

Complaint Intake Form

To be completed by Complainant / Reporter

Take a picture or scan of this completed form and submit to Complaint Handling Unit at Zyno Medical/InfuTronix/Intuvie at: feedback@intuvie.com

Date of Event:		Facility Involved:		
Product Involved:	<input type="checkbox"/> Pump	If Pump, select model:	<input type="checkbox"/> Z-800WF	<input type="checkbox"/> Nimbus II Plus <input type="checkbox"/> Nimbus II Flex <input type="checkbox"/> Nimbus II PainPRO
	<input type="checkbox"/> IV Set		<input type="checkbox"/> Z-800F <input type="checkbox"/> Z-800W <input type="checkbox"/> Z-800	
	<input type="checkbox"/> Other, Describe:	Pump Serial Number		
		If IV set, select model:	<input type="checkbox"/> AX-80075	<input type="checkbox"/> HS-001 <input type="checkbox"/> HS-002 <input type="checkbox"/> HS-003 <input type="checkbox"/> HS-004 <input type="checkbox"/> HS-005
			<input type="checkbox"/> FE01 <input type="checkbox"/> FE04	
<input type="checkbox"/> B2- _____ (Please complete rest of model number)	<input type="checkbox"/> BX- _____ (Please complete rest of model number)	<input type="checkbox"/> A2- _____ (Please complete rest of model number)		
	IV Set Product Lot Number:			
**Complainant Name:		Complainant Email:		
Complainant Address:		Complainant Phone:		
Complainant Health Care Professional?:	<input type="checkbox"/> Yes <input type="checkbox"/> No	If Health Care Professional, provide Title:		
Please provide a picture of failed product with the form:	Picture Attached? <input type="checkbox"/> Yes <input type="checkbox"/> No	Complainant Requires Response?	<input type="checkbox"/> Yes <input type="checkbox"/> No	

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Rev. A

Is product available for return?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Is product being returned?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Complaint Description: <i>Please provide details of the problem with the product or the event that occurred.</i>			
At what point was the complaint detected?	<input type="checkbox"/> Before Infusion <input type="checkbox"/> During Infusion <input type="checkbox"/> After Infusion		
Patient birth date or Approximate Age:			
Has/Was the Patient been hospitalized?	<input type="checkbox"/> Yes* <input type="checkbox"/> No (If yes, complete rest of the section)		
	*Duration:		
	*Hospital Name and Address:		
Has the Patient sought medical help?	<input type="checkbox"/> Yes* <input type="checkbox"/> No (If yes, complete rest of the section)		
	*Name of Dr. or Facility		
	* Dr. / facility Phone and email:		
Was there a report of an injury for which no medical help was sought?	<input type="checkbox"/> Yes* <input type="checkbox"/> No (If yes, complete rest of the section)		
	Describe injury:		
Has the Patient or someone on their behalf contacted a Regulatory Agency?	<input type="checkbox"/> Yes* <input type="checkbox"/> No (If yes, complete rest of the section)		
	*Whom:		
	*When:		
**Reporter Information (if other than Complainant):	Name:		
	Address:		
	Phone:		
	Email:		
To be Completed by Complaint Handling Unit			
Complaint No			