**USE CASE: Insulin Pump** using DRAFT v2.2 Patient-Safety Risk Framework

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|  | Lower risk | Medium Risk | Higher Risk / More Attention |
| Purpose of software product | Information-only; purpose is transparent and clear | Makes recommendations to user | Automated decision making (e.g., intelligent IV pump, AED) |
| Intended user(s) | Targeted user(s) are knowledgeable and can safely use product | Makes recommendations to knowledgeable user | Provides diagnosis or treatment advice directly to knowledgeable user |
| Severity of injury | Very low probability of harm | Potential for non-life threatening adverse event | Life-threatening potential |
| Likelihood of risky situation arising | Rare  (<1 per 100,000 patient-years) | Unpredictable, but risky situation arises > 1:100K pt-yrs and < once a year | Common (arises once per patient-year) |
| Transparency of software operations and data and included content providers | Software output is easy to understand and its “calculation” (data and algorithm) transparent | Software operates transparently and output is understandable by software expert | “Black box” |
| Ability to mitigate harmful conditions | Human intermediary knowledgeable and empowered to intervene to prevent harm | Human intermediary may be (but not routinely) involved | Closed loop (no human intervention) |
| Complexity of software and its maintenance | Application of mature, widely adopted technologies with information output that is easy to understand by the user | Medium complexity. Testing procedures exist that reliably assess patient-safety risk profile of product. | Complexity of data collection and “transformation” involved in producing output is significant. Difficult to test reliably for all safety risks |
| Complexity of implementation and upgrades | The “build” and configuration of the software is straight-forward and does not materially affect the integrity of the output. Safety upgrades can be accomplished easily. | The “build” and configuration of the software is moderately complex, but “guard rails” significantly limit types of changes that might induce life-threatening risk. | The “build” and configuration of the software is complex and can introduce substantial changes that can induce serious risk. Limited or no “guard rails.” |
| Complexity of training and use | The software system output is clear and easy to interpret. Minimal training needed. | Moderate complexity. Less than 2 hr of training required. | The complexity of the user interface and density of data presented can cause important errors or oversights that can lead to serious risk. Formal training necessary. |
| Use as part of more comprehensive software/hardware system | Used as a standalone product, or output is unambiguously used as part of larger integrated system. Certified to specific hardware. Redundancy reduces single points of failure | Software interacts with 1-3 other systems with mature, well described interfaces | Almost always used as part of a larger software system AND output is subject to interpretation or can be configured in multiple ways whose mis-interpretation may induce harm. [e.g., DDI thresholds]. |
| Network connectivity, standards, security | Wired or tightly controlled wireless spectrum compliant with standards | Unregulated spectrum, but low risk of interference | Wireless using unregulated spectrum; proprietary interfaces |

Exemplar 2 – Insulin Pump Software

**Description of Exemplar**

Embedded software in insulin pumps that control insulin infusion, both in response to in vivo glucose sensing and according to external programmatic commands. Wirelessly transmits monitoring and performance data to external receiver that uploads data to PHR or EHR. External commander module displays current situation and current pump responses and behavior.

**Target users**

* Patients with diabetes

**Implementation/configuration**

* Pairing with external commander device
* Pairing with wireless receiver
* Configure upload parameters in conjunction with wireless receiver
* Customize programmatic control of embedded insulin pump with patient-specific parameters

**Severity of injury**

* Life-threatening

**Likelihood of the risky situation arising**

* Software defect
* Unanticipated condition
* Assumes QMS process

**Transparency of software operation, data, and knowledge content sources**

* Commander module displays current conditions and pump responses

**Ability to mitigate harmful condition**

* Patient can over-ride automated program through external commander module

**Complexity of software and its maintenance**

* At least high school education

**Complexity of implementation and upgrades**

* Upgrades performed similar to updates of device firmware
  + Download software to computer
  + Connect external commander module
  + Wirelessly update firmware of insulin pump

**Complexity of training and use**

* Requires 2 hours training

**Use as part of more comprehensive software/hardware system**

* Must configure to communicate with PHR

**Network connectivity**

* BT or RF wireless to external commander module
* BT or RF to Internet-attached computer or smartphone