# InfuLife

## Staff Competency Assessment

Elastomeric Infusion Pump — Instructions for Use

Reference Document: PMP-1100 Rev F and PMP-1101 Rev A | First Medical Source (FMS), LLC

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| **Staff Name:** _____ | **Date:** _____ |
| **Unit/Department:** _____ | **Evaluator:** _____ |

### Instructions for Completion

- This assessment covers 12 questions drawn from the InfuLife IFU (PMP-1100).
- Select the single best answer for each question. Write your answer (A, B, C, or D) on the Answer line provided.
- Special attention should be given to questions about flow rate sensitivity to fill volume, height and temperature, as these have direct flow delivery implications.
- **Passing score: 80% (10/12 correct). Scores below 80% require remediation and retest.**
- The Answer Key with rationales is provided on the final page — for evaluator use only.

### Domain Color Key

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| Flow Sensitivity (5 Qs) | Temperature (3 Qs) | Safety / Alarms (2 Qs) | Fill Calculation (1 Q) | Filling Procedure (2 Qs) | Contraindications / Patient Pop. (2 Qs) |

## Assessment Questions

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| **Question 1** | **Flow Sensitivity** | |
| | *Clinical scenario: Your patient's InfuLife pump has the flow restrictor positioned 10 inches higher than body level.* | |
| | **According to the IFU, what effect does raising the flow restrictor 10 inches above the reference (body) height have on the infusion flow rate?** | |
| | A. The flow rate decreases by approximately 6% | |
| | B. The flow rate increases by approximately 6% | |
| | C. There is no clinically significant change in flow rate | |

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| | D. The flow rate increases by approximately 9% |
| **Answer:** | |

| **Question 2** | **Temperature** | |
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| | *Clinical scenario: The flow restrictor is exposed on top of the patient's blanket at room temperature (23°C/73°F) rather than against the patient's skin (31°C/88°F).* | |
| | **Compared to optimal placement against the skin, what happens to delivery time when the restrictor is at room temperature?** | |
| | A. Delivery time increases by approximately 9% | |
| | B. Delivery time decreases by approximately 9% (drug delivered faster than intended) | |
| | C. Delivery time increases by approximately 10% | |
| | D. There is no significant impact — only fill volume affects delivery time | |
| **Answer:** | | |

| **Question 3** | **Temperature** | |
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| | *Clinical scenario: A pharmacy-prepared InfuLife has been refrigerated overnight. The RN plans to begin infusion immediately after removal.* | |
| | **What does the IFU require before starting an infusion on a device stored in the refrigerator?** | |
| | A. Allow it to warm to room temperature before use | |
| | B. Begin immediately — cold storage slows the rate to a safer level | |
| | C. Prime the tubing with warm saline first, then connect | |
| | D. Refrigerated storage is not permitted; the device must be discarded | |
| **Answer:** | | |

| **Question 4** | **Fill Calculation** | |
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| | *Clinical scenario: What should be the fill volume of C270R0050 for a 48-hour infusion?* | |
| | **What is the correct fill volume to prepare?** | |
| | A. 240 mL (infusion time × flow rate only) | |

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| | B. 245 mL (from table PMP-1103 from the Clinician Guide PMP-1101) |
| | C. 250 mL (infusion time × flow rate + 10 mL residual volume) |
| | D. 270 mL (use nominal fill volume regardless) |
| **Answer:** | |

| **Question 5** | **Flow Sensitivity** |
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| | *Clinical scenario: An InfuLife is prepared with 5% dextrose (D5W) instead of the usual 0.9% sodium chloride.* |
| | **How does using 5% dextrose affect delivery time compared to normal saline?** |
| | A. Delivery time is approximately 10% shorter |
| | B. Delivery time is approximately 10% longer |
| | C. Delivery time is approximately 6% longer |
| | D. There is no difference — viscosity effects apply only to temperature |
| **Answer:** | |

| **Question 6** | **Contraindications** |
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| | **Which of the following is a listed contraindication for InfuLife use?** |
| | A. Subcutaneous delivery of local anesthetics |
| | B. Epidural infusion with a specifically designed epidural catheter |
| | C. Intra-articular infusion of local anesthetics |
| | D. Postoperative pain management at surgical wound sites |
| **Answer:** | |

| **Question 7** | **Safety / Alarms** |
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| | **A patient asks if the InfuLife will sound an alarm if the infusion stops or is blocked. What is the correct response?** |
| | A. Yes — a soft audible alarm activates if flow is interrupted for more than 15 minutes |
| | B. No — there is no alarm or alert when flow interruption occurs |

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| | C. An indicator light changes color when flow is interrupted |
| | D. The volume scale on the outer cover will flash to indicate a blockage |
| **Answer:** | |

| **Question 8** | Filling Procedure | |
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| | **What must be done with the clamp before dispensing drug solution into the reservoir during filling?** | |
| | A. Open the clamp to allow air to escape as fluid fills the reservoir | |
| | B. Close the clamp during filling to prevent premature flow | |
| | C. The clamp position does not matter during the filling step | |
| | D. Clamp should be half-open to maintain back-pressure | |
| **Answer:** | | |

| **Question 9** | Flow Sensitivity | |
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| | **The nominal flow rates listed for InfuLife are based on which reference conditions?** | |
| | A. 5% dextrose at 37°C (body temperature), at 5 inches of head height | |
| | B. 0.9% sodium chloride at 32°C, at 0 inches of head height per ISO 28620:2020 | |
| | C. Sterile water at 23°C (room temperature), at 0 inches of head height | |
| | D. 0.9% sodium chloride at 37°C, at 6 inches of head height | |
| **Answer:** | | |

| **Question 10** | Patient Population | |
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| | **Why is InfuLife contraindicated for neonates, infants, and children weighing less than 20 kg?** | |
| | A. The flow rate is too high for small body mass and cannot be adjusted | |
| | B. The device is too large for pediatric IV access sites | |
| | C. Potential exposure to ethylene oxide (EO) residuals | |

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| | D. The elastomeric bladder generates excessive pressure for small patients |
| **Answer:** | |

| **Question 11** | **Flow Sensitivity** | |
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| | *Clinical scenario: An RN fills a 270 mL InfuLife with only 240 mL — 30 mL below nominal.* | |
| | **What effect does underfilling the reservoir below nominal volume generally have on flow rate?** | |
| | A. Lower fill volume generally results in a lower flow rate | |
| | B. Lower fill volume generally results in a higher flow rate due to reduced back-pressure | |
| | C. Lower fill volume has no significant effect — the elastomer compensates | |
| | D. Lower fill volume increases delivery time by exactly 10% | |
| **Answer:** | | |

| **Question 12** | **Filling Procedure** | |
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| | **After priming the tubing and before connecting to the patient access site, what must the RN verify?** | |
| | A. That the filter is wet and no bubbles are visible in the filter housing | |
| | B. That the clamp on the tubing is closed before attaching to the injection site | |
| | C. That the pump has been at room temperature for at least 2 hours | |
| | D. That the outer cover scale reads the correct fill volume | |
| **Answer:** | | |

## Scoring Summary

| **Total Questions** **12** | **Number Correct** _____ / 12 | **Score (%)** _____ % |
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| **Pass (≥ 80%)** | **Fail (< 80%)** | Evaluator Signature: _____ |

## Answer Key & Rationale

*For evaluator use only. Do not distribute to candidates prior to assessment.*

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| **Q1** | **Correct Answer: A** | Per the IFU: 'An increase/decrease of 10 inches in head height will increase/decrease the flow rate by 6%.' Raising the restrictor decreases hydrostatic pressure, slowing down the delivery. Height management is critical for accurate dosing. |
| **Q2** | **Correct Answer: A** | The IFU states: 'When the device is used with restrictor at room temperature (23°C/73°F), delivery time will increase approximately 9%.' This means the drug is infused slower than intended. Always position the restrictor against or close to the patient's skin. |
| **Q3** | **Correct Answer: A** | The IFU explicitly states: 'If the device is stored in refrigerator, allow it to warm to room temperature before use.' Storage of a filled device beyond 8 hours before starting may also result in a 10% longer delivery time. Freezer storage is prohibited. |
| **Q4** | **Correct Answer: B** | IFU formula: Fill volume = (infusion time × flow rate) + residual volume 48x5+5=245 as indicated in PMP-1103 chart in the Clinician Guide PMP-1101. |
| **Q5** | **Correct Answer: B** | The IFU states: 'Use of 5% dextrose will result in 10% longer delivery time.' D5W has different viscosity properties than the reference solution (0.9% NaCl at 32°C). The total infusion time is extended — document and communicate to the care team if timing is clinically significant. |
| **Q6** | **Correct Answer: C** | The IFU explicitly contraindicates InfuLife for 'intra-articular infusion of anesthetics.' This is also reinforced in the Warnings section. All other options listed are approved indications or routes of administration. |
| **Q7** | **Correct Answer: B** | The IFU states: 'There is no alarm or alert when flow interruption occurs, therefore InfuLife is not recommended for life-supporting medications.' The outer cover scale provides only a general indication of remaining volume and is not accurate. Educate patients and monitor clinically. |
| **Q8** | **Correct Answer: B** | Step 3 of Directions for Filling states: 'Close the clamp and fill the device with no more than the recommended maximum fill volume.' The clamp must be closed before filling to prevent uncontrolled flow from the distal end during preparation. |
| **Q9** | **Correct Answer: B** | The IFU states: 'The nominal flow rates are based on sodium chloride (0.9%, 32°C) as reference, calculated per ISO 28620:2020, at 0 inch of head height.' Any deviation — different fluid, temperature, or height — will alter the actual flow rate from the nominal value. |

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| **Q10** | **Correct Answer: C** | The IFU states under Residual Risks: 'InfuLife is contraindicated for use on neonates, infants, and children weighing less than 20 Kg due to potential exposure to EO residuals.' Ethylene oxide is used in sterilization and residual amounts may pose a risk to smaller/younger patients. |

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| **Q11** | **Correct Answer: C** | The IFU states: 'Filling the pump less than nominal volume generally results in lower flow rate. However, the Chart PMP-1103 in the Clinician Guide PMP-1101 allows over/under filling by amounts indicated without significant impact on delivery time. Filling InfuLife above/below amounts permitted by the chart will generally speedup/slow down infusions. |

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| **Q12** | **Correct Answer: B** | Starting the Infusion step 3 states: 'Verify that the clamp on the tubing is closed' before attaching to the patient. This prevents an uncontrolled bolus on connection. The clamp is then opened (step 5) to begin the infusion. |