OPERATING INSTRUCTIONS
DROPER® FIELD 1000

MAHUSACA sprl
Lieu-dit « Maison Bois », 1
4877 OLNE (Belgium)

info@droper.be

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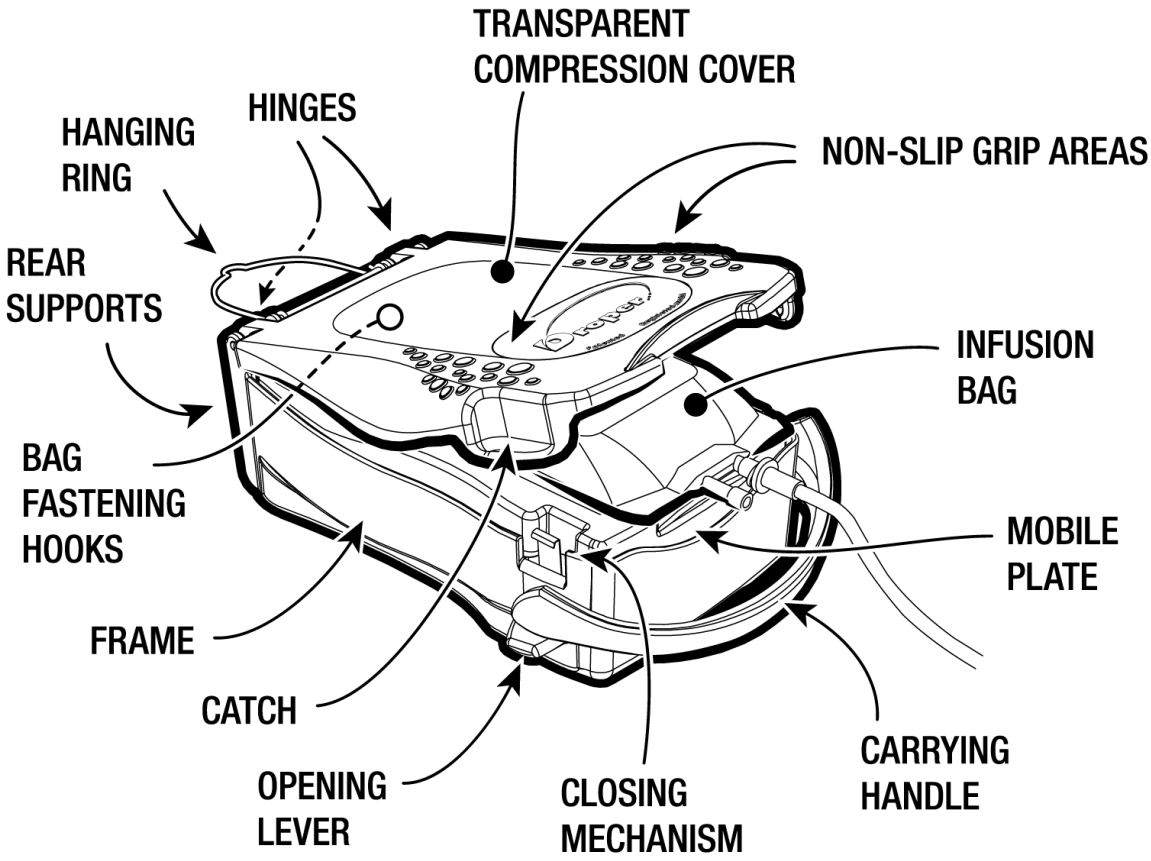
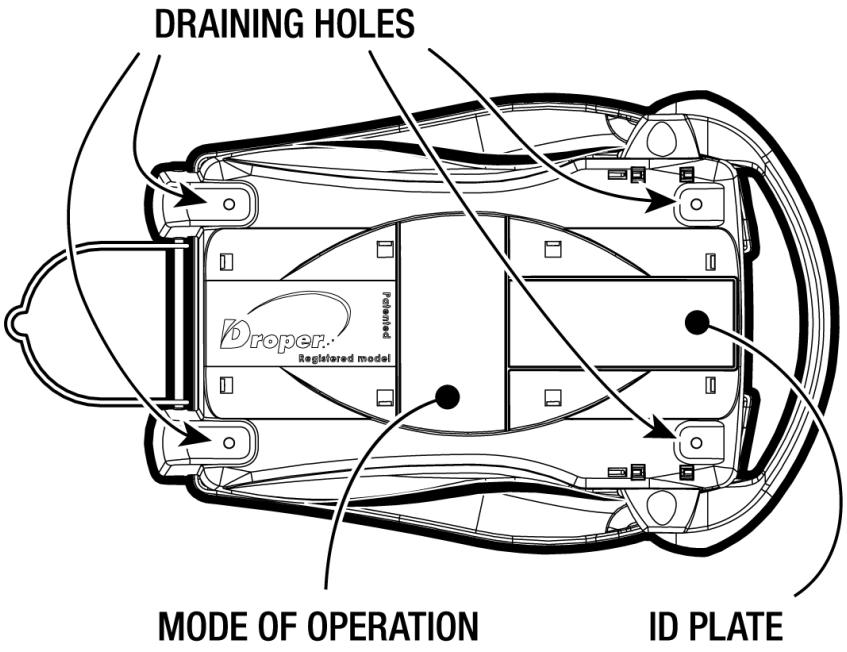
1. DESCRIPTION OF THE DROPER





2. USING THE DROPER FIELD 1000

The Droper Field is a medical device designed to pressurize flexible infusion bags containing all solutions suitable for intravenous infusion or transfusion.

Principally intended for use in emergency situations or catastrophes where stress levels are high, **the device must be used by healthcare professionals.**

The device is dimensioned in such a way as to be able to receive most infusion bags up to 1,000 ml commercially available at the time of its introduction.

Under no circumstances may rigid or semi-rigid bottles be inserted into the device.

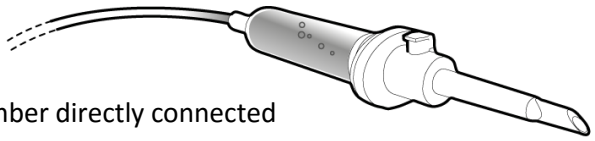
The safety instructions regarding the use of such bags must be known prior to use.

The infusion flow rate is entirely dependent on the pressure exerted and on the viscosity of the product in question.

The Droper Field works by pressurising the liquid bags. This imposes specific use rules similar to these used when using other transfusion or infusion devices working under pressure, like the pressure cuffs.

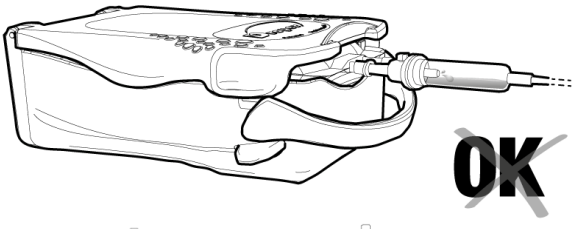
Infusion :

Two types of lines can be accepted :

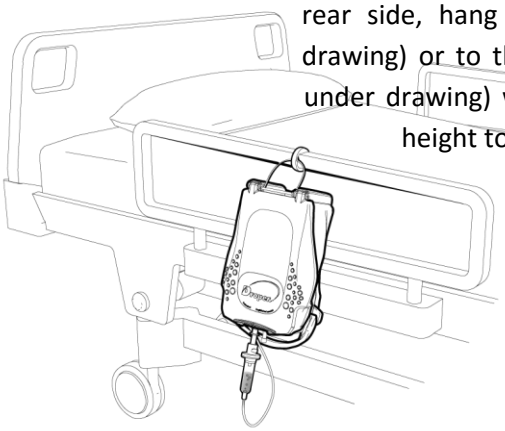


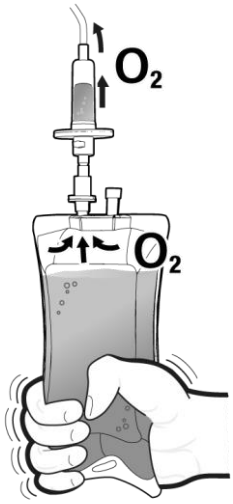
1. *Classic infusion lines* similar to these used with the pressure cuffs. These lines have normally a drip chamber directly connected to the spike (see attached drawing). With this accessory, there are two possible scenarios :

   a. *Droper used residentially with flow rate monitored through the drip chamber count – Possible with any type and ant size of colloids or crystalloids flexible bags up to 1000 ml,* – **Classical air line purge :** the drip chamber MUST stay in a vertical position, end side down. In fact, in case this drip chamber would turn into an horizontal position (see aside drawing) or worst into a vertical position with the drip chamber end side up (see aside drawing), the air volume entrapped in the drip chamber would be pushed towards the patient through the infusion line.

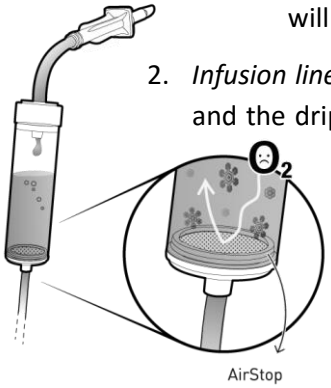


   By the mean of the hanging ring being on the Droper rear side, hang the Droper to a pole (see aside drawing) or to the stretcher or the bed patient frame (see under drawing) while making sure there is a sufficient free height to allow the drip chamber to stay vertical.



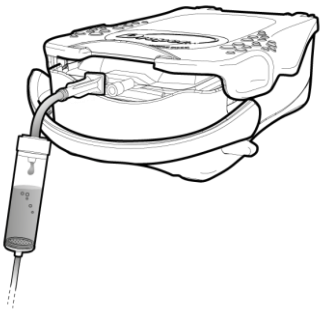


b. *Droper used ambulatory with flow rate monitored by a flow regulator – Possible with 1000 ml crystalloids bags* – **Air purge through the reverse purge technique :** for the same reason as above in point **1.a** (drip chamber becoming horizontal or vertical during moving the patient), the drip chamber and the infusion bag will have to be totally air purged by using the reverse purge technique (see aside drawing) and the flow regulation will be done through the mean of a flow rate regulator.



2. *Infusion line with air catching system and with an extension* between the spike and the drip chamber (see aside drawing) like the AirCatch™ infusion line from the Beldico company. With this accessory, there is one possible scenario :

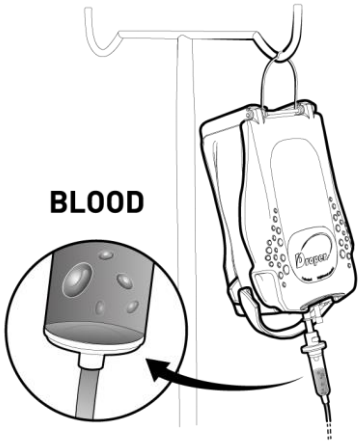
   a. *Droper used residentially or ambulatory with flow regulation through the drip chamber – Possible with all flexible crystalloid bag sizes up to 1000 ml* – **Classical air line purge :** the Droper can be used verticaly (hanged) or horizontaly (laid down) with its drip chamber directed downward (see aside drawing).

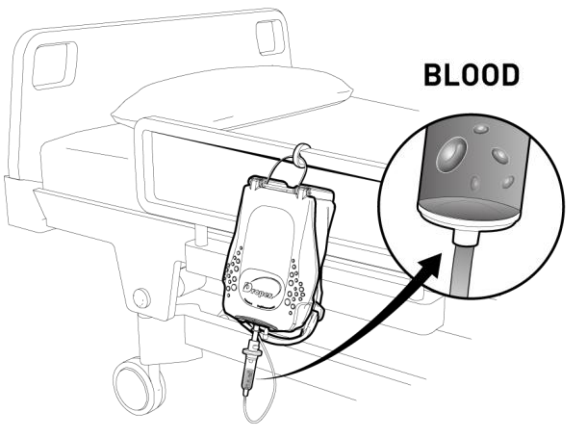


Transfusion :

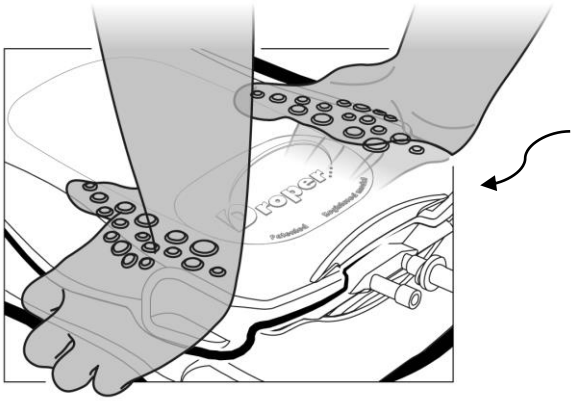
1. *Classical transfusion lines will be used*. Droper has verified with an accredited university laboratory that the pressure exerted on the blood bags does not generate any hemolysis (report available on request). With this accessory, there is one possible scenario, same as in point **1.a Infusion** above :

   a. *Droper used residentially with flow rate regulation through the drip chamber – Possible with all blood bag sizes (up to 1000 ml) including BB bags* – **Classical air line purge :** the drip chamber MUST stay in a vertical position, drip chamber end side down. In fact, in case this drip chamber would turn into an horizontal position or worst into a vertical position with the drip chamber end side up, the air volume entrapped in the drip chamber would be pushed towards the patient through the infusion line. By the mean of the hanging ring being on the Droper rear side, hang the Droper to a pole (see aside drawing) or to the stretcher or the bed patient frame (see aside drawing) while making sure there is a sufficient free height to allow the drip chamber to stay vertical.



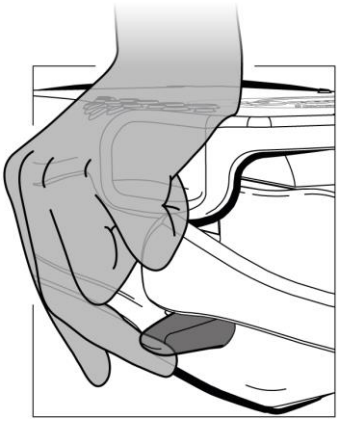


2.1 Opening the cover

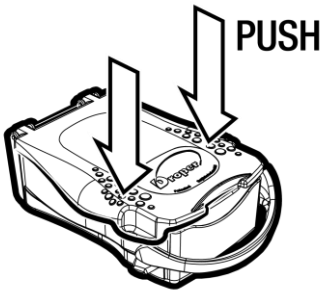


See handling diagrams opposite.
Position the Droper Field on a flat, stable surface.

Place your hands on the non-slip grip areas provided on either side of the cover.

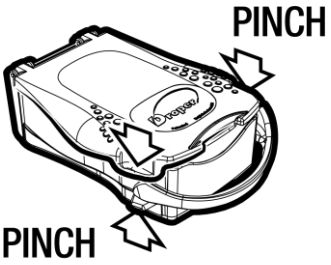


Place your middle finger of each hand underneath the left and right opening levers.

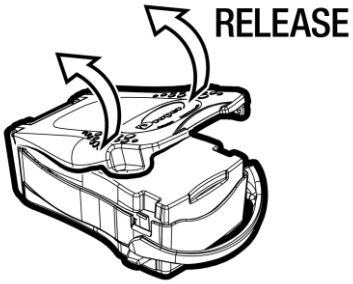


The device opens in three steps:

1. Exert pressure in a downwards direction on the cover using your body weight and with outstretched arms. A resulting small downwards movement can be observed.

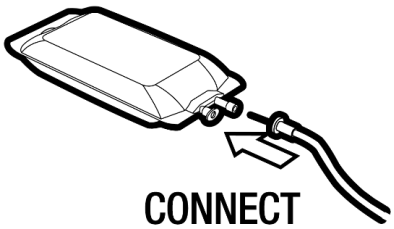


2. Without releasing the pressure exerted on the cover, rotate the two opening levers using your middle fingers of each hand. The fastening spring clips pivot inwards and release the cover.



3. While holding the two open levers in position, release the pressure exerted on the cover, then open the cover.

2.2 Inserting the infusion line



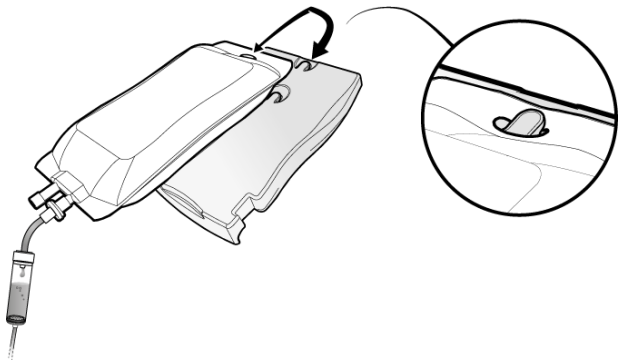
Check that the choke or flow regulator is set to the OFF position.

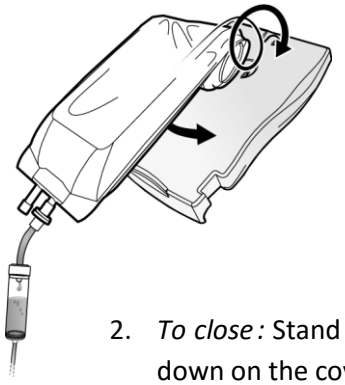
Insert the spike into the infusion bag.

2.3 Placing the infusion bag connected with the infusion / transfusion line and closing the device

1. *Insertion on the plate :* With the cover fully open, position the bag to be administered on the plate and attach it to one of the fastening hooks on the plate. Two fasteners are available according to the model of bag used.

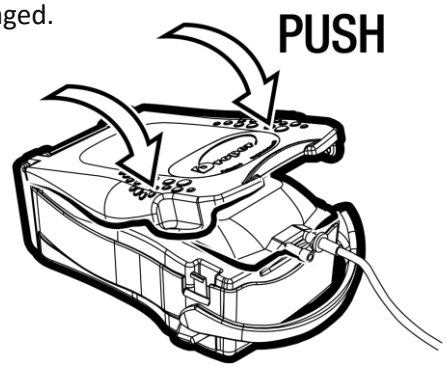
   If the fastener does not correspond to the bag model used, the operator must maintain pressure on this bag in a backwards direction to prevent it from sliding forwards when closing the device.





   If the bag shape is longer than the plate, fold the bag end on itself in order to meet a length ± equivalent to the plate length.

2. *To close :* Stand directly above the device with outstretched arms and press down on the cover. Push down until the fastening clips are engaged.



   The system is then closed and primed.

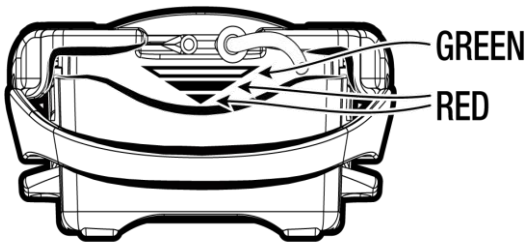
   In case only one fastening clip has been inserted, the plate will show an inclined position. In this event, just press the not engaged side down in order to correctly position the cover.

   This operation pressurises the bag.

3. *Positioning :* Ideally, the device should be positioned at the patient's midaxillary line level.

   If placed at a higher level, the pressure shall be increased and conversely if it is placed at a lower level (a 1 cm height difference is equivalent to ± 1 mbar).

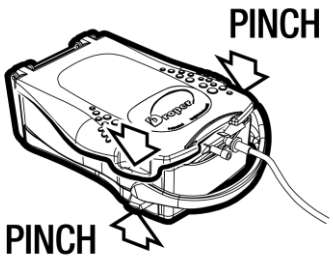
4. *Infusion / transfusion progress :* The administration stage may be assessed by the triangle drawn on the front surface of the mobile plate. The rising action of the plate during administration will show the different lines. The first line is wide and coloured green. The next two lines are red in colour. The peak of the pyramid indicates that the plate has reached its end point.



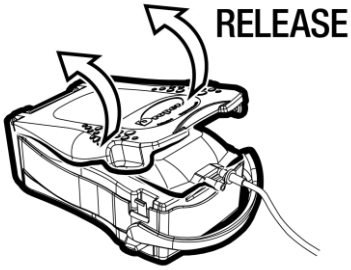
2.4 End of administration

The end of the administration can be checked by :

- observing the inverted pyramid drawn on the front surface of the mobile plate of the equipment when the final peak will be visible.
- coupled with the absence of flow of infusion solution in the drip chamber.
- if necessary, by observance of blood reflux in the tubing (with the device being located below the level on which the patient is lying).



Once administration is complete, open the Droper Field 1000 using the same method as described in point **2.1 Opening the cover**, and remove the bag from the device.



2.5 Stopping administration

This can be stopped by closing the roller clamp or flow regulator by turning them to the OFF position or by means of any other suitable device.

3. OPERATING ISSUES

3.1 Stop, insufficient or absence of administration due to a device malfunction

If the administration stops due to a device malfunction, characterised by a failure in bag pressurisation, this incident may be confirmed by a lack of flow of the product administered in the drip chamber of the line in use.

Firstly check that the cover of the Droper Field has been closed correctly. Where necessary, open and re-close the cover.

In the event that the cover is closed correctly, open the Droper Field 1000, unfasten the mobile plate from its tightening clips, check the following points and implement the relevant actions :

- Check that there are no objects blocking the mechanism. If this is the case, remove the object
  ↳ *Reinstall the mobile plate onto the mechanism by replacing the clips using pressure. Re-pressurise the system.*

- Check that one or several springs have not stopped working
  ↳ *Remove the bag of fluid and continue administration by gravity or manual pressure on the bag, or change device. Send the Droper Field 1000 to the maintenance department for repair.*

- Check whether the clamp, roller clamp or flow regulator is set to the OFF position
  ↳ *Reposition the clamp, roller clamp or flow regulator to the desired position.*

- Check whether the infusion / transfusion line is being pinched by excessive bending of the latter
  ↳ *Remove this bend.*

- Check whether the infusion / transfusion line is being clamped by an object crushing the line
  ↳ *Remove this object.*

- Check whether the infusion / transfusion line has been clamped between the cover and the plate when arming the Droper Field 1000
  ↳ *Open the Droper Field 1000 and move the infusion / transfusion line.*

3.2 Stop, insufficient or absence of administration due to a catheter obstruction

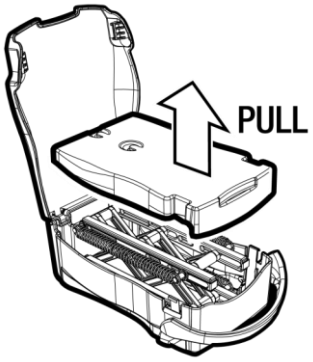
After checking the correct operation of the device, check whether the administration has stopped, is insufficient or is absent by observing the slowing or absence of flow of the infused fluid in the drip chamber

↳ *Reinsert another catheter*.

4. CLEANING / DISINFECTION

The device is made from plastic and metal materials that are not subject to either biodegradation or corrosion under normal operating conditions. The device was designed to allow for its full cleaning in the event of any leakage of bodily fluids, liquids being administered or any other external pollution.

4.1 Cleaning



To clean the device, place the Droper Field 1000 on a flat, stable surface. Open the Droper Field 1000 and pivot the cover backwards as far as possible. Firmly grip the end of the plate nearest the operator and pull obliquely upwards. This will result in the tightening clips releasing the plate from the mechanism (see diagram).

Normal cleaning can then take place by spraying and rinsing.

4.2 Disinfection

After disassembly and cleaning, the different parts removed according to the procedure described above in point **4.1 Cleaning** can be disinfected by soaking, scrubbing or spraying appropriate products.

The use of disinfectants applied using SPRAYS is ideal for routine disinfection operations and must take place in compliance with the disinfectants manufacturer's recommendations and at a distance of 30 cm from the device, while ensuring that no liquid product is accumulated on the device.

For further information, please contact your company's appropriate department for the provision of suitable cleaning and disinfection agents.

Precautions :

1. Solvent-based disinfectants are prohibited.
2. Do not place in an autoclave. Avoid abrasive scrubbing which may damage the elements.
3. Do not use cleaning products containing the following ingredients :
    - AMMONIUM / TRICHLORETHYLENE
    - DICHLOROETHYLENE
    - AMMONIUM CHLORIDE
    - CHLORINATED or AROMATIC HYDROCARBONS
    - METHYLENE CHLORIDE

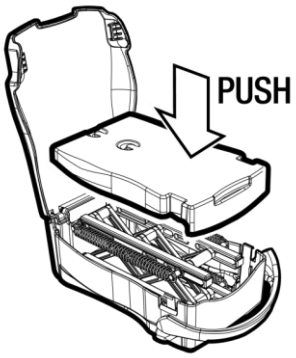
- KETONES
  ↳ These aggressive agents may damage the plastic parts and cause the device to malfunction.

- ALCOHOL-BASED SPRAYS (20% - 40% alcohol content)
  ↳ These cause the synthetic materials to tarnish and splinter.

- IODINE SOLUTIONS
  ↳ These may irreversibly stain certain clear plastic parts.

4.3 Re-installing the components

Once the parts are completely dry, re-insert the two components in the opposite manner to the disassembly method, presenting each part opposite its tightening clips. The plate must be presented with the infusion bag fastening hooks facing the rear of the device. Visually check the correct installation of the different elements.



5. PERIODIC INSPECTION

The device is designed to operate more than 6,000 times under normal operating conditions. However, the manufacturer advises that users perform annual maintenance and inspections to ensure the correct operation of the device, either by sending it to the manufacturer or distributor, or by using the method described below :

Place a 1000 ml bag of NaCl 0.9%, the design of which corresponds to the plate's surface (e.g. : 1000 ml Viaflo bag of NaCl 0.9% from Baxter) in the Droper Field and introduce the spike of a classic infusion line without a catheter or needle, and with the valve in the OFF position. Open the infusion line into a recipient placed at the same height as the device and measure the time required to drain the bag. The bag must be drained in less than or equal to 10 minutes.

6. STORAGE

The device must be stored in a temperature-controlled, dry place.

- Relative humidity : 20% to 90%
- Storage temperature : - 10°C to + 50°C

7. WARRANTY CONDITIONS

The Droper Field 1000 is guaranteed against any part or manufacture defects for a period of 1 year from its date of first use. To benefit from the parts and labour warranty from our After-Sales Service or from an approved service, the following conditions must be complied with :

- The device must have been used under the normal operating conditions described herein.
- The device must not have suffered from any deterioration caused by its storage, maintenance or incorrect handling.
- The device must not have been modified or repaired by persons not authorised by PROMOVET.
- The serial number of the device must not have been modified or erased.
- For item returns and repairs, please contact the After-Sales Service.

8. LIFE

The Droper Field 1000 was designed to operate for a period of 2 years, calculated based on a daily usage rate of 8 infusions per day from its commissioning date and for a period of 10 years from its date of manufacture. The user is responsible for recording the date of first use by any means deemed appropriate for traceability purposes.

9. USEFUL CONTACTS

Sales Department and After-Sales Service :

Promovet sarl
ZAC de la Route de Beauraing, 1
08600 GIVET (France)
Tél. : + 33 (0)3 24 42 15 71
E-mail : info@promovet.fr
Website : www.droper.be

CE 0499

Year of first commissioning : 2015