



FagronLab™ ELD

User Manual



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FagronLab™ ELD

1. Introduction

Thank you for purchasing the FagronLab™ ELD Easy Liquid Dispenser . This precise liquid dispensing device is specially designed for pharmacies to assist compounders in precise dosing needs of most frequently used liquid raw materials in daily preparations. You must carefully read and understand the contents of this manual prior to operating this device. After reading this manual, please put it in an appropriate position for easy access.

2. Service

In case of any problem, you can always contact the Service Department for technical support. Please provide the customer care representative with the following information:

- Description of problem.
- Methods and procedures adopted to resolve the problems.
- Your contact information.

Return for repair



Attention:

- For safety reasons only clean/decontaminated instruments can be checked/repared.
- Therefore: Clean and decontaminate the instrument carefully.
Return shipment has to be effected at the risk and cost of the sender.

3. Warranty

This device is under warranty and free from defects in materials and workmanship, under normal use and service, for a period of 12 months from the date of invoice (excluding consumable accessories, tubes, threads and glass insert). The warranty is extended only to the original purchaser. Warranty is not valid on device which has been damaged on account of improper installation, improper connections, misuse, accident or abnormal conditions of operation. If the warranty has been expired, Fagron would still responsible for repair with relative charges. For claims under the warranty please contact your local supplier.

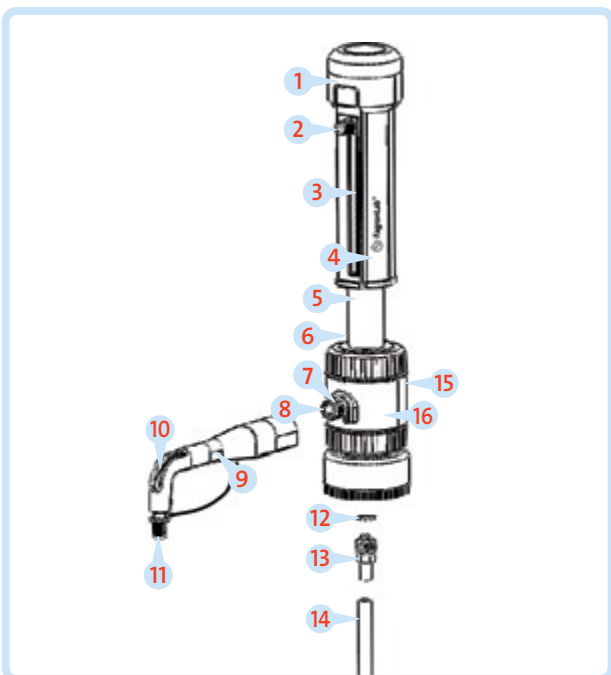
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4. Safety instructions

This instrument may be used with approved hazardous materials, operations, and equipment used for pharmaceutical compounding. This manual does not purport to address all of the safety problems associated with its use. It is the responsibility of whomever uses this instrument to consult and establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.

- Follow the general instructions for hazard prevention and safety regulations, e.g., wear protective clothing, eye protection and gloves as intended for safety in compounding preparations.
- Observe the raw material manufacturer's information.
- Every user must be acquainted with this Operating Manual before operation according to SOPs of compounding establishment.
- Use the instrument only for dispensing liquids, with strict regard to the defined Operating Exclusions and Limitations. If in doubt, contact the manufacturer or supplier.
- When dispensing, the discharge tube must always point away from the user or any other person. Avoid splashes. Only dispense into suitable vessels.
- Never carry the mounted instrument by the cylinder sleeve or the valve block. Breakage or loosening of the cylinder may lead to personal injury from content.
- Never press down the piston when the closure cap is pushed on.
- Never remove the discharge tube while the cylinder is filled.
- Use ONLY smooth gentle movements to operate the piston upwards and downwards.
- Use only original manufacturer's accessories and spare parts. Don't carry out technical modifications.
- Before use check the instrument for visual damages. In case of trouble (e.g., piston difficult to move, sticking valves or leakage), immediately stop dispensing. Clean the instrument according to the cleaning instructions before any further use of the instrument or contact the manufacturer.

5. Components



No	Description
1	Piston seat
2	Volume adjustment knob
3	Scale pointer
4	Cylinder sleeve
5	Piston
6	Glass cylinder
7	Discharge valve
9	Discharge tube sleeve
10	Discharge tube
11	Closure cap
12	Filling seal
13	Filling valve
14	Filling tube
15	Air vent cap
16	Valve block

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6. Application and design

This instrument is designed for dispensing liquids in compounding establishments observing the following limits:

- 15 to 40 °C of raw materials.
- Vapor pressure up to 500 mbar.
- Density up to 2.2 g/cm³.

7. Materials

When the instrument is correctly used, the dispensed liquid comes into contact with only the following chemically resistant materials: Borosilicate glass, PFA, FEP, PTFE, Hastelloy; PP (closure cap).

8. Operating exclusions

Never use this instrument for:

- Liquids attacking FEP, PFA, PTFE or Hastelloy.
- Liquids attacking borosilicate glass (e.g., hydrofluoric acid).
- Liquids which are decomposed catalytically by Hastelloy (e.g., H₂O₂).
- Explosive liquids.
- Suspensions as solid particles may clog or damage the instrument.

9. Operating limitations

Concentrated hydrochloric acid and concentrated nitric acid, chlorinated and fluorinated hydrocarbons, or liquids which form deposits may make the piston difficult to move or may cause jamming. When dispensing flammable media, make provisions to avoid static charging, e. g., do not dispense into plastic vessels; do not wipe instruments with a dry cloth.



Warning:

- If there is a sign of a potential malfunction (e.g., piston difficult to move) never use force. Immediately stop dispensing and follow cleaning instructions or contact the manufacturer.



Note:

- Compatibility of the instrument for this special application (e. g., trace material analysis) must be checked by the user or contact the manufacturer.

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10. Preparing instrument for use



Figure 1

- Always wear protective gloves when touching the instrument and the bottle, especially when using dangerous liquids. Carry the mounted instrument only as shown in figure 1.



Attention:

- The adapters supplied with the instrument are made of polypropylene (PP), and can only be used for media which does not attack PP.



Warning:

- Wear protective clothing, eye protection and gloves. Follow all Safety Instructions and observe the Operating Exclusions and Limitations.

Connecting the discharge tube

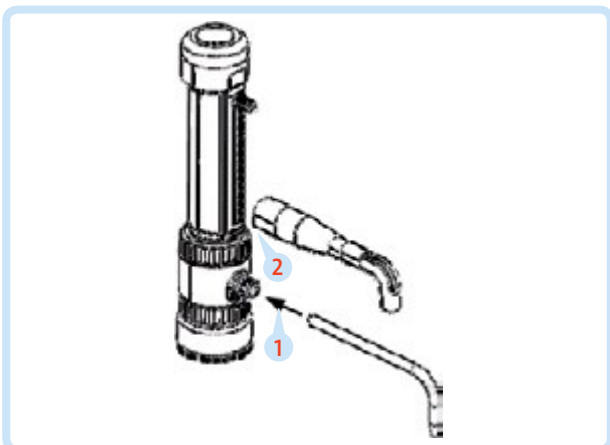


Figure 2

- 1 Firmly tighten the discharge valve with tools.
- 2 Push the discharge tube as far as possible into the discharge valve.



Warning:

- Do not use any other type of discharge tube.
- Never use damaged or deformed discharge tubes.

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Connecting the filling tube

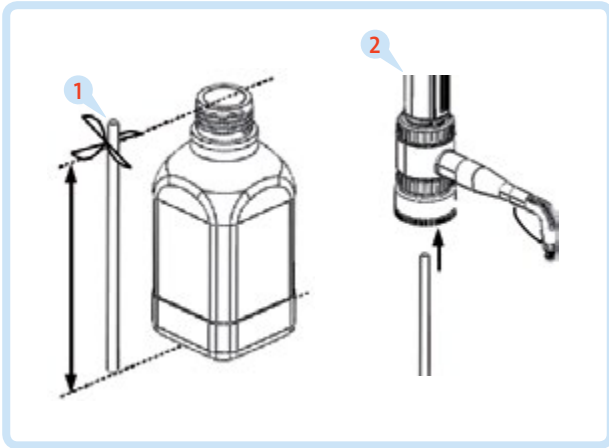


Figure 3

- 1 Cut off the bottom of the filling tube diagonally if it is larger than the used bottle.
- 2 Push the filling tube into the valve block as far as possible - with the diagonal end down.

Mounting instrument on bottle

The instrument can be screwed directly onto a GL 45 screwthread. For other bottles, use the accompanying adapters. Instrument is compatible to all Fagron Raw Material bottles.



Attention:

- The adapters supplied with the instrument are made of polypropylene (PP), and can only be applied for media which do not attack PP.

Priming the instrument

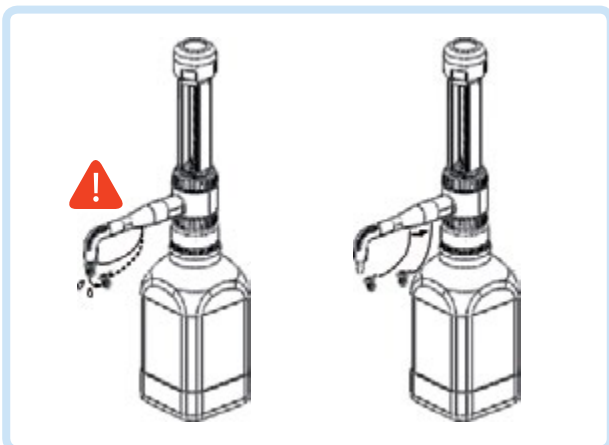


Figure 4

- Hold the discharge tube and carefully remove the closure cap.
- Slide the closure cap backwards on the tube support, away from the discharge tube opening.



Attention:

- For small bottles use a bottle stand to prevent tipping over.

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**Warning:**

- Raw material may drop off the discharge tube and closure cap.



Figure 5

- Hold an appropriate collecting vessel under the discharge tube opening.
- Gently pull the piston up, then press it down rapidly.
- Repeat this procedure until most of the air bubbles in the glass cylinder and discharge tube have been removed.

**Note:**

- Before using the instrument for the first time, ensure it is rinsed carefully or discard first few samples dispensed. When applying to a bottle for the first time make sure you pump out all air from the ELD tubes. Thus, first pump might not be accurate.

11. Priming/dispensing



Figure 6

**Warning:**

- Follow all Safety Instructions and observe the Operating Exclusions and Limitations. The discharge tube must always point away from the user or any other person. Never press down the piston when the closure cap is pushed on. Raw material may drop off the discharge tube and closure cap.

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Setting the volume

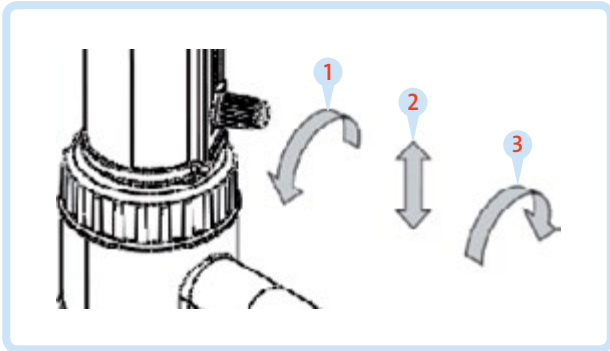


Figure 7

- Rotate to unlock the volume adjustment knob, move up and down to the desired quantity and rotate clockwise to lock.
- Hold an appropriate collecting vessel under the discharge tube opening.
- Pull the piston up slowly and evenly to the upper stop to draw raw material into the glass cylinder.
- Push the piston down gently and evenly to dispense the raw material into the vessel.

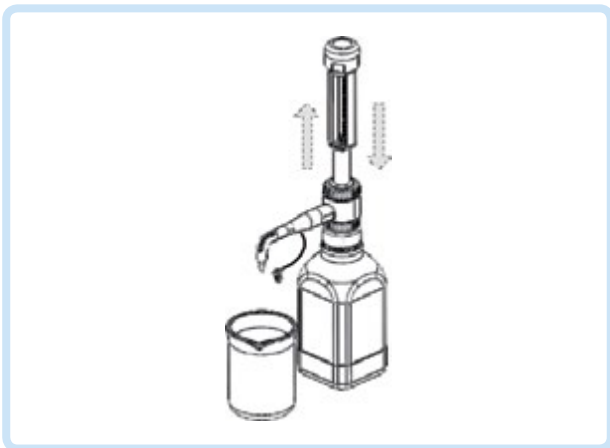


Figure 8



Attention:

- After use, always leave the piston in the down position.

12. Cleaning

The instrument must be cleaned in the following situations to assure correct operation:

- If the piston becomes difficult to move.
- After dispensing liquids which form deposits.
- Before changing the raw material.
- Prior to long term storage.
- Should liquid have accumulated in the closure cap.
- Prior to sterilization.
- Before replacing the valves.



Warning:

- Follow all Safety Instructions. The glass cylinder, valves, filling and discharge tubes contain raw material. Wear protective clothing, eye protection and appropriate hand protection.

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Note:

- Never change the pistons of the instruments!



Figure 9

- Push on the closure cap.
- Empty and unscrew the instrument from the bottle and lift the instrument so that the filling tube is out of the liquid but still in the bottle.
- Carefully tap the filling tube against the bottle from the inside so that the raw material runs back into the bottle.

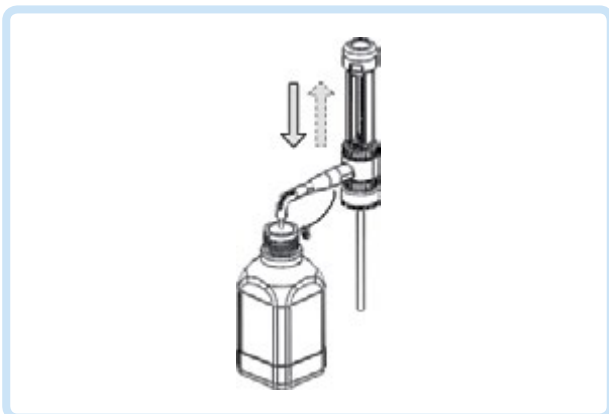


Figure 10

- Remove the closure cap, and dispense the remaining raw material into the bottle by repeated piston operation.
- Mount the instrument onto another bottle filled with an appropriate cleaning solution.
- Flush the instrument.
- Empty the bottle, flush it and fill it with water. Repeat step 6 and 7.
- Empty the instrument (Figure 10).

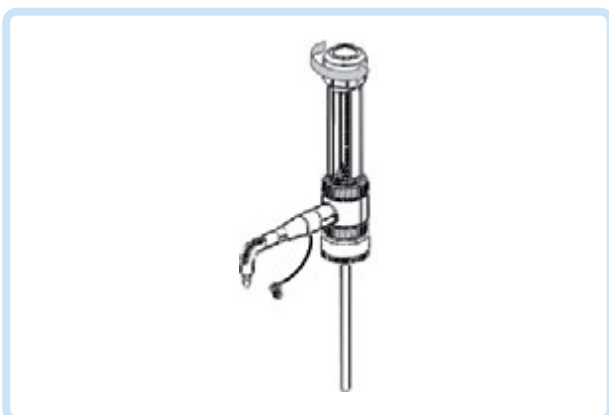


Figure 11

- Unscrew the piston seat (1).
- Carefully pull the piston (5) out of the glass cylinder (6) by pulling on the piston seat only.
- Carefully remove deposits at the edge of the glass cylinder with a screw driver. Clean piston and cylinder with a bottle-brush.
- Carefully reassemble the instrument in the reverse order. Flush instrument with distilled water.



Note:

- Insert the piston straight into the cylinder, not at an angle.

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Cleaning/replacing the filling valve

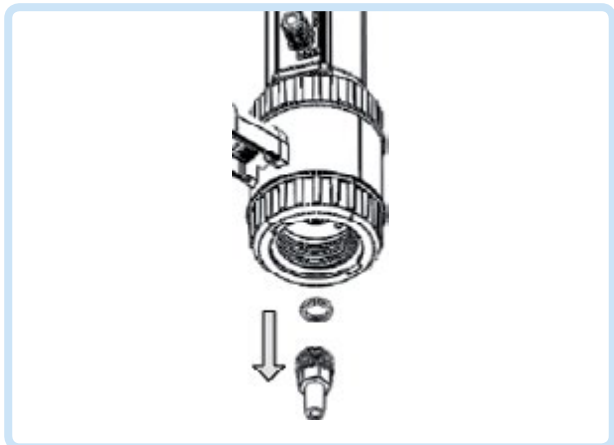


Figure 12

- Follow all cleaning instructions.
- Remove the filling tube.
- Unscrew the filling valve using the mounting tool. Remove the valve with its sealing washer. Make sure the sealing washer does not remain in the valve block.
- Rinse the filling valve in the cleaning solution, and clean with soft brush. Should valve ball stick, push into filling opening of valve with pointed instrument, and release valve ball.
- Screw the cleaned/new filling valve together with its sealing washer into the valve block and tighten it firmly using the mounting tool.

Cleaning/replacing the discharge valve

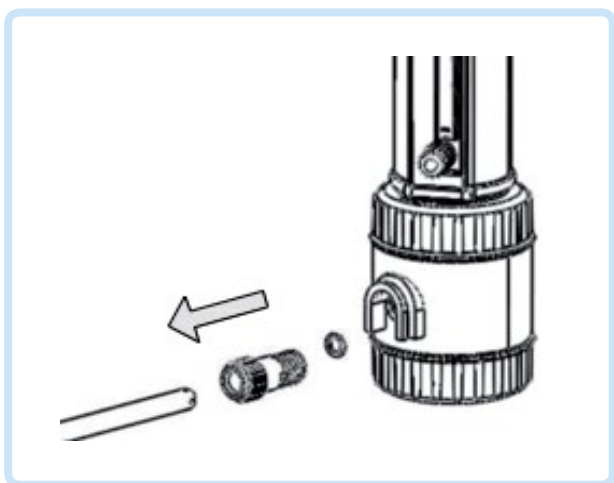


Figure 13

- Follow all cleaning instructions.
- Unscrew the discharge tube.
- Remove valve locking ring.
- Unscrew the discharge valve using the mounting tool. Remove the valve with its sealing washer. Make sure the sealing washer does not remain in the valve block.
- Rinse the discharge valve in the cleaning solution, and clean with soft brush. Should valve ball stick, push into filling opening of valve with pointed instrument (e.g., disposable pipette tip), and release valve ball.
- Screw the cleaned/new discharge valve together with its sealing washer into the valve block and tighten it firmly using the mounting tool.
- Slide on the valve locking ring making sure the two prongs properly align with the notches.

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13. Autoclaving

This instrument withstands steam sterilization at 121 °C, 2 bar absolute (15 psi) for 20 minutes in accordance with widely used guidelines. It is the user's responsibility to ensure effective autoclaving.

Preparation prior to the autoclaving

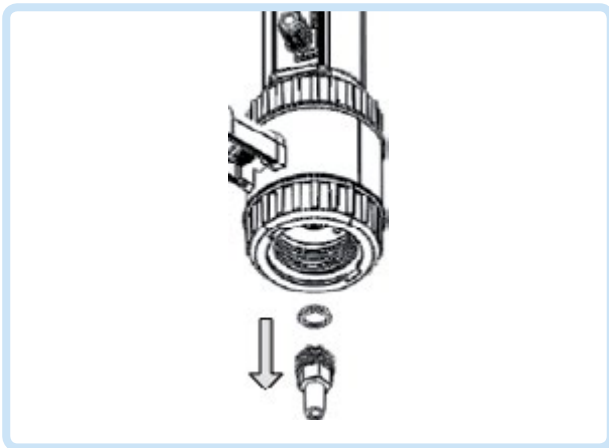


Figure 14

- Clean the instrument before sterilization.
- Remove the discharge tube (10) with removed closure cap (11), filling tube (14), and put all parts on a towel. **Avoid contact with hot metal surfaces.**
- Lay the instrument with piston in down position on the towel.
- Autoclave all parts.

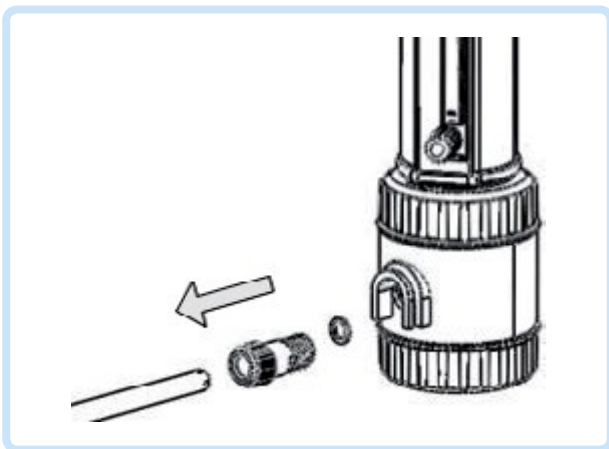


Figure 15



Note:

- Allow to cool down in the closed autoclave to avoid deformation through too rapid cooling. After every autoclaving, inspect all parts for deformities or damage. If necessary, replace them. Do not reassemble the instrument until it has cooled down to room temperature (cooling time approx. 2 hours). Mounting tool can be steam sterilized at 121 °C.

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14. Checking the volume

The accuracy and coefficient of variation of the instrument are determined gravimetrically as follows:

- Set to the nominal volume.
- Dispense distilled H₂O.
- Weigh the dispensed quantity on an analytical balance.
- Calculate the dispensed volume taking the temperature into account.
- Perform at least 10 dispensing and weighing operations.
- Calculate the accuracy (A%) and the coefficient of variation (CV%) by means of the formular used in statistical quality control. The proceeding is described e.g., in DIN EN ISO 8655-6. Observe the operating manual of the balance manufacturer and the corresponding standards.

Calculations (for the nominal volume)

Mean value $\bar{x} = \frac{\sum x_i}{n}$, x_i = results of weighing

Mean volume $\bar{V} = \bar{x} \cdot Z$, n = number of weighings

Z = correction factor (e. g. 1.0029 µl/mg at 20 °C, 1013 hPa)

Accuracy

$$A\% = \frac{\bar{V} - V_0}{V_0} \cdot 100$$

V_0 = nominal volume

Standard deviation

$$s = Z \cdot \sqrt{\frac{\sum (x_i - \bar{x})^2}{n - 1}}$$

Coefficient of variation

$$CV\% = \frac{100s}{\bar{V}}$$

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15. Trouble shooting

Problem	Possible cause	Corrective action
Piston difficult to move	Formation of crystals, dirty	Stop dispensing immediately. Loosen piston by circular motion, but do not disassemble. Follow all cleaning instructions.
Filling not possible	Volume adjusted to minimum setting	Set to required volume.
	Sticking filling valve	Clean the filling valve. If necessary replace the valve with sealing washer.
Instrument does not dispense liquid	Discharge tube closure cap pushed on	Remove closure cap.
	Discharge tube not firmly connected or damaged	Push on the closure cap. Hold the piston in place, and push the original manufacturer's discharge tube on firmly. Replace a deformed or damaged discharge tube.
Air bubbles in the instrument	Raw material with high vapor pressure has been drawn in too quickly	Slowly draw in raw material.
	Seal not inserted, knurled locking nuts not firmly connected	Double check that seal (12) is in place, and that the knurled locking nuts at the discharge tube are firmly seated and finger tight.
	Air not expelled from the instrument	Priming the instrument.
	Filling tube not firmly connected or damaged	Push the filling tube on firmly. If necessary cut off approx. 1 cm of tube at the upper end and reconnect it or replace filling tube.
	Valves dirty, not firmly installed or damaged	Cleaning procedure. Tighten the valves using the mounting tool. If necessary, replace the valves and sealing washers.
Dispensed volume is too low	Discharge tube not firmly connected or damaged	Push the original manufacturer's tube on firmly.
	Filling tube not firmly connected or damaged	Cleaning procedure. Push the filling tube on firmly. If this does not suffice, cut off approx. 1 cm of tube at the upper end and re-connect it or replace filling tube.
	Valves not firmly installed or damaged	Clean the instrument. Tighten the valves using the mounting tool, if necessary replace the valves and sealing washers.
	Sticking filling valve	Clean or replace discharge tube, if necessary.

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16. Technical data

Volume ml	Graduation ml	A* \pm		CV* \leq		Cat. No.	Adapter, PP	Filling
		%	μ l	%	μ l			
0.5 - 5	0.1	0.5	25	0.1	5	00-20-007	GL 25, GL 28, GL 32,	300 mm
5 - 50	1.0	0.5	250	0.1	50	00-20-010	GL 38, S40	

* Error limits (A = Accuracy, CV = Coefficient of variation) relative to the nominal capacity (maximum volume) indicated on the instrument, obtained at equal temperature (20 °C) of instrument, ambience and dist. water, and with smooth operation.

Items supplied



- Operating manual
- 1 discharge tube
- 1 mounting tool
- 1 filling tube and adapters of PP of the following sizes:

Nominal vol. tube	Adapter, PP	Filling
0.5 - 5	GL 25, GL 28, GL 32, GL 38, S40	300 mm
5 - 50		

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Notes

A series of horizontal dotted lines for taking notes.

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Notes

A series of 25 horizontal dotted lines for taking notes.

Together
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of personalized medicine.



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