

# New Device Type or Model Evaluation Form

Date:

**Note:** If field doesn't apply, please mark n/a to acknowledge the field was evaluated.

- IRB use evaluation  
 Clinical use evaluation

## General to model

## Device Specific

### 1. Basic Information

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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

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2.1 Requester  
Institution

2.2 Initial Discovery

2.3 Describe

### 3. Initial Purchase and Implementation

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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

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## 4. Documentation

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- 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

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- |  |     |    |  |
|--|-----|----|--|
| 5.1.1 Mfr PM Frequency                     |     |    | 5.6 Clinical System<br>Maintenance Frequency |
| 5.1.2 Inventory Frequency                  |     |    | 5.7 Service Support Type                     |
| 5.1.3 Mfr Battery<br>Replacement Frequency |     |    | 5.8 Additional Biomed<br>Support             |
| 5.1.4 Operators<br>Maintenance Frequency   |     |    | 5.9 Other departments<br>to be involved      |
| 5.2 Specific Competencies                  |     |    | 5.10 Label Instructions                      |
| 5.3 Special Tools/<br>Parts                |     |    | 5.11 Comments regarding maintenance          |
| 5.4 Proposed for<br>AEM Evaluation         | Yes | No |  |
| 5.5 Are loaner<br>devices needed?          |     |    |  |

## 6. General Equipment Attributes

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- |  |     |    |                                      |     |    |
|--|-----|----|--------------------------------------|-----|----|
| 6.1 PHI Capability?<br>(Store, display, or transmit) | Yes | No | 6.3 Actively Use PHI<br>Attributes   | Yes | No |
| 6.2 PHI Storage Media                                |     |    | 6.4 Actively Use<br>media Attributes | Yes | No |
| 6.5 Contains Clinical Alarms                         | Yes | No | 6.6 Software/Firmware<br>Version     |     |    |
|  |     |    | 6.7 Daylight Savings Time            |     |    |

## 7. Category- Specific Attributes

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- 7.1 Infusion Pump  
Drug Library Names

