# **New Device Type or Model Evaluation Form**

Date:				
<b>Note:</b> If field doesn't apply, please mark n/a to	☐ IRB use evaluation ☐ Clinical use evaluation ☐ Device Specific			
acknowledge the field was evaluated.				
General to model				
1. Basic Information				
1.1 Manufacturer				
1.2 Model				
1.3 Device Category/Subcategory	1.4 Device is Part of a System			
1.5 Multiple Categories				
1.6 New Category Yes No				
1.7 ECRI/Industry Device Category (UMDNS)				
1.8 FDA Approved	1.9 Device Use Off-label			
2. Initial Discovery				
	2.1 Requester Institution			
	2.2 Initial Discovery			
	2.3 Describe			
3. Initial Purchase and Implementation				
	3.1 Type of Use			
	3.2 IRB Protocol Number			
	3.3 Standard Warranty (years)			
	3.4 Extended Warranty (years)			
	3.5 Ownership Status			
	3.6 Accessories Acquired with the Purchase			

### **New Device Type or Model Evaluation Form**

#### 4. Documentation

4.1 User Manual Location

4.2 Service Manual Location

4.3 Specifications/
Data Sheet Location

4.4 Other Documents

Location

4.5 Supplies/Accessories

#### 5. Maintenance

5.1.1 Mfr PM Frequency 5.6 Clinical System

Maintenance Frequency

5.1.2 Inventory Frequency 5.7 Service Support Type

5.1.3 Mfr Battery 5.8 Additional Biomed

Replacement Frequency Support

5.1.4 Operators 5.9 Other departments

Maintenance Frequency to be involved

5.2 Specific Competencies 5.10 Label Instructions

5.3 Special Tools/

5.4 Proposed for Yes No AEM Evaluation

5.5 Are loaner devices needed?

**Parts** 

#### 6. General Equipment Attributes

6.1 PHI Capability? Yes No 6.3 Actively Use PHI Yes No

(Store, display, or transmit) Attributes

butes

5.11 Comments regarding maintenance

6.2 PHI Storage Media 6.4 Actively Use Yes No

media Attributes

6.5 Contains Clinical Alarms Yes No 6.6 Software/Firmware

Version

6.7 Daylight Savings Time

#### 7. Category- Specific Attributes

7.1 Infusion Pump
Drug Library Names

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7.2 Physiological Monitor Defaults

7.3 Patient/Infant Scale Measurement Units

7.4 Other

#### 8. Network Devices

8.1 Computer Hardware Type 8.2 Mfr/model of computer-based hardware			<ul><li>8.3 Select System</li><li>Integration</li><li>8.4 Operating System</li></ul>		
8.5 Wireless Capability	Yes	No	8.6 Using wireless capability		
8.7 Network Capabilities	Yes	No	8.8 Using network capabilities		
			8.9 DHCP	Yes	No
			8.10 MAC Address		
			8.11 IP Address		

#### 9. Risk Assessment

E: Equipment Function

A: Clinical Application

S: Scheduled Maintenance Frequency

F: Likelihood of Equipment failure

U: Environment of Use Classification

Calculate Risk Score
Total=E+A+[(S+F+U)/3]

Select Risk Level per score

Select Severity Level per MEMP

#### 10. Submit Form

Requester name