

Metrology in Health

Good Practices Guide - Part II

Chapter III

Infusion Pumps

Metrology in Health – Good Practices Guide
Part II
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Infusion Pumps

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Rua António Gião, 2
2825-513 CAPARICA Portugal
Tel +351 212 948 100
Fax + 351 212 948 101
e-mail: ipq@ipq.pt
www.ipq.pt

Authors

CS/09 – GT1 Metrology in Health

Coordination

Maria do Céu Ferreira, Portuguese Institute for Quality

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1. Infusion Pumps

In the human body, the circulatory system is responsible for the process of transporting blood, which among many other functions delivers nutrients to the cells. In accordance with this physiological principle, supporting methodologies for therapeutic processes were developed that have enabled medical measuring instruments to be developed. It was within this context that the first infusion pumps appeared in the 60 s and 70 s, that by using a pressure higher than the blood pressure allowed fluids to be administered directly into the human body, including medications, blood components, and nutrients amongst others.

Currently and according to the international standard IEC 60601-2-24 these devices are designated by infusion pumps. Because it is an infusion pump with the respective accessories, the term *perfusion systems* is also used as nomenclature throughout this document.

1.1 Characterisation

Infusion pumps are electronic medical instruments widely used in adult, paediatric and neonatal patients, with the purpose of delivering fluids in an intermittently or continuously manner. These instruments can be used in clinical environments or at home. An infusion pump is normally constituted by a fluid reservoir, a generating flow device, than can also have flow regulation functions and of a set of accessories (lines, administration sets, filters, etc.) that allow the fluid to be transported from the reservoir to the patient (Figure 1).

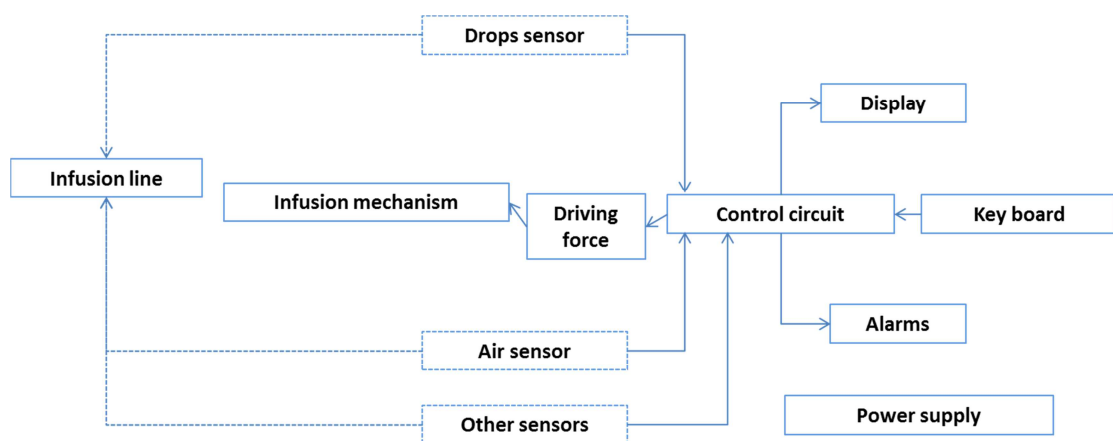


Figure 1: Demonstrative scheme of an infusion pump and its accessories

Regardless of the type of infusion pump, the main components of these systems are: the control circuit of the pump associated with the control panel, the alarms and the display, the

motor, the infusion mechanism, the existing sensors and the accessories that enable the fluids to be delivered to the patient (see 1.2).

For a better description, in table 1 it's presented the characteristics and functions of the main components of an infusion pump.

Table 1: Main components of an infusion system

Alarms	The alarms indicate adverse situations, for example, air bubbles or system occlusion, free flow, end of infusion, low battery, amongst others.
Control circuit	Allows the interpretation of the information introduced into the device, control the infusion mechanism, interpret the sensors signals and activate the alarms when needed; It can store the programmed information and data about the alarms, calculate doses, carry out variations in the infusion flow, amongst others; It can be either analogic or digital.
Infusion line and accessories	A set of disposable accessories that ensure the transportation of the fluid from the reservoir to the patient.
Infusion mechanisms	This component allows for infusion pressure generation that is responsible for the fluid flow. It can be peristaltic or by syringe.
Display and control panel	Alphanumeric displays or LCD (liquid crystal display). They give information about the undergoing infusion: the total volume which will be administered, the flow (ml/h or drops /min), the total time and the remaining time of infusion as well as information about the alarms, etc.
Motor	In general, step-by-step motors are used to activate the infusion mechanisms.
Drop sensor in peristaltic pumps	Used to refeed the electronic circuit of infusion control; It enables information regarding occlusion of the line (by filling the drip chamber), infusion without solution and free infusion (badly positioned system, which leads to an uncontrolled infusion); The drop sensor is placed near the drip chamber of the system.
Air sensor in the peristaltic pumps	Indicates the presence of air in the system; It is placed near the line, after the infusion mechanism.
Occlusion pressure sensor	Used to control the infusion pressure, by making it possible to quickly and reliably detect an occlusion in the line.
Keypad	Used to register the data that refers to the flow, the volume and the time of infusion.

Main parameters

In an infusion pump the main parameters that should be analysed are volume, time, flow and pressure (Alexander *et al.*, 2010).

The purpose of the **volume** parameter is to assess the relative values regarding the volume to be administered and the volume that has been administered. The volume to be administered refers to the total amount of fluid that is available in the reservoir and may vary between 0,1 ml and 9999,0 ml. The administered volume is the volume indicated by the pump at the end of the administration and is not programmable. It corresponds to the total quantity of administered fluid.

The infusion **time** corresponds to the time interval in which the fluid is administered. This parameter may be programmed according to the respective needs, such as the intermittent administration of medication. The pumps may be programmed in seconds, minutes and hours.

The parameter concerning **flow** is the volume of fluid administered throughout a long period of time. Although the majority of the infusion pumps administer in millilitres per hour (ml/h) – volumetric flow – some may be programmed to administer in milligrams per hour (mg/h) – mass flow. The control of the flow can be volumetric (measurements based on the volume) or non-volumetric (measurements through the drop count) and the programming of the values should be limited to the measuring interval of the instrument.

As far as the flow is concerned it is important to mention the *bolus* parameter which consists in administering a certain amount of fluid in a short interval of time.

The assessment of the parameter applied to the pressure of the infusion pump focuses, particularly, on the monitoring of the pressure to be administered, which can be generated by the pump under occlusion conditions of the fluid in the system.

1.1.1. Types of infusion pumps

According to the international standard IEC 60601-2-24, infusion pumps can be volumetric¹ or with syringe. There are also elastomeric pumps (Figure 2).

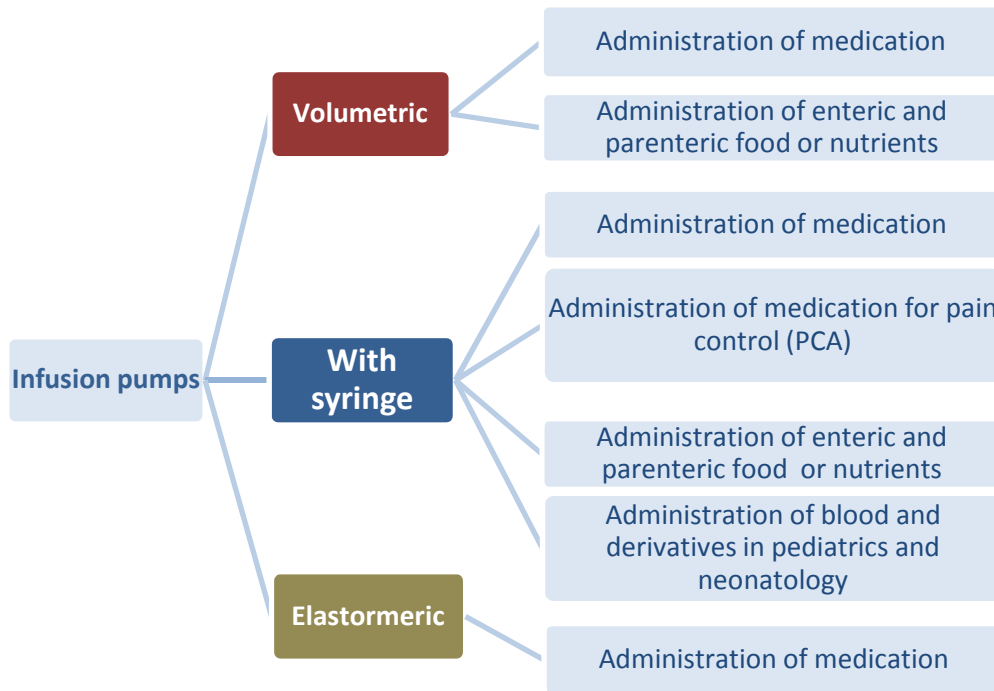


Figure 2: Types of infusion pumps

a) Volumetric infusion pumps

Volumetric infusion pumps are used to administer medications and nutrients or food (enteric and parenteral²). They can be used in a clinical environment or at home.

The figure 3 represents the schematic image of a volumetric pump under use.

¹ Volumetric infusion pumps are normally called peristaltic.

² Enteric nutrition is a way to provide nutrients through a tube placed in the stomach, or the small intestine. Parenteral nutrition, or intravenous feeding, is a method of getting nutrients into your body through your veins.

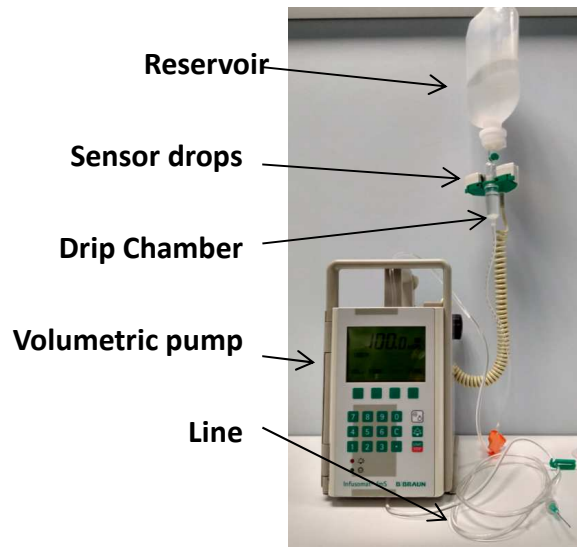


Figure 3: Volumetric pump system

In volumetric infusion pumps, a mechanical trigger causes the liquid within the tube to move by peristaltic action, thus enabling the administration of medications and nutrients or food. This mechanism can be classified as rotary or linear.

- The rotary mechanism (Figure 4) is made of a main rotor, complete with rollers that press a tube.
- The linear mechanism (Figure 5) is the most common type and it is composed by several independent fingers that press a silicon tube sinusoidally. These fingers carry out a peristaltic movement, forcing the passage of the flow by pressing the infusion line against the door of the equipment.

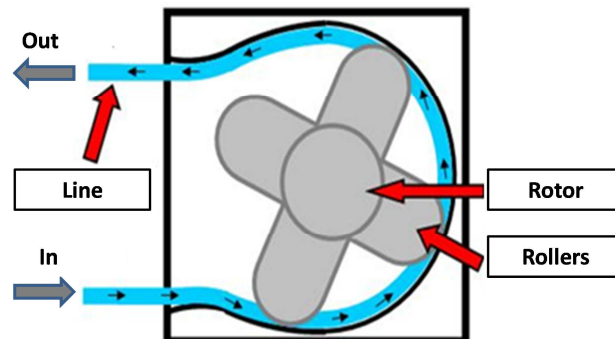


Figure 4: Rotary peristaltic mechanism

Source: Adapted from (ENTRENAMIENTO DE BOMBA DE INFUSIÓN, 2015).

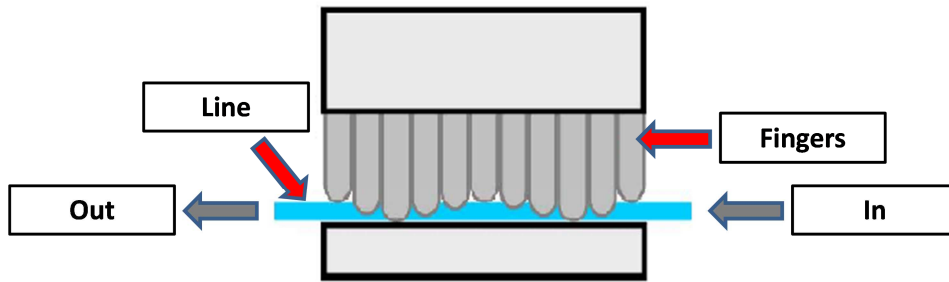


Figure 5: Linear peristaltic mechanism

Source: Adapted from (ENTRENAMIENTO DE BOMBA DE INFUSIÓN, 2015).

The mechanism is activated by a step-by-step motor with a reducer and controlled by an electronic circuit, which indicates on the display the flow and the amount of fluid that has to be administered. The majority of rotary and linear volumetric infusion pumps have a drop sensor, occlusion pressure sensors and an air sensor in the line.

The figure 6 illustrates some types of volumetric infusion pumps used to administer medication and parenteral nutrition



Figure 6: Illustrative example of volumetric infusion pumps for medication and parenteral nutrition or food administration.

The infusion pumps aimed at enteric nutrition administration have an identical mechanism to the one previously described. Nonetheless, these are simpler and do not have drop sensors and a maximum pressure sensor to administer (Figure 7).



Figure 7: Illustrative example of volumetric infusion pumps for enteric nutrition administration

b) Infusion pumps with syringe (syringe pumps)

Syringe pumps presuppose a system of a continuous, individual, resistant tube and without connexions in Y (Alexander *et al*, 2010).

The pump system is composed by an external electronic infusion pump, an infusion line and a syringe that is compatible with the system and which is usually disposable (Figure 8).

A compatible syringe is a device which the requirements and specifications are established in the manufacturer's recommendations.

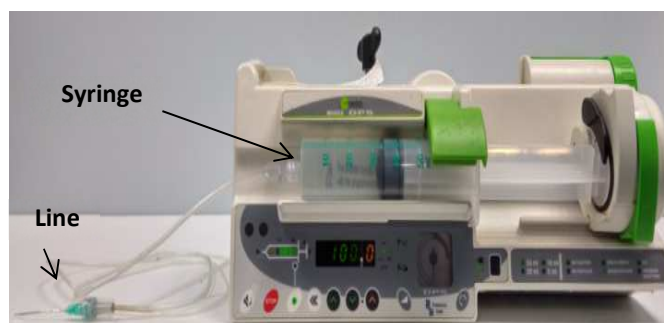


Figure 8: Syringe pump system

The disposable syringe is placed within the pump designed to support it, filled with the prescribed fluid. The piston is fitted within a receptacle and the instrument is programmed for that syringe either manually or automatically. The syringe pump has an endless screw that adjusts automatically to the syringe coupled to the instrument (Figure 9).

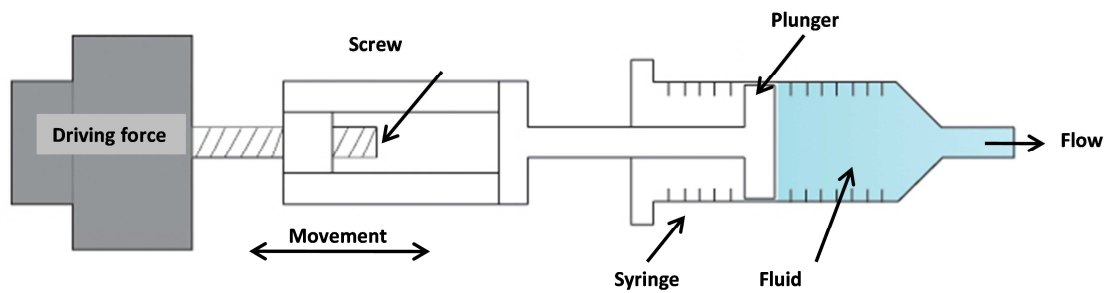


Figure 9: Syringe infusion mechanism

Source: Adapted from (Lewin, 2016).

Syringe pumps can be used individually or in a multichannel system (Figure 10). The multichannel systems can have two types of configurations:

- Two or more individual pumps that are programmed by a common control panel;
- Two or more individual pumps that are controlled by an autonomous module, which is laterally coupled to the system.



Figure 10: Illustrative example of syringe pumps

According to the specifications of ISO 7886-2, the volume of the syringe is limited by its dimension and respective manufacturer's specifications.

In order to obtain the lowest measuring error, the choice of syringe, as regards for volume should be adapted to the flow that has to be administered.

It is recommended that the specifications in Table 2 be used in order to guarantee the above and in accordance to the tests carried out in the Volume and Flow Laboratory of the National Metrology Laboratory of the Portuguese Institute for Quality (IPQ).

Table 2: Syringe volume and flow to administer.

Volume of syringe (ml)	Flow (ml/h)
2	≤ 2
5]2, 5]
10]5, 10]
20]10, 20]
50]20, 50]

When using syringe pumps there are specific applications, namely:

a) Syringe pumps for pain control

PCA syringe pumps (*Patient Controlled Analgesia*) differ from other pumps because they enable patients to self-administer medication to control their pain. In this case, there is a single infusion of narcotics when the patient presses the button on the pump. The amount of medication administered, when properly applied, is carried out in *bolus*.

A PCA syringe pump must be programmed with a lockout period in order to prevent overdoses. This lockout period ensures that, during that time, the patient will only receive the prescribed dosage of medication.

These instruments are designed (Figure 11) with a wide memory capacity that allows for programming the dosage of *bolus*, the lockout period and the basic administration (Alexander, 2010).



Figure 11: Illustrative example of a pain control syringe pump

b) Portable syringe pumps

Portable syringe pumps are used by autoimmune patients to administer medication in the hospital (Figure 12). The infusion can be continuous or intermittent allowing for the fluids to be administered in the same way as pumps used in clinical environment (Alexander, 2010).



Figure 12: Illustrative example of a portable syringe pump

c) Portable insulin syringe pumps

In most of the cases, these pumps use a catheter which is coated with a material that does not react with insulin in order to avoid the absorption of the liquid (with loss of insulin) and the clogging of the catheter. It is the catheter that allows insulin to be administered to the abdominal area. Normally the syringe has the capacity to store ± 3 ml of insulin.

Usually, for patients with Type I diabetes (insulin dependent) these syringe pumps work with a basal flux³ that is sufficient enough to ensure that the patient receives the necessary volume of glucose during the night and between meals. The basal flux is defined in units of insulin per hour. On the other hand, in patients with Type II diabetes (non-insulin-dependent) or with gestational diabetes, the dosage of insulin is administered in *bolus*, when applicable.

Some pumps have the capacity to store data and switch off automatically in order to stop the administration of insulin after a pre-programmed period, thus avoiding states of hypoglycaemia.



Figure 13: Illustrative example of a portable syringe pump to administer insulin

c) Elastomeric infusion pumps

Elastomeric infusion pumps are normally used for pain control, at home or in hospitals (Figure 14). In these pumps, the infusion pressure is obtained by filling the elastic balloon and flow control is carried out by the difference of pressure generated by the body temperature (which must be measured with a calibrated thermometer). Currently these instruments cannot be calibrated, therefore they will not be considered in the remaining chapters of this Good Practices Guide.

³ The basal flux corresponds to the dose of insulin which is continuously administered in order to maintain a stable level of glucose in the blood.



Figure 14: Illustrative example of an elastomeric infusion pump

1.1.2. Main accessories of infusion pumps

As referred previously besides the infusion pump, the system includes all of the parts that allow the fluid to be delivered. Considering the importance of the measuring system and its respective accessories, Table 3 gives a brief description of the disposable parts when using volumetric and syringe pumps.

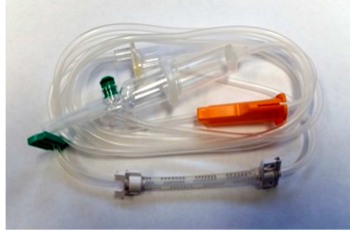
Table 3: Volumetric and syringe pumps main accessories⁴.

Syringes	There are several disposable syringes with different volumetric capacities. Their characteristics and dimensions can be consulted in ISO 7886.
Lines/ Extensions	The lines/extensions that are used should be made of teflon. They can be of different diameters and lengths, depending on the fluid to be administered. A unidirectional valve can be placed in the repective end to prevent the fluid from returning to the line.



⁴The manufacturers' recommendations should be respected in all of the accessories.

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Needle

Used to puncture and guarantee access to the blood vessels.



Catheter

The catheter is a thin, soft, flexible tube. There is a wide variety available on the market.



Valve

The function of the valve is to administer two differentiated and simultaneous therapies.



Filters

The filters can be antibacterial. Their function is to remove impurities, prevent contaminations and avoid the passage of air bubbles to the patient. In order to carry out these functions effectively, it is advisable that the filter be used only once in a clinical setting.



1.2 Advantages and disadvantages of infusion pumps

Infusion pumps have significant advantages when compared with manual administration (infusion systems by gravity), namely in their capacity to administer small quantities and rigorous flows in programmed time intervals, thus greatly reducing clinical error.

Within the field of infusion pumps, syringe pumps have greater advantages, especially at a low flow, thus eliminating the influence of the variation of drops in the homogeneity of the fluid flow to be administered. Besides this, there are other advantages, such as the possibility to change the flow, or the duration of the treatment during the therapy, and connecting various

types serial equipment. This means that when the level of fluid in a syringe is coming to an end, it will immediately be replaced by another, assuring uninterrupted therapy. This instrument also has several warning alarms, such as, a pre-warning signal for an almost-empty syringe, high pressure (if there is blockage in the line), the end of a therapy, amongst others.

However, syringe pumps can also have disadvantages related with the alarm system (flow interruption). Contrary to volumetric pumps, syringe pumps may not be properly equipped with air sensors or with other safety factors, situations which deserve special attention from health professionals and other users.

1.3. Technical and metrological requirements

The definition of technical and metrological requirements of measuring instruments is fundamental in characterising the instrument and the measurement process.

Health facilities should develop processes and procedures that guarantee the monitoring of measuring instruments in accordance with the applicable metrological requirements.

According to the recommendations of the International Organisation of Legal Metrology, namely OIML R 16-1 and OIML R 16-2, as well as to the standards of the International Electrotechnical Commission IEC 80601-2-30, the underlying requirements of a measuring instrument incorporate general, metrological, technical and safety requirements.

Conformity assessment

Under Law no. 145/2009, of 17th June and Ordinance no. 136/96, of 3rd May, the instruments are only placed on the market when they satisfy the essential established requirements, when they have been subjected to a conformity assessment (Ferreira, 2016) and when they respect the reciprocal compatibility among manufacturers.

Within this context, the infusion pumps that are in accordance with these essential requirements, shown in Table 4, should display the EU label applied by the manufacturer.

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Table 4: Main technical and metrological requirements of the infusion pumps

Parameters	Syringe Pump IEC 60601-2-24	Volumetric Pump IEC 60601-2-24												
General Requirements	Measuring Unit	For volumetric flow – cubic metre per second (m ³ /s) or millilitre per hour (ml/h) Occlusion pressure - kilopascal (kPa)												
	Identification of the measuring instrument	Clear and legible identification of the manufacturer and of the instrument (brand, model, serial number and inventory number)												
	Indications of the manufacturer	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 2px;">Maximum and minimal operating flow</td> <td style="width: 50%; padding: 2px;">Maximum and minimal operating flow</td> </tr> <tr> <td style="padding: 2px;">Type of syringe to be used and internal diameters</td> <td style="padding: 2px;">Occlusion pressure alarm</td> </tr> <tr> <td style="padding: 2px;">Range of flow and volume per syringe</td> <td style="padding: 2px;">Air detector</td> </tr> <tr> <td style="padding: 2px;">Occlusion pressure alarm</td> <td style="padding: 2px;">Bolus</td> </tr> <tr> <td style="padding: 2px;">Bolus</td> <td style="padding: 2px;">Types of lines</td> </tr> <tr> <td style="padding: 2px;">Types of lines</td> <td></td> </tr> </table>	Maximum and minimal operating flow	Maximum and minimal operating flow	Type of syringe to be used and internal diameters	Occlusion pressure alarm	Range of flow and volume per syringe	Air detector	Occlusion pressure alarm	Bolus	Bolus	Types of lines	Types of lines	
	Maximum and minimal operating flow	Maximum and minimal operating flow												
Type of syringe to be used and internal diameters	Occlusion pressure alarm													
Range of flow and volume per syringe	Air detector													
Occlusion pressure alarm	Bolus													
Bolus	Types of lines													
Types of lines														
Maximum Permissible Error⁵	<p>± 5 % for volumetric pump</p> <p>± 2 % for syringe pump</p> <p>Conditions of room temperature (<i>t</i>) between 10 °C and 40 °C, relative humidity (<i>rh</i>) between 30 % and 90 % and atmospheric pressure (<i>p</i>) between 500 mbar and 1060 mbar.</p>													
Metrologic Requirements	Measuring interval	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 2px;">Defined by the manufacturer: 0,01 ml/h to 999 ml/h</td> <td style="width: 50%; padding: 2px;">Defined by the manufacturer: 0,1 ml/h to 1200 ml/h</td> </tr> </table>	Defined by the manufacturer: 0,01 ml/h to 999 ml/h	Defined by the manufacturer: 0,1 ml/h to 1200 ml/h										
	Defined by the manufacturer: 0,01 ml/h to 999 ml/h	Defined by the manufacturer: 0,1 ml/h to 1200 ml/h												
Resolution	0,01 ml/h	0,01 ml/h												
Safety Requirements	Electrical safety	In accordance with IEC 60601-1:2015												
	Mechanical safety	Install the instrument in a safe place, to prevent falls and accidents.												

⁵Maximum Permissible Error should be defined by the manufacturer in conformity with ISO 60601-2-24.

1.4 Metrologic traceability and conformity

Similar to what happens with any other measurement in a clinical context, the measurement of flow requires the necessary accuracy, as well as the guarantee of conformity to the metrological requirements of the measuring instrument. Amongst other sources, the error and the uncertainty associated with the measurement of flow depend on the conditions of the infusion pump and on the type of components/consumables used.

Due to the fact that there is a vast quantity of infusion pumps in health facilities, priorities are frequently defined according to the criticality of use of the various instruments. The health services should define a calibration plan for the infusion pumps (see the example in Table 5). In addition, it should also be defined the calibration periodicity according to the history of the instrument, the context in which it is used and the manufacturer's recommendations.

In accordance with the performance of the instrument and of the agreed acceptance criteria, the periodicity of the calibration initially defined can be changed as long as it is properly justified.

It is recommended that the Good Practices Guide - Part I should be consulted as a complement to this information (IPQ, 2015).

Table 5: An example of calibration plan.

Instrument	Brand	Serial Number	Inventory Number	Calibration Periodicity	Date of the last Calibration
Syringe pump					
Volumetric Pump					

Calibration

In order to determine the error and the uncertainty associated with each infusion system, its calibration must be carried out through adequate procedures.

The flow calibration of infusion systems can be carried out through the gravimetric method, ISO 60601-2-24:2012 and ISO 7886:1996 or by using a Flow Infusion Pump Analyser (IDA).

Gravimetric Method

The gravimetric method is the primary method used to determine flow and it consists of determining the mass delivered from the infusion pump in relation to time. This value is then converted into volume/time through adequate formulas (1) for a reference temperature of 20 °C.

$$Q = \frac{1}{t_f - t_i} \left[\left((I_f - I_i) - (\delta m_{imp}) \right) \times \frac{1}{\rho_w - \rho_A} \times \left(1 - \frac{\rho_A}{\rho_B} \right) \times [1 - \gamma(T - 20)] \right] + \delta_{evap}$$

(Equation 1)

In which:

Q	Volumetric flow, in ml/s
t_f	Final time, in s
t_i	Initial time, in s
I_f	Result of the final weighing, in g
I_i	Result of the initial weighing, in g
δm_{imp}	Buoyancy, in g
ρ_A	Density of air in g/ml
ρ_B	Density of the mass pieces, g/ml
ρ_w	Density of water, in g/ml
T	Temperature of the water used in the experiment, in °C
γ	Coefficient of the thermal expansion of the material of which the tubing/syringe is made of, /°C
δ_{evap}	Evaporation rate, in ml/s

This method comprises the following main components: a collecting device integrated in the balance, a data acquisition system and the instrument to be calibrated (Figure 15). During the

calibration process the water to be used and the instrument to be calibrated must be at the same temperature. Therefore, the instrument should be placed in the testing room approximately 12 hours before the beginning of the calibration (Batista *et al.*, 2015).

The temperature of the water used should not vary more than 2 °C during the tests.

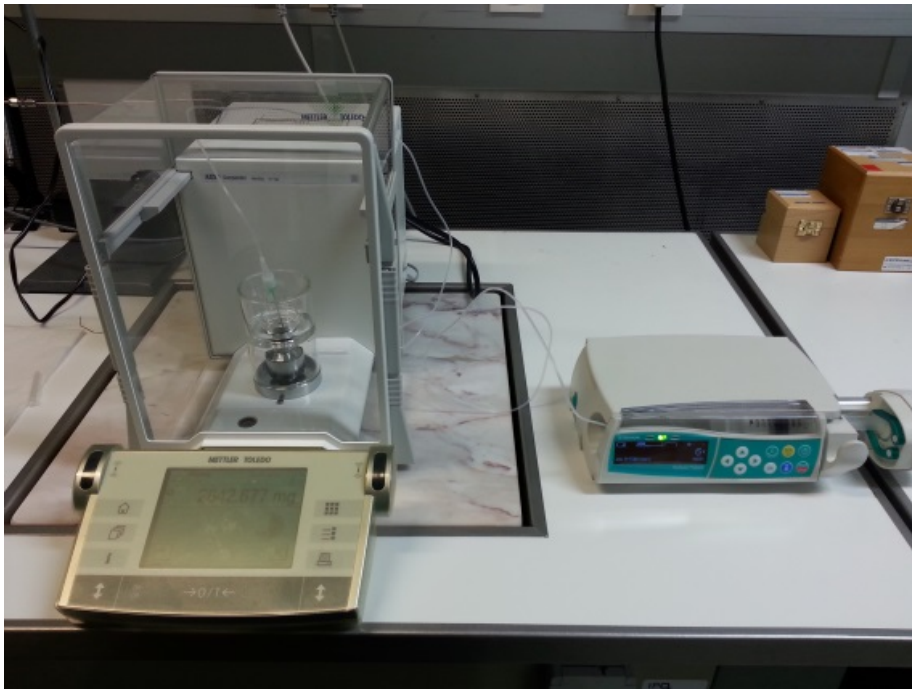


Figure 15: Calibration of a syringe pump through the gravimetric method

The established general procedure takes into account all of the constraints associated with the implementation of the experimental system, namely:

- The precautions regarding the type and the temperature of the liquid used (distilled water type III according to the ISO 3696);
- The need to purge in order to remove any air from the system;
- The positioning of the end of the tube/catheter below the surface of the fluid in the balance reservoir;
- The correction to the evaporation and to buoyancy, as well as the continual register of the environmental conditions that should be within the following intervals: relative humidity between 50 % and 80 %, room temperature between 17 °C and 23 °C and atmospheric temperature between 920 hPa to 1080 hPa.

The instruments used, namely the pressure, temperature and humidity sensors, as well as the balances should have the necessary characteristics to carry out calibration and should be calibrated.

Previous to undergoing the experimental testing, the air from the system should be purged (tubes and syringes), i.e., the system and the associated tubing should be filled with water before beginning the test. For this purpose, the system should stabilise at the programmed test flow during at least 10 minutes.

The time to collect the calibration data should not be less than 15 minutes.

The measuring instrument (infusion pump) should be calibrated in at least three points so as to guarantee the determination of the measurement error in the entire working range.

Calibration through the comparative method with Infusion Pump Analyser (IDA)

A properly calibrated pump analyser can be used when calibration is undertaken *in situ*. In this case the comparative method with an Infusion Pump Analyser is applied.

This calibration procedure consists of comparing the flow indicated in the infusion system with the value given in the IDA (Figure 16). The connection between the two instruments is ensured by the adequate lines in which a purge is carried out, so as to eliminate all the air bubbles from the system.

In order to ensure the flow stabilisation between the syringe and the IDA, there should be a waiting time of at least 10 minutes before beginning to collect the data. The data should be collected in conditions that will allow feasible results and according to the manufacturer's specifications. It is essential to ensure the monitoring and record of the temperature of the fluid to be administered and the environmental conditions, which should be in accordance with the manufacturer's specifications. In addition, it is very important that the humidity values be higher than 50 % in order to prevent evaporation. All of the necessary corrections should be considered in order to obtain precise and accurate results.

It is important to highlight that the results obtained should be in accordance with the manufacturer's specifications.

Distilled water should be used in the tests; it should be at room temperature and should not vary more than 2 °C during the test.

The measuring instrument (infusion pump) should be calibrated in at least three points so as to guarantee the determination of error measurement in the entire working range.



Figure 16: Calibration of a syringe pump through the comparative method

1.4.1 Intermediate verifications

Intermediate verification is a procedure for assessing the conformity of the instrument in between the calibration intervals. Depending on the infusion pump, the procedure that should be applied can be adapted. Nonetheless the parameters of continuous flow or by bolus or of occlusion pressure (IEC 60601-2-24) should always be respected.

As regards internal verification, the continuous flow or in bolus may be assessed by simultaneously using a cylinder that measures the delivered volume and a chronometer to measure the time necessary for the liquid delivery. The occlusion pressure is assessed through a manometer.

Although it is possible to use the described method, it is important to note that it lacks accurateness and reliability, with high measurement uncertainties.

Another way of undergoing this verification is by using an IDA, which permits graphical assessment of whether the values indicated by the instrument fall within the acceptance interval defined by the manufacturer.

All of these instruments should be calibrated and the respective certificates accepted to allow their use.

Figure 17 shows the layout and the image obtained from the intermediate verification by using an IDA.

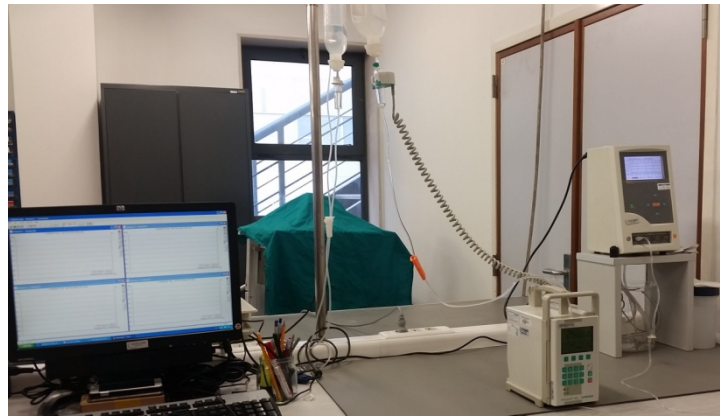


Figure 17: Functional tests of peristaltic infusion pumps by using IDA

1.4.2 Validation of the Calibration Certificate/ Test Report

In order to approve the condition of use of a measuring instrument, the Maximum Permissible Error is defined by applying the following equation:

$$|E| + |I| \leq \text{MPE} \quad (\text{Equation 2})$$

in which E corresponds to the indication error and I to the expanded uncertainty of the measurement. Consequently, for a certain instrument to be accepted and considered to be fit for use, after it has been calibrated or tested (by a recognised entity), the sum of the absolute amount of the error and of the uncertainty should be inferior or equal to the MPE, which is usually the criteria of acceptance defined by the owner of the instrument. This parameter can also be established by reference documentation (such as the manufacturer's instructions).

However, it must be said that the value that is to be considered as the MPE must always be justified by the technician responsible for the instrument/organisation.

It is recommended that the maximum permissible errors of the flow parameters be established before the instrument is used. It is also recommended that the Good Practices Guide – Part I (IPQ, 2015) and other applicable documents should be consulted in order to assess the error and the uncertainty associated with the measurement.

It is important to emphasise that the identification of the metrological condition of the infusion system should be easily accessible and be at the disposal of all those who use it for measurements in a clinical environment. To this effect and besides the respective calibration labels placed on the instrument, electronic platforms should be used in order to share information regarding the metrological state of the measuring instruments being used.

1.5 Maintenance

For the purpose of reducing and eliminating flaws, maintenance takes into account all of the preventive or corrective activities that are necessary for the appropriate operation of the instruments and of all their components. According to the European Standard EN 13306, **maintenance** is “the combination of all technical, administrative and management actions during the life cycle of an item intended in order to maintain it, or restore it to, a state in which it can perform the required function.” An **item** is understood as “any element, component, device, subsystem, functional unit, instrument or system that can be considered separately”.

Within this context the operations of inspection, cleaning and replacement of any component that wears out has a relevant character within the framework of good practices. However, in order to define the periodicity of adequate maintenance for each infusion pump, the following should always be analysed: the manufacturer’s recommendations, the use of the instrument, its location and the criticality of the obtained results (CS/09,2016), (CS/09,2015).

The requirements of visual inspection and of cleanliness should be carried out daily and are under the responsibility of the owner of the instrument. Further, the plans for preventive maintenance should consider the replacement of components if proven necessary.

Notwithstanding the basic principles of the good practices of handling, it is important to highlight that the operations of preventive maintenance that should comply with the actions and specifications described by the manufacturer of the instrument aim at preventing the occurrence of failure, increasing the mean time between them (MTBF – mean time between failure). In this way, it is possible to ensure the maximum reliability and operational availability of the instruments (Durão and Ferreira, 2016).

According to NP EN ISO 13460, maintenance operations are classified as preventive and corrective. Preventive maintenance is carried out so as to avoid failure, loss or function reduction. It takes place before loss of function of the instrument, when the intervention opportunity is identified during inspection or operation control. Corrective maintenance occurs after a failure or loss of function of an instrument, which may happen due to an intrinsic cause or as a result of an extrinsic cause, e.g., an accident, a collision or malfunction.

Adequate preventive maintenance must comply with three fundamental steps: a visual inspection, a functional verification and an electrical safety inspection (AAMI, 2010).

Visual inspection consists of assessment of the general state of the infusion pump (Figures 18, 19 and 20), namely the casing is verified (commonly called carcass), the drop sensor, (in the case of the volumetric pumps), the piston (in the case of the syringes), the supply cable, the display, the keypad, the battery, the doors and the hinges, if applicable. Besides this, the functioning state of the alarms are also verified, not only the audio, by listening to it, but also the visual part, by lighting up the signalling LED (Figures 18 and 19).



Figure 18: Visual inspection of a volumetric infusion pump: lateral verification (on the left); frontal (in the centre) and verification of the drop sensor (on the right).



Figure 19: Visual inspection of a volumetric infusion pump: exterior and interior door (on the left) and drop cable sensor (on the right).

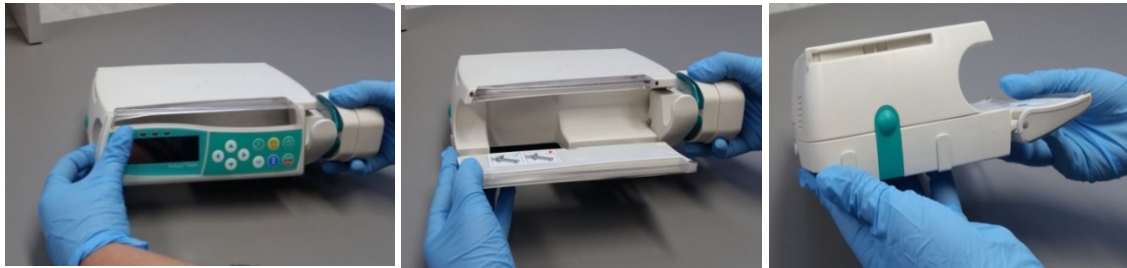


Figure 20: Visual inspection of a syringe pump: state of the casing, of the display/screen and of the buttons (on the left); state of the door, place where the syringe is placed and respective piston (in the centre) and verification of the sides and of the hinges of the instrument (on the right).

Due to the fact that these are instruments used in electromedicine, the inspection of the electrical security of the infusion pumps is a compulsory procedure. The electrical safety tests allow for determining the escape flows of power supply to the ground, of power supply to the framework and of the leaks through the patient according to the safety equipment defined in IEC 60601-1. Electrical security tests are carried out by using an electrical security analyser (Figure 21).



Figure 21 – Electrical security tests using a reference instrument

In case of intervention by an external supplier, the preventive and corrective maintenance of the infusion pumps follow the instructions of the respective manufacturers.

1.6 Good practices of use

The instructions defined by the manufacturer and the safety guidelines in the applicable standards must be followed in order to safely use the infusion pump. It is important to note that at an international level there are several documented safety incidents involving

patients associated with the use of this type of instrument. They occur mainly due to human error or failure of the equipment/accessories/consumables (FDA, 2014).

As a result, health facilities should define a policy for the acquisition, standardisation and management of this type of equipment so as to promote good practices and increase its safety when in use (Keay and Callender, 2004); (Kightley and Buchanan, 2006); (CHLC, 2013).

Here is a list of some considerations with respect to good practices of use:

Safety of the instrument

- Assure the preventive maintenance, as well as the operations that ensure the respective metrological traceability;
- Identify the equipment with a label that is resistant to decontamination;
- Identify the equipment as regards its state of maintenance and calibration;
- Decontaminate the equipment according to the manufacturer's instructions;
- Prevent the risk of explosion, by not using the equipment in the presence of flammable products.

Safe Handling

- Transport the equipment safely and if possible with support devices that have wheels;
- Fix the equipment in use, maintaining it in a safe place so it will not strike the patient in case it falls;
- Use accessories/consumables that are compatible with the equipment, in conformity with the manufacturer's specifications. Normally, syringes which are different from the ones recommended by the manufacturer have a different internal diameter to the one programmed in the pump. This can lead to a significant error in the dosage of the fluids. The case presented in the Best Practice Guide exemplifies this situation (Lucas et al., 2015): a variation of 5 % in the diameter of the syringe can result in a flow error above 10 %;
- During the installation of the syringe, verify if the referred and programmed dimensions in the pump are adequate;
- Block, if possible, the access to the configuration commands of the equipment, in case there is the risk of it being handled by non-authorized people (for example children or confused patients);

- Avoid using the infusion pump in battery mode and resorting to electrical extensions;
- In order to standardise the use of the instruments, they should be of the same model. In this manner, the errors in handling and in the utilisation of consumables are minimised;
- Place the configurations and the total amount of records to zero or to default values after using the devices/equipment as well as before its storage.

Storage

- Store the equipment in a safe place, protecting it from humidity;
- Assure that a sufficient amount of electrical outlets are available in order to charge the batteries of the equipment.

Safety in administration

- Select the adequate instrument for the prescribed treatment and the fluid flow to be administered;
- Verify all the equipment, the accessories, the connections, the audio and visual alarms before beginning to administer the fluids;
- Regularly check the systems in order to detect in advanced any failure in the instrument, the configurations or the accessories /consumables;
- Assure the use of sterile consumables;
- Interrupt the infusion during the replacement of the syringe/ bottle/ lines, in order to avoid the incorrect administration of fluids in the patient;
- Keep the administration lines free of all obstacles;
- The alarms should clearly indicate the specific problem which causes the alarm to go off;
- It should not be possible to disable audio alarms indefinitely. If momentarily silenced, they should be reactivated automatically, at least, after 2 minutes;
- It should not be possible to adjust audio volumes to inaudible volumes;
- The pump should be able to detect an occlusion⁶;
- The limit of the flow pressure in the patient⁷ should be below 1034 mmHg⁸ (to avoid the system to get lose). For the epidural lines, the pressure should oscillate around

⁶ Usually called *upstream*.

⁷ Usually called *downstream*.

⁸ In the majority of the applications (veins), infusion pressure below 207 mmHg is sufficient.

517 mmHg. For neonatal application, it should be possible to adjust the maximum pressure to values below 103 mmHg;

- When an occlusion occurs, the pump should interrupt the flow and the alarm should go off;
- When disconnected from the pump, the system should not allow for free flow to the patient (only a gravitational adjustment).

Incidents

- If any type of incident with a infusion pump should happen, the pump should stay out of service;
- All incidents with infusion pumps should be registered and communicated to the competent entities;
- In case of some sort type of failure /malfunction, a specialised technician should be called so as to solve the problem.

Technical aspects to be considered

- The use of syringes that are rigid and have a reduced volume as well as shorter lines with smaller internal diameters are recommended in order to minimise the effect of the delay in the dosage of the fluids, especially for flow values below 2 ml/h;
- For very small flows (for example 0,5 ml/h), normally used in neonatology, the conditions of use should be similar to the stipulated conditions for calibration operations so as to ensure that the error associated to the instrument be reproducible, in conditions of temperature, viscosity of the liquid and of pressure;
- In case of using several syringes connected to the same line, the influence of the dead volume caused by the variation of the programmed flows in each syringe should be considered. This interaction between the different infusion pumps can cause a variation in the error of dosage. Consequently, the use of accessories that will minimise the dead volume should be used, so as to reduce the response time of the pumps. The length of the lines between the mixing point of the fluids and the point of administration can also be shortened (Timmerman et al., 2015);
- The electronic register of the clinical data of the patient should be ensured through a standard information protocol;

- Given the importance of the software of the instrument to obtain precise measurements, the quality of the data transferred through protocols which allow the validation of the results should be guaranteed.

Further education and training

- Before using the instrument, health professionals should get the due training given by competent entities or by the manufacturer of the equipment;
- The manuals of the infusion pumps should be available in the original language of the user;
- Quick and easy reading guides containing the instructions/guidelines about the equipment operation and the safety procedures should be provided;
- Perform training in metrology;
- Undertake training in safety procedures and good practices;
- Endow the patients and their families/caretakers with the necessary information about the safety procedures and the instructions for using the infusion pumps at home. The health professionals should make sure that the patients and their families/caretakers have a clear understanding of how the instrument works as well as of the consequences of its incorrect use.

Bibliography

- Alexander, M., Corrigan, A., Gorski, et. al. (2010). Infusion Nursing: An Evidence-based Approach. 3rdEdition. Saunders Elsevier.
- Association for the Advancement of Medical Instrumentation (AAMI) & US Food and Drug Administration (FDA). 2010. Infusing Patients Safely Priority Issues From the AAMI/FDA Infusion Device Summit. URL: http://s3.amazonaws.com/rdcms-aami/files/production/public/FileDownloads/Summits/AAMI_FDA_Summit_Report.pdf.
- BATISTA, E., BISSIG, H., PETTER, H., et al. (2015). Primary standards for measuring flow rates from 100 nl/min to 1 ml/min – gravimetric principle. Biomedical Engineering, de Gruyter, 60:4.
- Centro Hospitalar de Lisboa Central (CHLC). 2013. Procedimento multisectoral, SDO.101 – Dispositivos Eletrónicos de Perfusão: Procedimentos de Segurança.
- Comissão Sectorial da Saúde-CS/09. (2015). Metrologia na Saúde – Guia de Boas Práticas. 1.ª Edição. Instituto Português da Qualidade. ISBN 978-972-763-158-2.
- Comissão Sectorial da Saúde-CS/09. (2016). Metrologia na Saúde – Guia de Boas Práticas: Instrumentos de Medição da Pressão Arterial. 1.ª Edição. Instituto Português da Qualidade. ISBN 978-972-763-160-5.
- Durão, C.; Ferreira, M. (2016). A Metrologia na Manutenção Hospitalar. TecnoHospital-TH77. ISSN 1645-9431.
- Ferreira, M. (2016). Contributo da Metrologia para a Qualidade dos Serviços de Saúde. TecnoHospital-TH 77. ISSN 1645-9431.
- IEC 60601-1:2015. Medical electrical equipment. Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- IEC 60601-2-24:2012 Medical electrical equipment - Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers.
- ISO 3696:1978. Water for analytical laboratory use -- Specification and test methods.
- ISO 7886:1993. Sterile hypodermic syringes for single use -- Part 1: Syringes for manual use.
- Kightley, R., Buchanan, B. (2006) Policy for the management of infusions with pumps. Clinical Policies. Portsmouth Hospitals NHS Trust.
- NP EN 13306:2010. Maintenance – Maintenance terminology.
- NP EN 13460:2009. Manutenção: documento para a manutenção.
- Timmerman, A., Snijder, R., Lucas, P. et al. (2015). How physical infusion system parameters cause clinically relevant dose deviations after set point changes. Biomedical Engineering, de Gruyter, 60:4.

- US Food and Drug Administration (FDA). 2014. Infusion Pumps.
URL:<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/>.
- ENTRENAMIENTO DE BOMBA DE INFUSIÓN. 2015. Hospital General Napoleon Davila. Córdoba, España. URL:
<http://hospitalgeneralchone.gob.ec/wpcontent/uploads/2015/10/si-ENTRENAMIENTO-EN-BOMBAS-DE-INFUSI%C3%93N.pdf>.
- Lewin, Ch. (2016). Precision Fluid Handling. Performance Motion Devices.

Annex 1

Working group – Metrology in Health

NAME	ENTITY
Maria do Céu Ferreira - Coordinator	Portuguese Institute for Quality
Ana Luísa	Santo António Hospital
António Silveira	Superior Institute of Engineering of Porto
Durão Carvalho	Santa Maria Hospital
Elsa Batista	Portuguese Institute for Quality
Emanuel Silva	São João Hospital
João Infante	Lisbon Central Hospital
Joaquim Alves	Superior Institute of Engineering of Porto
José Miguel Rodrigues	Santa Maria Hospital
Maria Adelina Gomes	Expert
Noélia Duarte	Expert
Núria Moreira	Tâmega and Sousa Hospital
Pedro Gomes	ISQ
Ruben Mendes	São João Hospital
Sílvia Moutinho	Santo António Hospital
Susana Ramos	Lisbon Central Hospital

The following members participated in the present Guide:

- Ana Luísa
- António Silveira
- Sílvia Moutinho
- Susana Ramos
- Durão Carvalho
- Elsa Batista
- Fernando Figueira
- Joaquim Alves
- José Miguel Rodrigues
- Maria do Céu Ferreira
- Núria Moreira
- Ruben Mendes