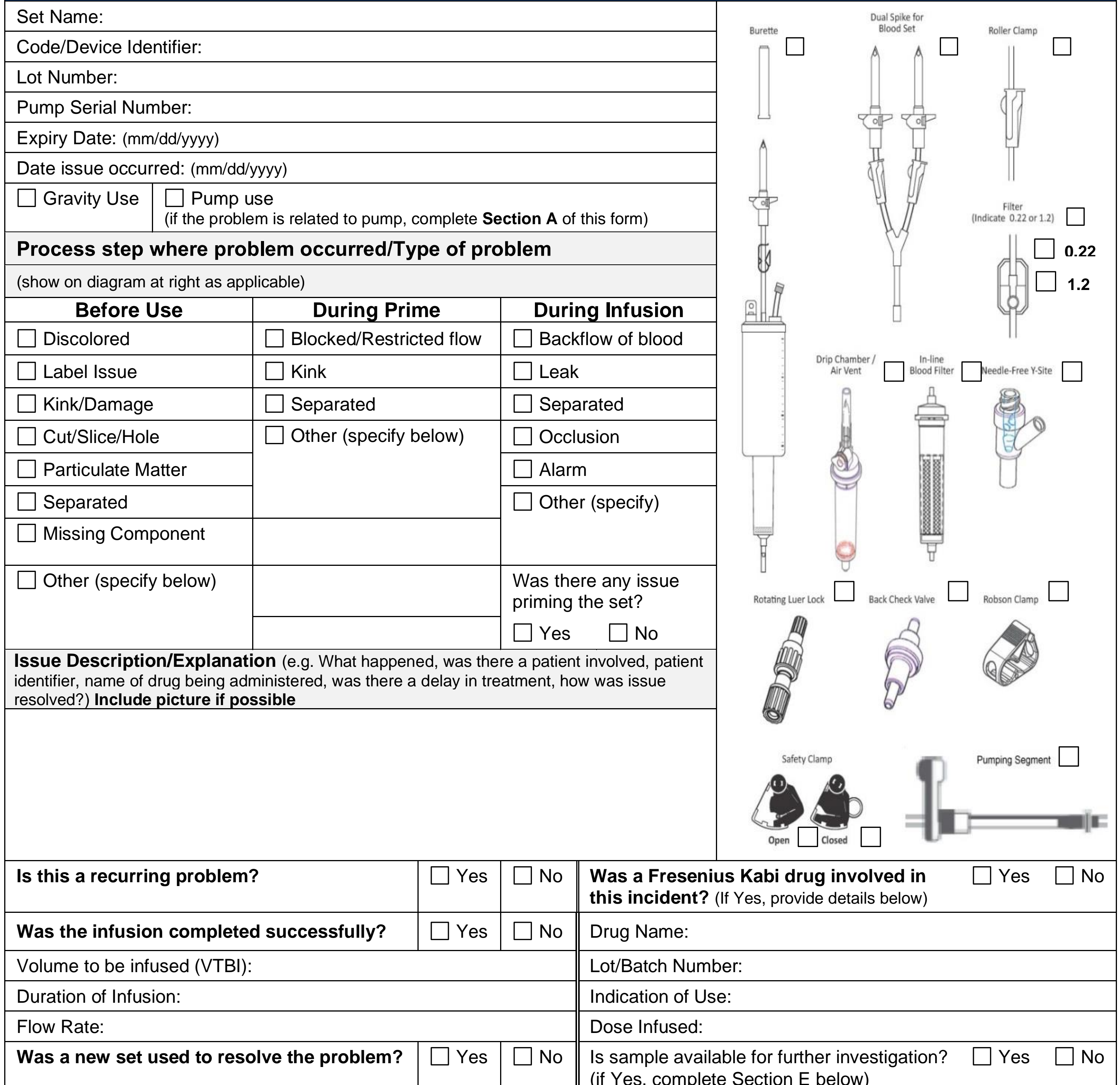
FRESENIUS KABI

MEDICAL DEVICE PERFORMANCE REPORT

CUSTOMER INFORMATION	
Facility Name:	Phone Number:
Contact Person:	Email:
Device Operator:	Email:

ISSUE RELATES TO		
Infusion Pump	☐ Yes (if Yes, complete Sections A and D)	☐ No
Infusion/IV Set	☐ Yes (if Yes, complete Sections B and D)	☐ No
Software	☐ Yes (if Yes, complete Sections C and D)	☐ No

SECTION A: INFUSION PUMP				
Pump Name:				
Code/Device Identifier **(on plate label)**:				
Serial Number:				
Software Version (if available):				
Date issue occurred: (mm/dd/yyyy)				
Process step where issue occurred:	☐ Set up	☐ Priming	☐ During Infusion – Was patient connected? ☐ Yes ☐ No	
	☐ Other (please specify):			
Alarm Issue/Error Number:		☐ Yes – Type of Alarm/Error:		☐ No
Defect/Malfunction/Issue: (select the box that applies)	☐ Does not turn on/power issue	☐ Damaged	☐ Flow rate issue	☐ Screen/display issue
	☐ Keypad	☐ Connectivity		☐ Label issue
	☐ Other (please specify):			
Issue Description/Explanation (What happened, was there a patient involved, name of drug being administered, was there a delay in treatment, how was issue resolved?)				
Is device available for investigation?	☐ Yes (If Yes, complete Section E below)			☐ No



SECTION B: INFUSION/IV SET

Set Name:

Code/Device Identifier:

Lot Number:

Pump Serial Number:

Expiry Date: (mm/dd/yyyy)

Date issue occurred: (mm/dd/yyyy)

☐ Gravity Use | ☐ Pump use (if the problem is related to pump, complete **Section A** of this form)

Process step where problem occurred/Type of problem

(show on diagram at right as applicable)

Before Use	During Prime	During Infusion
☐ Discolored	☐ Blocked/Restricted flow	☐ Backflow of blood
☐ Label Issue	☐ Kink	☐ Leak
☐ Kink/Damage	☐ Separated	☐ Separated
☐ Cut/Slice/Hole	☐ Other (specify below)	☐ Occlusion
☐ Particulate Matter		☐ Alarm
☐ Separated		☐ Other (specify)
☐ Missing Component		
☐ Other (specify below)		Was there any issue priming the set? ☐ Yes ☐ No

Issue Description/Explanation (e.g. What happened, was there a patient involved, patient identifier, name of drug being administered, was there a delay in treatment, how was issue resolved?) **Include picture if possible**

Is this a recurring problem?	☐ Yes	☐ No
Was the infusion completed successfully?	☐ Yes	☐ No
Volume to be infused (VTBI):		
Duration of Infusion:		
Flow Rate:		
Was a new set used to resolve the problem?	☐ Yes	☐ No

Was a Fresenius Kabi drug involved in this incident? (If Yes, provide details below)	☐ Yes	☐ No
Drug Name:		
Lot/Batch Number:		
Indication of Use:		
Dose Infused:		
Is sample available for further investigation? (if Yes, complete Section E below)	☐ Yes	☐ No

SECTION C: SOFTWARE

Software Name: Software Version:

Date of Installation/Deployment: (mm/dd/yyyy)

Deployer Name: Deployer Email:

Context: ☐ Workgroup ☐ Domain

Accounts (ask your local IT team to answer this, if needed)

Are you using an account member of the local group called Administrators?	☐ Yes	☐ No
Are you using an account member of domain group that is a member of the local group called Administrators ?	☐ Yes	☐ No
Are you using an account member of nested groups?	☐ Yes	☐ No

What device are you using? (check one) ☐ Personal Computer ☐ Laptop ☐ Tablet ☐ Smartphone

Device Operating System (exact version):

Is the device connected to a network: ☐ Yes ☐ No

Is there an error message? ☐ Yes (if Yes, provide message text below or provide a screenshot. Complete Section D of this form to send screenshot) ☐ No

Is this the first time this issue has occurred? ☐ Yes ☐ No Does this issue occur regularly? ☐ Yes ☐ No

Issue Description:

SECTION D: PATIENT INFORMATION

Was a patient involved? ☐ Yes ☐ No

Patient Outcome

Serious deterioration in health condition of patient? ☐ Yes (provide patient details below) ☐ No

Patient Identifier Initials: Age: Gender:

Patient medical condition/history if relevant and patient outcome:

SECTION E: SAMPLE/PICTURE RETURNS		
Is the pump/set/drug available for return? (manufacturer may request device back for investigation) ☐ Yes ☐ No		
Send _____ Boxes (indicate the number of boxes required for sample return)		
If the samples are contaminated with blood or blood components, samples must be accompanied by serology certificate. Samples with positive serology are not accepted for investigation by Fresenius Kabi Canada.		
Sending a picture? ☐ Yes ☐ No (If Yes, email to Canada_Product_Complaints@Fresenius-Kabi.com)		
Sample investigation letter required? ☐ Yes ☐ No		
Facility Address:		
Name:	Street:	
City:	Province:	Postal Code:
Facility Contact:		
Name:	Phone Number:	
Email:		

SECTION F: ADDITIONAL COMMENTS

Email all pages of the completed report and picture(s) (if any) to: Canada_Product_Complaints@Fresenius-Kabi.com
Include a copy of this report when returning a pump/set/drug/picture.