume (VTBI):	0.1 ml - 999.9 ml/kg, 0.01 mg - 99.99 mg/kg, 0.1 $\mu$ g/kg - 999.9 $\mu$ g/kg 0.1 un/kg - 999.9 un/kg
Safety Limits	min/max concentration min/max patient weight min/max initial bolus dose min/max surgeon bolus dose min/max base rate min/max VTBI
Configurations	1 Individual and 8 programmed (configured by user)
Labeling of the configurations	12 alpha numeric characters for each configuration. Configured through IR interface.
History	Up to 1500 data logs with real time stamps. Read out and printout through IR interface and PC.

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<sup>1</sup> un/h = units/hour, concentration in un/ml = units/ml

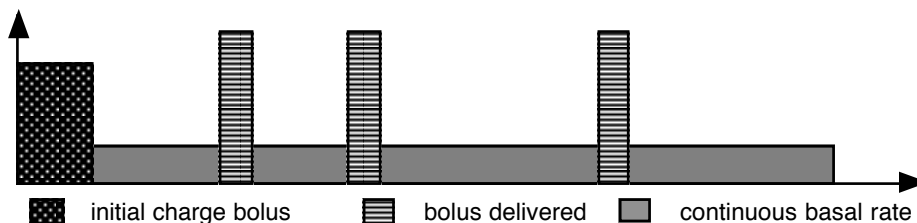
<sup>2</sup> Flash = Bolus is delivered with maximum bolus rate.

Remarks:

- Flash = Bolus is delivered with maximum bolus rate.
- The calculated rates are always in the range of 0.1 to 500.0 ml/h (Option 750.0 ml/h). The resolution of the rate is 0.1 ml/h and the resolution of the volume is 0.1 ml to 999.9 ml. Depending of the settings of unit, concentration and patient weight the calculated rates are limited or rounded according to the resolution of the pump if necessary.
- The displayed rate in the Rate ML (9) window is always in ml/h. In the DATA (10) and the LCD display (6) can be shown in the selected unit.
- The configuration password can be programmed by the user.

## 2.3 Anesthesia Configuration

The Syramed  $\mu$ SP6000-Anesthesia can be programmed to deliver a initial charge bolus if desired, a continues rate that can be dynamically adjusted at any time without stopping the infusion and can deliver additional bolus upon request:



The Syramed  $\mu$ SP6000-Anesthesia has two basic modes of operation:

- Set up Mode
- Application Mode.

The set up mode requires a password and allows to preset the units, values and safety limits. Each of the 8 programs can be configured independently. The set up shall only be done by a specialist who knows how to set the values and limits for the desired applications. The 8 programs can be labeled individually with 12 alpha numeric characters through IR interface.

The application mode does not require a password and allows to select a program, re-adjust and confirm the preset values within the limits and start / stop the infusion.

## 2.4 Anesthesia Setup Mode

Before using the syramed in the application mode, at least one program should be configured for later use. This has to be done only once, however the programs can be modified at any time later on by the user. To modify the set up a password is required (initial setting is 1001 but can be configured by the user). The LCD display (6) guides through all steps. If certain options such as the initial charge bolus are not required, set the value to zero (10). Confirm each step with the start key. To exit the setup, all steps have to be confirmed with the start key. To go back to a previous step use the 0.1 ml down key in the RATE ML (9) window. Depending on the settings of unit, concentration and patient weight, some inputs might be limited to avoid invalid entries.

**To enter the setup mode:**

- Switch off the pump.
- Hold the **Prime key** (8) and switch the pump on.
- The LCD display (6) shows 'Enter Password'. Enter the password (default 1001) in the DATA window and confirm with the start key (7).

window. Depending on the settings of unit, concentration and patient weight, some inputs might be limited to avoid invalid entries.

**To enter the setup mode:**

- Switch off the pump.
- Hold the **Prime key** (8) and switch the pump on.
- The LCD display (6) shows 'Enter Password'. Enter the password (default 1001) in the DATA window and confirm with the start key (7).
- The first step allows you to select one of the eight programs in the DATA (10) window. Confirm with the start key.
- Then the unit can be selected: ml/h, mg/h,  $\mu\text{g/h}$ ,  $\text{un/h}^3$ , ml/min, mg/min,  $\mu\text{g/min}$ , un/min in the DATA (10) window. Confirm with the start key (7).
- Go through each step, set the minimum and maximum values and confirm with the start key (7) until the pump returns to the normal mode.

**To save the configuration:** After all steps have been confirmed, hold the **OPTION key** (5) and switch the pump off.

**Important:**

Only one program can be saved at once. Repeat the above procedure for each program and save the set up first before editing the next program.

**The individual program can not be saved!** The individual program is intended for a single use application.

If the pump is in the normal mode, double click the PRIME key (5) to return to the steps if further modifications are required.

## 2.5 Anesthesia Application Mode

Once the pump has been set up, the pump is ready for the application. After switching on the pump a quick setup is available for the application. First the desired program can be chosen. Confirm with the start key (7) and go through the few steps to either adjust the values (within the preset limits) or confirm the values. After all values have been confirmed, the pump can be started.

Once the pump is running, the rate can be modified as on a standard syramed pump. However, the user has the possibility to modify the rate in the RATE ML (9) window or in the DATA (10) window in the selected unit without interruption of the infusion (dynamic rate change).

To activate the rate change hit one key (12) in the RATE ML (9) window while the pump is running. The LED display (9 & 10) starts flashing. The up/down keys (12) in the RATE ML window allow to change the rate in ml/h. The up/down keys (13) in the DATA window (10) allow to modify the rate in the selected unit (e.g. mg/kg/h). Confirm the rate change with the start key (7).

**Important:** The pump continues the infusion with the set rate. The new rate setting is ignored until it is confirmed with the start key (7).

Manual bolus and automatic bolus can be activated as on a standard syramed (see also 3.5).

To modify the VTBI the pump has to be stopped first. In the DATA (10) window the volume setting can be modified in ML. To modify the VTBI setting in the selected unit, double click the PRIME key (8) while the pump is in the stop mode. Go to the corresponding step hitting the start key and leave the program mode with the start key (7). Restart the pump.

## 3. Operation

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<sup>3</sup> un/h = units/hour, concentration in un/ml = units/ml

To modify the VTBI the pump has to be stopped first. In the DATA (10) window the volume setting can be modified in ML. To modify the VTBI setting in the selected unit, double click the PRIME key (8) while the pump is in the stop mode. Go to the corresponding step hitting the start key and leave the program mode with the start key (7). Restart the pump.

## 3. Operation

The figures in brackets refer to the illustrations of front and rear views shown in the appendices.

**CAUTION:** Use only approved disposable syringes!  
(cf. leaflet "Accessories and Consumables")

The pump may be configured for one or several brands of disposable syringe:

**B. Braun, Fresenius, Becton Dickinson, Monoject, Terumo.**

Permitted syringe sizes:

5, 10, 20, 30 and 50/60 ml. The size is identified automatically by the pump.

The functional safety of the pump cannot be guaranteed if non-approved syringes are used. The safety of the patient may be compromised as a result.

Disposable syringes are for single-use only. Single-use needles carry an infection hazard and must be disposed of in accordance with local guidelines.

Remark: To avoid air infusion, air filters can be used as there is no obligation to have an air in line detector on syringe pumps.

### **Important:**

- The patient must be disconnected during the loading and the removal or change of the syringe.
- The user must check that the pump and drive is not damaged and that the syringe plunger latch is in its home position before loading the syringe. In case of damage the syramed must not be used.
- The syramed must not be placed more than 50 cm above the patient and negative pressures must be avoided.
- In case of multiple or parallel infusions high pressures or negative pressures can influence the accuracy of the rate (see also 3.18). In the case of strong negative pressure siphoning can occur and the plunger can be pulled with considerable forces. It is important to know that these forces can also pull the plunger after the syringe latch is opened and the pump is not in control of the syringe.

### 3.1. Preparation and loading of syringe

- a) If the pump is to be operated on an infusion stand, care must be taken that the pump is not positioned more than 1.4m above the ground to ensure stability. Ideally use an "Arco Luxe" or "Arco Standard" infusion stand. If several pumps are mounted one above the other the maximum permitted height from the floor must be observed and measures taken to prevent instability.
- b) The pump may be fixed to the infusion stand by means of the pole clamp (22) on the rear of the unit.
- c) Where possible mains power should be used. Plug the mains power cable into the connector socket (18) at the rear of the pump. The mains pictogram illuminates as soon as the mains supply is connected. The battery is charged automatically.
- d) Draw up the infusate into the syringe using an aseptic technique and make sure there is sufficient excess volume to prime the extension set. Connect the extension set.
- e) Press the ON/OFF key (11). The audible alarm beeps and all indicators illuminate. The software revision number (rx.xx) and then the pump configuration (C.xxx)

- c) Where possible mains power should be used. Plug the mains power cable into the connector socket (18) at the rear of the pump. The mains pictogram illuminates as soon as the mains supply is connected. The battery is charged automatically.
- d) Draw up the infusate into the syringe using an aseptic technique and make sure there is sufficient excess volume to prime the extension set. Connect the extension set.
- e) Press the ON/OFF key (11). The audible alarm beeps and all indicators illuminate. The software revision number (rx.xx) and then the pump configuration (C.xxx) illuminate briefly.
- f) Open the pump door (15) by releasing the latch (1). Open the syringe clamp (2). The drive head (3) is powered automatically to extend fully to the right.
- g) Locate the syringe (4) in the pump with the Luer connector to the left so that the ears of the syringe are positioned in the slot in the pump body. **THIS IS IMPORTANT.** Push the syringe ears to the left so that they engage the front edge of the slot.

**Controlled automatic syringe loading:**

After closing the syringe clamp (2) the drive head stays extended to the right. Press the PRIME key (8) and hold it down so that the drive head is powered to engage the syringe and to lock onto the syringe plunger. When the infusion is finished press the PRIME key (8) to move the drive head to the parking position.

**CAUTION**

During the loading process, the user must check that infusion lines electrode leads or any other obstructions do not get caught up in the drive system and that the syringe plunger latch is in its correct home position to allow a correct syringe loading. Check that the plunger is correctly secured after loading.

- h) The LCD window (6) indicates the brand and size of syringe. Press the START/STOP key (7) to confirm this. If the pump is configured for several syringe brands, the OPTION key (5) must be pressed sequentially to select the brand. When the correct brand is displayed, press the START/STOP key (7) to confirm.
- i) The LCD window now indicates "purge". Press and hold the PRIME/BOLUS key (8) to prime the extension set. For safety reasons connect the patient only after correct loading and purging of the syringe.

**3.2. Setting rate (ml/h) and volume (ml)**

**See also 2.5 for setting of the anesthesia related values.**

Use the UP/DOWN keys (12) to select the required rate in ml/h indicated in the RATE display (9). Arrow up keys provide rate increase, arrow down keys provide rate decrease. Check that each key stroke changes one digit. The least significant digit (small size) indicates 0.1 (units).

If the full volume of the syringe is to be infused, make the patient connection and press the START key (7) to commence the infusion.

If a specific volume is to be infused, the required volume in mls may be selected in the DATA window (10) using the UP/DOWN keys (13) before starting the pump.

**3.3. Pump running**

When the pump is running, the green syringe symbol flashes. The DATA display now indicates the volume infused in mls. In order to display various data, such as pump condition, volume to be infused, infusion time, time to end of infusion, battery condition, syringe brand and size, pressure and pressure limit, press the OPTION key (5) sequentially and observe the LCD window (6) until the required data is displayed.

in the DATA window (10) using the UP/DOWN keys (13) before starting the pump.

### **3.3. Pump running**

When the pump is running, the green syringe symbol flashes. The DATA display now indicates the volume infused in mls. In order to display various data, such as pump condition, volume to be infused, infusion time, time to end of infusion, battery condition, syringe brand and size, pressure and pressure limit, press the OPTION key (5) sequentially and observe the LCD window (6) until the required data is displayed.

If a specific volume to be infused was selected the pump automatically switches to KVO operation when this volume has been infused and an audible and visual alarm (14) activates.

The near end of syringe alarm activates three minutes before the syringe is empty (audible and visual warning). The time before end of syringe may be adjusted (by a technician) as required. Press the ALARM SILENCE key (5) to silence the audible alarm for 2 minutes.

### **3.4. Resetting the volume infused**

In order to reset the volume infused, stop the pump by pressing the STOP key (7). Press the OPTION key (5) for 2 seconds until the DATA display (10) flashes. When the LCD window (6) displays "000", confirm this by pressing the START/STOP key (7) to reset the volume infused to zero. If it is not desired to reset the volume infused, press the OPTION key (5) until the normal display appears.

### **3.5. Infusing a bolus**

When the pump is infusing, a manual or an automatic bolus can be given.

#### **To infuse a manual bolus:**

Press the OPTION key (5) and the BOLUS key (8) together.

The bolus rate is displayed in the RATE window (9) and the bolus volume infused is displayed in the DATA window (10). The LCD window (6) indicates "Bolus manual". Keep the keys depressed until the required bolus volume has been infused. As soon as the keys are released the pump reverts to the normal infusion mode.

#### **To infuse an automatic bolus:**

Press the Bolus key (8) for 2 seconds until the display in the DATA window (10) flashes. The desired bolus volume in mls (or set unit) can then be preset in the DATA display using the DATA keys (13). Press the start key and set the desired time to infuse the bolus. Press the BOLUS key (8) to deliver the bolus automatically. If no bolus is required, press the OPTION key (5) to cancel.

During automatic bolus delivery, the RATE display (9) indicates the bolus rate and the DATA display (10) indicates the bolus volume infused. The LCD window (6) indicates "Bolus automatic".

To stop the pump at any time press the STOP key (7).

After the selected bolus volume has been delivered, the pump switches automatically to normal delivery mode.

Following bolus infusion, the bolus volume is added to the total ml infused.

### **3.6. Removing or changing a syringe**

Press the START/STOP key (7) to stop the pump. Open the door (15) and open the syringe clamp (2). The syringe plunger unlocks automatically and the drive head (3) extends fully to the right.

If a new syringe is to be fitted to continue the infusion, it can be loaded as in section 3.1 without switching the pump off. Rate, volume to be infused and volume infused data are stored.

### **3.7. Recall of previous data**

### **3.6. Removing or changing a syringe**

Press the START/STOP key (7) to stop the pump. Open the door (15) and open the syringe clamp (2). The syringe plunger unlocks automatically and the drive head (3) extends fully to the right.

If a new syringe is to be fitted to continue the infusion, it can be loaded as in section 3.1 without switching the pump off. Rate, volume to be infused and volume infused data are stored.

### **3.7. Recall of previous data**

If the pump has been accidentally switched off, data such as rate, volume to be infused and volume infused may be recalled during start up. The anesthesia specific settings are also recalled with this function.

Press the START/STOP key (7) and the ON/OFF key (11) together to recall all data.

### **3.8. Setting volume and time**

If a specific volume is to be infused in a given time the RATE display must be left at zero. When the syringe has been primed, press the START/STOP key (7) to confirm. Then press and hold the OPTION key (5) until the RATE and DATA displays flash. The time in hours and minutes may be selected in the RATE display (9) and the volume selected in the DATA display (10). The pump automatically calculates the infusion rate. Check this carefully in the LCD window (6) before starting the infusion.

### **3.9. Pressure system**

The Syramed SP6000 has automatic pressure monitoring whereby the pressure in the system is measured via the syringe plunger. The alarm pressure limit can be set automatically or manually.

#### **Automatic setting:**

If the pump is configured for this mode, the alarm pressure limit is automatically matched to the set rate, the lower the rate, the lower the alarm pressure limit.

Example (Injectomat):

- 50 ml syringe, 25 ml/h, press. limit 800 mBar, Time to alarm: 160 sec.
- 10 ml syringe, 5 ml/h, press. limit 300 mBar, Time to alarm: 100 sec.

#### **Manual setting:**

Press the OPTION key (5) sequentially to display pressure and alarm pressure limit in the LCD window (6). Hold down the OPTION key (5) until the DATA display (10) flashes "Lxxx". The pressure limit may be manually set using the DATA keys (13) in the DATA display (10) and the data in the LCD window changes accordingly. This can also be done while the infusion is in progress. NOTE: Manual setting of pressure deactivates the automatic pressure setting, i.e. the pressure remains at the current level independent of the rate selected.

Example (Injectomat):

- 50 ml syringe, 25 ml/h, press. limit 500 mBar, Time to alarm: 100 sec.
- 10 ml syringe, 5 ml/h, press. limit 200 mBar, Time to alarm: 70 sec.

If the pressure rises beyond the limit set, the pump stops and the stored bolus is automatically reduced to virtually zero volume. An audible and visual alarm is activated. Check the IV carefully for the cause of the alarm. Do not restart the pump until the occlusion is released.

### 3.10. Setting time and date

Press the OPTION key (5) sequentially to display date and time in the LCD window (6). Hold the OPTION key (5) down until the display flashes. The time may be set using the volume keys (13) in the Volume display (10), e.g. h9.45 = 9:45 am. This can also be done while the infusion is in progress.

The syramed has the possibility to automatically adjust the daylight save time (summer time). The adjustments can be done as per EU, US or Australian regulations. If the text 'Clock !' should appear, replace the Lithium backup battery on the main PCB.

To set the date, first switch the pump off. Press the DATA 0.1 ml DOWN and DATA 100 ml DOWN keys (13) together whilst switching the pump on. This enables the Service Mode. Select the RATE display (9) according to the following table using the RATE keys (12). Then select the corresponding data in the DATA display (10) using the DATA keys (13). Press the START key (7) each time to confirm each setting:

RATE ML display (9)	DATA display (10)	Function
145	0 - 99	Year
144	1 - 12	Month
143	1 - 31	Date
142	1 - 7	Weekday (Monday = 1, Sunday = 7)

Press the ON/OFF key (11) to switch the pump off.

Note: Incorrect setting of date or time does not affect the correct functioning of the pump.

### 3.11. Different configurations

If a different configuration is required, please contact our Customer Service Department or the official ARCOMED distributor in your country.

### 3.12. Accessories and consumables

Accessories, expendable parts and single-use items may only be used if they comply with the appropriate international standard and national approvals. Syringes, filters and extension sets must be CE marked.

The Instructions for Use and the mains power supply cable are included as standard equipment with the Syramed  $\mu$ SP6000.

### 3.13. START/STOP key (7)

The START/STOP key (7) is used to start the pump after the rate has been selected. The pump may be stopped at any time using this key. An additional function of this key is to confirm various parameters.

### 3.14. Prime / Bolus key (8)

The PRIME/BOLUS key (8) key is used to prime the extension set. It is also used to initiate a manual or automatic bolus (3.5).

### 3.15. AUDIBLE ALARM SILENCE/ OPTION key (5)

The audible alarm may be silenced for 2 minutes using the ALARM SILENCE/OPTION key (5). The audible alarm is re-activated after this period.

If there is no audible alarm, the key serves as an OPTION key which enables selection of any option.

### 3.16. ON/OFF key (11)

The pump may be switched off using the ON/OFF key (11) if the infusion has been completed. All data displayed (rate and volume) is lost when the pump is switched

If there is no audible alarm, the key serves as an OPTION key which enables selection of any option.

### **3.16. ON/OFF key (11)**

The pump may be switched off using the ON/OFF key (11) if the infusion has been completed. All data displayed (rate and volume) is lost when the pump is switched off. In order to avoid switching the pump off accidentally, the ON/OFF key (11) must be pressed for at least one second before the pump switches off.

If the pump is connected to the mains, the STANDBY mode will switch in when the pump is switched off. This means that the battery will be charged and the charge condition indicated in the LCD window.

### **3.17. Keep-Vein-Open (KVO) - Rate**

The pump may be configured to infuse at the keep vein open rate when the volume to be infused has been delivered. The KVO rate is preset at 0.3 ml/h and may be set (by a technician) to suite individual requirements if necessary. If the set rate is smaller than the KVO rate, the rate is not changed.

Remark: The latest standard uses the new wording Keep-Open-Rate (KOR). The meaning is identical to the KVO-rate.

### **3.18. Using the pump in parallel or multiple infusions**

If additional infusion systems are connected to the patient's vascular system, this may lead to complications e.g. infusion of air, reverse-flow, interruptions due to alarms and inaccurate flow.

To prevent such incidents, please observe the recommendations as stipulated in DIN VDE 0753, Part 5 or contact your distributor.

### **3.19. Options for external connection to the pump**

External equipment may only be connected to the Nurse call connector (20) if the system which results from this meets the requirements of draft norm EN601-1-1 and if their safety has been certified by an approved international body. Use cable number 94070 to connect the Nurse call system.

Please contact the Customer Service Department of ARCOMED AG for details of the RS232 interface (IR interface) and how to link it to external systems.

If an external 12/15V ac/dc power supply is used and is linked to other equipment, ensure that the safety of the system complies with IEC601-1.

## **4. Alarm system**

### **4.1. Alarm causes**

The electronic self-monitoring system continuously monitors the correct functioning of the pump and its displays whilst in operation. If a fault should occur, the infusion is stopped

immediately and the alarm activates. The corresponding alarm symbol is illuminated continuously with a red colour and there is a continuous audible alarm. The nurse call alarm is activated at the same time.

The pump will not start:

- if no rate has been set (0 ml/h).
- if the syringe clamp is open.
- if the door is open.

During operation an audible alarm activates and the pump switches to the KVO rate if:

- the START/STOP key is operated.

The pump will not start:

- if no rate has been set (0 ml/h).
- if the syringe clamp is open.
- if the door is open.

During operation an audible alarm activates and the pump switches to the KVO rate if:

- the START/STOP key is operated.
- attempts are made to alter the rate during operation.

During operation an audible alarm activates and the pump stops if:

- the syringe is empty.
- battery capacity is low and the charge rate can no longer ensure controlled infusion.
- the infusion pressure exceeds the limit set.
- the syringe clamp is opened.
- there is an internal defect.

## **4.2. Canceling the alarm condition**

After rectifying the cause of the alarm or acknowledging the rate change, the alarm condition is canceled and infusion resumed by pressing the START/STOP - key (18).

## **4.3. Pressure limit/occlusion alarm**

If the pressure in the system reaches the set pressure limit due either to a total or partial occlusion, the alarm activates and the occlusion alarm symbol and rate display flash. The LCD window displays "occlusion! check line!" The vein site should be checked to ensure there is no complication.

If the cause of the occlusion is removed, the occlusion symbol flashes and the pump may be started again.

## **4.4. Near end of syringe alarm**

This alarm activates 3 minutes before the syringe is empty. The rate and volume displays and the red syringe alarm symbol flash. The LCD window indicates "Empty in 3 minutes" and counts down until the syringe is empty.

## **4.5. Syringe empty alarm**

When the total volume in the syringe has been infused, the alarm activates and the pump stops. The RATE display flashes and the red syringe alarm symbol illuminates continuously. The LCD window indicates "syringe end! reload".

## **4.6. Battery alarm**

The pump may be operated independently of the mains power supply using the internal battery. If the mains power supply fails, the pump switches automatically to battery operation to continue the infusion without interruption.

Battery operation is indicated by illumination of the battery symbol (17). Battery capacity permits from 3 up to 12 hours operation (1.85 Ah battery) depending on the infusion rate set. After approximately 3 to 12 hours operation the battery symbol in the alarm display (14) illuminates and an audible alarm activates. Alarms are canceled automatically as soon as mains power is restored.

A low battery alert is activated approximately 30 minutes before the battery depleted alarm. The battery symbol (17) flashes and an audible alarm activates. To silence the audible alarm, press the ALARM SILENCE key (5). The battery symbol continues to flash until the pump is reconnected to the mains.

A cautionary alarm is activated if the pump is disconnected from the mains power supply whilst in operation. This alarm may be silenced using the ALARM SILENCE

Alarms are canceled automatically as soon as mains power is restored.

A low battery alert is activated approximately 30 minutes before the battery depleted alarm. The battery symbol (17) flashes and an audible alarm activates. To silence the audible alarm, press the ALARM SILENCE key (5). The battery symbol continues to flash until the pump is reconnected to the mains.

A cautionary alarm is activated if the pump is disconnected from the mains power supply whilst in operation. This alarm may be silenced using the ALARM SILENCE key (5).

#### 4.7. Nurse call

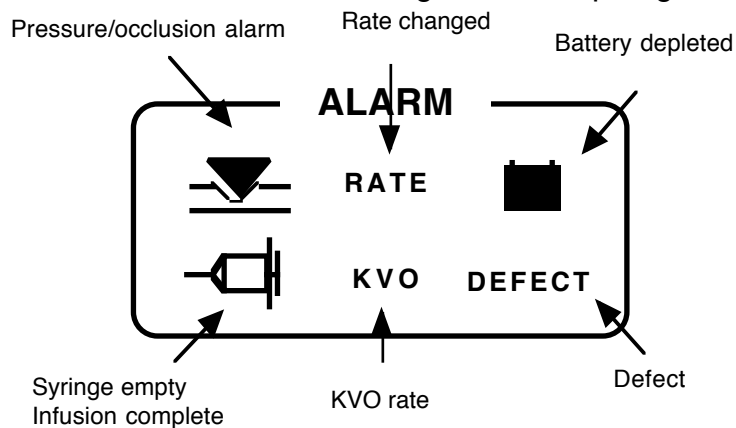
The pump may be connected to the external nurse call system via the connector (20) on the rear of the unit using cable part number 94070. All alarms are transmitted to the nurse call station. The normal pump alarms and displays continue to function.

#### 4.8. Alarm silence

Audible alarms may be silenced for approximately 2 minutes using the ALARM/SILENCE key (5). The audible alarm is reactivated after this period.

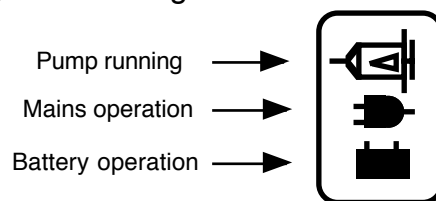
#### 4.9. Alarm indicators (14)

The cause of the alarms are indicated using illuminated pictograms as shown:



#### 4.10. Power and running indicators (17)

These are indicated by the following:



#### 4.11. LCD window (6)

Various messages and infusion parameters are displayed in this window.

## 4.9. Technical description

The syramed  $\mu$ SP6000 is a microprocessor-controlled infusion pump with stepper motor drive and comprehensive software management function monitoring. The pump is operating range enables infusion rates from 0.1 ml/h to 1,500 ml/h (50/60 ml syringe) to be made. An internal rechargeable battery allows the unit to operate independently of the mains in emergencies or when used as a mobile unit. The mechanism is driven by a step motor via a toothed belt and friction spindle. All important operating parameters are clearly shown on an LED indicator. Setting the desired values is done via touch-pad keys. The unit is manufactured using the latest surface mounted control technology (SMD).

## 5. Warranty

Arcomed AG offers a twelve month warranty on each Syramed  $\mu$ SP6000 syringe pump effective from date of delivery.

The warranty covers the installation and replacement of faulty parts if caused by faulty assembly or materials. The warranty is rendered null and void if changes or repairs are carried out by persons who have not been authorized in writing to do so by Arcomed AG or Arcomedical Infusion Ltd and if the inspection and maintenance intervals are not observed.

The warranty does not cover the elimination of problems caused by incorrect operation, inappropriate handling or normal wear and tear,  
The supplier only accepts responsibility for the safety, functional reliability and performance of the equipment providing that

- assembly, extension work, resetting, modification or installations are carried out by personnel authorized by him.
- the electrical system at the operating site meets IEC requirements.
- the unit is used in accordance with these Instructions for Use.

The information provided in this manual applies to the currently prevailing situation and is given in good faith. The manufacturer reserves the right to make modifications in the interest of technical progress.

### 5.1. Design changes

Arcomed AG endeavour to ensure that future improvements and modifications are compatible with earlier models.

NOTE: Always state the model, serial number and where applicable the colour of the unit in question when ordering spares.

## 6. Scope and schedule of safety checks of the syramed® μSP6000 anesthesia syringe pump

Schedule: every 24 months or after 10,000 hours operation: this unit must be checked by technical staff who have been trained and authorised in writing to do so by Arcomed AG or Arcomedical Infusion Ltd.

Check list		Check for	Result
<b>Visual check</b> Case, door, control panel Door latch Syringe clamp Mechanical parts, drive system Labelling Visual displays Connector, fuses		Hair-line cracks Contamination Contamination Function, clean None missing Function Damage, blown	
<b>Functional checks</b> Loading and removing syringes Syringe recognition Plunger lock	Use several sizes	Syringe capture	
Accuracy testing at 25 ml/h and Rate 100 ml/h  Pressure transducer	Measurement of rate using water  Set pressure limit to 500 mbar	as per specification  Alarm response time Pressure reading	
Test nurse call system RS232 data link (only on RS 232C option)		Function Pump STOP function	
Earth leakage current  Earth bonding test including mains cable	Test as in IEC 601/1	Within type CF limits  $\leq 300 \text{ mOhm}$	

Fuse ratings must correspond to the manufacturer's specification.  
(T200 mA/250V IEC127/III/SEV 1064).

Test results must be recorded in the Equipment Log.  
**CAUTION:** After repairs and any replacement of parts, test runs must be carried out in accordance with the manufacturer's protocols.

## 7. Performance data

### 7.1 The significance of trumpet graphs in clinical practice

Trumpet graphs indicate the maximum and minimum percentage deviation from the set flow rate for observation windows of duration 2 to 31 minutes. The maximum deviation from the set rate can therefore be determined for clinically relevant periods of time. For instance, many drugs used for infusion have a pharmacological and biological half-life of less than 5 minutes.

One agent commonly used to support the cardiac output in a critically ill patient has a half-life of 2.5 minutes. When infusing this agent, it is important that the fluctuations in flow from the syringe pump measured over a time period of 2.5 minutes, do not cause the therapeutic limits of the drug to be exceeded. It has been observed that cardiac stability can be disturbed by excessive fluctuations in pump output over short time periods.

Fluctuations in pump output depend to a great extent on the rate set and decrease as the rate is increased.

**Remark:** Performance data on other syringes can be requested at Arcomed. The accuracy depends mainly on the tolerances of the syringes.

Table 1: Mean accuracy measured over 60 minutes (typical values)

<u>rate (ml/h)</u>	<u>measured rate (ml/h)</u>	<u>% error</u>
1.0	1.01	0.75
2.0	1.99	-0.12
5.0	4.91	-1.83
25.0	25.25	+1.00

Table 2: Short term accuracy (typical values)

<u>rate (ml/h)</u>	<u>2 min window</u>		<u>5 min window</u>	
	Max	Min	Max	Min
1.0	+4.84%	-3.70%	+3.89%	-2.18%
2.0	+3.35%	-2.65%	+1.81%	-0.89%
5.0	+1.97%	-1.30%	+0.90%	-0.38%
25.0	+0.95%	-0.66%	+0.67%	-0.50%

**7.2. Trumpet curve  $\mu$ SP6000 at 25 ml/h and 2 ml/h  
(BD Plastipak 50 ml)**

**Notes:**

## 9 EMV Verhalten der Syramed® µSP 6000

### Aussage:

Die Syramed® µSP6000 Series ist ein medizinisches Elektrogerät welches im Punkte EMV spezielle Vorkerhungen erfordert. Die Pumpen müssen entsprechend der empfohlenen Hinweise in diesem Dokument eingesetzt werden.

### Warnung:

Bewegliche und mobile HF Geräte zur Kommunikation (Mobile Telefone, Pager, Sprechfunkgeräte) können medizinische Elektrogeräte beeinflussen.

### Warnung:

Die Pumpen der Syramed® µSP6000 Series sollten nicht mit anderen medizinischen Elektrogeräten in einem Stapel oder unmittelbar nebeneinander verwendet werden. Falls sich eine solche anordnung nicht vermeiden lässt, so sollten alle Geräte von einer dazu geeigneten Person überwacht werden.

### Aussage:

Die grundlegenden Leistungsmerkmale der Syramed® µSP6000 Serie sind die folgenden:  
- Infusion eines bestimmten Volumen eines Medikamentes bei einer bestimmten Förderrate

<b>Guidance and manufacturer's declaration - electromagnetic emission</b>		
The Syramed µSP6000 Series is intended for use in the electromagnetic environment specified below. The customer or the user of the Syramed µSP6000 Series should assure that it is used in such an environment.		
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>
RF emissions CISPR 11	Group 1	The Syramed µSP6000 Series uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Syramed µSP6000 Series is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

<b>Guidance and manufacturer's declaration - electromagnetic immunity</b>			
The Syramed µSP6000 Series is intended for use in the electromagnetic environment specified below. The customer or the user of the Syramed µSP6000 Series should assure that it is used in such an environment.			
<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 610004-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of typical commercial or hospital environment.

Surge IEC 61000-4-5	± 1 kV differential mode  ± 2 kV common mode	± 1 kV differential mode  no common mode test as system has no protective earth	Mains power quality should be that of typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % $U_T$ (>95 % dip in $U_T$ ) for 0.5 cycle  40 % $U_T$ (60 % dip in $U_T$ ) for 5 cycles  70 % $U_T$ (30 % dip in $U_T$ ) for 25 cycles  <5 % $U_T$ (>95 % dip in $U_T$ ) for 5 sec	<5 % $U_T$ (>95 % dip in $U_T$ ) for 0.5 cycle  40 % $U_T$ (60 % dip in $U_T$ ) for 5 cycles  70 % $U_T$ (30 % dip in $U_T$ ) for 25 cycles  <5 % $U_T$ (>95 % dip in $U_T$ ) for 5 sec	As the Syramed $\mu$ SP6000 Series is powered by an internal battery, no special precautions must be taken.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	400 A/m	400 A/m	
NOTE $U_T$ is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The Syramed $\mu$ SP6000 Series is intended for use in the electromagnetic environment specified below. The customer or the user of the Syramed $\mu$ SP6000 Series should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 $V_{rms}$ 150 kHz to 80 MHz outside ISM bands <sup>a</sup>	10 V	Portable and mobile RF communications equipment should not be used no closer to any part of the Syramed $\mu$ SP6000 Series, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance</b> $d = 0.35\sqrt{P}$  $d = 1.2\sqrt{P}$
		10 V	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz  where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m). <sup>b</sup>  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>c</sup> should be less than the compliance level in each frequency range. <sup>d</sup>

Interference may occur in the vicinity of equipment marked with the following symbol:



NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

<sup>a</sup> The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.7 MHz.

<sup>b</sup> The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

<sup>c</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Syramed  $\mu$ SP6000 Series is used exceeds the applicable RF compliance level above, the Syramed  $\mu$ SP6000 Series should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Syramed  $\mu$ SP6000 Series.

<sup>d</sup> Over the frequency range 150 kHz to 80 MHz, field strength should be less than 10 V/m.

### Recommended separation distances between portable and mobile RF communications equipment and the Syramed $\mu$ SP6000 Series

The Syramed  $\mu$ SP6000 Series is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Syramed  $\mu$ SP6000 Series can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Syramed  $\mu$ SP6000 Series as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter			
	150 kHz to 80 MHz outside ISM bands $d = 0.35\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.04	0.12	0.12	0.23
0.1	0.13	0.38	0.38	0.73
1	0.40	1.2	1.2	2.3
10	1.3	3.8	3.8	7.3
100	4.0	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.7 MHz.

NOTE 3 An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.