**IHE Change Proposal**

**Tracking information:**

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| IHE Domain | Patient Care Device (PCD) |
| Change Proposal ID: | CP-PCD-147 |
| Change Proposal Status: | Submitted |
| Date of last update: | 2019-10-22 |
| Person assigned: | Christophe FOURNIER |

**Change Proposal Summary information:**

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| **Adding TCI Mode Information** | |
| Submitter’s Name(s) and e-mail address(es): | Christophe FOURNIER  christophe.fournier@fresenius-kabi.com |
| Submission Date: | 2019-10-17 |
| Integration Profile(s) affected: | Infusion Pump Event Communication (IPEC) |
| Actor(s) affected: | Device Observation Reporter (DOR) and Device Observation Cunsumer (DOC) |
| IHE Technical Framework or Supplement modified: | IPEC profile in Technical Framework Supplement, dated Oct 25, 2015 |
| Volume(s) and Section(s) affected: | IHE PCD TF Vol 2,  IHE PCD TF Vol 3 (Pump Containment Tree), |
| Rationale for Change:  TCI is a pump mode that is used outside the US, especially in Europe, and is not documented in the current IHE  TCI is based on an algorithm that modelizes the concentration of a drug in different compartments of the body ( brain, blood, muscle, fat) and at which rate these compartments exchange each others the drug.  TCI is programmed regarding 3 modes:  Plasma : the user specifies the concentration target of plasma compartment (blood)  Effect : the user specifies the concentration target of effect compartment (brain)  View Mode: the user specifies a flowrate  Whatever the programmation, 3 values are calculated: flowrate / current Plasma concentration and current Effect concentration | |

***Appendix X Infusion Pump Events****, add the following in* ***X.1.2.1 Infusion Event Parameters*** *as new parameters after the last line of* ***Table X.1.2.1-1****:* ***Mapping of Infusion Pump Event Parameters to MDC Codes***

|  |  |
| --- | --- |
| **Parameter** | **MDC Code** |
| **Active Source Parameters:** | |
| TCI Mode | **MDC\_PUMP\_TCI\_MODE** |
| TCI Model used | **MDC\_PUMP\_TCI\_MODEL** |
| TCI Target Concentration | **MDC\_CONC\_TCI\_TARGET** |
| TCI current Plasma concentration | **MDC\_CONC\_TCI\_CURRENT\_PLASMA** |
| TCI current Effect concentration | **MDC\_CONC\_TCI\_CURRENT\_EFFECT** |

***Appendix X Infusion Pump Events****, add the following in* ***X.1.2.1 Infusion Event Parameters*** *as new parameters after the last line of* ***Table X.1.2.1-2: Infusion Pump Delivery Event Parameters***

|  |  |
| --- | --- |
| **Parameter** | **Note** |
| TCI Mode | Optional  See ENUM \_MDC\_PUMP\_TCI\_MODE below |
| TCI Model used | Required if MDC\_PUMP\_TCI\_MODE is present and different from pump-tci-none  Free String |
| TCI Target Concentration | Same definition as MDC\_CONC\_DRUG  Required if MDC\_PUMP\_TCI\_MODE is present and different from pump-tci-none and pump-tci-user |
| TCI current Plasma concentration | Same definition as MDC\_CONC\_DRUG  Required if MDC\_PUMP\_TCI\_MODE is present and is different from pump-tci-none |
| TCI current Effect concentration | Same definition as MDC\_CONC\_DRUG  Required if MDC\_PUMP\_TCI\_MODE is present and is different from pump-tci-none |

Enum for TCI Mode: ENUM MDC\_PUMP\_TCI\_MODE

* + **pump-tci-none**: pump not in TCI mode (OBX is optional in that case)
  + **pump-tci-target-plasma**: pump in TCI plasma target mode
  + **pump-tci-target-effect**: pump in TCI effect target mode
  + **pump-tci-user**: pump in TCI no target mode

***Appendix X Infusion Pump Events****, add the scenario to the* ***Table X.1.2.1-4: Clinical Scenarios***

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| --- | --- | --- | --- |
| **Clinical Scenario** | **PCD-10 Event** | **Parameters** | **Discussion** |
| *TCI Infusion – Plasma Target*  **Infusion starts**  Automatic Rate Change  End of Infusion | MDC\_EVT\_PUMP\_DELIV\_ START | **Pump Delivery Info Parameters:**  Infusing Status=pump-status-infusing  Current Pump Fluid Flow=current rate  Pump Active Sources= pump-source-info-primary  **Active Source Parameters:**  Current Delivery Status=pump-delivery-status-delivering  Program Delivery Mode=pump-program-delivery-mode-continuous  Source Channel Label=vendor-specific  Rate=current rate  Dose Rate=current dose rate  Volume Programmed= initial volume in syringe  Current Segment Volume Delivered=0  Cumulative Volume Delivered=0  Volume Remaining=current volume in syringe  TCI State=pump-tci-target-plasma  TCI Model used= model name  TCI Target Concentration=programmed plasma concentration  TCI current Plasma concentration=current value  TCI current Effect concentration=current value | There is no **Volume Programmed** for TCI, so the Volume Programmed is the initial volume in the syringe.  The pump is always adapting the flowrate, so a **Time** **Remaining** is senseless. |
| *TCI Infusion – Plasma Target*  Infusion starts  **Automatic Rate Change**  End of Infusion | MDC\_EVT\_PUMP\_DELIV\_ STOP | **Pump Delivery Info Parameters:**  Infusing Status=pump-status-infusing  Current Pump Fluid Flow=pump reported rate  Pump Active Sources=pump-source-info-primary  **Active Source Parameters:**  Current Delivery Status=pump-delivery-status-transitioning  Program Delivery Mode= pump-program-delivery-mode-continuous  Source Channel Label=vendor-specific  Rate=old rate  Dose Rate=old dose rate  Volume Programmed= initial volume in syringe  Current Segment Volume Delivered=volume delivered since last DELIV\_START  Cumulative Volume Delivered=sum of “Current Segment Volume Delivered” values across all segments for the delivery, including the one just completed  Volume Remaining= current volume in syringe  TCI State=pump-tci-target-plasma  TCI Model used= model name  TCI Target Concentration=programmed plasma concentration  TCI current Plasma concentration=current value  TCI current Effect concentration=current value | There will be several Automatic Rate Change |
| MDC\_EVT\_PUMP\_DELIV\_ START | **Pump Delivery Info Parameters:**  Infusing Status=pump-status-infusing  Current Pump Fluid Flow=new rate  Pump Active Sources=pump-source-info-primary  **Active Source Parameters:**  Current Delivery Status=pump-delivery-status-delivering  Program Delivery Mode= pump-program-delivery-mode-continuous  Source Channel Label=vendor-specific  Rate=new rate  Dose Rate=new dose rate  Volume Programmed= initial volume in syringe  Current Segment Volume Delivered=0  Cumulative Volume Delivered=sum of “Current Segment Volume Delivered” values across all segments for the delivery prior to this one  Volume Remaining= current volume in syringe  TCI State=pump-tci-target-plasma  TCI Model used= model name  TCI Target Concentration=programmed plasma concentration  TCI current Plasma concentration=current value  TCI current Effect concentration=current value |  |
| *TCI Infusion – Plasma Target*  Infusion starts  Automatic Rate Change  **End of Infusion** | MDC\_EVT\_PUMP\_DELIV\_ COMP | **Pump Delivery Info Parameters:**  Infusing Status=pump reported status  Current Pump Fluid Flow=pump reported rate  Pump Active Sources= pump-source-info-primary  **Active Source Parameters:**  Current Delivery Status= pump-delivery-status-not-delivering  Program Delivery Mode=pump-program-delivery-mode-continuous  Source Channel Label=vendor-specific  Rate=last rate  Dose Rate=last dose rate  Volume Programmed=volume programmed  Current Segment Volume Delivered= volume programmed  Cumulative Volume Delivered=volume programmed  Volume Remaining=0  TCI State=pump-tci-target-plasma  TCI Model used= model name  TCI Target Concentration=programmed plasma concentration  TCI current Plasma concentration=current value  TCI current Effect concentration=current value |  |

***TF Volume 3***

***7.1.3 Channel: Delivery : add the following*** *to* ***Table 7.1.3-1: Infusor Delivery Channel Parameters***

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| --- | --- | --- | --- | --- |
| **Infusor Delivery Channel Parameters** | | | | |
| **Name** | **Term Code** | **Data Type** | **Units** | **Values** |
| TCI Mode | MDC\_PUMP\_TCI\_MODE | Enumeration::TEXT | N/A | “pump-tci-none”+”pump-tci-target-plasma”+”pump-tci-target-effect”+  “pump-tci-user” |
| TCI Model used | MDC\_PUMP\_TCI\_MODEL | TEXT | N/A | TCI Model dependant |
| TCI Target Concentration | MDC\_CONC\_TCI\_TARGET | Numeric::FLOAT-Type | Depends | - |
| TCI current Plasma concentration | MDC\_CONC\_TCI\_CURRENT\_PLASMA | Numeric::FLOAT-Type | Depends | - |
| TCI current Effect concentration | MDC\_CONC\_TCI\_CURRENT\_EFFECT | Numeric::FLOAT-Type | Depends | - |