ANSI/HIBC 3.1-2010

POSITIVE IDENTIFICATION FOR PATIENT SAFETY

Part 1: Medication Delivery

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* When calling from within the U.S., you must first dial 011.

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1 Foreword

Positive Identification for Patient Safety; Part 1: Medication Delivery resulted from work carried out by Massachusetts General Hospital (MGH), a hospital within the Partners Healthcare System. MGH embarked on a project in 2004 to develop a safer system for the administration of medication to patients. The proposed system and resulting specification requires the use of “barcodes”, “2-D” symbols or RFID tags to automatically capture data, thereby reducing transcription / data entry errors and improving patient safety.

Positive Identification for Patient Safety; Part 1: Medication Delivery standardizes the processes, data formats and message designs specified by the authors in a manner in which the specification can be made available for widespread adoption. Wherever appropriate, the original data formats and message designs have been modified to satisfy and conform to existing American and international standards.

This standard is administered by HIBCC, and future revisions will be the responsibility of the Auto-ID Technical Committee (AITC).

The Partners Healthcare special work team creating the original work consisted of the following members:

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2 Normative References

- ISO/IEC 15434, Information Technology – Transfer Syntax for High Capacity ADC Media
- ISO/IEC 16022, Information technology – Automatic identification and data capture techniques - Data Matrix bar code symbology specification
- ISO/IEC 15418. ASC Data Identifiers and EAN.UCC Application Identifiers and maintenance
- ANSI/HIBC 1 – 1997, The Health Industry Bar Code (HIBC) Provider Applications Standard
- ANSI/HIBC 2 – 1997, The Health Industry Bar Code (HIBC) Supplier Labeling Standard
- General EAN.UCC Specifications
- Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) NDC Directory TBLUNITS.TXT
- Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) Data Standards Manual
- IEEE Std 802.3-2005 IEEE Standard for Information technology— Telecommunications and information exchange between systems - Local and metropolitan area networks

3 Scope

The scope of this standard is to define the data formats for the data carriers (barcodes, 2-D symbols, or RFID Tags) which are used to automatically capture information to positively identify objects in the processes around medication administration and management.

The objects include:

- Employee Badges
- Patient Wristbands
- Non-IV Medications
- IV-Medications and Smart Infusion Pumps
- Device License Plate labeling for intelligent devices

Employee Badges

Information contained in employee badge data carriers for identification and access control.

Patient Wristbands

Information contained in patient wristband data carriers for identification.

Non-IV Medications

Information contained in non-IV medication bar codes for identification and tracking.
This may also include patient specific information and order information.

IV-Medications and Smart Infusion Pumps

Information contained in IV medication bar codes for identification and tracking. This may also include patient specific information and order information to program a smart infusion pump.

Device License Plate labeling for intelligent devices

Information contained in bar coded labels placed on intelligent devices to assist in identification and association with other intelligent devices.

4 Overall Design Goals

The message architecture and record layouts were designed to meet the following goals:

- The interface structure is extensible to provide additional information functions as the capabilities of information systems expand.
- The interface supports versioning. Wherever it is practical, the specification for future versions will be backwards compatible.
- Message components are optional and combinable to provide a range of protocol options. A symbol on a drug label may just contain drug identification information or be extended to include patient and administration information.
- The interface includes standard definitions for data elements. These establish the specific meaning and context of the information in the messages.
- The message structures are clearly discernable from the other information. This provides systems the ability to discriminate what information is being read. A patient medical record number cannot be confused with a drug identification number.
- The message structures provide the ability to identify the issuing provider within a provider network.
- The message structure should be designed to result in a very compact symbol.
- The messages should be human readable. This provides the ability to interpret the information from the raw output of a scanner, imager or reading device and simplifies the parsing process. Auditing and validation processes are much easier to perform with human readable data.
- The messages should be embeddable within an overall larger message. Since the area on a label may be limited, all auto-id information can be contained in one symbol.
- The records should allow embedding of data structures within fields where feasible. This provides compatibility with other specifications and legacy systems. For example, some legacy systems encode a patient name in one field with special delimiters.

5 Overview of Data and Message Formats

The specifications cover five major identification uses:

- Employee badges
- Patient Identification (wristbands)
- Non-IV medications
- IV Medications
- Device license plates

Although it would be possible to simply associate a unique serial number with each employee, patient, and medication, and then use a computer network to look up the information associated with each in back-end databases during medication administration, not all hospital entities have the necessary infrastructure in place (or plans to implement it) to allow this approach. This standard therefore accommodates a data set rich enough to implement a medication administration record system even in the absence of such connectivity. As a result, each specification enumerates both a small number of required data elements (more appropriate to a connected environment), as well as a larger number of optional ones that support more robust functionality in a non-connected (or standalone) environment.

The specifications provide a dictionary of the mandatory and optional data elements for each area of use and also describe how this information is to be organized. The more robust forms use message tags and records, in which the data is organized into messages delineated by tags bracketing one or more records. In it, tags identify the type of message and its substructures (sections) and are followed by one or more records which contain the data itself. Rather than being fully tagged (like XML) records are preceded by a record identifier and positional fields follow the record identifier, which are delimited by separator characters. This results in a smaller symbol size than would be possible with a fully tagged format. (Symbol size can be critical when a bar code or 2D symbol needs to be imprinted on a small object.)

An example of a type of fully tagged message *(one that is not used by this specification)* is:

<SDID>$^{R}_{S}$
<VER>$^{R}_{S}$
<VersionNumber>1.0<\VersionNumber>$^{R}_{S}$
<\VER>$^{R}_{S}$
<DID>$^{R}_{S}$
<UDI>36800432621<\UDI>$^{R}_{S}$
<DrugAlias>3012345678<\DrugAlias>$^{R}_{S}$
<DrugName>DrugABC<\DrugName>$^{R}_{S}$
<StrengthAmount>30<\StrengthAmount>$^{R}_{S}$
<StrengthAmountUnitsOfMeasure>mg<\StrengthAmountUnitsOfMeasure>$^{R}_{S}$
<CarrierAmount>1<\ CarrierAmount >$^{R}_{S}$
<CarrierAmountUnitsOfMeasure>TAB<\ CarrierAmountUnitsOfMeasure>$^{R}_{S}$
<ExpirationDate>20071212<\ ExpirationDate>$^{R}_{S}$
…
…
<\DID>$^{R}_{S}$
<\SDID>

An example of the tag and record message *that is used by this specification* is:

<SDID>$^{R}_{S}$VER1.0$^{R}_{S}$DIA|36800432621|3012345678|DrugABC|30|mg|||20071212$^{R}_{S}$<\SDID>

This type of message is used in the specification to meet the design goals of a compact symbol.

In this case, "<SDID>" is the message tag that identifies this as a non-IV drug ID message. It is followed by two records: a version record (VER1.0) and a drug identification label record (DIA), which consist of fields separated using data separators. The convention for depicting the record separator uses $^{R}_{S}$ to represent the single ASCII linefeed character. Data elements are separated using the ASCII vertical line "|" character (ASCII 124). For a complete explanation of the fields in this example, refer to the Drug Auto-ID Interface Specification in Section 8. The message is terminated with the <\SDID> tag indicating the end of the message. It is important to note that because all data fields are not tagged in this design, the order in which all data fields are included in the message must follow the convention specified in this standard.

When needed, section tags bracket records that are to be read together in a specific context. In the fully tagged example, the <DID> tag is a section for drug information.

Message tags are mandatory but section tags may be omitted if they do not add any differentiating value. In version 1.0 of these specifications, there are no repeated records requiring segregation in separate sections so section tags are generally omitted to reduce symbol size. In future versions of the specification, for example, two patient identification record sets might be needed to describe donor and recipient information. The donor information records would be bracketed in a DONOR section and the recipient information in a PID section. No donor section tags are defined in this version and this is just an example of the extensibility of the architecture.

All records begin with a three-character code that uniquely identifies the record. This is the record identifier.

In record definitions and the data dictionaries, fields between {} are optional, all others are mandatory. If multiple fields between {} are bold, this indicates that at least one of the fields are required.

Other data formats are also specified in this standard as alternatives for certain applications. Some are based on other existing standards. The ANSI/HIBC-1 Provider Application Standard, for example, is still applicable for the coding of Employee ID and Patient ID. The ANSI/HIBC-1 standard relies on data identifiers to identify the data components. It is also based on the "license plate" method, where the data string communicated through the interface is purely an ID, and relies on back-end databases to cross reference the specific details about the object. This should not be confused with the *Device License Plate* part of this specification in Section 10 which is much more extensive.

The specifications defined in this standard support versioning. Each use area's specification can be versioned independently of the others. To the extent that it is possible, later versions of the standard will maintain backward compatibility with earlier versions.

Each of the specifications is designed to be extensible; data elements can be added to the data dictionaries and message layouts in future versions in order to accommodate new applications or functionality. Revisions to the specifications are under the auspices of HIBCC. Prototyping records are established to allow building of example records for consideration for inclusion in the specifications.

Each record may be implemented in more than one area. The record and data definitions are presented in detail in the first area where they may be implemented.

In addition to providing data dictionaries and message layouts, the specifications outline some additional considerations for several of the data types. Specifically:

- The addition of bar-coded information to an employee ID badge doesn't assume that existing ID systems will be replaced; a bar code can simply be added to existing ID badges.

- Any clinical information included on the patient wristband should be from a known, reliable "source of truth" and should not be subject to change, as it would be difficult to ensure that the wristband would be updated as the information changes.

- In addition to identifying the medication to be infused, the IV drug specification also defines methods and message structures used to program "smart" infusion pumps.

- The information contained in both drug specifications (non-IV and IV) could be used by inventory systems and/or electronic medication record (eMAR) systems.

- Both drug specifications (non-IV and IV) can accommodate investigational drugs, even when a Universal Drug Identifier (UDI) such as the NDC number (which is normally a mandatory field in the drug message layouts) has not been issued.

The specifications conclude by recommending specific symbologies for each of the data types. The recommended symbologies are:

- For linear bar codes, CODE128;
- For employee ID badges, PDF417, Aztec or Data Matrix ECC200;
- For patient wristbands and all medications, Aztec or Data Matrix ECC200.

6 ANSI\HIBC 3.X in ISO\IEC 15434

ANSI\HIBC 3.X may be encoded in an ISO\IEC 15434 structure. The leading **+<** characters signify that the message contains ANSI\HIBC 3.X standards data.

This is an example message:

[ ) > Rs 06 Gs +<SDID> Lf

VER|1.0 Lf

DIA|36800432621|3012345678|DrugABC|300|mg|||20071212 Lf

<\SDID> Lf Rs EoT

Lf stands for a LineFeed character ASCII (10).

[ ) > Rs 06 Gs is the header and Rs EoT is the trailer for ISO\IEC 15434.

Space is shown between characters for readability.

After the message header and trailer are removed, the resulting data is:

<SDID> Lf

VER|1.0 Lf

DIA|36800432621|3012345678|DrugABC|300|mg|||20071212 Lf

<\SDID> Lf

Note: The ending Lf is optional but is useful for application compatibility with imagers connected to workstations in a wedge or keyboard mode. The < of the +< identifier must be maintained in the message after the header and trailer are removed.

7 Employee Identification Specification

7.1 Overview and Implementation Considerations

The *Employee Badge Auto-ID Interface Specification* defines methods and message structures for communicating employee identification and other information on employee badges using bar codes, 2D symbols and other devices such as RFID tags. The message structures are intended to be used with devices and systems such as security and access systems, the next generation of infusion pumps (generally referred to as "smart" infusion pumps), Electronic Medication Administration Record systems (eMAR), and other systems requiring employee identification information. The term SEID will be used to refer to the "Employee Identification Data" interface for the rest of the document.

The primary purpose served by the employee badge is to identify the employee. The information used for identification in printed format is the employee's name and often a photo. Other useful information may also be present such as an employee id number and name (or identifier) of the issuing provider. Badges have multiple means of conveying information such as bar codes, 2D symbols, magnetic stripe, Weigand wires, RFID tags or smart card interface. More than one of these methods is often implemented in a badge.

It is important to distinguish an employee ID number from a badge ID number. The employee ID number is typically used to identify the person in HR systems, time clock systems, eMAR systems and any other system where the person needs to be identified. A badge ID is a serial number that identifies the badge itself. If an employee loses a badge and a new badge is issued, the replacement badge will have a different badge ID from the original. Badge ID numbers are typically used for access control systems. The access control system will check if the badge ID number is permitted to unlock a door, for example. When reviewing an access log, the association of the badge id to the employee id identifies the person in the access control and badge information system.

Recognizing that many providers may not have bar code scanners or imagers capable of reading 2D symbols, or information systems capable of decoding the SEID message structure, the SEID specification includes a minimum requirement of the employee ID number that can be encoded in a linear bar code or RFID chip. This number may be an employee number or a badge number.

Care should be taken when choosing to implement a single identifier in a linear bar code or RFID chip on a badge. From an access and security perspective, the badge ID number is the most attractive identifier since the badge number can be deactivated, preventing access with a lost or stolen badge. A cross-reference system of badge ID to employee ID is then needed to identify the employee assigned to the badge.

Use of the employee number as the single identifier allows systems to identify the person, but at the risk of permitting access with a lost or stolen badge.

With an SEID implementation, systems capable of authentication can verify that the badge number is active, and capture the employee ID and badge ID.

It is highly recommended that both the badge number and employee ID number are implemented.

The badge should not be used alone for authentication purposes such as when logging into a computer system. The combination of the badge and some other information that only the employee knows such as a PIN number should be implemented. This method is also recommended for card access systems into critical areas.

7.2 Potential Interoperability Issues with other Systems:

Point of Care Data Management Systems often require employee ID authentication using a bar coded employee ID badge. The ID number used for these systems is managed separately from HR and security systems and includes employees who are certified to perform point of care tests, such as glucose tests. These types of systems, along with any Laboratory or Pharmacy Information systems that require an employee ID for authentication, should be kept in mind when selecting the appropriate number to use for the employee ID badge; whether it is the badge number, employee ID number or both. Systems requiring unique employee authentication may find the Custom User Identifier (CUI) in this specification useful.

7.3 Minimum Requirements

The employee identifier or the badge number is required as the minimum data conveyed on an employee badge implementing a linear bar code, 2-D symbol or RFID tag.

EmployeeID

EmployeeID – Employee ID number or Badge ID Number

Where the minimum data is chosen as the option for the encoding to the employee badge data carrier, the format should follow ANSI/HIBC-1, The Health Industry Bar Code (HIBC) Provider Applications Standard (PAS).

There are two basic options for the format of the data in the Employee ID badge using ANSI/HIBC-1.

7.4 Option 1 – Embedding a HIN in the data

This option is suitable for applications where the employee may work in multiple locations, and the issuing entity for the employees badge needs to be clearly identified. The data format using this option is described below:

IU9C8341600/EDDDDDDDDDDDDDDC

The data components for this code are defined in the table below:

Data component	Format	Description
I	Text, Length = 1	Flag character “I” indicating that the data is coded to an Identification Card (or badge)
U	Text, Length = 1	Flag character “U” indicating that the data following is the HIN for the issuing entity.
9C8341600	Text, Length = 9	The HIN for the issuing entity.
/	Text Length = 1	The slash is a data delimiter that concatenates the data string.
E	Text, Length = 1	Flag character “E” indicating that the data following is a Personnel ID number, or badge ID number.
DDDDDDDDDDDDDD	Text, Length = Var (15)	The Personnel or Badge ID number data.
C	Text, Length = 1	The check sum – calculated using Modulus 43

7.5 Option 2 – Without HIN

This option is suitable for internal applications where the system is local only, and there is no need to differentiate between issuing entities:

IEDDDDDDDDDDDDDDC

The data components for this code are defined in the table below:

Data component	Format	Description
I	Text, Length = 1	Flag character “I” indicating that the data is coded to an Identification Card (or badge)
E	Text, Length = 1	Flag character “E” indicating that the data following is a Personnel ID number, or badge ID number.
DDDDDDDDDDDDDD	Text, Length = Var(15)	The Personnel or Badge ID number data.
C	Text, Length = 1	The check sum – calculated using Modulus 43 (See ANSI/HIBC 1 PAS for calculation)

Reliable symbologies such as code 128 should be used when implementing a linear bar code.

7.6 SEID Message Structure

An SEID message is a combination of tags and records. Tags identify the SEID message and SEID sections such as EID.

The structure of the SEID follows the format:

<SEID>$^{R}_{S}$**VER|1.0** $^{R}_{S}$**<EID>**$^{R}_{S}$ **EII**<Employee ID Information>$^{R}_{S}$**EI2**<Employee Supplemental Information>$^{R}_{S}$**<\EID>** $^{R}_{S}$**<\SEID>**

Sections are used for separating record groups for specific purposes.

The following tags are defined for SEID version 1.0 and are reserved tag words.

TAG	Description
<SEID>	Employee Identification Badge Message Start
<EID>	Employee Identification Data Section Start
<\EID>	Employee Identification Data Section End
<\SEID>	Employee Identification Badge Message End

Versioning is handled by new record identifiers or the addition of fields to the end of an existing record as authorized by HIBCC. Once a record identifier is issued, it cannot change.

To reduce symbol size, the <EID> and <\EID> section tags may be omitted if not needed.

7.7 Sections for the SEID Message

As of version 1.0, only the <EID> section is defined for inclusion within the <SEID><\SEID> message for the employee identification badge. To make the symbol more compact, the <EID> section may be eliminated. The records would be bracket by the SEID message tags.

7.8 Records for the EID Section

Please see the data dictionary in Section 6.12 for field lengths. Required fields appear in boldface for clarity.

7.8.1 Employee Identification Information (EII)

This record contains the employee id and other optional information.

EII|IssuingEntityId|{EmployeeID}|{BadgeNumber}|

IssuingEntityID	A unique identifier for the entity issuing the badge. Ideally, the provider's Health Industry Number (HIN) would be used.
Employee ID	Employee Identification code or number
BadgeNumber	A serialized number uniquely identifying the badge

Example: EII|9C8341600|0654321|33345A12Q|

Employee 0654321 issued by entity with HIN 9C8341600, badge serial number 33345A12Q

Notes:

- In the EII record, at least the Employee ID or the BadgeNumber must be implemented. The implementation of both is recommended.

7.8.2 Employee Supplemental Information (EI2)

This record contains the employee name

EI2|LastName|{FirstName}|{MiddleIntial}|

LastName	Employee Last Name (see notes)
FirstName	Employee First Name
MiddleIntial	Employee Middle Initial

Notes:

The last name field should be used for the entire employee's name if the host information system stores the employee name in one field.

7.8.3 Custom User Identifier (CUI)

This record contains custom user identifiers for use with a variety of information systems such as lab, pharmacy, and provider order entry. These systems often have their own employee identifiers that are unique to the system. Multiple CUI records may exist but the combination of SystemContextIdentifer, UserIdentifier and IssuingEntityID must be unique.

CUI|SystemContextIdentifier|UserIdentifier|{IssuingEntityID}|

SystemContextIdentifier	A unique identifier that indicates the system and use.
UserIdentifier	The user id associated with the person within the system defined by the SystemContextIdentifier.
IssuingEntityID	A unique identifier for the entity issuing the badge. Ideally, the provider's Health Industry Number (HIN) would be used. This allows for system privileges in a provider network.

Example 1:

CUI|CPOEPhysicianNumber|6|
CUI|TelephoneLDAccess|665431|

The employee is physician number 6 in the Computerized Provider Order Entry system (CPOE) and her telephone access code is included in the badge symbol RFID tag. The badge can be used as part of the sign-on process in the CPOE system and the system can retrieve the physician id from the badge. A secured telephone can retrieve the long distance access code from the badge.

Example 2:

CUI|CPOEPhysicianNumber|6|DFCI|
CUI|CPOEPhysicianNumber|22|MGH|

The physician has privileges at two hospitals and the respective identifiers for each CPOE system are contained in the message.

Notes:

Systems implementing the CUI record are considered to be closed systems and the identifiers can be arbitrarily set by the institution. It is recommended that the HIN be used for the IssuingEntityID where possible.

7.8.4 Version Record (VER)

This record identifies the version of the records within the <SEID> message.

VER|VersionNumber|

VersionNumber	A unique number indicating the version of the message in which it is contained

Example: VER|1.0| <SEID> records are version 1.0 records

Note:

Version records are intended to occur within each message section such as SEID. Although the overall specification has a version, each section can be upgraded independently. Generally, the VER record immediately follows the first tag and applies to all sections and records in the entire message.

7.8.5 Cyclic Redundancy Check Record (CRC)

This record provides a means to perform CRC checking on the message. CRC32 IEEE 802.3 is the CRC32 method implemented. The CRC is performed on ***all*** data in the message with the exception of the CRC record and the trailing record separator. This includes any prototyping records such as ZEx.

CRC|CRC32Value|

CRCValue	The uppercase ASCII hexadecimal representation of the CRC32 checksum implementing the CRC32 IEEE 802.3 method.

Example: CRC|FFA46DF|

Note:

In this example, the bold data would be included in the CRC calculation.

<SEID>$^{R}_{S}$
VER|1.0$^{R}_{S}$
EII|9C8341600|0654321|33345A12Q$^{R}_{S}$
EI2|Iswell|Dr. Al|L$^{R}_{S}$
CUI|CPOEPhysicianNumber|22|MGH$^{R}_{S}$
CRC|98C2A3D6$^{R}_{S}$
<\SEID>

7.8.6 Employee Id Prototype Record (ZEx)

This record provides a means to prototype new or modifications to existing records within the <SEID> message. The letter x is replaced by a letter or number to create a temporary record identifier. These records may be implemented in a closed system for testing until the HIBCC AITC issues a formal revision to the specification.

ZEx|User Defined Field1| User Defined Field2|…
User Defined Field...n|

Example: ZEB|A+|

A provider wishes to submit for consideration inclusion of the employee blood type. A ZEB record is created for testing purposes.

7.9 SEID Message Examples

The minimum information for an SEID message is the EII record. In the example below, both the Employee ID and the Badge Number are included.

<SEID>[RS]VER|1.0[RS]<EID>[RS]EII|9C8341600|0654321|33345A12Q|<EID>[RS]<\EID>

This message, broken down to its components is expressed as follows:

<SEID>
VER|1.0
<EID>
EII|9C8341600|0654321|33345A12Q
<\EID>
<\SEID>

In the example below, all possible records and fields are used and the <EID><\EID> tags removed to reduce symbol size.

<SEID>[RS]VER|1.0[RS]EII|9C8341600|0654321|33345A12Q[RS]EI2|Iswell|Dr. Al|L[RS]
CUI|CPOEPhysicianNumber|22|MGH[RS]CRC|FFFFFFFF[RS]<\SEID>

<SEID>
VER|1.0
EII|9C8341600|0654321|33345A12Q
EI2|Iswell|Dr. Al|L
CUI|CPOEPhysicianNumber|22|MGH
CRC|5DFFB3D1
<\SEID>

Employee: 0654321

Issued By: 9C8341600 (HIN for Provider)

Badge Number 33345A12Q

Name: Dr. Al L. Iswell

CPOE Physician Number: 22 at provider MGH

CRC Value: 5DFFB3D1

Aztec

Data Matrix

QR Code

7.10 SEID Records Summary

The following table lists all records that may be implemented in an SEID message.

Record	Description
CRC	CRC checksum (CRC32 IEEE 802.3)
CUI	Custom User Identifier
EII	Employee Identification Information
EI2	Employee Supplemental Information
VER	Version
ZEx	Prototyping record for Employee Badges

7.11 SEID Data Dictionary and Format Definitions

Data Element	Character Set	Type	Max Length
*BadgeNumber	Alphanumeric	Variable Length	15
CRCValue	Alphanumeric (Hex)	Fixed Length	8
*EmployeeID	Alphanumeric	Variable Length	15
FirstName	Alphanumeric	Variable Length	30
IssuingEntityID	Alphanumeric	Variable Length	20
*LastName	Alphanumeric	Variable Length	50
MiddleIntial	Alphanumeric	Fixed Length	1
RecordIdentifier	Alphanumeric	Fixed Length	3
SystemContextIdentifier	Alphanumeric	Variable Length	48
UserIdentifier	Alphanumeric	Variable Length	48
VersionNumber	Alphanumeric	Variable Length	3

Lengths are the maximum length of the data expressed as text.

Fixed length fields must be the length specified.
* Required fields (either BadgeNumber or EmployeeID is required)

8 Patient Identification Interface Specification

8.1 Overview and implementation considerations

The *Patient Identification Interface Specification* defines methods and message structures for communicating patient ID and other patient information on patient wristbands or other medium to which the patient identifier is attached, using bar codes, 2D symbols and other devices such as RFID tags. The message structures are intended to be used with devices and systems such as the next generation of infusion pumps generally referred to as “smart” infusion pumps and Electronic Medication Administration Record systems (eMAR). The term SPID will be used for the rest of the document to refer to this interface.

The primary purpose served by patient wristbands (or identifiers) is to identify the patient. The information used for identification in printed format is the patient’s name and medical record number (MRN) or patient ID. Other useful information may also be present on a wristband such as date of birth, blood type, and admission date.

The MRN is the primary means of patient identification for most information systems.

Recognizing that many providers may not have bar code scanners or imagers capable of reading 2D symbols, or information systems capable of decoding the PID message structure, the SPID specification includes a minimum requirement of the MRN that can be encoded in a linear bar code or RFID chip.

If clinical information is included in the patient identifier, it should be information that does not change and must originate from the medical record or other reliable ‘source of truth’. There is a provision for inclusion of data that does change over time and this must be implemented with great care.

8.2 SPID Design

In addition to the overall design goals, the SPID bar code or 2-D symbol should be compact as it must fit on a variety of wristbands including small pediatric bands.

8.3 Minimum Requirements

The **Patient ID** field is the minimum required data to be included on the data carrier. The **Patient ID** field will carry either the Patient ID or the MRN.

For compatibility with existing systems implementing ANSI/HIBC-1, the entire data message should be encoded in the Patient ID field with the format following ANSI/HIBC-1, The Health Industry Bar Code (HIBC) Provider Applications Standard (PAS).

There are two basic options for the format of the data in the Patient ID (applied to wristband) using ANSI/HIBC-1. One format includes the Health Industry Number (HIN) and the other does not.

8.4 Option 1 – Embedding an HIN in the data

This option is suitable for applications where the patient may move between different institutions and the issuing entity for the patient ID needs to be clearly identified. The data format using this option is described below:

AU9C8341600/CDDDDDDDDDDDDDDC

The data components for this code are defined in the table below:

Data component	Format	Description
A	Text, Length = 1	Flag character “A” indicating that the data is coded to a patient identifying device such as a wristband.
U	Text, Length = 1	Flag character “U” indicating that the data following is the HIN for the issuing entity.
9C8341600	Text, Length = Var(9)	The HIN for the issuing entity.
/	Text Length = 1	The slash is a data delimiter that concatenates the data string.
C	Text, Length = 1	Flag character “C” indicating that the data following is a Patient ID number – or MRN
DDDDDDDDDDDDDDD	Text, Length = Var(15)	The Patient ID or MRN
C	Text, Length = 1	The check sum – calculated using Modulus 43

8.5 Option 2 – Without HIN

This option is suitable for internal applications where the system is local only, and there is no need to differentiate between issuing entities:

ACDDDDDDDDDDDDDDC

The data components for this code are defined in the table below:

Data component	Format	Description
A	Text, Length = 1	Flag character “A” indicating that the data is coded to a patient identifying device such as a wristband.
C	Text, Length = 1	Flag character “C” indicating that the data following is a Patient ID number – or MRN
DDDDDDDDDDDDDD	Text, Length = Var(15)	The Patient ID or MRN
C	Text, Length = 1	The check sum – calculated using Modulus 43

Reliable symbologies such as code 128 should be used when implementing a linear bar code.

8.6 SPID Message Structure

A compact symbol is very important when printed on patient wristbands. The structure of the SPID message follows the format:

<SPID>$^{R}_{S}$ **VER|1.0**$^{R}_{S}$**<PID>**$^{R}_{S}$**PII**<Patient ID Information>$^{R}_{S}$
PHY<Physician Information>$^{R}_{S}$**SID**<Security Information>$^{R}_{S}$**<\PID>** $^{R}_{S}$**<\SPID>**

The SPID message may be embedded within a larger set of data conveyed in a symbol but it must be the primary source of patient identification data from the entire set of data contained in the symbol.

Sections are used for separating record groups for specific purposes.

The following tags are defined for SPID version 1.0 and are reserved tag words.

TAG	Description
<SPID>	Patient Identification Message Start
<PID>	Patient Identification Information Section Start
<\PID>	Patient Identification Information Section End
<\SPID>	Patient Identification Message End

To reduce symbol size, the <PID> and <\PID> section tags may be omitted if no other tags within the <SPID><\SPID> message exist.

8.7 Sections for the SPID Message

As of version 1.0, only the <PID> section is defined.

8.8 Records for the PID Section

8.8.1 Patient Identification Information (PII)

This record contains the patient ID or MRN, date of birth and other optional information.

PII|PatientID|DateOfBirth|{Source}**|**{Gender}|{IssuingEntityID}|
{VisitNumber}|{AdmitVisitDate}|{LastName}|{FirstName}|{MiddleIntial}|
{Age}|{AgeUnits}|{IssuingEntityCode}|

PatientID	Patient ID or Medical Record Number
DateOfBirth	Date of Birth in YYYYMMDD format. This is mandatory on patient wristbands. This may be extended to include time as YYYYMMDDHHMM as needed.
Source	Source of the information – from where the data was read - such as a patient wristband, patient medical file label, etc. Please refer to the codes list in Section 7.10
Gender	Patient Gender or Sex
IssuingEntityID	A number or code indicating the provider in a network that issued the wristband, or place of issue within a single provider. Ideally this will be the HIN.
VisitNumber	A number indicating the visit number or encounter number for the patient.
AdmitVisitDate	The date the patient was admitted or the outpatient visit date
LastName	Patient Last Name (see notes)
FirstName	Patient First Name
MiddleIntial	Patient Middle Initial
Age	Age of the patient in terms of AgeUnits
AgeUnits	Code indicating units for Age such as days, hours, etc.
IssuingEntityCode	Code indicating the IssuingEntityID source. “U” indicates the IssuingEntityID is a HIN number.

Example: PII|445414|19561214|A|F|MGH|01234572|20041212|

Female patient MRN 445414 born on 12/14/1956 from a patient wristband issued by MGH for visit number 01234572 and was admitted on December 12th, 2004. The patient name is Ima N. Otwell.

Example with HIN: PII|445414|19561214|A|F|9C8341600|2|20041212|Ima|Otwell|N|||U|

Gender may be more than one character in length to accommodate trans-gender codes.

Notes:

- In the PII record, the PatientID is a mandatory field. When a PII record is used on a patient wristband or other identifying device, the date of birth is also mandatory. When the PII record is used in other messages such as SmartIV or SDID, the date of birth is optional.

- The last name field should be used for the entire patient's name if the host information system stores the patient name in one field. Field separator characters may be embedded within the last name field but must not conflict with the field and record separators used in this specification.

- The time component of the DateOfBirth is in 24 hour format if implemented.

- Age and Age Units must be used with extreme care on the patient wristband for the non-adult patient population. For the non-adult patient population, age should be dynamically calculated from date of birth (including time)

8.8.2 Physician Information (PHY)

This record contains information about the physician.

PHY|PhysicianID|LastName|{FirstName}|{MiddleIntial}|

PhysicianID	Physician Identifier (see notes)
LastName	Physician Last Name (see notes)
FirstName	Physician First Name
MiddleIntial	Physician Middle Initial

Example: PHY|12306|Iswell|Dr. Al|L|

Notes:

- No designation is made with regards to the admitting versus attending physician. This determination is up to the provider to make for their particular implementation.
- The PhysicianID is usually assigned by an order entry system, and is often not an HR system employee ID. It is relative to the IssuingEntityID in the PII record.
- The last name field should be used for the entire physician's name if the host information system stores the physician name in one field. Field separator characters may be embedded within the last name field but must not conflict with the field and record separators used in this specification.

8.8.3 Security Information Data (SID)

This record contains information for security purposes

SID|IssueNumber|

IssueNumber	This is a sequence number relative to the patient and visit number used to prevent more than one wristband being used at a time for a patient.

Example: SID|12|

This indicates the particular wristband is number 12 for this patient during this visit.

8.8.4 Patient Clinical Data (PCD)

The use of this record is optional. In Version 1.0, it conveys information about the patient blood type. If used, the data must be obtained from a verifiable source (e.g. medical record, blood typing process, longitudinal medical record, etc.) or other reliable 'source of truth'. The record must not contain data that can change over time. Field additions to this record in future versions must meet the same tests.

PCD|{BloodType}|{BloodTypeFlag**}**

BloodType	Code indicating the blood type of the patient.
BloodTypeFlag	Code indicating the BloodType is ISBT128 blood group or private. "I" = ISBT128, otherwise private.

Examples:

PCD|A|

The patient has blood type A

PCD|A+|

The patient has blood type A+

8.8.5 Patient Variable Data (PVD)

The use of this record is optional. It conveys information about the patient that can change over time. **If used, great care must be taken to insure that the information is safe to use considering the particular use case and the date and time the measurement was taken.** Depending on the area of care and provider practices, a patient weight that is a few days old may be acceptable to use for medication dose instructions for an IV pump but may be unacceptable for pediatrics. Although this record may be implemented on a patient wristband, it is more likely to be implemented in an <ORDERS> section of a drug or IV symbol. Multiple records may be included to transmit each measurement.

PVD|MeasurementTypeCode|MeasurementUnits|
MeasurementUnitsOfMeasure|MeasurementDate|MeasurementTime|

MeasurementTypeCode	Code indicating the type of measurement. WT – Patient weight HT – Patient height
MeasurementUnits	The measured amount such as 81.64 for a weight of 81.64 kilograms.
MeasurementUnitsOfMeasure	The units of measure for the measurement such as kg for weight and cm for height. See Section 7.14 for units of measure codes.
MeasurementDate	The date the measurement was taken in YYYYMMDD format
MeasurementTime	The time the measurement was taken in HHMM{SS} format.

Examples:

PVD|WT|81.64|KG|20061212|160000|

The patient has a weight of 81.64 kilograms and the measurement was taken on December 12th, 2006 at 4:00 PM

PVD|HT|179.832|CM|20061212|160000|

The patient has a height of 179.832 centimeters and the measurement was taken on December 12th, 2006 at 4:00 PM

8.8.6 Patient ID Prototype Record (ZPx)

This record provides a means to prototype new or modifications to existing records within the <SPID> message. The letter x is replaced by a letter or number to create a temporary record identifier. These records may be implemented in a closed system for testing until the HIBCC AITC issues a formal revision to the specification.

ZPx|User Defined Field1| User Defined Field2|…
User Defined Field…n|

Example: ZPC|1|The patient needs eyeglasses to read.|

A provider wishes to submit for consideration inclusion of a comment record to the patient wristband. A ZPC record with a sequence number followed by a text message is created for testing.

8.9 Source Codes

The codes for source follow a subset of ANSI/HIBC-1, The Health Industry Bar Code (HIBC) Provider Applications Standard (PAS) application flag characters but may be extended.

A – Patient: An identifying device affixed to the patient, e.g., identity imprinted and encased in a wrist-fastened bracelet or an RFID tag.

B – Patient Care Record: Any document utilized as a unique patient record, including, but not limited to: medical abstract, patient chart, patient's laboratory cumulative summary, medication administration record, discharge plan, progress notes, ancillary service documents, patient file or chart folder label, etc. This may also include patient charges, subject to individual institution's philosophy.

C – Specimen Container: An article (tube, jar, syringe, pan, etc.) used to hold and/or convey a non-reusable patient specimen from source of origin (patient) to another point (anatomical pathology, laboratories, etc.).

D - Direct Patient Image Item: Any image (film, recording, etc.) acquired in diagnostic testing, including, but not limited to: X-rays, ECG, EEG, Myelograms.

J – Product Container: Container for administrable product. All patient specific medications carrying a PII record would contain the J code for the source.

8.10 SPID Message Examples

The minimum information for an SPID message is the patient identifier or medical record number (MRN). Such an SPID message would contain:

VER 1.0 and Patient ID (minimum requirements)

The message structure for the minimum requirements would be formatted as follows:

<SPID>$^{R}_{S}$VER|1.0$^{R}_{S}$<PID> PII|4454145 $^{R}_{S}$ <\PID>$^{R}_{S}$<\SPID>

This message, broken down to its components is expressed as follows:

<SPID>
VER|1.0
<PID>
PII|4454145
<\PID>
<\SPID>

In the following example, all possible records and fields for Patient Identification are used:

<SPID>[R]S VER|1.0[R]S <PID>[R]S PII|4454145|19561214|A|F|9C8341600|2|20051223|
Otwell|Ima|N|50|YRS[R]S PHY|12306|Iswell|Dr. Al|L[R]S SID|1[R]S PCD|A[R]S
PVD|WT|81.64|KG|20061212|160000|[R]S PVD|HT|179.832|CM|20061212|160000|[R]S
<\PID>[R]S CRC|FFFFFFFF[R]S <\SPID>

```
<SPID>
 VER|1.0
 <PID>
      PII|4454145|19561214|A|F|9C8341600|2|20051223|Otwell|Ima|N|50|YRS
      PHY|12306|Iswell|Dr. Al|L
     SID|1
      PCD|A|
      PVD|WT|81.64|KG|20061212|160000|
      PVD|HT|179.832|CM|20061212|160000|
<\PID>
    CRC|2BB97D02
<\SPID>
```

The data represented above is as shown below:

Patient: 4454145
Date of Birth: 12/14/1956
Source: A – Patient Wristband
Gender: Female
Issued: By 9C8341600 (Provider HIN)
Visit: 2
Admitted: 12/23/2005
Name: Ima N. Otwell
Age: 50
AgeUnits: YRS
PhysicianID: 12306
Physician: Dr. Al L. Iswell
Wristband Issue No: 1
BloodType: A
Weight: 81.64 kilograms taken on December12th, 2006 at 4:00 PM
Height: 170.832 centimeters taken on December12th, 2006 at 4:00 PM
CRC Value: 2BB97D02

Note:

The Date Of Birth is a mandatory field for patient wristbands and optional when the PII record is used in other messages such as SmartIV or SDID.

Aztec

Data Matrix

QR Code

8.11 SPID Records Summary

The following table lists all records that may be implemented in an SPID message.

Record	Description
CRC	CRC checksum (CRC32 IEEE 802.3)
PCD	Patient Clinical Data
PHY	Physician Information (Admitting or Attending)
PII	Patient Identification Information
PVD	Patient variable Data
SID	Security Information Data
VER	Version Information
ZPx	Prototyping record for Patient Identification

8.12 SPID Data Dictionary and Format Definitions

Data Element	Character Set	Type	Max Length
AdmitVisitDate	Alphanumeric	YYYYMMDD	8
Age (in age units)	Numeric	9999.9999	9
Age Units (see table)	Alphanumeric	Variable Length	8
BloodType	Alphanumeric	Variable Length	15
BloodTypeFlag	Alphanumeric	Fixed Length	1
CRCValue	Alphanumeric (Hex)	Fixed Length	8
DateOfBirth	Alphanumeric	YYYYMMDD{HHMM}	8 or 12
FirstName	Alphanumeric	Variable Length	30
Gender	Alpha	Variable Length	20
IssuingEntityCode	Alphanumeric	Fixed Length	1
IssuingEntityID	Alphanumeric	Variable Length	20
IssueNumber	Numeric	Variable Length	3
LastName	Alphanumeric	Variable Length	50
*MeasurementTypeCode	Alpha	Variable Length	8
*MeasurementUnits	Numeric	9999.9999	9

Data Element	Character Set	Type	Max Length
MeasurementUnitsOfMeasure	Alphanumeric	Variable Length	8
MeasurementDate	Numeric	YYYYMMDD	8
MeasurementTime	Numeric	HHMM{SS}	4 or 6
MiddleIntial	Alphanumeric	Fixed Length	1
PatientID	Alphanumeric	Variable Length	48
PhysicianID	Alphanumeric	Variable Length	15
RecordIdentifier	Alphanumeric	Fixed Length	3
Source	Alphanumeric	Variable Length	3
VersionNumber	Alphanumeric	Variable Length	3
VisitNumber	Alphanumeric	Variable Length	15

Lengths are the maximum length of the data expressed as text.

Fixed length fields must be the length specified.

8.13 Age Units and PVD Units of Measure Codes

These codes are time units of measure codes to be used in the Age Units field. Singular and plural forms are supported as listed.

Codes	Description
YR or YRS	Years
MO or MOS	Months
WK or WKS	Weeks
DAY or DYS	Days
HR or HRS	Hours
MIN	Minutes
SEC	Seconds

These codes are length and mass units of measure codes to be used in PVD records. Singular and plural forms are supported as listed.

Codes	Description
FT	Feet
IN	Inches
M	Meters
CM	Centimeters
MM	Millimeters
KG or KGS	Kilograms
GM or GMS	Grams
MCG	Micrograms

9 Drug Auto-ID Specification – Non IV Drugs

9.1 Overview and Implementation Considerations

The *Drug Auto-ID Interface Specification* (SDID) defines methods and message structures for communicating drug information and other related information on drug packaging labels using bar codes, 2D symbols and other devices such as RFID tags. The message structures are intended to be used with devices and systems such as electronic medication administration record systems (eMAR), pharmacy, and inventory systems.

The primary purpose served by the drug identification data is to identify the drug. There are a variety of numbering systems in place today that serve this purpose such as NDC, HIBCC LIC, GTIN, etc. We use the data element of UDI for Universal Drug Identifier to represent a placeholder for mandated numbering systems where applicable. At the time version 1.0 of this specification was written, FDA rulings require drug manufacturers to implement the NDC numbering system. In the future, other numbering systems may prevail and the UDI field will be used to implement these systems. Providers often implement a private numbering scheme to meet their particular needs. These numbers or codes are called drug aliases and are implemented in a distinct field. The drug alias is the primary linking mechanism between records in the specification. The term SDID will be used to refer to this Drug ID interface for the remainder of the document.

We recognize that in order to correctly determine that we administer the right drug we must also know the strength or concentration. The SDID interface requires that the drug alias (if used) at a minimum uniquely identifies the drug by product name and strength. The alias may also identify an amount and unit of measure. If the alias does not directly relate to a specific amount and unit of measure, the SDID message must include this information.

An eMAR system can verify that the right amount is administered by checking the required amount calculated from drug amount and strength to the amount scanned from the label. If 20 ML is required to give the patient the correct dose, it can come from one 20 ML vial, two 10 ML vials of the same strength, or it can be a partial draw from a 50 ML vial of the same strength. Note: **If a** p**artial draw is used, other processes are needed to confirm the correct amount is administered.**

The SDID message is structured to keep the symbol compact. The best case scenario is when the drug alias references the amount and unit of measure and the lot number and expiration date are not needed.

Including an expiration date and lot number in the data provides benefits for patient safety, traceability, and supply chain needs.

Drug identification marking and labeling is particularly challenging with small unit of use or unit dose items such as vials, tablets, and capsules. Often there is insufficient room to encode a drug alias, expiration date, lot number, packaging level and drug name in a symbol.

Re-labeling does not always imply repackaging. Re-labeling should only be done if the manufacturer's label does not contain bar-coded information required for implementation. Usually it is items in bulk containers that need to be repackaged into unit of use, and they are both repackaged and relabeled. Items that are already in unit of use packaging may need to have an additional bar-code label added that contains the SDID message. These labels should be placed in an open area or on the bottom of the package (For example: on the bottom of a vial.)

The scanners, imagers, readers and associated application software need to read a variety of numbering systems and cross-reference them with the correct drug alias.

The Unit Dose Indicator, Package Type, and the Package Count support supply chain and inventory needs if the provider wishes to repackage and/or re-label packages. The Unit Dose Indicator is optional

if the system using the symbol or tag data implements a Drug Alias at the unit dose level and does a lookup to determine the unit of use.

Patient safety takes priority over supply chain needs.

It is essential that the drug aliases are used consistently across all systems such as CPOE, Pharmacy and eMAR.

The SDID interface also provides the means to communicate information about investigational drugs that are intended for a specific patient by the use of the additional patient information record.

When labeling drugs that are manufactured or repackaged for an external provider, cross-reference records can be included that contain the external provider drug alias and their patient information (if known).

9.2 Drug Alias and NDC Considerations

- The implementation of the NDC number in the UDI is mandatory for manufacturers using this specification for product labeling if an NDC number exists for the drug. Manufacturers should never include a drug alias unless they are making a provider specific product and know the provider-assigned drug alias. Repackagers may also include the drug alias if repackaging a provider specific product, and have been given the provider-assigned drug alias.

- Providers must implement a drug alias if they are utilizing additional records such as medication administration records since the drug alias is the primary linking mechanism between records in the specification.

- The drug alias must be implemented if the drug does not have an NDC assigned.

- It is recommended that the NDC and drug alias both be implemented. This allows the flexibility to use equivalent drugs from different manufacturers freely and verify right drug and right dose via the drug alias while maintaining traceability to the manufacturer.

- Great care must be exercised when issuing drug aliases. They are considered private numbers that only correctly reference drugs at the issuing provider.

- If a provider wishes to use the NDC as a drug alias, the NDC number used for the alias must correctly represent the strength, dosage form, and packing level down to the unit of use or unit dose for the drug.

- When providers exchange drugs (such as when drugs are manufactured for another hospital), it is essential that they know each other's drug aliases for the drugs involved and that their information systems can cross reference them. This is particularly critical when the drugs do not have NDC numbers, such as investigational drugs.

9.3 Existing Product Identification Standards

Most manufacturers of non-IV drugs use the Global Trade Item Number (GTIN) administered by GS1 International (Formerly EAN.UCC) standard barcode to identify their products. The NDC for the drug is embedded within the GTIN. However, most drugs do not include a machine-readable barcode for secondary information, including lot number and expiration date. Therefore, the use of the GTIN has only limited application for patient safety considerations, where a higher degree of product traceability is required.

Furthermore, the GTIN is generally only applied to the smallest "selling" unit. Therefore, there is rarely a GTIN that is applied to the individual unit of use drug items.

Details about the GTIN standard can be referenced from the General EAN.UCC Specifications.

If the Manufacturers' GTIN barcode is used, then it will be a requirement that the systems utilize a comprehensive product database that references drug details, cross referenced to the GTIN.

9.4 Package Level and Count

Most existing numbering schemes implement arbitrary packaging levels that are limited in range and do not clearly identify a quantity without a lookup of the UDI (Universal Drug Identifier). Furthermore, a clear unit dose indictor is often missing due to products being labeled to the smallest *selling* unit. This specification includes a Unit Dose Indicator that signifies the drug has been packaged (or repackaged) to its smallest unit of issue. It also includes a package type field and a package count field that, if

implemented, will clearly identify the type of packaging for the drug and the number of doses in that package type.

9.5 Patient Specific Drugs and Order Administration Information

Drugs and drug mixtures may be manufactured or labeled for a specific patient. The SDID message structure allows for the addition of patient specific information and medication administration information. These types of labels would normally be produced by the provider, not a manufacturer.

Section tags should be implemented when patient and medication administration information is included within the SDID message. Patient identification information may be included in an SDID message resulting in <DID> and <PID> sections but medication administration information should only be included together with patient identification information. To reduce symbol size, <PID><\PID> and <DID><\DID> tags may be omitted but the <ORDERS><\ORDERS> tags must bracket all records.

9.6 SDID Tag Rules

The SDID message may be used to identify commercially manufactured drugs, provider manufactured drugs, patient specific drugs, and to label or tag a medication order drug container. To distinguish what use is intended from an SDID message and allow for a compact symbol size, the following rules must be applied:

For a commercially manufactured drug that is not patient specific, only the DID tags should exist within the SDID tags. They (the <DID> tags) may be omitted resulting in valid combinations of:

<SDID>$^{R}_{S}${DIA Record}$^{R}_{S}$<\SDID>

Example with DID section tags omitted:

<SDID>$^{R}_{S}$ DIA|3680043262|3012345678| Pseudoephedrine HCL 30 MG|30|MG|1|TAB|1|4555A34561|20071212|TAB|ORAL|12345678| PRV||1||123$^{R}_{S}$<\SDID>

Or

<SDID>$^{R}_{S}$<DID>$^{R}_{S}${DIA Record}$^{R}_{S}$<\DID>$^{R}_{S}$<\SDID>

Example with DID section tags included:

<SDID>$^{R}_{S}$ <DID>$^{R}_{S}$ DIA|3680043262|3012345678| Pseudoephedrine HCL 30 MG|30|MG|1|TAB|1|4555A34561|20071212|TAB|ORAL|12345678| PRV||1||123$^{R}_{S}$<\DID>$^{R}_{S}$ <\SDID>

The DIA record must contain the UDI\NDC issued by the manufacturer.

For a commercially manufactured drug that is patient specific, the DID tags and PID tags may be implemented. The DIA record must contain the UDI\NDC issued by the manufacturer.

<SDID>$^{R}_{S}$<DID>$^{R}_{S}${DIA Record}$^{R}_{S}$<\DID>$^{R}_{S}$<PID>$^{R}_{S}${PII Record}$^{R}_{S}$<\PID>$^{R}_{S}$<\SDID>

The section tags may be omitted resulting in:

<SDID>$^{R}_{S}${DIA Record}$^{R}_{S}${PII Record}$^{R}_{S}$<\SDID>

For provider manufactured drugs or investigational drugs that do not have a UDI\NDC number, the same tag rules apply but the DIA record may have the UDI unpopulated. The manufacturer or the provider must include a provider drug alias in DrugAlias field the absence of the UDI.

For labels that contain medication administration information, there are two options.

- The DID and PID sections contain drug and patient information records respectively. The ORDERS section contains the order administration information.

<SDID>
VER|1.0
<PID>
PII Record – Patient Information
<\PID>
<DID>
DIA Record – Drug Information
<\DID>
<ORDERS>
DDA Record – Dose Information
<\ORDERS>
<\SDID**>**

- The ORDERS tags are implemented and all records are contained within the ORDERS section.

<SDID>
VER|1.0
<ORDERS>
PII Record – Patient Information
DIA Record – Drug Information
DDA Record – Dose Information
<\ORDERS>
<\SDID>

9.7 SDID Message Structure

The structure of the basic SDID message follows the format:

<SDID>$^{R}_{S}$VER|1.0 $^{R}_{S}$<DID> $^{R}_{S}$DIA|<Drug ID Information>**$^{R}_{S}$<\DID> $^{R}_{S}$ <\SDID>**

The SDID message may be embedded within a larger set of data conveyed in a symbol but is considered the primary mechanism for auto-id drug identification when implemented.

Sections are used for separating record groups for specific purposes.

The following tags are defined for SDID version 1.0 and are considered reserved tag words even if not implemented.

<SDID>	Drug ID Message Start
<DID>	Optional Start Tag bracketing drug identification information.
<\DID>	Optional End Tag bracketing drug identification information.
<PID>	Optional Start Tag bracketing patient identification information.
<\PID>	Optional End Tag bracketing patient identification information.
<ORDERS>	Mandatory Start Tag bracketing medication administration information or all records if the drug is patient specific or includes medication administration records.
<\ORDERS>	Mandatory End Tag bracketing medication administration information or all records if the drug is patient specific or includes medication administration records.
<\SDID>	Drug ID Message End

To reduce symbol size, the <DID><\DID> and <PID><\PID> tags may be omitted if not needed.

9.8 Records for the DID Section

The following records are normally contained within the <DID> section or the <SDID> message if the <DID> tags are omitted. They may alternatively be contained within the <ORDERS> section.

The following drug information records are normally contained within a <DID> section. Please see section 8.5 for information about reducing symbol size by omitting certain tags. This section is introductory and other records may be implemented in the DID section. Please refer to section 13 for a complete list or records that may be implemented and to the appropriate sections for detailed record information.

9.8.1 Drug Identification Information Amount (DIA)

This record contains the drug identification information with the total amount of the drug specified. Only one DIA record may be included in a SDID message.

DIA|UDI|{DrugAlias}|{DrugName}|{StrengthAmount}|
{StrengthAmountUnitsOfMeasure}|{CarrierAmount}|
{CarrierAmountUnitsOfMeasure}|{UnitDoseIndicator}|{LotNumber}|
{ExpirationDate}|{DoseForm}|{DoseRoute}|{GenericEquivalenceNumber}|
{GenericEquivalenceSource}|{PackageType}|{PackageCount}|
{ProtocolNumber}|{ContainerID}

UDI	A universal drug identifier as mandated by law for drug manufacturers. As of version 1.0 of this specification, this is the National Drug Code NDC number in the United States of America. The NDC number should be for the closest packaging level to the unit of use that is feasible. Often, the NDC number will be for a non-unit of use packaging level. The DrugAlias is not required if the NDC is for the unit of use and the provider information systems do not implement an alias system.
DrugAlias	A number or code indicating the drug product name, strength, and potentially the amount or volume and dose form. This is considered a private number and must be cross-referenced to some other number such as the UDI/NDC. The DrugAlias may be used as a grouping number that relates to several different UDI/NDC numbers for the same drug of the same strength made by different manufacturers. This is mandatory if other records are implemented.
DrugName	The name of the drug such as Acetaminophen. Some names may include strength in the name.
StrengthAmount	The amount of the drug such as 30 for 30 MG. This is the total amount of the drug

	within the mass or volume of the carrier specified.
StrengthAmountUnitsOfMeasure	The units of measure for the amount of the drug such as MG for 30 milligrams.
CarrierAmount	The amount of the liquid, powder, cream etc. that the drug is contained within. This can be a volume, mass or "1" depending on the form of the drug.
CarrierAmountUnitsOfMeasure	The units of measure for the CarrierAmount. This can be a volume, mass or dose form code depending on the form of the drug. This can also be the dose form when the drug is a unit dose.
UnitDoseIndicator	A "1" means that this drug item is packaged (or has been re-packaged) at the unit dose level. (Dispense quantity of 1) Note: If this is set to a '1', then the PackageCount field is assumed to be '1' as well, *and does not need to be entered.*
LotNumber	The manufacturer's lot number
ExpirationDate	The expiration date for the drug. In YYYYMM or YYYYMMDD format.
DoseForm	The dose form code for the dose. (See Appendix 3. Use Name or Short Name only)
DoseRoute	The dose route (of administration) code for the dose. This is normally the intended dose route for the medication as manufactured but may be superseded by administration instructions. (See Appendix 2. Use Name or Short Name only)
GenericEquivalenceNumber	A unique number that is specific to drug generic ingredient combination, route of administration, dosage form, and drug strength. It is the same across manufacturers or package sizes. Normally, 100% equivalency is assumed. It is the responsibility of the provider to determine the acceptable use of this number with regards to

	the level of equivalency as provided from the source of the equivalency information.
GenericEquivalenceSource	A code indicating the source of the equivalency number and code. Currently, five codes are supported: “FDG” for FirstDataBank GCN, “FDS” for FirstDatabank GCNSeqno, “FDF” for FirstDataBank FormularyID, “FDC” for ” FirstDataBank ClinicalFormularyID and “PRV” for private. “PRV” indicates a closed system and the equivalency is determined by the provider.
PackageType	A code that distinguishes the type of packaging for this drug. (Bottle, Jar, Dose pack, Package, Case, etc.) If the UDI numbering system includes such an indicator, it should be duplicated here if it accurately indicates the packaging type. In order of preference, use the following: ▪ UDI Packaging Level Indicator ▪ Full name or FDA Code from Appendix 1 ▪ Other types not in Appendix 1 such as “MASTERCARTON” ▪ “VARIABLE” for variably quantity packages with the unit of use quantity in PackageCount. (See Appendix 1 for Package Types. Use full Name or FDA code.)
PackageCount	The number of individual unit of use (unit dose) items contained within the package type or container.
ProtocolNumber	The protocol number for investigational drugs. More than one drug may be part of a protocol.
ContainerID	The identification number of the parent container. This is used for tracking container sources for certain drugs; or may be used for drugs that have been repackaged.

9.8.2 Drug Identification Information Secondary Ingredient Amount Form (DSA)

This record contains the drug identification information with the total amount of the drug being specified as a secondary ingredient. (See IV Drugs section for specific use of DSA for IV's.) Multiple DSA records may exist in the message. The field layout and definitions are identical to the DIA record.

DSA|UDI|{DrugAlias}|{DrugName}|{StrengthAmount}|
{StrengthAmountUnitsOfMeasure}|{CarrierAmount}|
{CarrierAmountUnitsOfMeasure}|{UnitDoseIndicator}|{LotNumber}|
{ExpirationDate}|{DoseForm}|{DoseRoute}|{GenericEquivalenceNumber}|
{GenericEquivalenceSource}|{PackageType}|{PackageCount}|
{ProtocolNumber}|{ContainerID}

9.8.3 Drug Component Ingredient Information Amount (DXA)

This record contains the information about each individual drug ingredient in a combination drug such as Calcium Citrate \ Vitamin D.

DXA|UDI|{DrugAlias}|{UNII}|{UNIISource}|{IngredientName}|{StrengthAmount}|
{StrengthAmountUnitsOfMeasure}|{CarrierAmount}|
{CarrierAmountUnitsOfMeasure}||{GenericEquivalenceNumber}|
{GenericEquivalenceSource}

UDI	A universal drug identifier as mandated by law for drug manufacturers. As of version 1.0 of this specification, this is the National Drug Code NDC number in the United States of America. The NDC number should be for the closest packaging level to the unit of use that is feasible. Often, the NDC number will be for a non-unit of use packaging level. The DrugAlias is not required if the NDC is for the unit of use and the provider information systems do not implement an alias system.
DrugAlias	A number or code indicating the drug product name, strength, and potentially the amount or volume and dose form. This is considered a private number and must be cross-referenced to some other number such as the UDI/NDC. The DrugAlias may be used as a grouping number that relates to several different UDI/NDC numbers for the same drug of the same strength made by different manufacturers.
UNII	A unique ingredient identifier that provides a unique id for the ingredient.

UNIISource	A code indicating the source of the UNII. For data version 1.2 of the standard, the following codes are supported: “0” for private: indicates a closed system and the ingredient database is maintained by the provider. “1” indicates the UNII database of the Food and Drug Administration of the United States of America.
IngredientName	The name of the ingredient such as Acetaminophen or Bupivacaine.
StrengthAmount	The amount of the drug such as 30 for 30 MG. This is the total amount of the drug within the mass or volume of the carrier specified.
StrengthAmountUnitsOfMeasure	The units of measure for the amount of the drug such as MG for 30 milligrams.
CarrierAmount	The amount of the liquid, powder, cream etc. that the drug is contained within. This can be a volume, mass or “1” depending on the form of the drug.
CarrierAmountUnitsOfMeasure	The units of measure for the CarrierAmount. This can be a volume, mass or dose form code depending on the form of the drug. This can also be the dose form when the drug is a unit dose.
GenericEquivalenceNumber	A unique number that is specific to drug generic ingredient combination, route of administration, dosage form, and drug strength. It is the same across manufacturers or package sizes. Normally, 100% equivalency is assumed. It is the responsibility of the provider to determine the acceptable use of this number with regards to the level of equivalency as provided from the source of the equivalency information.
GenericEquivalenceSource	A code indicating the source of the equivalency number and code. Currently, five codes are supported: “FDG” for FirstDataBank GCN, “FDS” for FirstDatabank GCNSeqno, “FDF” for FirstDataBank FormularyID, “FDC” for ” FirstDataBank ClinicalFormularyID and “PRV” for private. “PRV” indicates a closed system and the equivalency is determined by the provider.

9.8.4 Drug Identification Prototype Record (ZDx)

This record provides a means to prototype new or modifications to existing records within the <SDID> message. The letter x is replaced by a letter or number to create a temporary record identifier. These records may be implemented in a closed system for testing until the HIBCC AITC issues a formal revision to the specification.

ZDx|User Defined Field1| User Defined Field2|
… User Defined Field…n|

Example: ZDC|1|RDNA Origin|

A provider wishes to submit for consideration inclusion of a comment record to the drug identification message. A ZDC record with a sequence number followed by a text message is created for testing.

9.9 Mandatory Fields and Traceability

It is mandatory that either the UDI or DrugAlias field is implemented. Some providers may choose to implement the same DrugAlias number for the same drug purchased from several different manufacturers. In this case the manufacturer identity is lost unless the UDI/NDC number is also implemented.

If the provider wishes to implement lot number and expiration date traceability from the pharmacy inventory to the patient, either the UDI/NDC number must be implemented or the DrugAlias must be unique to a manufacturer if the UDI/NDC is not implemented.

Example:

DIA|UDI|{DrugAlias}|{DrugName}|{StrengthAmount}|
{StrengthAmountUnitsOfMeasure}|{CarrierAmount}|
{CarrierAmountUnitsOfMeasure}|{UnitDoseIndicator}|{LotNumber}|
{ExpirationDate}|{DoseForm}|{DoseRoute}|{GenericEquivalenceNumber}|
{GenericEquivalenceSource}|{PackageType}|{PackageCount}|
{ProtocolNumber}|{ContainerID}

DIA|3680043262|3012345678| Pseudoephedrine HCL 30 MG|30|MG|1|TAB|1|
4555A34561|20071212|TAB|ORAL|12345678|PRV||1||123

NDC: 3680043262
DrugAlias: 3012345678
DrugName: Pseudoephedrine HCL 30 MG
StrengthAmount: 30
StrengthAmountUnitsOfMeasure: MG
CarrierAmount: 1
CarrierAmountUnitsOfMeasure: TAB
UnitDoseIndicator: 1
LotNumber: 4555A34561
Expiration Date: 2007/12/12 – December 12th, 2007
Dose Form: TAB
Dose Route: ORAL
GenericEquivalenceNumber: 12345678
GenericEquivalenceSource: PRV (Private)
PackageType: none
PackageCount: 1
Protocol Number: none
ContainerID: 123

Notes:

- If the DrugAlias data also references the strength amount, units of measure, and dose form, the minimum record would be:

  DIA|3680043262|3012345678

- It is recommended that both the UDI/NDC and the DrugAlias be implemented.

9.10 Records for the ORDERS Section

These records provide order administration information.

Please see the record implementation table in **Section 13** for a complete list of records.

9.10.1 Physician Information (PHY)

When this record is implemented within the <ORDERS> section, it specifies the ***ordering*** physician.

9.10.2 Order Lifetime Information (OLI)

This record contains the order number, start and discontinue date-times and useable timeframe information.

OLI|OrderNumber|OrderSystem|{OrderStartDate}|{OrderStartTime}|
{OrderDCDate}|{OrderDCTime}

OrderNumber	A unique order number for the medication. This may be a pharmacy order number or a CPOE\EMAR order number depending on the OrderSystem field.
OrderSystem	A code indicating the source of the order number. This field may contain: • "POE" – The order number is issued from the provider order entry system. • "PHARM" – the order is issued from the pharmacy system.
OrderStartDate	The starting date for the order in YYYYMMDD format.
OrderStartTime	The starting time of the order in HHMM{SS} format.
OrderDCDate	The discontinue date of the order in YYYYMMDD format.
OrderDCTime	The discontinue time of the order in HHMM{SS} format.

9.10.3 Dose Stability Lifetime (DSL)

This record contains the stability timeframe information for a dose.

DSL|DrugAlias|{TrackingNumber}|**StabilityEndDate**|{StabilityEndTime}|(StabilityStartDate}|{StabilityStartTime}

DrugAlias	A number or code indicating the drug product name, strength, and potentially the amount or volume, and dose form. This is considered a private number and must be cross-referenced to some other number such as the UID/NDC. The DrugAlias may be used as a grouping number that relates to several different UID/NDC numbers for the same drug of the same strength made by different manufacturers.
TrackingNumber	The provider tracking number for the dose
StabilityEndDate	The ending date that the dose is useable from a stability standpoint. This is intended to be used for medications which have a limited lifetime after mixing or manufacture. Traditionally, this information may be communicated in a label comment such as “Use within 8 hours”. Note that the resulting useable end date and time may occur before or after the OrderDCDate and time.
StabilityEndTime	The ending time that the dose is usable from a stability standpoint. This field must not be implemented without the StabilityEndDate field.
StabilityStartDate	The starting date that the dose is useable from a stability standpoint. This should be implemented with a corresponding StabilityEndDate to provide an expression of a useable timeframe for the dose such as an 8 hour time span such as communicated through a label comment “Use within 8 hours”.
StabilityStartTime	The starting time that the dose is usable from a stability standpoint. This field must not be implemented without the StabilityStartDate field.

Note:
When the stability end date and time fields are implemented and the dose is for an infusion, the pump may be capable of comparing the calculated infusion end date and time against the stability end date and time and alarm if the infusion would extend beyond the time the mixture is stable.

9.10.4 Order Schedule Information (OSI)

This record contains the Order Schedule information. Many orders will have a 'finite' time determined for their administration by their originating system, and this time will be in the DSS or VSS records for the order. There are some schedules, however, that do not lend themselves to fixed scheduling. These include (but aren't limited to) PRN (as needed) schedules, and schedules with 'modifiers'. This record provides a vehicle for communication of non-timed or non-standard schedules to the caregiver.

OSI|{SchedCode}|{Schedule Description}

SchedCode	A provider-specific abbreviation code for administration schedule.
ScheduleDescription	Description of provider-specific schedule description; or special administration instructions.

Example: OSI|| Give 1 hour after evening meal

9.10.5 Care Area Information (CAR)

This record contains the Care Area and indications for the order. This record is optional. It can be implemented with devices that can hold the identity of areas of care; or be used with devices where the care area is selected by the clinician. Orders can be rejected where the care area set in the device does not match the care area received in the orders. (See *Set Care Area in Section 9*).

CAR|CareArea|{CareAreaIndication}

CareArea	A code established in a drug library or other system indicating the area of care. ED, ICU, NICU CHEMO, etc are some examples. These codes are considered private to the provider.
CareAreaIndication	An optional code established in a drug library or other system that relates to the use of the drug within the care area.

Example: CAR|PED| - Order is for pediatrics areas, no indications.

9.10.6 Drug Delivery Information by Amount (DDA) and Volume (DDV)

These records contain dosing amount or “Give” information for the drug in the form of

X drug units (DDA)
OR
X volume units (DDV)

DDA specifies that the GiveUnits and GiveUnitsOfMeasure are in terms of the drug amount such as milligrams.

DDV specifies that the GiveUnits and GiveUnitsOfMeasure are in terms of the volume such as milliliters.

DDA|DrugAlias|GiveUnits|GiveUnitsOfMeasure|{MultiComponentDose|
DeliveryDate|DeliveryTime}

DDV|DrugAlias|GiveUnits|GiveUnitsOfMeasure|{MultiComponentDose|
DeliveryDate|DeliveryTime}

DrugAlias	A number or code indicating the drug product name, strength, and potentially the amount or volume, and dose form. This is considered a private number and must be cross-referenced to some other number such as the UID/NDC. The DrugAlias may be used as a grouping number that relates to several different UID/NDC numbers for the same drug of the same strength made by different manufacturers.
GiveUnits	The amount to give to the patient.
GiveUnitsOfMeasure	The units of measure for the amount to give.
MultiComponentDose	The number of separate order components to make the dose when it takes more than one to make a dose. This may be fractional such as 1.5
MultiComponentDoseUnits OfMeasure	The units of measure for the separate order components in a multi-component dose. This could be a volume or mass unit of measure as well as a packaging description such as TABLETS.
DeliveryDate	A specific date to deliver the dose such as 20050422 (04/22/2005)
DeliveryTime	The time to deliver the dose such as 1435

Example: DDA|8165000|300|MG

This indicates that 300 milligrams of drug 8165000 should be given.

Example: DDV|1234567|30|mL

This indicates that 30 milliliters of drug 1234567 should be given.

Example: DDA|8165002|45|MG|1.5|TABLETS|12202008|1400

This indicates that 45 milligrams of drug 8165002 should be given at 2:00 PM on 12/20/2008 and that there are 1.5 components to this dose. (1 and one-half tablets, for example).

9.10.7 Dose Tracking Information (DTI)

This record contains a tracking number that is unique to the specific medication "dose" to which it is attributed**. The "dose" is assigned this single number for tracking purposes although the actual drug delivery may consist of one continuous IV dose, one capsule, one tube, or multiple tablets.**

DTI|DrugAlias|TrackingNumber|{OrderDoseSequenceNumber}

DrugAlias	A number or code indicating the drug product name, strength, and potentially the amount or volume, and dose form. This is considered a private number and must be cross-referenced to some other number such as the UID/NDC. The DrugAlias may be used as a grouping number that relates to several different UID/NDC numbers for the same drug of the same strength made by different manufacturers.
TrackingNumber	The provider tracking number for the dose
OrderDoseSequenceNumber	This is a sequence number or ID that is relative to the order.

Example: DTI|1234567|10000000000081423|2

This tracking number is 10000000000081423 for the dose for drug alias 1234567. The OrderDoseSequendeNumber is 2.

Notes:

This record is intended to be logged into a device and later downloaded or sent real-time from the device. This information might be used to update a system to show delivery of a medication to a patient's location. The OrderDoseSequenceNumber is relative to the order (order number).

9.10.8 Custom Message Record (CMR)

This record is for use with devices capable of displaying text messages on a screen. Multiple or long messages may be sent and ordered by a sequence number.

Priority affects how the message will be displayed and action the device may take.

CMR|SequenceNumber|Priority|MessageText

SequenceNumber	The order in which messages are displayed or the sequence number for a part of a long message.
Priority	A number that affects display properties, alarm and device actions.
MessageText	The message to be displayed

Priority	Action
0	Default display, no alarm or action
1	Display prominently
2	Display prominently, alarm, require clinician acknowledgement

Example 1:

CMR|1|0|Wish the patient a Happy Birthday!|

Just displays the message on the screen

Example 2:

CMR|1|2|Drug may cause light sensitivity.

CMR|2|2|Keep room window blinds closed.

The messages are displayed prominently on the screen. The device alarms and requires acknowledgement from the clinician.

Example 3:

CMR|1|2|Patient is allergic to latex.

The message is displayed prominently on the screen. The device alarms and requires acknowledgement from the clinician.

9.10.9 Drug Inventory Record (DIR)

This is an optional record for tracking a medication container or drug by one or more optional identifiers definable by the provider with the exception of lot number. A tracking number for the container; a lot number for the drug or IV mixture; a private internal item number and private internal serial number – any or all of these may be tracked. A device is expected to store this information and allow it to be downloaded or reported later. If the DrugAlias is left empty, the tracking numbers are for the container. If multiple drugs are in the container, a DIR record for each drug may be implemented and individual tracking numbers per drug may be implemented. Since the fields with the exception of lot number are privately assigned, the provider is free to choose the context or meaning of the fields. The TrackingNumber or SerialId fields may be implemented as dose tracking numbers.

DIR|{DrugAlias}|{TrackingNumber}|{LotNumber}|{ItemNumber}|
{SerialID}

DrugAlias	A number or code indicating the drug product name, strength, and potentially the amount or volume, and dose form. This is considered a private number and must be cross-referenced to some other number such as the UDI/NDC. The DrugAlias may be used as a grouping number that relates to several different UDI/NDC numbers for the same drug of the same strength made by different manufacturers.
TrackingNumber	The container tracking number or drug tracking number. **If the DrugAlias is left empty, the tracking numbers are for a container**. This may be implemented as a dose tracking number.
LotNumber	Lot number for the drug if the DrugAlias is present. If not this can represent a repackaging lot number for the container.
ItemNumber	Internal provider item number. This can represent whatever the provider elects.
SerialId	Internal provider serial number.

Example 1:

DIR|1234567||33A65433B6|||

Only one drug is in the container and the tracking number is left blank. Drug 1234567 has a lot number of 33A65433B6

Example 2:

DIR|1234567|81423567|33A65433B6|||

DIR|6632451|81423567|662300A001333|||

Two drugs are in the same container 81423567 and both lot numbers are indicated.

Example 3:

DIR|1234567|81423567||6657342||

We are tracking the item number 6657342 for drug 1234567 in container 81423567.

Example 4:

DIR|1234567|81423567|||88867A2|

We are tracking the serial number 88867A2 for drug 1234567 in container 81423567.

Example 5:

DIR||81423567||||

DIR|1234567|1000012|33A65433B6|||

DIR|6632451|100013|662300A001333|||

The container is tracked by number 81423567 and contains two drugs (1234567 and 6632451). Each drug has an individual tracking number (dose ids – 1000012 and 100013) and the lot numbers are indicated (33A65433B6 and 662300A001333).

Notes:

The lot number is normally included in a DIA, DSA, DIC or DSC record. It may be implemented here if it is not carried in those records or the container is used to contain multiple items and it is desirable to encode the lot numbers in a symbol or tag. The lot number from the DIR is traceable to the manufacture ***only*** if the drug alias is manufacturer specific or the drug alias is matched to a DIA, DSA, DIC or DSC record to retrieve the corresponding UDI.

9.10.10 Drug Repeated Dose (DRI) and Volume Repeated Dose (VRI)

These records carry repeated dose instructions for delivery of a repeated dose at a fixed interval, with an optional time offset from the start of the medication delivery. The DRI record is used when the delivery is in terms of drug units of measure and the VRI record is used when the delivery is in terms of volume units of measure. The delivery amount must be specified in a DDA or DDV record. Use DRI with DDA, VRI with DDV.

DRI|DrugAlias|DeliveryUnits|DeliveryUnitsofMeasure|IntervalTimeUnits|IntervalTimePeriodUnitsOfMeasure|{OffsetTimeUnits}|{OffsetTimePeriodUnitsOfMeasure}|

DrugAlias	A number or code indicating the drug product name, strength, and potentially the amount or volume, and dose form. This is considered a private number and must be cross-referenced to some other number such as the UDI/NDC. The DrugAlias may be used as a grouping number that relates to several different UDI/NDC numbers for the same drug of the same strength made by different manufacturers.
DeliveryUnits	The amount to deliver or give.
DeliveryUnitsOfMeasure	The units of measure for DeliveryUnits.
IntervalTimeUnits	The interval amount (every X).
IntervalTimePeriodUnitsOfMeasure	The units of measure for IntervalTimeUnits.
OffsetTimeUnits	The offset amount from medication start.
OffsetTimePeriodUnitsOfMeasure	The units of measure for the offset time interval.

Example 1:

For this example, assume that Drug Alias 1234567 represents drug = Acetaminophen (tablet, 325 mg)

DDA|1234567|325|MG

DRI|1234567|325|MG|4|HRS|||

Give 325 milligrams every 4 hours.

Example 2:

For this example, assume that Drug Alias 1234567 represents drug = Acetaminophen and codeine elixir (24mg/10ml packaged in 10ml amts)

DDV|1234567|20|ML|

VRI|1234567|20|ML|6|HRS|4|HRS|

Give 20 milliliters of drug 1234567 every 6 hours beginning 4 hour after the initial dose.

Notes:

By using the optional offset from start, other doses such as a higher initial dose can be delivered before the repeated dose delivery begins; or a sliding scale of doses can be defined.

9.10.11 Specific Dose at time offset from start (DSO\VSO)

These records carry dose instructions for delivery of a specific dose at a specific time based on an offset from the medication delivery start (first dose*).* The DSO record is used when the delivery is in terms of drug units of measure and the VSO record is used when the delivery is in terms of volume units of measure. *Delivery rate fields are intended to be used with infusion pumps and the examples here are for tablets or capsules with the rate fields left empty.*

DSO|DrugAlias|DeliveryRateUnits|DeliveryRateUnitsOfMeasure| DeliveryTimePeriodUnitsOfMeasure|DeliveryUnits|DeliveryUnitsOfMeasure|OffsetTimeUnits|OffsetTimePeriodUnitsOfMeasure|

VSO|DrugAlias|DeliveryRateUnits|DeliveryRateUnitsOfMeasure| DeliveryTimePeriodUnitsOfMeasure|DeliveryUnits|DeliveryUnitsOfMeasure|OffsetTimeUnits|OffsetTimePeriodUnitsOfMeasure|

DrugAlias	A number or code indicating the drug product name, strength, and potentially the amount or volume, and dose form. This is considered a private number and must be cross-referenced to some other number such as the UDI/NDC. The DrugAlias may be used as a grouping number that relates to several different UDI/NDC numbers for the same drug of the same strength made by different manufacturers.
DeliveryRateUnits	Delivery rate amount. (used with IV's)
DeliveryRateUnitsOfMeasure	Delivery rate units of measure. (used with IV's)
DeliveryTimePeriodUnitsOfMeasure	Delivery time units of measure (for 1 time period)
DeliveryUnits	The amount to deliver or give.
DeliveryUnitsOfMeasure	The units of measure for DeliveryUnits.
OffsetTimeUnits	The offset amount from medication start.
OffsetTimePeriodUnitsOfMeasure	The units of measure for the offset time interval.

Examples:

DSO|1234567||||4|MG|2|HR|

Deliver 4 milligrams of drug 1234567 2 hours after the initial dose.

VSO|1234567||||20|ML|145|MIN|

Deliver 20 ML of drug 1234567 145 minutes after the initial dose.

9.10.12 Specific Dose at specific time (DSS\VSS)

These records carry dose instructions for delivery of a specific dose at a specific date and time. The DSS record is used when the delivery is in terms of drug units of measure and the VSS record is used when the delivery is in terms of volume units of measure. *Delivery rate fields are intended to be used with infusion pumps and the examples here are for tablets or capsules with the rate fields left empty.*

DSS|DrugAlias|DeliveryRateUnits|DeliveryRateUnitsOfMeasure|
DeliveryTimePeriodUnitsOfMeasure|DeliveryUnits|
DeliveryUnitsOfMeasure|DeliveryTime|DeliveryDate|

DrugAlias	A number or code indicating the drug product name, strength, and potentially the amount or volume, and dose form. This is considered a private number and must be cross-referenced to some other number such as the UDI/NDC. The DrugAlias may be used as a grouping number that relates to several different UDI/NDC numbers for the same drug of the same strength made by different manufacturers.
DeliveryRateUnits	Delivery rate amount. (used with IV's)
DeliveryRateUnitsOfMeasure	Delivery rate units of measure. (used with IV's)
DeliveryTimePeriodUnitsOfMeasure	Delivery time units of measure (for 1 time period)
DeliveryUnits	The amount to deliver or give.
DeliveryUnitsOfMeasure	The units of measure for DeliveryUnits.
DeliveryTime	The time to deliver the dose such as 1435
DeliveryDate	A specific date to deliver the dose such as 20050422 (04/22/2005)

Examples:

DSS|1234567||||20|MCG|1400|

Deliver 20 micrograms of drug 1234567 at 2:00 PM.

VSS|1234567|||20|ML|0800|20050422|

Deliver 20 ML of drug 1234567 at 8:00 AM on April 22nd, 2005

Multiple records constitute a schedule and should be processed by a device in the order of occurrence in the message. This allows the times to cross midnight without the need for dates. Midnight (or 12AM) is

expressed as 000000. For schedules where the doses occur three times a day with the first dose at 8:00 AM, the DSS records would be:

DSS|1234567|4|MG|HR|20|MCG|080000|

DSS|1234567|4|MG|HR|20|MCG|160000|

DSS|1234567|4|MG|HR|20|MCG|000000|

9.10.13 Patient Clinical Information Message (PCI)

This record contains a patient specific clinical advisory message for display on the pump screen.

PCI|ClinicalInformationMessage|

ClinicalInformationMessage	Text message for screen display

Example: PCI|Patient is allergic to latex|

Notes:

The text message in this record is intended to be displayed on a screen. It should be displayed in a significant manner such as a larger bold font or a color font.

9.10.14 Drug Dose Form and Route Information (DFR)

This record contains information about the dose form and route for the order.

DFR|{DoseForm}|{DoseRoute}|{DoseRouteDescription}

DoseForm	The dose form code. Example: CAP
DoseRoute	The Route of Administration code. Example: TOPIC or ORAL
DoseRouteDescription	A readable description of the Route (of Administration) Example: TOPICAL or ORAL

Example: DFR|CREAM|TOPIC|TOPICAL|

This drug is a CREAM and is for TOPICAL use.

Notes:

1. This record is normally in the context of an ORDER. If the order has a mixture of ingredients, the DFR record contains the intended dose form and route of administration code for the total mixture.

   Note: Dose Form and Dose Route are also parts of the DIA (Drug Identification Amount) record. If Dose Form and Dose Route are used in the DFR record **AS WELL**, they will supersede the dose form and route entries in the DIA records.

2. Dose form and Route of Administration codes used are the Federal Drug Administration (FDA) CDER Short Names. (See Appendix 3 and 2, respectively)

9.11 SDID Message Examples

The following examples include the format for the message under a number of scenarios, including:

- Standard message for regular commercially available drugs (not investigational)
- Message for investigational drugs including protocol number
- Drugs prescribed to specific patients
- Drugs intended for external providers

In the examples, the repeated field separators for empty fields ("||||||") at the end of the records have been removed as would normally be done to produce the most compact symbol.

9.12 Standard Message for SDID

<SDID>$^{R}_{S}$VER|1.0$^{R}_{S}$DIA|3680043262|3012345678|
Pseudoephedrine HCL |30|MG|1|TAB|1|4555A34561|20071212$^{R}_{S}$<\SDID>

The data in this message is broken down to the following records and fields:

<SDID>
VER
Version 1.0
DIA
NDC: 3680043262
DrugAlias: 3012345678
DrugName: Pseudoephedrine HCL
StrengthAmount: 30
StrengthAmountUnitsOfMeasure: MG
CarrierAmount: 1
CarrierAmountUnitsOfMeasure: TAB
UnitDoseIndicator:1
LotNumber: 4555A34561
Expiration Date: 2007/12/12 – December 12th, 2007
Dose Form: <blank>
Dose Route: <blank>
GenericEquivalenceNumber: <blank>
GenericEquivalenceSource: <blank>
PackageType: none
PackageCount: 1*(defaulted)*
Protocol Number: <blank>
ContainerID: <blank>
<\SDID>

Aztec

Data Matrix

QR Code

9.13 Message for Investigational Drugs

For drugs that are for investigational use, the DIA record in is implemented with a protocol number.

<SDID>$^{R}_{S}$VER|1.0$^{R}_{S}$DIA||7024600|Arimoclonal Study|
100|MG|1|TAB|1|13611A34561|20071212|||||1|R96-01$^{R}_{S}$<\SDID>

The data in this message is broken down to the following records and fields:

<SDID>
VER
Version 1.0
DIA
UDI(NDC): (none)
Drug Alias: 7024600
DrugName: Arimoclonal Study
StrengthAmount: 100
StrengthAmountUnitsOfMeasure: MG
CarrierAmount: 1
CarrierAmountUnitsOfMeasure: TAB
UnitDoseIndicator: 1
LotNumber: 13611A34561
Expiration Date: 2007/12/12 – December 12th, 2007
Dose Form: <blank>
Dose Route: <blank>
GenericEquivalenceNumber: <blank>
GenericEquivalenceSource: <blank>
PackageType: none
PackageCount: 1
Protocol Number: R96-01
ContainerID: <blank>
<\SDID>

9.14 Drugs for specific patients

When drugs are intended for a specific patient, a Patient Identification Information record is implemented by adding the PID record to the DID message. This applies to all drugs intended for a specific patient.

9.14.1 Non Investigational

<SDID>[R][S]VER|1.0[R][S]DIA|00173073500|8887100|Sumatriptan Succinate|25|MG|1|TAB|1|1615432101|20071206[R][S] PII|4454145|19561214|B|F|9C8341600|2|20060412|Otwell|Ima|N|50|YRS|U[R][S]<\SDID>

The data in this message is broken down to the following records and fields:

<SDID>

VER

Version 1.0

DIA

UDI(NDC): 00173073500
DrugAlias: 8887100
DrugName: Sumatriptan Succinate
StrengthAmount: 25
StrengthAmountUnitsOfMeasure: MG
CarrierAmount: 1
CarrierAmountUnitsOfMeasure: TAB
UnitDoseIndicator: 1
LotNumber: 1615432101
Expiration Date: 2007/12/06 – December 06th, 2007
Dose Form: <blank>
Dose Route: <blank>
GenericEquivalenceNumber: <blank>
GenericEquivalenceSource: <blank>
PackageType: none
Package Count: 1 *(defaulted)*
Protocol Number: <blank>
ContainerID: <blank>

PII

Patient ID or MRN: 4454145
Date of Birth: 14 December 1956
Source: B (Patient Care Record)
Patient Gender: Female
Provider: 9C8341600 (HIN)
Visit Number : 2
Admit Date: 12 April, 2006
Patient Last Name: Otwell
Patient First Name: Ima
Patient Middle Initial: N.
Age: 50
Age Units: YRS
IssuingEntityCode: U (HIN)

<\SDID>

Aztec

Data Matrix

QR Code

9.14.2 Investigational

Here, a protocol number is added for the investigational drug.

<SDID>$^{R}_{S}$VER|1.0$^{R}_{S}$DIA||7024600|Arimoclonal Study|100|MG|1|TAB|1|13611A34561|20071212|||||1|R96-01$^{R}_{S}$PII|4454145|19561214|B|F|9C8341600|2|20060412|Otwell|Ima|N|50|YRS|U$^{R}_{S}$<\SDID>

The data in this message is broken down to the following records and fields:

<SDID>

VER

Version 1.0

DIA

UDI(NDC): (none)
Drug Alias: 7024600
DrugName: Arimoclonal Study
StrengthAmount: 100
StrengthAmountUnitsOfMeasure: MG
CarrierAmount: 1
CarrierAmountUnitsOfMeasure: TAB
UnitDoseIndicator: 1
LotNumber: 13611A34561
Expiration Date: 2007/12/12 – December 12th, 2007
Dose Form: <blank>
Dose Route: <blank>
GenericEquivalenceNumber: <blank>
GenericEquivalenceSource: <blank>
PackageType: none
PackageCount: 1
Protocol Number: R96-01
ContainerID: <blank>

PII

Patient ID or MRN: 4454145
Date of Birth: 14 December 1956
Source: B (Patient Care Record)
Patient Gender: Female
Provider: 9C8341600 (HIN)
Visit Number : 2
Admit Date: 12 April, 2006
Patient Last Name: Otwell
Patient First Name: Ima
Patient Middle Initial: N.
Age: 50
Age Units: YRS
IssuingEntityCode: U (HIN)

<\SDID>

9.15 Drugs intended for external providers

When drugs are manufactured or shipped to an external provider, some means of cross-referencing drug aliases and patient id's is needed.

9.15.1 External Provider Order (EXO)

This record contains information to cross-reference an external provider's order number. This record should be used if cross-referencing is not possible from the issuing provider. The external provider thus has the responsibility to cross-reference the issuing provider's DrugAlias into their system.

IssuingEntityID	A unique identifier *for the issuing entity or provider.* The issuing provider's HIN is recommended. (Sender)
ExternalProviderID	A unique identifier for the external provider. The HIN is recommended.
OrderNumber	The external provider's order number

Example: EXO|AU1234C00|770801|

Notes:

- The OrderNumber is mandatory. The use of the ExternalProviderID is recommended.
- Use of this record assumes that the external provider has a cross-reference system for the issuing provider's drug aliases (DrugAlias) or a reliable process to identify the drug in the absence of a UDI.

Example Message – Drug for an external provider with an order number

<SDID>$^{R}_{S}$VER|1.0$^{R}_{S}$DIA||3012345678|Acetaminophen|325|MG|1|TAB|1|
4555A34561|20071212$^{R}_{S}$EXO|MGH|AU1234C00|770801$^{R}_{S}$<\SDID>

9.15.2 EXO Message Example

The data in this message is broken down to the following records and fields:

<SDID>
VER
Version 1.0
DIA
UDI (NDC): <blank>
Drug Alias: 3012345678
Drug Name: Acetaminophen
StrengthAmount: 325
StrengthAmountUnitsOfMeasure: MG
CarrierAmount: 1
CarrierAmountUnitsOfMeasure: TAB
UnitDoseIndicator: 1
Lot Number: 4555A34561
Expiration Date: 12 December 2007
Dose Form: <blank>
Dose Route: <blank>
GenericEquivalenceNumber: <blank>
GenericEquivalenceSource: <blank>
PackageType: None
PackagingCount: 1 *(defaulted)*
Protocol Number: <blank>
ContainerID: <blank>
EXO
Issuing Entity ID: MGH
External Provider ID: AU1234C00 (this is formatted as a HIN)
Order Number: 770801
<\SDID>

9.15.3 External Provider Cross Reference (EXR)

This record contains information to cross-reference an external or receiving provider's patient and drug information when a drug is repackaged or manufactured for shipment to an external provider. Patient information is mandatory if a PII record is part of the data. The data in this record is the external provider's (recipient's) data.

The companion DIA record contains the drug alias of the manufacturing or *sending* provider. This insures that the drug is correctly identified by drug alias while at the sending provider.

The receiving provider should use the EXR drug alias or the UDI in the DIA record for identification of the drug. It is recommended that the drug is repackaged and/or relabeled with recipient DIA record information at time of receipt.

EXR|{DrugAlias}**|IssuingEntityID**
ExternalProviderID|{PatientID}|{OrderNumber}|{ProtocolNumber}|

DrugAlias	A number or code indicating the drug product name, strength, and potentially the amount or volume. This is considered a private number and must be cross-referenced to some other number such as the UDI/NDC. The DrugAlias may be used as a grouping number that relates to several different UDI/NDC numbers for the same drug of the same strength made by different manufacturers. *This is the drug alias for the external (receiving) provider*
IssuingEntityID	A unique identifier *for the issuing entity or provider.* The issuing provider's HIN is recommended. (Sender)
ExternalProviderID	A unique identifier *for the external entity or provider.* The external provider's HIN is recommended. (Recipient)
PatientID	The *external provider's (recipient's)* Patient ID or Medical Record Number
OrderNumber	The *external provider's (recipient's)* order number
ProtocolNumber	The *external provider's (recipient's)* protocol number for investigational drugs. More than one drug may be part of a protocol.

Example: EXR|6012345621|MGH|DFCI|666414|770801|33-3401-12|

The drug represented by DFCI Drug Alias of 6012345621 is being prepared externally for DFCI patient #666414, DFCI Order # 770801, and the DFCI protocol number of 33-3401-12.

Notes:

- The PatientID must be left empty if the drug is not for a specific patient.
- Use of this record assumes that the issuing provider has a cross-reference system to correctly map the DrugAlias between provider systems if UDI is not implemented.

Example Message – Drug for an external provider cross-referenced with order number and patient id.

<SDID>[R]S[VER|1.0[R]S[DIA|3680043262|3012345678|Acetaminophen|325|MG|1|TAB|1|1|4555A34561|20071212[R]S[EXR|6012345621|MGH|AU1234C00|4454145|770801[R]S<\SDID>

The data in this message is broken down to the following records and fields:

<SDID>
VER
Version 1.0
DIA
UDI(NDC): 3680043262
Drug Alias: 3012345678 (Issuing Provider's)
Drug Name: Acetaminophen
StrengthAmount: 325
StrengthAmountUnitsOfMeasure: MG
CarrierAmount: 1
CarrierAmountUnitsOfMeasure: TAB
UnitDoseIndicator: 1
Lot Number: 4555A34561
Dose Form: <blank>
Dose Route: <blank>
GenericEquivalenceNumber: <blank>
GenericEquivalenceSource: <blank>
PackageType: None
PackageCount: 1*(defaulted)*
Protocol Number: <blank>
ContainerID: <blank>
EXR
Drug Alias: 6012345621 (Receiving Provider's)
Issuing Entity ID: MGH
External Provider ID: AU1234C00 (formatted as HIN)
Patient ID or MRN: 4454145
Order Number: 770801
Protocol Number: <blank>
<\SDID>

Example Message – Investigational drug Bicalutamide for a specific patient, 4454145, Otwell, Ima N., protocol R96-01, for an external provider

<SDID>$^{R}_{S}$VER|1.0$^{R}_{S}$DIA||7195200|Bicalutamide|1|EA|1|EA|1|4555A34561|20071212||||||R96-01$^{R}_{S}$
PII|4454145|19561214|B|F|9C8341600|2|20060412|Otwell|Ima|N|50|YRS|U$^{R}_{S}$
EXR||7195200|3012345678|AU1234C00|666414|770801|R96-01$^{R}_{S}$<\SDID>4

The data in this message is broken down to the following records and fields:

<SDID>
VER
Version: 1.0
DIA
UDI(NDC): <blank>
Drug Alias: 7195200
Drug Name: Bicalutamide
StrengthAmount: 1
StrengthAmount Units of Measure: EA
CarrierAmount: 1
CarrierAmountUnitsOfMeasure: EA
UnitDoseIndicator: 1
Lot Number: 4555A34561
Expiration Date: 12 December 2007
Dose Form: <blank>
Dose Route: <blank>
GenericEquivalenceNumber: <blank>
GenericEquivalenceSource: <blank>
PackageType: None
PackageCount: 1*(defaulted)*
Protocol Number: R96-01
ContainerID: <blank>
PII
Patient ID or MRN: 4454145
Date of Birth: 14 December 1956
Source: B (Patient Care Record)
Patient Gender: Female
Provider: 9C8341600 (HIN)
Visit Number: 2
Admit Date: 12 April, 2006
Patient Last Name: Otwell
Patient First Name: Ima
Patient Middle Initial: N.
Age: 50
Age Units: YRS
IssuingEntityCode: U (HIN)
EXR
UDI(NDC): (<blank>
Drug Alias: 7195200
IssuingEntity ID: MGH
ExternalProviderID: AU1234C00 (formatted as HIN)
Patient ID or MRN: 4454145
Order Number: 770801
Protocol Number: R96-01
<\SDID>

9.16 Drugs with Administration Information

Here is an example of a drug with an <ORDERS> section.

<SDID>$^{R}_{S}$VER|1.0$^{R}_{S}$<ORDERS>$^{R}_{S}$ DIA|3680043262|3012345678|Acetaminophen|325|MG|1|TAB|1|1|4555A34561|20071212$^{R}_{S}$
PII|4454145|19561214|B|F|9C8341600|2|20060412|Otwell|Ima|N|50|YRS|U$^{R}_{S}$
OLI|6661234|POE|20061213|0800|20061217|1800$^{R}_{S}$
OSI|PRN|As needed every 4 hours$^{R}_{S}$
<\ORDERS>$^{R}_{S}$ <\SDID>

The data in this message is broken down to the following records and fields:

<SDID>
VER
Version 1.0
<ORDERS>
DIA
UDI(NDC): 3680043262
Drug Alias: 3012345678 (Issuing Provider's)
Drug Name: Acetaminophen
StrengthAmount: 325
StrengthAmountUnitsOfMeasure: MG
CarrierAmount: 1
CarrierAmountUnitsOfMeasure: TAB
UnitDoseIndicator: 1
Lot Number: 4555A34561
Expiration Date: 12 December 2007
Dose Form: <blank>
Dose Route: <blank>
GenericEquivalenceNumber: <blank>
GenericEquivalenceSource: <blank>
PackageType: None
PackageCount: 1*(defaulted)*
Protocol Number: <blank>
ContainerID: <blank>
PII
Patient ID or MRN: 4454145
Date of Birth: 14 December 1956
Source: B (Patient Care Record)
Patient Gender: Female
Provider: 9C8341600 (HIN)
Visit Number: 2
Admit Date: 12 April, 2006
Patient Last Name: Otwell
Patient First Name: Ima
Patient Middle Initial: N.
Age: 50
Age Units: YRS
IssuingEntityCode: U (HIN)
OLI
OrderNumber: 6661234
OrderSystem: POE
OrderStartDate: Dec 12th, 2006
OrderStartTime: 8:00 AM
OrderDCDate: Dec 17th, 2006

OrderDCTime: 6:00 PM
StabilityEndDate: <blank>
StabilityEndTime: <blank>

OSI

SchedCode: PRN
ScheduleDescription: As needed every 4 hours

DDA

Drug Alias: 3012345678
Give Units: 300
GiveUnitsOfMeasure: MG

<\ORDERS>

<\SDID>

The next example adds the admitting physician and the order physician. A PID section tag must be implemented as there are two PHY records in the message.

<SDID>[R][S]VER|1.0[R][S]<PID>[R][S] PII|4454145|19561214|B|F|9C8341600|2|
20060412|Otwell|Ima|N|50|YRS|U[R][S]PHY|12306|Iswell|Dr. Al|L|[R][S]<\PID>[R][S]
<ORDERS>[R][S] DIA|3680043262|3012345678|Acetaminophen
|325|MG|1|TAB|1|1|4555A34561|20071212[R][S]
OLI|6661234|POE|20061213|0800|20061217|1800[R][S]
OSI|PRN|As needed every 4 hours[R][S]PHY|128911|Noharm|Dewy[R][S]
<\ORDERS>[R][S] <\SDID>

<SDID>

VER

Version 1.0

<PID>

PII

Patient ID or MRN: 4454145
Date of Birth: 14 December 1956
Source: B (Patient Care Record)
Patient Gender: Female
Provider: 9C8341600 (HIN)
Visit Number: 2
Admit Date: 12 April, 2006
Patient Last Name: Otwell
Patient First Name: Ima
Patient Middle Initial: N.
Age: 50
Age Units: YRS
IssuingEntityCode: U (HIN)

PHY

PhysicianID: 12306 (admitting)
LastName: Iswell
FirstName Dr. Al
MiddleIntial: L

PII

Patient ID or MRN: 4454145
Date of Birth: 14 December 1956
Source: B (Patient Care Record)
Patient Gender: Female
Provider: 9C8341600 (HIN)
Visit Number: 2
Admit Date: 12 April, 2006
Patient Last Name: Otwell

Patient First Name: Ima
Patient Middle Initial: N.
Age: 50
Age Units: YRS
IssuingEntityCode: U (HIN)

<\PID>

<ORDERS>

DIA

UDI(NDC): 3680043262
Drug Alias: 3012345678 (Issuing Provider's)
Drug Name: Acetaminophen
StrengthAmount: 325
StrengthAmountUnitsOfMeasure: MG
CarrierAmount: 1
CarrierAmountUnitsOfMeasure: TAB
UnitDoseIndicator: 1
Lot Number: 4555A34561
Expiration Date: 12 December 2007
Dose Form: <blank>
Dose Route: <blank>
GenericEquivalenceNumber: <blank>
GenericEquivalenceSource: <blank>
PackageType: None
PackageCount: 1*(defaulted)*
Protocol Number: <blank>
ContainerID: <blank>

OLI

OrderNumber: 6661234
OrderSystem: POE
OrderStartDate: Dec 12th, 2006
OrderStartTime: 8:00 AM
OrderDCDate: Dec 17th, 2006
OrderDCTime: 6:00 PM
StabilityEndDate: <blank>
StabilityEndTime: <blank>

OSI

SchedCode: PRN
ScheduleDescription: As needed every 4 hours

DDA

Drug Alias: 3012345678
Give Units: 300
GiveUnitsOfMeasure: MG

PHY

PhysicianID: 128911 (ordering)
LastName: Noharm
FirstName Dewy
MiddleIntial: <blank>

<\ORDERS>

<\SDID>

9.17 Implementing Component Ingredient Information DXA

Certain drugs are combinations of two or more ingredients that themselves are drugs or have dosages that need to be tracked. Some examples are Percocet, Vicodin, and Calcium Citrate with Vitamin D. The component ingredient strengths are often only available in the description printed on the package. The DXA record (and the companion DXC record in the IV Drug section) provide a mechanism to provide ingredient strength information in machine readable form.

The DXA record is linked to its parent DIA record by including the same UDI and or DrugAlias. The DIA record does not carry strength information as this is found in the DXA records for each ingredient.

This is an example for Percocet (APAP) 5/325.

<SDID>$^{R}_{S}$VER|1.2$^{R}_{S}$DIA|6348162775|9012345678|Percocet (APAP) 5/325|||||1|4555A34561|20071212|||||TAB|1$^{R}_{S}$
DXA|6348162775|9012345678|C1ENJ2TE6C|1|Oxycodone Hydrochloride|5|MG|1|TAB$^{R}_{S}$
DXA|6348162775|9012345678|362O9ITLD|1|Acetaminophen|325|MG|1|TAB$^{R}_{S}$
<\SDID>

<SDID>
VER
Version 1.2
DIA
UDI(NDC): 6348162775
Drug Alias: 9012345678 (Issuing Provider's)
Drug Name: Percocet (APAP) 5/325
StrengthAmount:
StrengthAmountUnitsOfMeasure:
CarrierAmount:
CarrierAmountUnitsOfMeasure:
UnitDoseIndicator: 1
Lot Number: 4555A34561
Expiration Date: 12 December 2007
Dose Form: <blank>
Dose Route: <blank>
GenericEquivalenceNumber: <blank>
GenericEquivalenceSource: <blank>
PackageType: TAB
PackageCount: 1*(defaulted)*
Protocol Number: <blank>
ContainerID: <blank>
DXA
UDI(NDC): 6348162775
Drug Alias: 9012345678 (Issuing Provider's)
UNII: C1ENJ2TE6C
UNIISource: 1
Ingredient Name: Oxycodone Hydrochloride
StrengthAmount: 5
StrengthAmountUnitsOfMeasure: MG
CarrierAmount: 1
CarrierAmountUnitsOfMeasure: TAB
GenericEquivalenceNumber: <blank>
GenericEquivalenceSource: <blank>
DXA

UDI(NDC): 6348162775
Drug Alias: 9012345678 (Issuing Provider's)
UNII: 362O9ITLD
UNIISource: 1
Ingredient Name: Acetaminophen
StrengthAmount: 325
StrengthAmountUnitsOfMeasure: MG
CarrierAmount: 1
CarrierAmountUnitsOfMeasure: TAB
GenericEquivalenceNumber: <blank>
GenericEquivalenceSource: <blank>
<\SDID>

The GenericEquivalenceNumber and GenericEquivalenceSource may contain the same information as the DIA record, implementing it as a third identifier for linking.

Aztec

Data Matrix

QR Code

9.18 Units of Measure

The standards defined by the FDA Center for Drug Evaluation and Research (CDER) Data Standards shall be used at all times unless noted otherwise (Structured Product Labeling – SPL Data Standards). The data standards for units of measure include:

- Package Types (Detailed list included in Appendix 1). The FDA code shall be used to define the package type. For example, AMP = Ampule, AP = Applicator.

- Route of Administration (Detailed list included in Appendix 2). The Short Name shall be used to define the route of administration. For example, the Short Name for Epidural is EPIDUR.

- Dosage Form (Detailed list included in Appendix 3). The Short Name shall be used to define the dosage form. For example, the Short Name for Capsule is CAP.

- Potency (Detailed list included in Appendix 4). The FDA Code shall be used to define the potency. For example, Milligram – MG; Microgram = MCG. Systems producing or interpreting units of measure codes should not be case sensitive.

- The following codes are used for time units of measure:

Codes	**Description**
YR or YRS	Years
MO or MOS	Months
WK or WKS	Weeks
DAY or DYS	Days
HR or HRS	Hours
MIN	Minutes
SEC	Seconds

9.19 SDID Data Dictionary and Format Definitions

Data Element	Character Set	Type	Max Length
Age	Numeric	9999.9999	9
AgeUnits	Alpha	Variable Length	8
CareArea	Alphanumeric	Variable Length	15
CareAreaIndication	Alphanumeric	Variable Length	15
CarrierAmount	Numeric	99999999.9999	13
CarrierAmountUnitsOfMeasure	Alpha	Variable Length	8
ClinicalInformationMessage	Alphanumeric	Variable Length	80
ContainerID	Alphanumeric	Variable Length	48
DeliveryDate	Numeric	YYYYMMDD	8
DeliveryRateUnits	Numeric	99999999.9999	13
DeliveryRateUnitsOfMeasure	Alpha	Variable Length	8
DeliveryTime	Numeric	HHMM{SS}	4 or 6
DeliveryTimePeriodUnitsOfMeasure	Alpha	Variable Length	8
DeliveryUnits	Numeric	99999999.9999	13
DeliveryUnitsOfMeasure	Alpha	Variable Length	8
DoseForm	Alphanumeric	Variable Length	15
DoseRoute	Alphanumeric	Variable Length	20
DoseRouteDescription	Alphanumeric	Variable Length	50
DateOfBirth	Numeric	YYYYMMDD{HHMM}	8 or 12
DrugAlias	Alphanumeric	Variable Length	48
DrugName	Alphanumeric	Variable Length	48
ExpirationDate	Alphanumeric	YYYYMM{DD}	6 or 8
ExternalProviderID	Alphanumeric	Variable Length	20
FirstName	Alphanumeric	Variable Length	30
Gender	Alpha	Fixed length	1
GenericEquivalenceNumber	Alphanumeric	Variable Length	48
GenericEquivalenceSource	Alphanumeric	Variable Length	48

Data Element	Character Set	Type	Max Length
GiveUnits	Numeric	99999999.9999	13
GiveUnitsOfMeasure	Alpha	Variable Length	8
IngredientName	Alphanumeric	Variable Length	48
IntervalTimeUnits	Numeric	9999.9999	9
IntervalTimePeriodUnitsOfMeasure	Alpha	Variable Length	8
IssuingEntityID	Alphanumeric	Variable Length	20
ItemNumber	Alphanumeric	Variable Length	48
LastName	Alphanumeric	Variable Length	50
LotNumber	Alphanumeric	Variable Length	48
MessageText	Alphanumeric	Variable Length	80
MiddleIntial	Alphanumeric	Variable Length	30
MultiComponentDose	Numeric	99999999.9999	13
MultiComponentDoseUnitsofMeasure	Alphanumeric	Variable Length	20
OffsetTimeUnits	Numeric	9999.9999	9
OffsetTimePeriodUnitsOfMeasure	Alpha	Variable Length	8
OrderDCDate	Numeric	YYYYMMDD	8
OrderDCTime	Numeric	HHMM{SS}	4 or 6
OrderDoseSequenceNumber	Alphanumeric	Variable Length	10
OrderNumber	Alphanumeric	Variable Length	20
OrderStartDate	Numeric	YYYYMMDD	8
OrderStartTime	Numeric	HHMM{SS}	4 or 6
OrderSystem	Alphanumeric	Variable length	10
PatientID	Alphanumeric	Variable Length	15
PackageType	Alphanumeric	Variable Length	20
PackageCount	Numeric	Variable Length	20
Priority	Numeric	9	1
ProtocolNumber	Alphanumeric	Variable Length	20
ProviderID	Alphanumeric	Variable Length	15

Data Element	Character Set	Type	Max Length
RecordIdentifier	Alphanumeric	Fixed Length	3
SchedCode	Alphanumeric	Variable Length	15
SchedDescription	Alphanumeric	Variable Length	48
SequenceNumber	Numeric	999	3
SerialID	Alphanumeric	Variable Length	48
StabilityEndDate	Numeric	YYYYMMDD	8
StabilityEndTime	Numeric	HHMM{SS}	4 or 6
StabilityStartDate	Numeric	YYYYMMDD	8
StabilityStartTime	Numeric	HHMM{SS}	4 or 6
StrengthAmount	Numeric	99999999.9999	13
StrengthAmountUnitsOfMeasure	Alpha	Variable Length	8
TrackingNumber	Alphanumeric	Variable length	48
UDI	Numeric	Variable Length	48
UNII	Alphanumeric	Variable Length	48
UNIISource	Alphanumeric	Variable Length	10
UnitDoseIndicator	Numeric	Fixed Length	1
VersionNumber	Alphanumeric	Variable Length	8

Lengths are the maximum length of the data expressed as text.

Fixed length fields must be the length specified.

Numeric fields of 99999999.9999 provide a range capability to express the amount in the next higher or lower units of measure without modifying the units of measure. Ex: 100000.5 ML or 0.001 ML.

These fields are considered variable length and will only use the number of digits needed to clearly express the value.

A leading zero is required for amounts less than 1.

Examples:

5.03

0.01

100.5

10 Drug Auto-ID Specification – IV Drugs and Smart Infusion Pump Programming

This section deals with IV drugs and programming of smart infusion pumps using data structures conveyed via bar codes, 2-D Symbols, RFID, IrDA, network packets and other means. Some of the previously documented records are repeated for clarity.

10.1 Overview and Implementation Considerations

The *SmartIV Interface Specification* defines methods and message structures for communicating orders and other information to the next generation of infusion pumps generally referred to as SmartIV pumps.

SmartIV pumps incorporate bar code readers or imagers capable of reading linear and 2D bar code symbologies. A significant amount of data can be encoded in a 2D symbol that can be used to configure and program an infusion pump directly from the information provided on the IV container label that includes such a symbol. This interface specification may also be used with other technologies such as RFID tags.

SmartIV pumps that incorporate a drug library and the SmartIV interface combine the benefits of automation, reduced data entry errors and the safeguards of the drug library.[1]

Although IV pump systems with computer networking capabilities exist, many providers cannot afford to implement such an integrated network. In the event of a network failure, a backup system is needed for programming the pumps.

The SmartIV interface provides an economical method to take advantage of this technology today, and a backup system for those providers who have implemented integrated computer networks.

10.2 Smart Infusion Pump Capabilities

The SmartIV Interface Specification makes some assumptions about the capabilities and modes of operation of smart infusion pumps.

The “Smart” pumps have:

- The ability to read or enter employee and patient identification information such as employee id, pass (override) codes and patient id. The reader may be part of the pump or a separate device connected to; or that communicates with the pump.
- A data logging feature that records a chronology of the actions of the pump, alarms, employee pass codes, and certain tracking information as indicated in the SmartIV record definitions.
- A means to signal alarms audibly and visually.
- A keypad to accept manual programming, pass codes, etc.
- The ability to retain and execute a schedule of dose events. It is intended that the pump sounds an alarm and requires authorization before each dose is administered.
- The ability for acceptance of a dose specification in terms of volume or drug units.

[1] A drug library is a set of data that contains information about drugs, standard concentrations, minimum and maximum dose rates and their indications and other optional data. Pumps compare the requested dose to the drug library information to see if the dose is within a safe range.

- The ability for implementation of a pump-resident drug library.
- A built-in calendar and clock.

SmartIV accommodates several present and potential future infusion pump capabilities and modes of operation. These are implemented through records in the SmartIV message.

The records and information they convey are categorized into levels of increasing complexity.

Due to physical characteristics, smart infusion pumps may not be able to incorporate all of the capabilities represented. A small pump may not have a large enough display screen to implement the patient clinical information or custom messages, for example.

The basic SmartIV (Level I) items are expected to be implemented in all devices supporting the SmartIV interface.

These levels should not be confused with implementation phases or protocols which dictate the particular capabilities an institution chooses to implement.

Basic SmartIV (Level I)

- Care Area Information and Indications for use with a drug library
- Patient Information
- Drug Identification Information (Primary Additive Information)
- Dose Tracking Information
- Dose Form and Route Information
- IV Infusion Volume (VTBI)
- IV Drug Delivery Rate (preferred)
- IV Volume Delivery Rate
- PCA and PCEA Delivery Parameters

Level II

- Total Volume (IV Container)
- Scheduled Delivery Modes
- Patient Clinical Information Messages
- Drug Inventory Record
- Secondary Additive Information Record
- Diluent Information Record
- Volume Alarm Stop
- Custom Message Records
- Library Information Record

Level III (administrative)

- Override Code List Management
- Set Pump Care Area

Level IV

- Manufacturer specific

10.3 Delivery Modes

SmartIV accommodates several delivery modes. Some delivery modes are intended to be stacked and ordered by time and sequence. An example would be to program a loading dose to start immediately and then a continuous standard delivery at a specific time after the bolus has been completed.

SmartIV supports delivery variables in two forms. The first form is delivery in terms of drug units such as MCG\hr. The second form is delivery in terms of volume such as ML\hr.

The first form which is in terms of the amount of drug delivered over time is the preferred method to use with the implementation of a drug library.

Standard Delivery (Level I)

A standard delivery amount and delivery rate is in terms of drug units or volume. This is considered a single dose. This is the most common form of delivery.

Drug Specific Dose at time offset from pump start **(Level II)**

This will deliver a dose at a specified rate at a specified time offset from pump start.

Drug Specific Dose *at specified time* **(Level II)**

This will deliver a dose at a specified rate at a specified time such as 1435

Drug Repeated Dose at a fixed rate with optional offset from pump start **(Level II)**

This will repeat a dose at a pre-defined rate over fixed time intervals

Drug Scheduled Dose at fixed rate and specific time **(Level II)**

This will deliver a dose at a pre-defined rate at a specific time such as 1435

Drug Bolus Dose at time offset from pump start **(Level II)**

This will deliver a Bolus dose at a specific time offset from pump start.

The Bolus dose rate and dose amount are specified.

10.4 Alarms

SmartIV accommodates programming an alarm to occur after a specified volume has been delivered. The alarm occurs once per SmartIV symbol scan which equates to each IV container. Some scheduled dose modes may also cause the pump to stop and alarm requiring a clinician to review and approve the dose change. This may be configurable on some pumps.

10.5 SmartIV Message Structure

A SmartIV message is a combination of tags and records. Tags identify the SmartIV message and SmartIV sections.

10.6 Orders Section ORDERS

The structure of the SmartIV message for ORDERS follows the format:

<SmartIV>VER|1.0$^{R}_{S}$**<ORDERS>**$^{R}_{S}$<order related data>$^{R}_{S}$ **<\ORDERS>**$^{R}_{S}$**<\SmartIV>**$^{R}_{S}$

The following records are defined for ORDERS version 1.0.

LEVEL 1	
CAR	Care Area Information
DIC	Drug Identification Information by Concentration (Primary Additive)
DSC	Drug Identification Information Concentration (Secondary Additives)
DIA	Drug Identification Information by Amount (Primary Additive)

DSA	Drug Identification Information Amount (Secondary Additive)
DDR	IV Drug Delivery Rate Information
VDR	IV Volume Delivery Rate Information
DFR	Dose Form and Route
DIL	Diluent Information
DTI	Dose Tracking Information
PII	Patient Identification Information
VTI	IV Total Infusion Delivery Volume Information
LEVEL 2	
OLI	Order Lifetime Information
LIR	Library Information Record
CMR	Custom Message Record
DIR	Drug Inventory Record
DLD	Drug Loading Dose
VLD	Volume Loading Dose
DRI	Drug Repeated Dose (at DDR or VDR rate and optional offset)
VRI	Volume Repeated Dose (at VDR or DDR rate and optional offset)
DSB	Drug Bolus Dose at time offset from pump start
VSB	Volume Bolus Dose at time offset from pump start
DSO	Drug Specific Dose at time offset from pump start
VSO	Volume Specific Dose at time offset from pump start
DSS	Drug Specific Dose at specific time
VSS	Volume Specific Dose at specific time
DST	Drug Scheduled Dose at DDR rate and specific time
VST	Volume Scheduled Dose at VDR rate and specific time
PDD	Patient Demand Dose (Drug Amount)

PDV	Patient Demand Dose (Volume Amount)
PCI	Patient Clinical Information Message
VAS	Volume Alarm Stop
VTV	IV Total Volume Information

Tags and records are delimited or ended in accordance with *ISO/IEC 15434, Information Technology – Transfer Syntax for High Capacity ADC Media*. Versioning is handled by new record identifiers. Once a record identifier is issued, it cannot change.

10.7 Pump Administration Section PUMPADMIN

The structure of the SmartIV message for PUMPADMIN follows the format:

<SmartIV>$^{R}_{S}$**<PUMPADMIN>**$^{R}_{S}$**VER**$^{G}_{S}$**1.0**$^{R}_{S}$<Pump Admin related data>$^{R}_{S}$
<\PUMPADMIN>$^{R}_{S}$**<\SmartIV>**

The PUMPADMIN section should not be embedded within a larger set of data conveyed in a symbol.

Sections are used for separating record groups for specific purposes.

The following records are defined for PUMPADMIN version 1.0 and are considered reserved words.

LEVEL 3	
SDI	Set Device ID
SDT	Set Date and Time
SCA	Set Care Area
PSR	Patient ID Scan Required
PMR	Patient Match Required

10.8 Override ID Codes

Override ID codes are a set of security codes or pass codes stored in the pump that when entered on the pump keypad or scanned by a reader allow the overriding of certain conditions where the pump would normally refuse to start. Examples are: overdose, patient mismatch, wrong care area, etc. The intended use of an override is for emergency situations.

The use of the code, date, time and conditions that were overridden should be logged into pump memory for downloading at a later time. If alphanumeric codes are used such as when having employees scan their id badges, some numeric codes should be issued for fast entry via the pump keypad.

COC	Clear Override ID Codes
AOC	Add Override ID Codes
ROC	Require Override Codes

10.9 Records for the PUMPADMIN Section

The PUMPADMIN message is used to communicate pump configuration parameters. It should not be combined with other messages.

10.9.1 Set Device ID (SDI)

This record is used to set provider issued device identifier information for the pump that may be included in data transmission or logs.

SDI|DeviceIdentifier|{DeviceIdentifierType}

DeviceIdentifier	A unique alphanumeric identifier for the pump.
DeviceIdentifierType	A code indicating the type of identifier such as EUI64.

10.9.2 Set Date and Time (SDT)

SDT|Date|{Time}

Date – date in YYYYMMDD format ex: “12/25/2005”

Time – Time in HHMMSS (24 hr format) ex: 132355

Date	The Date in YYYYMMDD format ex: “20051225” for 12/25/2005
Time	The Time in HHMMSS (24 hr format) ex: 132355.

10.9.3 Set Care Area (SCA)

SCA|CareArea

CareArea	See below. *(site/institution specific)*

CareArea – This is a code that indicates which area in the facility the pump is located such as ICU, Pediatrics, Chemotherapy, Transfusion Medicine, etc. When implemented, the pump can verify the care area for the orders via keypad entry or from the ORDERS data in SmartIV. Pumps delivered to a nursing floor or specific care area can be set via a durable placard with a SmartIV barcode in which the care area is encoded. Prevention of accepting adult orders with adult doses in a pediatrics area is an example of how the care area can be utilized for patient safety.

10.9.4 Patient ID Scan Required (PSR)

PSR|Required

Required	Required is Y for Yes, or N for No. 'Yes'- configures the pump to require a scan or entry of the patient ID or medical record number.

10.9.5 Patient Match Required (PMR)

PMR|Required

Required	Required is Y for Yes or N for No. 'Yes" configures the pump to require that the scan of the patient ID or medical record number matches the id in the Patient Information Record of the SmartIV orders. The pump will not allow the IV to be delivered without a match.

10.9.6 Clear Override ID codes (COC)

COC|Clear

Clear	Y is for Yes. This clears the pump clear of all existing override codes.

10.9.7 Add Override ID Code (AOC)

This record adds override or pass codes to the pump that allow override of certain operations that the pump would not normally perform. An example is allowing a higher infusion rate than the drug library would normally permit.

AOC|IDCode

IDCode	Employee ID or pass code. These are normally entered on the pump keypad.

Note: The IDCode is an alphanumeric code but many pumps may not have an alphanumeric keypad or a fast method of entering alphanumeric data. If alphanumeric codes are implemented as bar codes on employee badges that the pump scanner can read, the institution may want to implement a set of numeric codes that can be entered through the pump's keypad for emergency use.

10.9.8 Require Override Codes (ROC)

This record modifies how the pump implements override codes.

ROC|Required

Required	M - Must match an entry in override codes stored in the pump. A - Any code accepted. N - Not required – some alternative means of override must be provided by the pump; or is not required to proceed.

10.10 Records for the ORDERS Section

10.10.1 Physician Information (PHY)

When this record is implemented within the <ORDERS> section, it specifies the ***ordering*** physician.

10.10.2 Care Area Information (CAR)

This record contains the Care Area and indications for the order. This record is optional and in most cases the clinician will select the care area and indications through the pump keypad. This is for use with a Drug Library or for location verification of the orders. The pump can reject orders where the care area set in the pump does not match the care area received in the orders. (See *Set Care Area earlier in this document*).

CAR|CareArea|{CareAreaIndication}|

CareArea	Care Area codes established in the drug library
CareAreaIndication	Indication codes established in the drug library

Example: CAR|PED| - Order is for pediatrics areas, no indications

10.10.3 Drug Identification Information Amount (DIA)

This record contains the **primary** drug additive identification information with the total amount of the drug being specified. Only one DIA record may be included in a SmartIV message. In a mixture, the DIA record identifies the primary ingredient or additive. Use DSA records for secondary additives.

DIA|UDI|{DrugAlias}|{DrugName}|{StrengthAmount}|
{StrengthAmountUnitsOfMeasure}|{CarrierAmount}|{CarrierAmountUnitsOfMeasure}|
{UnitDoseIndicator}|{LotNumber}|{ExpirationDate}|{DoseForm}|{DoseRoute}|
{GenericEquivalenceNumber}|{GenericEquivalenceSource}|{PackageType}|
{PackageCount}|{ProtocolNumber}|{ContainerID}

UDI	A universal drug identifier as mandated by law for drug manufacturers. As of version 1.0 of this specification, this is the National Drug Code NDC number in the United States of America. The NDC number should be for the closest packaging level to the unit of use that is feasible. Often, the NDC number will be for a non-unit of use packaging level. The DrugAlias is not required if the NDC is for the unit of use and the provider information systems do not implement an alias system.
DrugAlias	A number or code indicating the drug product name, strength, and potentially the amount or volume and dose form. This is considered a private number and must be cross-referenced to some other number such as the UDI/NDC. The DrugAlias may be used as a grouping number that relates to several different UDI/NDC numbers for the same drug of the same strength made by different manufacturers. This is mandatory if other records are implemented.
DrugName	The name of the drug, such as Aztreonam. Some names may include strength in the name.
StrengthAmount	The amount of the drug such as **1** (for 1 Gram) or **1000** (for 1000 milligrams). (In IV's) this is the total amount of the drug in the IV within the mass or volume of the carrier specified.
StrengthAmountUnitsOfMeasure	The units of measure for the amount of the drug such as **GM** or **MG**.
CarrierAmount	The amount of the liquid, powder, cream etc. that the drug is contained within. This can be a volume, (example **15 -** as in 15 ml), mass or "1" depending on the form of the drug.

	For an IV additive, this represents the total amount of 'additive volume' for this DIA drug amount. (*i.e. excludes diluent*)
CarrierAmountUnitsOfMeasure	The units of measure for the CarrierAmount. This can be a volume, mass or dose form code depending on the form of the drug. Example: ML (as in 15 **ML**).
UnitDoseIndicator	A "1" means that this drug item is packaged (or has been re-packaged) at the unit dose level. (Dispense quantity of 1) Note: If this is set to a '1', then the PackageCount field is assumed to be '1' as well, *and does not need to be entered.*
LotNumber	The manufacturer's lot number
ExpirationDate	The expiration date for the drug. In YYYYMM or YYYYMMDD format.
DoseForm	The dose form code for the dose. (See Appendix 3. Use Name or Short Name only)
DoseRoute	The dose route (of administration) code for the dose. This is normally the intended dose route for the medication as manufactured but may be superseded by administration instructions. (See Appendix 2. Use Name or Short Name only)
GenericEquivalenceNumber	A unique number that is specific to drug generic ingredient combination, route of administration, dosage form, and drug strength. It is the same across manufacturers or package sizes. Normally, 100% equivalency is assumed. It is the responsibility of the provider to determine the acceptable use of this number with regards to the level of equivalency as provided from the source of the equivalency information.
GenericEquivalenceSource	A code indicating the source of the equivalency number and code. Currently, five codes are supported: "FDG" for FirstDataBank GCN, "FDS" for FirstDatabank GCNSeqno, "FDF" for FirstDataBank FormularyID, "FDC"

	for ” FirstDataBank ClinicalFormularyID and “PRV” for private. “PRV” indicates a closed system and the equivalency is determined by the provider.
PackageType	A code that distinguishes the type of packaging for this drug. (Bottle, Jar, Dose pack, Package, Case, etc.) If the UDI numbering system includes such an indicator, it should be duplicated here if it accurately indicates the packaging type. In order of preference, use the following: ▪ UDI Packaging Level Indicator ▪ Full name or FDA Code form Appendix 1 ▪ Other types not in Appendix 1 such as “MASTERCARTON” ▪ “VARIABLE” for variably quantity packages with the unit of use quantity in PackageCount. (See Appendix 1 for Package Types. Use full Name or FDA code.)
PackageCount	The number of individual unit of use (unit dose) items contained within the package type or container.
ProtocolNumber	The protocol number for investigational drugs. More than one drug may be part of a protocol.
ContainerID	The identification number of the parent container. This is used for tracking container sources for certain drugs; or may be used for drugs that have been repackaged.

Example:

This is a Drug Identification record for Amiodarone, UDI=63323061613,DrugAlias = 456789, Total amount of Amiodarone in this container is 150 MG and its Carrier Amount is 3 ML.

DIA|63323061613|456789|Amiodarone|150|MG|3|ML|1||||||VIALSD

DIA

UDI(NDC): 63323061613
Drug Alias: 456789 (Issuing Provider's)
Drug Name: Amiodarone
StrengthAmount: 150
StrengthAmountUnitsOfMeasure: MG
CarrierAmount: 3
CarrierAmountUnitsOfMeasure: ML
UnitDoseIndicator: 1
Lot Number: <blank>
Expiration Date: <blank>
Dose Form: <blank>
Dose Route: <blank>
GenericEquivalenceNumber: <blank>
GenericEquivalenceSource: <blank>
PackageType: VIALSD
PackageCount: 1*(defaulted)*
Protocol Number: <blank>
ContainerID: <blank>

10.10.4 Drug Identification Information Concentration (DIC)

This record contains information about the **primary** drug additive and its *final*[2] concentration. It has structure similar to the DIA record but has four fields implemented differently as noted and 2 additional fields. Only one DIC record should be implemented in a SmartIV message. In a mixture, the DIC record identifies the primary ingredient or additive. Use DSC records for secondary additives. DIA and DSA records cannot be implemented with DIC and DSC records.

DIC|UDI|{DrugAlias}|{DrugName}|{StrengthAmount}|
{StrengthAmountUnitsOfMeasure}|{CarrierAmount}|{CarrierAmountUnitsOfMeasure}|
{UnitDoseIndicator}|{LotNumber}|{ExpirationDate}|{DoseForm}|{DoseRoute}|
{GenericEquivalenceNumber}|{GenericEquivalenceSource}|{PackageType}|
{PackageCount}|{ProtocolNumber}|{ContainerID}|{TotalDrugAmount}|
{TotalDrugAmountUnitsOfMeasure}

UDI	A universal drug identifier as mandated by law for drug manufacturers. As of version 1.0 of this specification, this is the National Drug Code NDC number in the United States of America. The NDC number should be for the closest packaging level to the unit of use that is feasible. Often, the NDC number will be for a non-unit of use packaging level. The DrugAlias is not required if the NDC is for the unit of use and the provider information systems do not implement an alias system.
DrugAlias	A number or code indicating the drug product name, strength, and potentially the amount or volume and dose form. This is considered a private number and must be cross-referenced to some other number such as the UDI/NDC. The DrugAlias may be used as a grouping number that relates to several different UDI/NDC numbers for the same drug of the same strength made by different manufacturers. This is mandatory if other records are implemented.
DrugName	The name of the drug such as Aztreonam. Some names may include strength in the name.
StrengthAmount	This is the final concentration amount of this primary additive in the IV. (Strength amount portion).
StrengthAmountUnitsOfMeasure	The units of measure for the final concentration amount of the drug such as MG for 20 milligrams.

[2] Final concentration is the concentration of the drug after dilution in the total IV container volume.

CarrierAmount	The IV primary additive final concentration carrier amount such as 1 (example: **1** (for ML or MCG or U)
CarrierAmountUnitsOfMeasure	The units of measure for the CarrierAmount. This can be a volume, mass or dose form code depending on the form of the drug. (example: 1 for **ML** or **MCG** or **U**).
UnitDoseIndicator	A "1" means that this drug item is packaged (or has been re-packaged) at the unit dose level. (Dispense quantity of 1) Note: If this is set to a '1', then the PackageCount field is assumed to be '1' as well, *and does not need to be entered.*
LotNumber	The manufacturer's lot number
ExpirationDate	The expiration date for the drug. In YYYYMM or YYYYMMDD format.
DoseForm	The dose form code for the dose. (See Appendix 3. Use Name or Short Name only)
DoseRoute	The dose route (of administration) code for the dose. This is normally the intended dose route for the medication as manufactured but may be superseded by administration instructions. (See Appendix 2. Use Name or Short Name only)
GenericEquivalenceNumber	A unique number that is specific to drug generic ingredient combination, route of administration, dosage form, and drug strength. It is the same across manufacturers or package sizes. Normally, 100% equivalency is assumed. It is the responsibility of the provider to determine the acceptable use of this number with regards to the level of equivalency as provided from the source of the equivalency information.
GenericEquivalenceSource	A code indicating the source of the equivalency number and code. Currently, five codes are supported: "FDG" for FirstDataBank GCN, "FDS" for FirstDatabank GCNSeqno, "FDF" for FirstDataBank FormularyID, "FDC"

	for ” FirstDataBank ClinicalFormularyID and “PRV” for private. “PRV” indicates a closed system and the equivalency is determined by the provider.
PackageType	A code that distinguishes the type of packaging for this drug. (Bottle, Jar, Dose pack, Package, Case, etc.) If the UDI numbering system includes such an indicator, it should be duplicated here if it accurately indicates the packaging type. In order of preference, use the following: ▪ UDI Packaging Level Indicator ▪ Full name or FDA Code form Appendix 1 ▪ Other types not in Appendix 1 such as “MASTERCARTON” ▪ “VARIABLE” for variably quantity packages with the unit of use quantity in PackageCount. (See Appendix 1 for Package Types. Use full Name or FDA code.)
PackageCount	The number of individual unit of use (unit dose) items contained within the package type or container.
ProtocolNumber	The protocol number for investigational drugs. More than one drug may be part of a protocol.
ContainerID	The identification number of the parent container. This is used for tracking container sources for certain drugs; or may be used for drugs that have been repackaged.
TotalDrugAmount	The total amount of drug.
TotalDrugAmountUnitsOfMeasure	The units of measure for the total drug amount such as MG for 20 milligrams.

Example: DIC||1234567|Vasopressin|0.4|Unit|1|mL||||||||||200|Units

This is a drug identification record for Vasopressin, (DrugAlias 1234567) that indicates a ***final concentration*** of 0.4 units of the drug per 1 ML of diluent, and a total amount of 200 Units of Vasopressin.

10.10.5 Drug Identification Information Secondary Additive Amount (DSA)

This record is identical to the DIA record and is used to list secondary additives with their absolute amounts.

10.10.6 Drug Identification Information Secondary Additive Concentration (DSC)

This record is identical to the DIC record and is used to list secondary additives with their *final* concentrations.

10.10.7 Drug Identification Information Diluent Amount (DIL)

This record is identical to the DIA record and is used to indicate the diluent of an IV mixture. This record is used when a list of the additives is included in the SmartIV symbol in a recipe format or when the pump will calculate the final concentration of the primary additive by implementation of the DIA and DSA records. The final concentration for the primary additive is calculated from the DIA drug amount divided by sum of the DIA, DSA and DIL CarrierAmount values.

Example:

DIL||12345690|D5W|||100|ML|

10.10.8 Drug Component Ingredient Information Amount (DXA)

This record contains the information about each individual drug ingredient in a combination drugs such as 0.25% BUPIVACAINE HCL AND EPINEPHRINE 1:200,000 INJECTION. Multiple DXA records may be included in an SDID message.

DXA|UDI|{DrugAlias}|{UNII}|{UNIISource}|{IngredientName}|{StrengthAmount}|
{StrengthAmountUnitsOfMeasure}|{CarrierAmount}|
{CarrierAmountUnitsOfMeasure}||{GenericEquivalenceNumber}|
{GenericEquivalenceSource}

UDI	A universal drug identifier as mandated by law for drug manufacturers. As of version 1.0 of this specification, this is the National Drug Code NDC number in the United States of America. The NDC number should be for the closest packaging level to the unit of use that is feasible. Often, the NDC number will be for a non-unit of use packaging level. The DrugAlias is not required if the NDC is for the unit of use and the provider information systems do not implement an alias system.
DrugAlias	A number or code indicating the drug product name, strength, and potentially the amount or volume and dose form. This is considered a private number and must be cross-referenced to some other number such as the UDI/NDC. The DrugAlias may be used as a grouping number that relates to several different UDI/NDC numbers for the same drug of the same strength made by different manufacturers.
UNII	A unique ingredient identifier that provides a unique id for the ingredient.
UNIISource	A code indicating the source of the UNII. For data version 1.2 of the standard, the following codes are supported: “0” for private: indicates a closed system and the ingredient database is maintained by the provider. “1” indicates the UNII database of the Food and Drug Administration of the United States of America.

IngredientName	The name of the ingredient such as Acetaminophen or Bupivacaine.
StrengthAmount	The amount of the drug such as 30 for 30 MG. This is the total amount of the drug within the mass or volume of the carrier specified.
StrengthAmountUnitsOfMeasure	The units of measure for the amount of the drug such as MG for 30 milligrams.
CarrierAmount	The amount of the liquid, powder, cream etc. that the drug is contained within. This can be a volume, mass or “1” depending on the form of the drug.
CarrierAmountUnitsOfMeasure	The units of measure for the CarrierAmount. This can be a volume, mass or dose form code depending on the form of the drug. This can also be the dose form when the drug is a unit dose.
GenericEquivalenceNumber	A unique number that is specific to drug generic ingredient combination, route of administration, dosage form, and drug strength. It is the same across manufacturers or package sizes. Normally, 100% equivalency is assumed. It is the responsibility of the provider to determine the acceptable use of this number with regards to the level of equivalency as provided from the source of the equivalency information.
GenericEquivalenceSource	A code indicating the source of the equivalency number and code. Currently, five codes are supported: “FDG” for FirstDataBank GCN, “FDS” for FirstDatabank GCNSeqno, “FDF” for FirstDataBank FormularyID, “FDC” for ” FirstDataBank ClinicalFormularyID and “PRV” for private. “PRV” indicates a closed system and the equivalency is determined by the provider.

10.10.9 Drug Component Ingredient Information Concentration (DXC)

This record contains the information about each individual drug ingredient in a combination drugs such as Calcium Citrate \ Vitamin D in concentration form. Multiple DXC records may be included in an SDID or SmartIV message.

DXC|UDI|{DrugAlias}|{UNII}|{UNIISource}|{IngredientName}|{StrengthAmount}|
{StrengthAmountUnitsOfMeasure}|{CarrierAmount}|
{CarrierAmountUnitsOfMeasure}||{GenericEquivalenceNumber}|
{GenericEquivalenceSource}|{TotalDrugAmount}|{TotalDrugAmountUnitsOfMeasure}

UDI	A universal drug identifier as mandated by law for drug manufacturers. As of version 1.0 of this specification, this is the National Drug Code NDC number in the United States of America. The NDC number should be for the closest packaging level to the unit of use that is feasible. Often, the NDC number will be for a non-unit of use packaging level. The DrugAlias is not required if the NDC is for the unit of use and the provider information systems do not implement an alias system.
DrugAlias	A number or code indicating the drug product name, strength, and potentially the amount or volume and dose form. This is considered a private number and must be cross-referenced to some other number such as the UDI/NDC. The DrugAlias may be used as a grouping number that relates to several different UDI/NDC numbers for the same drug of the same strength made by different manufacturers.
UNII	A unique ingredient identifier that provides a unique id for the ingredient.
UNIISource	A code indicating the source of the UNII. For data version 1.2 of the standard, the following codes are supported: “0” for private: indicates a closed system and the ingredient database is maintained by the provider. “1” indicates the UNII database of the Food and Drug Administration of the United States of America.

IngredientName	The name of the ingredient such as Acetaminophen or Bupivacaine.
StrengthAmount	The amount of the drug such as 30 for 30 MG. This is the total amount of the drug within the mass or volume of the carrier specified.
StrengthAmountUnitsOfMeasure	The units of measure for the amount of the drug such as MG for 30 milligrams.
CarrierAmount	The amount of the liquid, powder, cream etc. that the drug is contained within. This can be a volume, mass or “1” depending on the form of the drug.
CarrierAmountUnitsOfMeasure	The units of measure for the CarrierAmount. This can be a volume, mass or dose form code depending on the form of the drug. This can also be the dose form when the drug is a unit dose.
GenericEquivalenceNumber	A unique number that is specific to drug generic ingredient combination, route of administration, dosage form, and drug strength. It is the same across manufacturers or package sizes. Normally, 100% equivalency is assumed. It is the responsibility of the provider to determine the acceptable use of this number with regards to the level of equivalency as provided from the source of the equivalency information.
GenericEquivalenceSource	A code indicating the source of the equivalency number and code. Currently, five codes are supported: “FDG” for FirstDataBank GCN, “FDS” for FirstDatabank GCNSeqno, “FDF” for FirstDataBank FormularyID, “FDC” for ” FirstDataBank ClinicalFormularyID and “PRV” for private. “PRV” indicates a closed system and the equivalency is determined by the provider.
TotalDrugAmount	The total amount of drug.
TotalDrugAmountUnitsOfMeasure	The units of measure for the total drug amount such as MG for 20 milligrams.

10.10.10 Final Concentration and Absolute Amount

Why is final concentration so important? Many of the 'smart' IV pumps that use onboard libraries use the drug final concentration amount of the primary additive as one of the critical comparison fields.

Therefore, either the actual final concentration for the primary additive must be available for the pump; or it must be given the means to calculate it.

Final concentration

The *final* concentration is most frequently expressed as the amount of drug per 1 'carrier amount' (usually per milliliter) in the IV mixture; or as a reduced ratio in terms of one unit of total mixture volume. **The drug amount in the concentration ratio of a DIC or DSC record must never be used to determine the total amount of the drug.** (Note: the concentration calculations assume the addition of the additive amount to the diluent for total volume.)

The preferred method of expressing the final concentration in DIC or DSC records is to express the ratio in terms of 1 unit of carrier such as per 1 ml.

Example: 300 milligrams of a drug contained in 100ML of a carrier are mixed with 400ML of diluent for a total volume of 500ML.

A DIC record would contain the final concentration:

StrengthAmount: 0.6 (300MG/500ML)

StrengthAmountUnitsOfMeasure: MG

CarrierAmount: 1

CarrierAmountUnitsOfMeasure: ML

If the host information system cannot export the final concentration in I unit of carrier terms, the DIC record could be encoded as:

StrengthAmount: 300 (drug amount)

StrengthAmountUnitsOfMeasure: MG

CarrierAmount: 500 (total volume)

CarrierAmountUnitsOfMeasure: ML

For both examples, if the TotalDrugAmount fields are implemented, they would contain

TotalDrugAmount: 300

TotalDrugAmountUnitsOfMeasure: MG

Any system reading the DIC and DSC records must be able to reduce the ratio to "per 1 unit of carrier" terms and to perform any units of measure conversions as needed. The total drug amount would be calculated from the final concentration times the total volume.

It cannot be overstressed that the DIC and DSC drug amounts must never be interpreted as the total drug amount. The capability to express the final concentration in total drug amount / total volume is to provide compatibility with host systems that cannot export the final concentration in terms of 1 unit of carrier.

In a recipe style format, the absolute amounts are encoded.

A DIA record would contain the absolute amounts of the additive drug:

(Additive)

StrengthAmount: 300

StrengthAmountUnitsOfMeasure: MG

CarrierAmount: 100

CarrierAmountUnitsOfMeasure: ML

A DIL record would contain the absolute amount of the diluent:

(Diluent)

StrengthAmount: <blank>

StrengthAmountUnitsOfMeasure: <blank>

CarrierAmount: 400

CarrierAmountUnitsOfMeasure: ML

The pump would calculate the final concentration:

300 MG of drug in (100 ML + 400ML) of fluid = 0.6MG/1 ML final concentration for the drug.

10.10.11 IV Drug Dose Form and Route Information (DFR)

This record contains information about the dose form and route for the order.

DFR|{DoseForm}|{DoseRoute}|{DoseRouteDescription}

DoseForm	The dose form code.
DoseRoute	The Dose Route (of Administration) code. Example: IV or EPIDUR
DoseRouteDescription	A readable description of the Dose Route (of Administration) Example: Intravenous or Epidural

Example: DFR|SOL|EPIDUR|Epidural|

This drug is a SOL (Solution), and is for Epidural use.

Notes:

1. This record is normally in the context of an ORDER. If the order has a mixture of ingredients, the DFR record contains the intended dose form and route of administration code for the total mixture.

   Note: Dose Form and Dose Route are also parts of the DIA (Drug Identification Amount) record. If Dose Form and Dose Route are used in the DFR record **AS WELL**, they will supersede the dose form and route entries in the DIA records.

2. Dose form and Route of Administration codes used are the Federal Drug Administration (FDA) CDER Short Names. (See Appendix 3 and 2, respectively)

10.10.12 IV Delivery Rate Information - Drug (DDR), Volume (VDR)

These records contain infusion delivery rate information for the drug in the form of

X drug units per 1 time period (DDR)
OR
X volume units per 1 time period (VDR)

DDR specifies that the DeliveryRateUnits and DeliveryRateUnitsOfMeasure are in terms of the drug amount per time period such as MCG/hr.

VDR specifies that the DrugDeliveryRateUnits and DrugDeliveryRateUnitsOfMeasure are in terms of the volume per time period such as ML/hr.

DDR|DrugAlias|DeliveryRateUnits|DeliveryRateUnitsOfMeasure|DeliveryTimePeriodUnitsOfMeasure

VDR|DrugAlias|DeliveryRateUnits|DeliveryRateUnitsOfMeasure|DeliveryTimePeriodUnitsOfMeasure

DrugAlias	The drug identifier for the primary additive.
DeliveryRateUnits	Rate Units to deliver (DDR Example **30** as in 30 MG per HR) (VDR Example: **12** as in 12 ML per HR)
DeliveryRateUnitsOfMeasure	Unit of measure for rate units to deliver (DDR Example **MG** as in 30 MG per HR) (VDR Example: **ML** as in 12 ML per HR)
DeliveryTimePeriodUnitsOfMeasure	Time units of measure (per 1 time unit) (DDR Example **HR** as in 30 MG per HR) (VDR Example: **HR** as in 12 ML per HR)

Example: DDR|1234567|4|MCG|HR|

This indicates a delivery rate of 4 micrograms per hour for drug 1234567

Example: VDR|1234567|5.03|ML|HR|

This indicates a delivery rate of 5.03 ML per hour for drug 1234567

Notes:

3. The DDR units/measure/time must match the 'Mode' settings in the drug library entry. This is institution specific.

4. When using a drug library, the DDR information can be directly compared to the min and max values in the library. The pump must calculate the amount of drug delivered per time period if VDR is used.

5. The DeliveryRateUnitsOfMeasure may be expressed as a ratio such as MCG\kg and the DDR record would look like DDR|1234567|4|MCG\kg|HR|.

10.10.13 Dose Tracking Information (DTI)

This record contains a tracking number that is unique to the specific medication "dose" to which it is attributed**. The "dose" is assigned this single number for tracking purposes although the actual drug delivery may consist of one continuous IV dose, one capsule, one tube, or multiple tablets.**

DTI|DrugAlias|TrackingNumber|{OrderDoseSequenceNumber}

DrugAlias	A number or code indicating the drug product name, strength, and potentially the amount or volume, and dose form. This is considered a private number and must be cross-referenced to some other number such as the UID/NDC. The DrugAlias may be used as a grouping number that relates to several different UID/NDC numbers for the same drug of the same strength made by different manufacturers.
TrackingNumber	The provider tracking number for the dose
OrderDoseSequenceNumber	This is a sequence number or ID that is relative to the order.

Example: DTI|1234567|1000000000081423|2

This tracking number is 1000000000081423 for the dose for drug alias 1234567. The OrderDoseSequendeNumber is 2.

Notes:

This record is intended to be logged into a device and later downloaded or sent real-time from the device. This information might be used to update a system to show delivery of a medication to a patient's location. The OrderDoseSequenceNumber is relative to the order (order number).

10.10.14 IV Total Infusion Delivery Volume Information (VTI)

This record contains information about the total volume to be delivered or volume to be infused (VTBI)

VTI|DrugAlias|DeliveryUnits|DeliveryUnitsOfMeasure

DrugAlias	The drug identifier for the primary additive (*site/institution specific)*
DeliveryUnits	Total volume units to deliver
DeliveryUnitsOfMeasure	The units of measure for volume units to deliver

Example: VTI|1234567|116|ML|

This indicates a total volume to be infused of 116 ML for drug 1234567.

10.10.15 Library Information Record (LIR)

This record is for use with pumps libraries that contain an identifier of the issuing provider. If the identifier in the pump library does not match the identifier in this record, the pump will not accept the order. The purpose is to prevent the accidental use of a different provider's drug library.

LIR|IssuingEntityID|

IssuingEntityID	A unique provider identifier for the drug library. The HIN is strongly recommended here, especially for leased pumps that may contain foreign drug libraries upon return from repair.

Note:

The IssuingEntity applies to all drug libraries that may be resident in a pump. Care should be taken when creating the identifier to minimize the risk of duplication of the identifier by another provider. The HIN should be implemented when possible to avoid multiple providers issuing the same provider generated identifier.

10.10.16 Custom Message Record (CMR)

This record is for use with pumps capable of displaying text messages on a screen. Multiple or long messages may be sent and ordered by a sequence number.

Priority affects how the message will be displayed and action the pump may take.

CMR|SequenceNumber|Priority|MessageText|

SequenceNumber	The order in which messages are displayed or the sequence number for a part of a long message.
Priority	A numerical value 0 – 9 that affects display, alarm and pump actions
MessageText	The message to be displayed

Priority	**Action**
0	Default display, no alarm or action
1	Display prominently
2	Display prominently, alarm, require clinician acknowledgement

Example 1:

CMR|1|0|Wish the patient a Happy Birthday!|

Just displays the message on the screen

Example 2:

CMR|1|2|Drug may cause light sensitivity.

CMR|2|2|Keep room window blinds closed.

The pump displays the messages prominently on the screen, alarms, and requires acknowledgement from the clinician.

Example 3:

CMR|1|2|Patient is allergic to latex.

The message is displayed prominently on the screen. The pump alarms and requires acknowledgement from the clinician.

10.10.17 Drug Inventory Record (DIR)

This is an optional record for tracking a medication container or drug by one or more optional identifiers definable by the provider with the exception of lot number. A tracking number for the container; a lot number for the drug or IV mixture; a private internal item number and private internal serial number – any or all of these may be tracked. A device is expected to store this information and allow it to be downloaded or reported later. If the DrugAlias is left empty, the tracking numbers are for the container. If multiple drugs are in the container, a DIR record for each drug may be implemented and individual tracking numbers per drug may be implemented. Since the fields with the exception of lot number are privately assigned, the provider is free to choose the context or meaning of the fields. The TrackingNumber or SerialId fields may be implemented as dose tracking numbers.

DIR|{DrugAlias}|{TrackingNumber}|{LotNumber}|{ItemNumber}|
{SerialID}

DrugAlias	A number or code indicating the drug product name, strength, and potentially the amount or volume, and dose form. This is considered a private number and must be cross-referenced to some other number such as the UDI/NDC. The DrugAlias may be used as a grouping number that relates to several different UDI/NDC numbers for the same drug of the same strength made by different manufacturers.
TrackingNumber	The container tracking number or drug tracking number. **If the DrugAlias is left empty, the tracking numbers are for a container**. This may be implemented as a dose tracking number.
LotNumber	Lot number for the drug if the DrugAlias is present. If not this can represent a repackaging lot number for the container.
ItemNumber	Internal provider item number. This can represent whatever the provider elects.
SerialId	Internal provider serial number.

Example 1:

DIR|1234567||33A65433B6|||

Only one drug is in the container and the tracking number is left blank. Drug 1234567 has a lot number of 33A65433B6

Example 2:

DIR|1234567|81423567|33A65433B6|||

DIR|6632451|81423567|662300A001333|||

Two drugs are in the same container 81423567 and both lot numbers are indicated.

Example 3:

DIR|1234567|81423567||6657342||

We are tracking the item number 6657342 for drug 1234567 in container 81423567.

Example 4:

DIR|1234567|81423567|||88867A2|

We are tracking the serial number 88867A2 for drug 1234567 in container 81423567.

Example 5:

DIR||81423567||||

DIR|1234567|1000012|33A65433B6|||

DIR|6632451|100013|662300A001333|||

The container is tracked by number 81423567 and contains two drugs (1234567 and 6632451). Each drug has an individual tracking number (dose ids – 1000012 and 100013) and the lot numbers are indicated (33A65433B6 and 662300A001333).

Notes:

The lot number is normally included in a DIA, DSA, DIC or DSC record. It may be implemented here if it is not carried in those records or the container is used to contain multiple items and it is desirable to encode the lot numbers in a symbol or tag. The lot number from the DIR is traceable to the manufacture ***only*** if the drug alias is manufacturer specific or the drug alias is matched to a DIA, DSA, DIC or DSC record to retrieve the corresponding UDI.

10.10.18 Drug Loading Dose (DLD) and Volume Loading Dose (VLD)

These records instruct the pump to deliver a loading dose at pump start. Subsequent delivery instructions are followed after the completion of the loading dose. The DLD record is used when the delivery is in terms of drug units of measure and the VLD record is used when the delivery is in terms of volume units of measure.

DLD|DrugAlias|DeliveryRateUnits|DeliveryRateUnitsOfMeasure|
DeliveryTimePeriodUnitsOfMeasure|DeliveryUnits|
DeliveryUnitsOfMeasure|

VLB|DrugAlias|DeliveryRateUnits|DeliveryRateUnitsOfMeasure|
DeliveryTimePeriodUnitsOfMeasure|DeliveryUnits|
DeliveryUnitsOfMeasure|

DrugAlias	The drug identifier. *(site/institution specific)*
DeliveryRateUnits	Loading dose delivery rate amount.
DeliveryRateUnitsOfMeasure	Loading dose delivery rates unit of measure for DeliveryRateUnits.
DeliveryTimePeriodUnitsOfMeasure	Loading dose delivery time units of measure (for 1 time period)
DeliveryUnits	The amount to deliver.
DeliveryUnitsOfMeasure	The units of measure for DeliveryUnits.

Example 1:

DLD|1234567|150|MG|HR|50|MG|

Deliver a Loading Dose of 150 milligrams of drug 1234567 at a rate of 50 milligrams per hour.

Example 2:

VLD|1234567|3|ML|HR|1|ML|

Deliver a Loading Dose of 3 ML of drug 1234567 at a rate of 1 ML per hour.

10.10.19 Drug Repeated Dose (DRI) and Volume Repeated Dose (VRI)

These records instruct the pump to deliver a repeated dose at a fixed interval with an optional time offset from the start of the pump. The DRI record is used when the delivery is in terms of drug units of measure and the VRI record is used when the delivery is in terms of volume units of measure. The delivery rate must be specified in a DDR or VDR record. Use DRI with DDR, VRI with VDR.

DRI|DrugAlias|DeliveryUnits|DeliveryUnitsofMeasure|
IntervalTimeUnits|IntervalTimePeriodUnitsOfMeasure|
{OffsetTimeUnits}|{OffsetTimePeriodUnitsOfMeasure}|

DrugAlias	The drug identifier. *(site/institution specific)*
DeliveryUnits	The repeated dose amount.
DeliveryUnitsOfMeasure	The repeated dose amount units of measure.
IntervalTimeUnits	The interval amount (every x).
IntervalTimePeriodUnitsOfMeasure	The units of measure for the interval time.
OffsetTimeUnits	Offset time amount from pump start.
OffsetTimePeriodUnitsOfMeasure	Offset time period units of measure.

Examples:

DDR|1234567|4|MCG|HR|

DRI|1234567|3|MCG|30|MIN|

Deliver 3 micrograms every 30 minutes at the rate of 4 micrograms per hour.

VDR|1234567|40|ML|HR|

VRI|1234567|10|ML|30|MIN|1|HR|

Deliver 10 ML of drug 1234567 every 30 minutes beginning 1 hour after pump start at a rate of 40 ML per hour.

Notes:

By using the optional offset from the pump start, other doses such as a loading dose or Bolus can be delivered before the repeated dose delivery begins or between the repeated doses. The pump will alarm and stop at each interval before delivery. A clinician will have to approve delivery to start the pump.

10.10.20 Bolus Dose at time offset from pump start - Drug (DSB), Volume (VSB)

These records instruct the pump to deliver a Bolus dose at a specific time based on an offset from the pump start. The DSB record is used when the delivery is in terms of drug units of measure and the VSB record is used when the delivery is in terms of volume units of measure.

DSB|DrugAlias|DeliveryRateUnits|DeliveryRateUnitsOfMeasure|
DeliveryTimePeriodUnitsOfMeasure|DeliveryUnits|
DeliveryUnitsOfMeasure|OffsetTimeUnits|
OffsetTimePeriodUnitsOfMeasure|

VSB|DrugAlias|DeliveryRateUnits|DeliveryRateUnitsOfMeasure|
DeliveryTimePeriodUnitsOfMeasure|DeliveryUnits|
DeliveryUnitsOfMeasure|OffsetTimeUnits|
OffsetTimePeriodUnitsOfMeasure|

DrugAlias	The drug identifier. *(site/institution specific)*
DeliveryRateUnits	Bolus dose delivery rate amount.
DeliveryRateUnitsOfMeasure	Bolus dose delivery rates unit of measure for DeliveryRateUnits.
DeliveryTimePeriodUnitsOfMeasure	Bolus dose delivery time units of measure (for 1 time period)
DeliveryUnits	The dose amount.
DeliveryUnitsOfMeasure	The dose amount units of measure.
OffsetTimeUnits	Offset time amount from pump start.
OffsetTimePeriodUnitsOfMeasure	Offset time period units of measure.

Examples:

DSB|1234567|35|MG|MIN|35|MG|1|MIN|2

Deliver a Bolus of 35 milligrams of drug 1234567 at a rate of 35 milligrams per minute 2 minutes after pump start.

VSB|1234567|50|ML|HR|5|ML|||

Deliver a Bolus of 5 ML of drug 1234567 at a rate of 50 ML per hour immediately at pump start.

10.10.21 Specific Dose at time offset from pump start - Drug (DSO), Volume (VSO)

These records instruct the pump to deliver a specific dose at a specific time based on an offset from the pump start. The DSO record is used when the delivery is in terms of drug units of measure and the VSO record is used when the delivery is in terms of volume units of measure.

DSO|DrugAlias|DeliveryRateUnits|DeliveryRateUnitsOfMeasure|
DeliveryTimePeriodUnitsOfMeasure|DeliveryUnits|
DeliveryUnitsOfMeasure|OffsetTimeUnits|
OffsetTimePeriodUnitsOfMeasure|

VSO|DrugAlias|DeliveryRateUnits|DeliveryRateUnitsOfMeasure|
DeliveryTimePeriodUnitsOfMeasure|DeliveryUnits|
DeliveryUnitsOfMeasure|OffsetTimeUnits|
OffsetTimePeriodUnitsOfMeasure|

DrugAlias	The drug identifier. *(site/institution specific)*
DeliveryRateUnits	Dose delivery rate amount.
DeliveryRateUnitsOfMeasure	Dose delivery rates unit of measure for DeliveryRateUnits.
DeliveryTimePeriodUnitsOfMeasure	Dose delivery time units of measure (for 1 time period)
DeliveryUnits	The dose amount.
DeliveryUnitsOfMeasure	The dose amount units of measure.
OffsetTimeUnits	Offset time amount from pump start.
OffsetTimePeriodUnitsOfMeasure	Offset time period units of measure.

Examples:

DSO|1234567|4|MCG|HR|20|MCG|145|MIN|

Deliver 20 micrograms of drug 1234567 at a rate of 4 micrograms per hour 145 minutes after pump start.

VSO|1234567|4|ML|HR|20|ML|145|MIN|

Deliver 20 ML of drug 1234567 at a rate of 4 ML per hour 145 minutes after pump start.

Note: The pump will alarm and stop at each interval before delivery. A clinician will have to approve delivery to start the pump.

10.10.22 Specific Dose at specific time- Drug (DSS), Volume (VSS)

These records instruct the pump to deliver a specific dose at a specific time. The DSS record is used when the delivery is in terms of drug units of measure and the VSS record is used when the delivery is in terms of volume units of measure.

DSS|DrugAlias|DeliveryRateUnits|DeliveryRateUnitsOfMeasure|
DeliveryTimePeriodUnitsOfMeasure|DeliveryUnits|
DeliveryUnitsOfMeasure|DeliveryTime|DeliveryDate|

DrugAlias	The drug identifier. *(site/institution specific)*
DeliveryRateUnits	Dose delivery rate amount.
DeliveryRateUnitsOfMeasure	Dose delivery rates unit of measure for DeliveryRateUnits.
DeliveryTimePeriodUnitsOfMeasure	Dose delivery time units of measure (for 1 time period)
DeliveryUnits	The dose amount.
DeliveryUnitsOfMeasure	The dose amount units of measure.
DeliveryTime	The time to start the delivery of the dose in 24 hr format HHMM.
DeliveryDate	The date to start the delivery of the dose in YYYYMMDD format.

Examples:

DSS|1234567|4|MCG|HR|20|MCG|1400|

Deliver 20 micrograms of drug 1234567 at a rate of 4 micrograms per hour starting at 2:00 PM.

VSS|1234567|4|ML|HR|20|ML|080000|20050422|

Deliver 20 ML of drug 1234567 at a rate of 4 ML per hour starting at 8:00 AM on April 22nd, 2005

Multiple records constitute a schedule and should be processed by the pump in order of occurrence in the message. This allows the times to cross midnight without the need for dates. For 24-Hour IV medications where the doses occur three times a day with the first dose at 8:00 AM, the DSS records would be:

DSS|1234567|4|MCG|HR|20|MCG|080000|

DSS|1234567|4|MCG|HR|20|MCG|160000|

DSS|1234567|4|MCG|HR|20|MCG|000000|

10.10.23 Scheduled Dose at fixed rate and specific time – Drug (DST), Volume (VST)

These records instruct the pump to deliver a pre-defined dose at a specific time. The DST record is used when the delivery is in terms of drug units of measure and the VST record is used when the delivery is in terms of volume units of measure. The delivery rate must be specified in a DDR or VDR record. Use DST with DDR and VST with VDR.

DST|DrugAlias|DeliveryUnits|DeliveryUnitsOfMeasure|

DeliveryTime|DeliveryDate|

VST|DrugAlias|DeliveryUnits|DeliveryUnitsOfMeasure|
DeliveryTime|DeliveryDate|

DrugAlias	The drug identifier. *(site/institution specific)*
DeliveryUnits	The dose amount.
DeliveryUnitsOfMeasure	The dose amount units of measure.
DeliveryTime	The time to start the delivery of the dose in 24 hr format HHMM.
DeliveryDate	The date to start the delivery of the dose in YYYYMMDD format.

Examples:

DDR|1234567|4|MCG|HR|

DST|1234567|20|MCG|140000|

Deliver 20 micrograms of drug 1234567 at starting at 2:00 PM at a rate of 4 micrograms per hour.

VDR|1234567|40|ML|HR|

VST|1234567|20|ML|080000|

Deliver 20 ML of drug 1234567 starting at 8:00 AM at a rate of 40 ML per hour.

Multiple records constitute a schedule and should be processed by the pump in order of occurrence in the message. This allows the times to cross midnight without the need for dates. For 24-Hour IV medications where the doses occur three times a day with the first dose at 8:00 AM, the DDR and DST records would be:

DDR|1234567|4|MCG|HR|

(IV Drug Delivery Rate for drug 123567 of 4 MCG/hr)

DST|1234567|20|MCG|080000|

(Deliver 20 MCG of drug 123567 at 8:00 AM using previous Rate of 4 MCG/hr).

DST|1234567|20|MCG|160000|

(Deliver 20 MCG of drug 123567 at 4:00 PM using previous Rate of 4 MCG/hr).

DST|1234567|20|MCG|000000|

(Deliver 20 MCG of drug 123567 at midnight using previous Rate of 4 MCG/hr).

10.10.24 IV Patient Demand Dose - Drug Units) (PDD) and Volume Units (PDV)

These records are for the communication of programming parameters for patient initiated demand dosing such as for PCA (patient controlled analgesia) Use of a DFR record specifying the dose route is strongly recommended when implementing these records. A DFR record containing a dose route code of EPIDUR would inform a multi-mode PCA pump to switch modes and drug libraries from PCA to PCEA (Epidural mode).

PDD is used when the delivery information is in terms of drug units.

PDV is used when the delivery information is in terms of volume units.

PDD|DrugAlias|DeliveryUnits|DeliveryUnitsOfMeasure|
DeliverTimeUnits|DeliveryTimeUnitsOfMeasure|
MaxDosesPerTimePeriod|MaxDosesTimePeriodUnits|
MaxDosesTimePeriodUnitsOfMeasure|DemandLockoutTimeUnits|
DemandLockoutTimeUnitsOfMeasure|

DrugAlias	The drug identifier. *(site/institution specific)*
DeliveryUnits	Demand dose delivery amount.
DeliveryUnitsOfMeasure	Demand dose delivery amount units of measure in drug units (PDD) or volume units (PDV).
DeliveryTimeUnits	The amount of time to deliver the dose.
DeliveryTimeUnitsOfMeasure	The time units of measure for DeliveryTimeUnits.
MaxDosesPerTimePeriod	The maximum number of doses allowed in a time period..
MaxDosesTimePeriodUnits	The amount of time for the max doses time period.
MaxDosesTimePeriodUnitsOfMeasure	The time units of measure for the MaxDosesTimePeriodUnits.
DemandLockoutTimeUnits	The amount of time to lockout the pump from delivering a dose after a dose has been delivered.
DemandLockoutTimeUnitsOfMeasure	The time units of measure for DemandLockoutTimeUnits.

Example 1:

PDD|1234567|2|MCG|45|SEC|6|1|HR|10|MIN|

This indicates a demand dose will deliver 2 micrograms of drug 1234567 over 45 seconds. The dosing is limited to 6 doses per (1) hour with a lockout time between doses of 10 minutes.

Example 2:

PDV|1234567|2|ML|1|MIN|6|1|HR|10|MIN|

This indicates a demand dose will deliver 2 ML of drug 1234567 over 1 minute.
The dosing is limited to 6 doses per hour with a lockout time between doses of 10 minutes.

10.10.25 Patient Clinical Information Message (PCI)

This record contains a patient specific clinical advisory message for display on the pump screen.

PCI|ClinicalInformationMessage|

ClinicalInformationMessage	The text message for the screen display.

Example: PCI|Patient is allergic to latex|

Notes:

The text message in this record is intended to be displayed on a screen. It should be displayed in a significant manner such as a larger bold font or a color font.

10.10.26 Volume Alarm Stop (VAS)

This instructs the pump to stop after X volume units have been delivered

VAS|DrugAlias|DeliveryUnits|DeliveryUnitsOfMeasure

DrugAlias	The drug identifier. *(site/institution specific)*
DeliveryUnits	The volume amount delivered at which the pump should stop and alarm.
DeliveryUnitsOfMeasure	The units of measure for the DeliveryUnits.

Example:

VAS|1234567|90|ML

Stop and alarm after 90 ML of drug 1234567 has been delivered.

10.10.27 IV Total Volume Information (VTV)

This record contains information about the total volume in the IV container.

VTV|VolumeUnits|VolumeUnitsOfMeasure

VolumeUnits	The total volume in the container.
VolumeUnitsOfMeasure	The volume units of measure.

Example: VTV|120|ML|

This indicates that the total volume for the container is 120 ML.

Note:

This record must be used if all of the drugs (and the diluent) in an IV aren't listed using the DIA/DSA/DIL records. This is needed in order to have the total volume for the pump to calculate final concentration to match to the drug library entries.

10.11 Units of Measure

The SmartIV units of measure data may be derived from data formatted for presentation and may vary among providers. SmartIV pumps must be case insensitive to the received data. ML, ml, Ml and mL are considered equivalent for example. The casing of the data may not match the casing in the drug library and the pump comparison must be case insensitive.

Wherever appropriate, standard units of measure shall be used. For drug potency information, the FDA CDER NDC units of measure should be used (See appendix 4). For time units of measure, the codes in this specification shall be used.

10.12 SmartIV Message Examples

10.12.1 Minimum requirements

The minimum information for a SmartIV message is the intended patient and information about the drug, concentration, and amount to infuse. This is an example of what a SmartIV message would contain:

Patient ID and Drug Information (minimum patient safety requirements)

<SmartIV>$^{R}_{S}$<ORDERS>$^{R}_{S}$VER|1.0$^{R}_{S}$PII|4454145$^{R}_{S}$DIC|1234567|
Vasopressin|1|Unit|1|ML$^{R}_{S}$<\ORDERS>$^{R}_{S}$<\SmartIV>

<SmartIV>
<ORDERS>
VER|1.0
PII|4454145
DIC|1234567|Vasopressin|1|Unit|1|ML
<\ORDERS>
<\SmartIV>

In this example, the pump is ordered to give patient 4454145 drug 1234567 (Vasopressin) that has a concentration of 1 unit per (1) ML. The clinician will have to enter the delivery rate and VTBI.

10.12.2 Examples involving more programming for ORDERS

Addition of VTI record to indicate the VTBI:

<SmartIV>$^{R}_{S}$<ORDERS>$^{R}_{S}$VER|1.0$^{R}_{S}$PII|4454145$^{R}_{S}$DIC|1234567|Vasopressin|1|Unit|1|ML
$^{R}_{S}$VTI|1234567|114|ML$^{R}_{S}$<\ORDERS>$^{R}_{S}$<\SmartIV>

<SmartIV>
<ORDERS>
VER|1.0
PII|4454145
DIC|1234567|Vasopressin|1|Unit|1|ML
VTI|1234567|114|ML
<\ORDERS>
<\SmartIV>

The pump is ordered to give patient 4454145 drug 1234567 (Vasopressin) that has a concentration of 1 unit per ML. The VTBI is 114 ML. The clinician will have to enter the delivery rate.

By adding a DDR record, the *drug* delivery rate is specified. In this example, the pump is ordered to give 114 ML at a rate of 2 units per hour.

<SmartIV>$^{R}_{S}$<ORDERS>$^{R}_{S}$VER|1.0$^{R}_{S}$PII|4454145$^{R}_{S}$DIC|1234567|Vasopressin|1|unit|1|ML$^{R}_{S}$VTI||1234567|114|ML$^{R}_{S}$DDR|1234567|2|UNITS|HR$^{R}_{S}$<\ORDERS>$^{R}_{S}$<\SmartIV>

<SmartIV>
<ORDERS>
VER|1.0
PII|4454145
DIC|1234567|Vasopressin|1|UNIT|1|ML
VTI||1234567|114|ML
DDR|1234567|2|UNITS|HR
<\ORDERS>
<\SmartIV>

The pump is ordered to give patient 4454145 drug 1234567 (Vasopressin) that has a concentration of 1 unit per ML. The VTBI is 114 ML and the delivery rate is 2 units per hour. The clinician will have to confirm the information.

This following example is of a non-drug item where the delivery date is specified in terms of volume.

<SmartIV>$^{R}_{S}$<ORDERS>$^{R}_{S}$VER|1.0$^{R}_{S}$PII|4454145$^{R}_{S}$DIC|1111111|D5W|1|ML|1|ML$^{R}_{S}$VTI|1111111|1000|ML$^{R}_{S}$VDR|1111111|200|ML|HR$^{R}_{S}$<\ORDERS>$^{R}_{S}$<\SmartIV>

<SmartIV>
<ORDERS>
VER|1.0
PII|4454145
DIC|1111111|D5W|1|ML|1|ML
VTI|1111111|1000|ML
VDR|1111111|200|ML|HR
<\ORDERS>
<\SmartIV>

The pump is ordered to give patient 4454145 drug 1111111 (D5W) that has a concentration of 1 ML per ML. The VTBI is 1000 ML and the delivery rate is 200 ML per hour.

The clinician will have to confirm the information.

The following is an example of a 24 hour IV where we will schedule three doses at specific times.

<SmartIV>$^{R}_{S}$<ORDERS>$^{R}_{S}$VER|1.0$^{R}_{S}$PII|4454145$^{R}_{S}$
DIC|1234567|Vasopressin|1|UNIT|1|ML$^{R}_{S}$VTI|1234567|114|ML
DDR|1234567|6|UNITS|HR$^{R}_{S}$DST|1234567|38|080000$^{R}_{S}$
DST|1234567|38|160000$^{R}_{S}$DST|1234567|38|000000$^{R}_{S}$<\ORDERS>$^{R}_{S}$<\SmartIV>

<SmartIV>
<ORDERS>
VER|1.0
PII|4454145
DIC|1234567|Vasopressin|1|UNIT|1|ML
VTI|1234567|114|ML
DDR|1234567|6|UNITS|HR
DST|1234567|38|UNITS|080000
DST|1234567|38|UNITS|160000
DST|1234567|38|UNITS|000000
<\ORDERS>
<\SmartIV>

The pump is ordered to give patient 4454145 drug 1234567 (Vasopressin) that has a concentration of 1 unit per ML. The VTBI is 114 ML and the delivery rate is 6 units per hour. The effective VTBI per dose is 38 milliliters. Delivery will occur at 8:00 AM, 4:00 PM and midnight.

The clinician will have to confirm the information.

The pump will alarm each time before executing the delivery and require a clinician to confirm that delivery is to begin.

10.13 Implementing Ingredient Information DXC

Certain drugs are combinations of two or more ingredients that themselves are drugs or have dosages that need to be tracked. Some examples are Percocet, Vicodin, and Calcium Citrate with Vitamin D. The component ingredient strengths are often only available in the description printed on the package. The DXC record and the companion DXA record provide a mechanism to provide ingredient strength information in machine readable form.

The DXC record is linked to its parent DIC record by including the same UDI and or DrugAlias. The DIC record does not carry strength information as this is found in the DXC records for each ingredient.

This is an example for:

0.25% BUPIVACAINE HCL AND EPINEPHRINE 1:200,000 INJECTION.

This may be implemented using <SmartIV> or <SDID> tags.

<SmartIV>$^{R}_{S}$VER|1.2$^{R}_{S}$DIC|00405904201|3458902|0.25% BUPIVACAINE HCL& EPINEPHRINE 1:200,000 INJ|||||6555A34561|20101212|
||||VIAL|1$^{R}_{S}$
DXC|00405904201|3458902|7TQO7W3VT8|1|BUPIVACAINE HCL|2.5|MG|1|ML$^{R}_{S}$
DXC|00405904201|3458902|YKH834O4BH|1|EPINEPHRINE|
5|MCG|1|ML$^{R}_{S}$
VTV|10|ML$^{R}_{S}$<\SmartIV>

<SmartIV>
VER
Version 1.2
DIC
UDI(NDC): 00405904201
Drug Alias: 3458902 (Issuing Provider's)
Drug Name: 0.25% BUPIVACAINE HCL AND EPINEPHRINE 1:200,000 INJ
StrengthAmount:
StrengthAmountUnitsOfMeasure:
CarrierAmount:
CarrierAmountUnitsOfMeasure:
UnitDoseIndicator: 1
Lot Number: 6555A34561
Expiration Date: 12 December 2010
Dose Form: <blank>
Dose Route: <blank>
GenericEquivalenceNumber: <blank>
GenericEquivalenceSource: <blank>
PackageType: VIAL
PackageCount: 1*(defaulted)*
Protocol Number: <blank>
ContainerID: <blank>
DXC
UDI(NDC): 00405904201
Drug Alias: 3458902 (Issuing Provider's)
UNII: 7TQO7W3VT8
UNIISource: 1
Ingredient Name: BUPIVACAINE HCL
StrengthAmount: 2.5
StrengthAmountUnitsOfMeasure: MG

CarrierAmount: 1
CarrierAmountUnitsOfMeasure: ML
GenericEquivalenceNumber: <blank>
GenericEquivalenceSource: <blank>
TotalDrugAmount: 25
TotalDrugAmountUnitsOfMeasure: MG

DXC

UDI(NDC): 00405904201
Drug Alias: 3458902 (Issuing Provider's)
UNII: YKH834O4BH
UNIISource: 1
Ingredient Name: EPINEPHRINE
StrengthAmount: 5
StrengthAmountUnitsOfMeasure: MCG
CarrierAmount: 1
CarrierAmountUnitsOfMeasure: ML
GenericEquivalenceNumber: <blank>
GenericEquivalenceSource: <blank>
TotalDrugAmount: 50
TotalDrugAmountUnitsOfMeasure: MCG

VTV

VolumeUnits: 10
VolumeUnitsOfMeasure: ML

<\SmartIV>

The GenericEquivalenceNumber and GenericEquivalenceSource may contain the same information as the DIC record implementing it as a third identifier for linking.

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Data Matrix

QR Code

10.14 PUMPADMIN Section Examples

The following example configures all items:

<SmartIV>$^{R}_{S}$<PUMPADMIN>$^{R}_{S}$VER|1.0$^{R}_{S}$SDI|SIV123MGH003$^{R}_{S}$
SDT|20051219$^{R}_{S}$SCA|ICU$^{R}_{S}$PSR|Y$^{R}_{S}$PMR|Y$^{R}_{S}$COC|Y$^{R}_{S}$AOC|5551212$^{R}_{S}$
AOC|4441313$^{R}_{S}$AOC|MJohnson$^{R}_{S}$AOC|SH712$^{R}_{S}$AOC|HM313$^{R}_{S}$ROC|M$^{R}_{S}$
<\PUMPADMIN>$^{R}_{S}$<\SmartIV>$^{R}_{S}$

<SmartIV>	
<PUMPADMIN>	
VER|1.0	Version 1 of PUMPADMIN Records
SDI|SIV123MGH003	Set Device ID to SIV123MGH003
SDT|20051219	Set date to 19 Dec 2005 Time omitted
SCA|ICU	Set Care Area to ICU
PSR|Y	Patient ID Scan or entry required
PMR|Y	Patient ID on orders must match ID entered or scanned
COC|Y	Clear all existing override codes
AOC|5551212	Add override code 5551212 (emergency)
AOC|4441313	Add override code 4441313 (emergency)
AOC|MJohnson	Add override code (employee badge)
AOC|SH712	Add override code (employee badge)
AOC|HM313	Add override code (employee badge)
ROC|M	Override codes must match an entry in pump
<\PUMPADMIN>	
<\SmartIV>	

The following example configures selected items and is an example of what could be implemented on a placard on a nursing floor to configure the pump for that floor. Other items are pre-configured.

<SmartIV>$^{R}_{S}$<PUMPADMIN>$^{R}_{S}$VER|1.0$^{R}_{S}$SCA|W23$^{R}_{S}$AOC|5551212$^{R}_{S}$
AOC|4441313$^{R}_{S}$AOC|MJohnson$^{R}_{S}$<\PUMPADMIN>$^{R}_{S}$<\SmartIV>$^{R}_{S}$

<SmartIV>	
<PUMPADMIN>	
VER|1.0	Version 1.0 of PUMPADMIN Records
SCA|W23	Set Care Area to W23
AOC|5551212	Add override code 5551212 (emergency)
AOC|4441313	Add override code 4441313 (emergency)
AOC|MJohnson	Add override code (employee badge)
<\PUMPADMIN>	
<\SmartIV>	

10.15 SmartIV Data Dictionary and Format Definitions

Data Element	Character Set	Type	Max Length
Age	Numeric	9999.9999	9
AgeUnits	Alpha	Variable Length	8
BottleID	Alphanumeric	Variable Length	48
CareArea	Alphanumeric	Variable Length	15
CareAreaIndication	Alphanumeric	Variable Length	15
CarrierAmount	Numeric	99999999.9999	13
CarrierAmountUnitsOfMeasure	Alpha	Variable Length	8
Clear	Alpha	Fixed Length	1
ClinicalInformationMessage	Alphanumeric	Variable Length	80
Date	Alphanumeric	YYYYMMDD	8
DateOfBirth	Alphanumeric	YYYYMMDD	8
DeliveryDate	Alphanumeric	YYYYMMDD	8
DeliveryRateUnits	Numeric	99999999.9999	13
DeliveryRateUnitsOfMeasure	Alpha	Variable Length	8
DeliveryTime (24 hour format)	Alphanumeric	HHMM{SS}	4 or 6
DeliveryTimePeriodUnitsOfMeasure	Alpha	Variable Length	8
DeliveryUnits	Numeric	999999999.9999	13
DeliveryTimeUnits	Numeric	9999.9999	9
DeliveryTimeUnitsOfMeasure	Alpha	Variable Length	8
DeliveryUnitsOfMeasure	Alpha	Variable Length	8

Data Element	Character Set	Type	Max Length
DemandLockoutTimeUnits	Numeric	9999.9999	8
DemandLockoutTimeUnitsOfMeasure	Alpha	Variable Length	8
DeviceIdentifier	Alphanumeric	Variable Length	48
DeviceIdentifierType	Alphanumeric	Variable Length	10
DoseForm	Alphanumeric	Variable Length	15
DoseRoute	Alphanumeric	Variable Length	20
DoseRouteDescription	Alphanumeric	Variable Length	50
DrugAlias	Alphanumeric	Variable length	48
DrugName	Alphanumeric	Variable length	48
ExpirationDate	Alphanumeric	YYYYMMDD	6 or 8
ExternalProviderID	Alphanumeric	Variable Length	20
FirstName	Alphanumeric	Variable Length	30
Gender	Alpha	Variable Length	15
GenericEquivalenceNumber	Alphanumeric	Variable Length	48
GenericEquivalenceSource	Alphanumeric	Variable Length	48
GiveUnits	Numeric	99999999.9999	13
GiveUnitsOfMeasure	Alpha	Variable Length	8
IDCode	Alphanumeric	Variable Length	15
IngredientName	Alphanumeric	Variable length	48
IntervalTimeUnits	Numeric	9999.9999	9
IntervalTimePeriodUnitsOfMeasure	Alpha	Variable Length	8
IssuingEntityID	Alphanumeric	Variable Length	15
ItemNumber	Alphanumeric	Variable Length	48
LastName	Alphanumeric	Variable Length	50
LotNumber	Alphanumeric	Variable Length	48
MaxDosesPerTimePeriod	Numeric	999	3
MaxDosesPerTimePeriodUnits	Numeric	9999.9999	9
MaxDosesPerTimePeriodUnitsOfMeasure	Alpha	Variable Length	8
MessageText	Alphanumeric	Variable Length	80
MiddleIntial	Alphanumeric	Variable Length	30
MultiComponentDose	Numeric	99999999.9999	13
OffsetTimeUnits	Numeric	9999.9999	9
OffsetTimePeriodUnitsOfMeasure	Alpha	Variable Length	8
OrderDCTime	Numeric	HHMM{SS}	4 or 6

Data Element	Character Set	Type	Max Length
OrderDoseSequenceNumber	Alphanumeric	Variable Length	10
OrderNumber	Alphanumeric	Variable Length	20
OrderStartDate	Numeric	YYYYMMDD	8
OrderStartTime	Numeric	HHMM{SS}	4 or 6
OrderSystem	Alphanumeric	Variable length	10
PackageCount	Numeric	Variable Length	20
PackageType	Alphanumeric	Variable Length	20
PatientID	Alphanumeric	Variable Length	15
Priority	Numeric	9	1
ProtocolNumber	Alphanumeric	Variable Length	20
ProviderID	Alphanumeric	Variable Length	15
RecordIdentifier	Alphanumeric	Fixed Length	3
Required	Alpha	Fixed Length	1
SchedCode	Alphanumeric	Variable Length	15
SchedDescription	Alphanumeric	Variable Length	48
SequenceNumber	Numeric	999	3
SerialID	Alphanumeric	Variable Length	48
StabilityEndDate	Numeric	YYYYMMDD	8
StabilityEndTime	Numeric	HHMM{SS}	4 or 6
StrengthAmount	Numeric	99999999.9999	13
StrengthAmountUnitsOfMeasure	Alpha	Variable Length	8
Time (24 hour format)	Alphanumeric	HHMMSS	8
TotalDrugAmount	Numeric	99999999.9999	13
TotalDrugAmountUnitsOfMeasure	Alpha	Variable Length	8
TrackingNumber	Alphanumeric	Variable Length	48
UDI	Numeric	Variable Length	48
UNII	Alphanumeric	Variable Length	48
UNIISource	Alphanumeric	Variable Length	10
UnitDoseIndicator	Numeric	Fixed Length	1
VolumeUnits	Numeric	9999.9999	9
VolumeUnitsOfMeasure	Alpha	Variable Length	8
VersionNumber	Alphanumeric	Variable Length	8

Lengths are the maximum length of the data expressed as text.

Fixed length fields must be the length specified.

Numeric fields of 9999.9999 provide a range capability to express the amount in the next higher or lower units of measure without modifying the units of measure. Ex: 1000.0 ML or 0.001 ML.

These fields are considered variable length and will only use the number of digits needed to clearly express the value.

A leading zero is required for amounts less than 1.

Examples:

5.03

0.01

100.5

11 Intelligent Device License Plate ID Specification

This section deals with license plate labeling of intelligent devices.

11.1 Overview and Implementation Considerations

The *Device License Plate Auto-ID Interface Specification* defines methods and message structures for communicating information about intelligent devices using bar codes, 2D symbols and other devices such as RFID tags. The message structures are intended to be used by other intelligent devices for purposes such as association before 2-way communication via IRDA, Bluetooth, or other wireless means. The information contained in the license plate enables intelligent devices to dynamically configure their interface protocols for the devices with which they are communicating.

11.2 Intelligent Device Communication Capabilities

Intelligent devices may contain one or more communication interfaces such RS-232 serial, USB, Bluetooth, IRDA and WiFi. The Device License Plate assists in establishing communication between two devices by providing information about the device. The manufacturer and model provide information needed to determine what interfacing protocol is needed. The serial number along with the other data provides a unique identifier. This is needed to insure that only the two intended devices are exchanging information in a wireless environment such as IRDA and Bluetooth. Since radio and network interfaces may be replaced with a resulting change in MAC address or IP address, the intelligent device is expected to handle association based on MFG\MODEL\SERIALNUMBER which should always uniquely identify the device.

Two device license plate labels are anticipated. The first label is created by the manufacturer and is considered permanent. A second label is created by the institution or contracted distributor that contains updated information such as firmware revisions and institution specific information such as asset numbers, IP addresses, last service dates, etc.

11.3 Message Structure

There are two options applicable for the license plate for intelligent devices: UID and Data Tags.

11.4 Existing Unique Device Identifier (UID) Standards

Many suppliers of devices are currently using a Unique Device Identifier (UID) based on existing standards. The UID contains information to uniquely identify the device model, and its serial number. This information is also often included in a barcode, or 2-D symbol.

The internationally recognized standard for coding data to form a UID is *ISO/IEC 15418 – ASC Data Identifiers and EAN.UCC Application Identifiers and maintenance*. This standard uses data identifiers (DI's) or Application Identifiers (AI's) to create a data structure for the UDI.

Typically, the coding scheme for a device identifier would consist of 3 basic elements:

- A code that uniquely identifies the manufacturer of the device
- The model number for the device
- The serial number for the device

Using the ASC Data Identifiers (DI's), the message structure takes the following format:

(25P)<IAC><Company Code><Model Number>Gs(S)<Serial Number>

For example, a supplier that is using the HIBCC LIC, would structure the data as follows:

(25P)LHB123ABC123+(S)SER123456789

25P	The DI for Part Number (used with unique company prefix as per approved issuing agencies)
LH	The Issuing Agency Code for HIBCC
B123	The LIC for the company
ABC123	The model number
Gs	The data delimiter
S	The DI for serial number
SER123456789	The serial number for the device

Note: The brackets in the string are only included in the human readable form to indicate the DI's. The actual string does not include the brackets.

Using this standard does require that the provider has in place a registry (or database) of detailed information about the device, which cross references the model number.

For detailed information, refer to the standard: ISO/IEC 15418.

11.5 Using Data Tags

A much richer set of data can be communicated using a tagged structure and record specification.

A Device License Plate message is a combination of tags and records. Tags identify and bracket the Device License Plate message and sub-structures.

A Device License Plate message begins with the tag <Device> and ends with the tag <\Device>.

The format for the message using Tags as defined in this standard is as follows:

<Device>$^{R}_{S}$VER|1.0$^{R}_{S}$DEV|{Device Information Record}$^{R}_{S}$<\Device>

The Device License Plate message may be imbedded within a larger set of data conveyed in a symbol. Associating devices should only process data between the <Device> and <\Device> tags.

A device License Plate message looks like:

<Device>
VER – a version record
DEV – Device Information Record
… Other related records
<\Device>

Version records occur within each sub-structure as needed.

Sub-structures or sections are used for separating record groups for specific purposes.

The following tags are defined for version 1.0 and are reserved words.

TAG	Description
<Device>	Device License Plate message start
<\Device>	Device License Plate message end

The following records are defined for version 1.0 - 1.2 and are reserved words.

Record	Description
DEV	Device Information
DMC	Device Multifunction Capabilities
DFI	Device Firmware Information
DEI	Device Identification
DEP	Device Data Exchange Protocols
DCI	Device Capabilities Interfacing
DIS	Device Interfacing Specifications
DPA	Device Provider Asset
DSI	Device Service Information

11.6 Records for the Device Message

11.6.1 Device Information Record (DEV)

This record contains information about the device as described below. Note that all **bolded** fields are mandatory

DEV|DeviceTypeCode|Manufacturer|ModelNumber|SerialNumber|
{MfgDate}

DeviceTypeCode	Indicates the type of device
Manufacturer	Name of Manufacturer
ModelNumber	The model number or model name of the device
SerialNumber	The serial number of the device
MfgDate	The date of manufacture in YYYYMMDD format

Example: SIGMA Spectrum IV pump serial number 700188 manufactured on October 12th, 2006

DEV|01|SIGMA|SPECTRUM|700188|20061012

11.6.2 Device Identification (DEI)

This record is used to communicate provider issued device identifier information for a device that may be included in data transmission or logs.

DEI|DeviceIdentifier|{ DeviceIdentifierType}

DeviceIdentifier	A unique alphanumeric identifier for the device.
DeviceIdentifierType	A code indicating the type of identifier such as EUI64.

11.6.3 Device Multifunction Capabilities (DMC)

This record contains information about the device capabilities when it is a multifunction device such as a vital signs monitor. The record consists of a series of codes.

DMC|Code1|Code2|Code3|…

Code...n	Indicates a specific capability of the device such as blood pressure monitoring, oximeter, etc.

The list of codes is to be determined.

11.6.4 Device Firmware Information (DFI)

This record contains information about the base firmware device capabilities. Some devices contain operating systems such as PDA's and some devices maintain a separate boot-up code image.

DFI|FirmwareVersion|{FirmwareDate}|{OSVersion}|{OSDate}|
BootFirmwareVersion}|{BootFirmwareDate|

FirmwareVersion	The version of the device firmware.
FirmwareDate	The release or revision date of the device firmware
OSVersion	The version of the device operating system
OSDate	The release or revision date of the device operating system
BootFirmwareVersion	The version of the device boot code firmware
BootFirmwareDate	The release or revision date of the device boot code firmware

11.6.5 Device Data Exchange Protocol Information (DEP)

This record contains information about the data exchange protocols the device supports. Multiple DEP records are used for devices supporting multiple protocols, or multiple version of the same protocol. Not all protocols may be supported on each interface. Manufacturer custom protocols may be encountered.

DEP|ProtocolCode|{ProtocolVersion}

ProtocolCode	A code indicating a support protocol.
ProtocolVersion	The version number of the supported protocol.

Example:

DEP|HL7|2.3

The device supports HL7 version 2.3

Codes List

ProtocolCode	**Description**
DICOM	The DICOM protocol
HL7	The HL7 protocol
HIBCCPAS	The HIBCC PAS protocols
MiSimMLPS	The MiSim MLPS protocol for printing

11.6.6 Device Capabilities Interfacing (DCI)

This record contains information about the device interfacing capabilities for mechanisms that are not direct wire connections such as RS232 or USB. The record consists of a series of codes for exposed interfaces

DCI|Code1|{Code2}**|…**

Code n	A code indicating a specific interface is available on the device.

Code List	**Description**
IRDA	IRDA Port
BLUT	Bluetooth
EMC	Electro-Magnetic coupling
WIFI	Wireless such as 802.11
LBSC	Linear bar code scanner
IMGR	2D Imager
USB1	USB 1.x Interface
USB2	USB 2.x interface
RS232	RS232 Serial communications interface
ENET	Wired Ethernet
PRFID	Passive RFID Tag
ARFID	Active RFID Tag
MEMB	Memory Button, Touch Memory

11.6.7 Device Interface Specifications (DIS)

This record contains information with connectivity information for each exposed interface where applicable. The fields differ depending on the interface code.

DIS|InterfaceCode|Specific Field List

InterfaceCode	The code indicating which interface is specified.
FieldList…n	The parameter list for the interface.

11.6.8 Connectivity Information per Interface

All parameters are in ASCII text representations. Colons and dashes often encountered in MAC addresses and radio address are removed.

Interface Code	Configuration or Connectivity
IRDA	None
BLUT	{Radio Address}|{FriendlyName} Radio Address – ASCII text hexadecimal representation of the radio address Friendly Name – Device friendly name.
EMC	None
WIFI	{IP address}|{MAC address} IP Address – IPV4 or IPV6 dotted decimal notation of the IP address MAC address - ASCII text hexadecimal representation for the MAC address
LBSC	None
IMGR	None
USB1	{VID}|{PID} VID - ASCII text hexadecimal representation for the vendor ID PID - ASCII text hexadecimal representation for the product ID
USB2	{VID}|{PID} VID - ASCII text hexadecimal representation for the vendor ID PID - ASCII text hexadecimal representation for the product ID
RS232	{BaudRate}|{DataBits}|{Parity}|{StopBits}| {Handshaking}

	BaudRate - Communication speed (numeric) DataBits – Number of data bits (numer0c) Parity – Parity from the following list: ▪ n – none ▪ e – even ▪ o – odd ▪ m – mark ▪ s – space StopBits – Number of stop bits (numeric) Handshaking – Flow control handshaking from the following list: ▪ n – none ▪ x – XON\XOFF (to and from host) ▪ h – hardware (RTS\CTS) ▪ a – ACK\NACK
ENET	{IP address}|{MAC address} IP Address – IPV4 or IPV6 dotted decimal notation of the IP address MAC address - ASCII text hexadecimal representation for the MAC address
PRFID	None
ARFID	None
MEMB	None

11.6.9 Device Provider Asset (DPA)

This record contains information specific to the provider concerning asset numbers.

DPA|IssuingEntityID|{OwnerEntityID}|{ProviderAssetNumber}|
{OwnerAssetNumber}

IssuingEntityID	Identifier for the institution issuing the license plate such as the provider's HIN.
OwnerEntityID	Identifier for the owner of the device such as a HIN or ID for a leasing company
ProviderAssetNumber	The unique asset number assigned by the provider
OwnerAssetNumber	The unique asset number assigned by the owner

11.6.10 Device Service Information (DSI)

This record contains information specific to the provider concerning service dates.

DSI|{LastServiceDate}|{LastCalibrationDate}|{LastBatteryDate}

LastServiceDate	The last date the device was serviced or had preventative maintenance and tests performed
LastCalibrationDate	The last date the device had calibration or calibration tests performed
LastBatteryDate	The last date the device had batteries replaced or serviced

11.7 Device License Plate Examples

The following is an example data string for Device License Plate:

<Device>$^{R}_{S}$VER|1.0$^{R}_{S}$DEV|001|SIGMA|ABC123|700188$^{R}_{S}$<\Device>

<Device>
VER|1.0
DEV|001|SIGMA|ABC123|700188
<\Device>

This data string represents a device type for IV Pump, manufactured by SIGMA, with Model Number ABC123 and Serial Number 700188

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Data Matrix

QR Code

11.8 Records Summary for Device

The following table lists all records that may be implemented in a Device message.

Record	Description
DEV	Device Information
DMC	Device Multifunction Capabilities
DFI	Device Firmware Information
DEI	Device Identification
DEP	Device Data Exchange Protocols
DCI	Device Capabilities Interfacing
DIS	Device Interfacing Specifications
DPA	Device Provider Asset
DSI	Device Service Information

11.9 Device Data Dictionary and Format Definitions

Data Element	Character Set	Type	Max Length
BootFirmwareVersion	Alphanumeric	Variable Length	20
BootFirmwareDate	Numeric	YYYYMMDD	8
CodeList..n	Alphanumeric	Variable Length	10
FieldList..n	Alphanumeric	Variable Length	48
FirmwareVersion	Alphanumeric	Variable Length	20
FirmwareDate	Numeric	YYYYMMDD	8
DeviceIdentifier	Alphanumeric	Variable Length	48
DeviceIdentifierType	Alphanumeric	Variable Length	10
DeviceTypeCode	Alphanumeric	Fixed Length	3
InterfaceCode	Alphanumeric	Variable Length	10
IssuingEntityID	Alphanumeric	Variable Length	15
LastBatteryDate	Numeric	YYYYMMDD	8
LastCalibrationDate	Numeric	YYYYMMDD	8
LastServiceDate	Numeric	YYYYMMDD	8
Manufacturer	Alphanumeric	Variable Length	48
MfgDate	Numeric	YYYYMMDD	8
ModelNumber	Alphanumeric	Variable Length	48
OSVersion	Alphanumeric	Variable Length	20
OSDate	Numeric	YYYYMMDD	8
OwnerAssetNumber	Alphanumeric	Variable Length	48
OwnerEntityID	Alphanumeric	Variable Length	15
ProtocolCode	Alphanumeric	Variable Length	20
ProtocolVersion	Alphanumeric	Variable Length	15
ProviderAssetNumber	Alphanumeric	Variable Length	48
SerialNumber	Alphanumeric	Variable Length	48

Device Type Codes

001 – IV Pump
011 – Vital Signs Monitor

021 – Glucose Meter

This list will grow as more devices gain intelligent interfaces

12 Summary of All Tag Message and Section Types

Message	Description
SEID	Employee Identification Message
SPID	Patient Identification Message
SDID	Drug Identification Message
SmartIV	SmartIV Device Programming Message
Device	Device License Plate Message
EID	Employee Identification Section
PID	Patient Identification Section
DID	Drug Identification Section
ORDERS	Drug Order Administration Information and Programming Section
PUMPADMIN	Smart Infusion Pump Administration and Configuration Section

13 Record Implementation

This table lists the records that may be implemented within each message type. Please see the relevant section of the document for details about each record.

Record	Description	Employee ID	Patient ID	Drug ID	Smart IV	Device LP
AOC	Add Override ID Code				X	
CAR	Care Area Information				X	
CMR	Custom Message Record				X	
COC	Clear Override ID Codes				X	
CRC	Cyclic Redundancy Check	X	X	X	X	X
CUI	Custom User Identifier	X				
DCI	Device Capabilities Interfacing					X
DDA	Drug Delivery Information			X		

Record	Description	Employee ID	Patient ID	Drug ID	Smart IV	Device LP
	Amount					
DDR	IV Drug Delivery Rate				X	
DDV	Drug Delivery Information Volume			X		
DEI	Device Identification					X
DEP	Device Data Exchange Protocols					X
DEV	Device Information Record					X
DFI	Device Firmware Information					X
DFR	Dose Form And Route				X	
DIA	Drug Identification Information (Amount Form)			X	X	
DIC	Drug Identification Information (Concentration Form)				X	
DIL	Diluent Information				X	
DIR	Drug Inventory Record			X	X	
DIS	Device Interfacing Specifications					X
DLD	Drug Loading Dose				X	
DMC	Device Multifunction Capabilities					X
DPA	Device Provider Asset Information					X
DRI	Drug Repeated Dose			X	X	
DSA	Drug Identification Information Secondary Additive (Amount Form)			X	X	

Record	Description	Employee ID	Patient ID	Drug ID	Smart IV	Device LP
DSB	Drug Bolus Dose (offset)				X	
DSC	Drug Identification Information Secondary Additive (Concentration Form)				X	
DSI	Device Service Information					X
DSL	Dose Stability Lifetime			X	X	
DSO	Drug Specific Dose (offset)			X	X	
DSS	Drug Specific Dose (specific time)			X	X	
DST	Drug Scheduled Dose (specific time)				X	
DTI	Dose Tracking Information			X	X	
DXA	Drug Component Ingredient Information Amount			X	X	
DXC	Drug Component Ingredient Information Concentration			X	X	
EII	Employee Identification	X				
EI2	Employee Supplemental Information	X				
EXO	External Provider Order			X	X	
EXR	External Provider Cross Reference			X	X	
LIR	Library Information Record				X	
OLI	Order Lifetime Information			X	X	

Record	Description	Employee ID	Patient ID	Drug ID	Smart IV	Device LP
OSI	Order Schedule Information			X	X	
PCD	Patient Clinical Information		X			
PCI	Patient Clinical Information Message			X	X	
PDD	Patient Demand Dose Drug Units				X	
PDV	Patient Demand Dose Volume Units				X	
PHY	Physician Information		X	X	X	
PII	Patient Identification Information		X	X	X	
PMR	Patient Match Required				X	
PSR	Patient ID Scan Required				X	
PVD	Patient variable Data		X	X	X	
ROC	Require Override ID Codes				X	
SCA	Set Device Care Area				X	
SDI	Set Device ID				X	
SDT	Set Device Date and Time				X	
SID	Security Information Data		X			
VAS	Volume Alarm Stop				X	
VDR	IV Volume Delivery Rate				X	
VER	Version Information	X	X	X	X	X
VLD	Drug Loading Dose				X	
VRI	Volume Repeated Dose			X	X	

Record	Description	Employee ID	Patient ID	Drug ID	Smart IV	Device LP
VSB	Volume Bolus Dose (offset)				X	
VSO	Volume Specific Dose (offset)			X	X	
VSS	Volume Specific Dose (specific time)			X	X	
VST	Volume Scheduled Dose (specific Time)				X	
VTI	IV Total Infusion Delivery Volume (VTBI)				X	
VTV	IV Total Volume Information				X	
ZDx	Drug ID Prototype			X	X	
ZEx	Employee ID Prototype	X				
ZPx	Patient ID Prototype		X			
ZSx	SmartIV Prototype				X	
ZVx	Device License Plate Prototype					X

14 Symbology Recommendations

Systems must be capable of scanning and decoding the variety of bar codes and two-dimensional symbols encountered on medications and medical products. For implementation of these specifications, the following symbologies are recommended.

For linear bar codes, CODE128 is recommended.

Code 128 is a very high-density alphanumeric bar code. It can encode all 128 ASCII characters and will produce the shortest length bar code of the linear symbologies when the data contains 6 or more numeric characters. Due to it's compactness, the narrow bar dimension can be wider that that of a comparable CODE39 bar code resulting in better read rates and tolerance of printing ladder style on thermal printers. Although the number of characters that can be encoded is virtually unlimited, the space generally available on the label results in a practical limit of about 50 characters. The symbol can be read by virtually any type of scanner.

CODE 128
(Linear)

For employee badges, PDF417 or Data Matrix is recommended.

PDF417 is a stacked Symbology. PDF stands for Portable Data File. Up to 2000 characters can be encoded. A PDF417 symbol can be read with modified handheld laser or CCD scanners although the use of an imager based scanner is recommended. The advantage of using this symbology on employee badges is that the symbol can be somewhat shaped to fit a certain rectangular area, that is the width can be set and the symbol grows vertically as data is added.

PDF417
(2D)

For SmartIV, Drug Identification, Patient Identification, Aztec and Data Matrix are recommended.

Aztec and Data Matrix are 2-D matrix codes designed to pack a lot of information in a very small space. Aztec and Data Matrix symbols can store 2000-3000 characters. Symbols are scalable between a 1-mil square to a 14-inch square resulting in a maximum theoretical density of 500 million characters to the inch. The practical density is determined by the resolution of the printing and reading technology used. Using the ECC200 mode, Data Matrix incorporates Reed-Solomon error correction.

These symbols are not as susceptible to printing defects as is traditional bar code. The coding scheme has a high level of redundancy with the data "scattered" throughout the symbol. It can also be read with a contrast ratio as low as 20%. Normally, these symbols grow vertically and horizontally as more data is added. There is a rectangular form of Data Matrix and Aztec has a special capability of spanning a message across multiple symbols that can be oriented horizontally or vertically. Aztec has two other features that make it more attractive to healthcare applications. The finder pattern and timing marks are located in the center of the symbol. It is read from the center outward. This allows multiple symbols to be printed side by side which is very helpful on patient wristbands. Aztec also has a better first read rate on curved surfaces compared to Data Matrix due to the location of the finder pattern and timing marks.

These symbologies are read by CCD video camera (imagers) and some CCD scanners.

AZTEC
(2D)

DATA MATRIX
(2D)

15 Glossary of Terms & Acronyms

2-D	Two dimensional symbol that carries data (e.g. Aztec, Data Matrix)
AZTEC	A 2-D Symbology Specification
AITC	Auto-ID Technical Committee. Committee of HIBCC developing standards for automatic identification technologies
ASCII	American Standard Code for Information Interchange. ASCII codes represent text in computers, communications equipment, and other devices that work with text. Most modern character encodings have a historical basis in ASCII.
Auto-ID	Term that refers to Automatic Identification Technologies
CCD	Charged Couple Device
CDER	Center for Drug Evaluation and Research
Code 128	Bar Code Symbology Standard Specification
CPOE	Computerized Provider Order Entry System
Data delimiter	A symbol or character that separates data elements in a continuous string
Data Matrix	A 2-D Symbology Specification
eMAR	Electronic Medical Administration Record system.
FDA	Food and Drug Administration
HIBC	Health Industry Bar Code
HIBCC	Health Industry Business Communications Council
Imager	Technology used in bar code scanners engineered to read 2-D Matrix codes (using CCD technology).

IV Drugs	Drugs that are administered intravenously or otherwise infused into the body.
LIC	Labeler Identification Code. Issued by HIBCC to companies. This is a unique 4 character code.
License Plate	The unique identification label used to uniquely identify objects.
MRN	Medical Record Number
NDC	National Drug Code **NDC Number** Each listed drug product listed is assigned a unique 10-digit, 3-segment number. This number, known as the NDC, identifies the labeler, product, and trade package size. The first segment, the labeler code, is assigned by the FDA. A labeler is any firm that manufactures (including re-packers or re-labelers), or distributes (under its own name) the drug. The second segment, the product code, identifies a specific strength, dosage form, and formulation for a particular firm. The third segment, the package code, identifies package sizes and types. Both the product and package codes are assigned by the firm. The NDC will be in one of the following configurations: 4-4-2, 5-3-2, or 5-4-1. An asterisk may appear in either a product code or a package code. It simply acts as a place holder and indicates the configuration of the NDC. Since the NDC is limited to 10 digits, a firm with a 5 digit labeler code must choose between a 3 digit product code and 2 digit package code, or a 4 digit product code and 1 digit package code. Thus, you have either a 5-4-1 or a 5-3-2 configuration for the three segments of the NDC. Because of a conflict with the HIPAA standard of an 11 digit NDC, many programs will pad the product code or package code segments of the NDC with a leading zero instead of the asterisk. Since a zero can be a valid digit in the NDC, this can lead to confusion when trying to reconstitute the NDC back to its FDA

	standard. Example: 12345-0678-09 (11 digits) could be 12345-678-09 or 12345-678-90 depending on the firm's configuration. By storing the segments as character data and using the * as place holders we eliminate the confusion. In the example, FDA stores the segments as 12345-*678-09 for a 5-3-2 configuration or 12345-0678-*9 for a 5-4-1 configuration.
Non-IV Drugs	Drugs not administered intravenously
PAS	Provider Applications Standard (Developed and Administered by HIBCC)
RFID	Radio Frequency Identification
Symbology	A bar code or 2-D matrix specification
UDI	Unique Device Identifier or Unique Drug identifier
UNII	Unique Ingredient Identifier

16 Revision Summary and Versioning

ANSI/HIBC 3.0 Positive Identification for Patient Safety: Part 1 Medication Delivery incorporates an internal version number of 1.0 expressed in a VER record. The internal version number relates to the record structures and data definitions for the standard whereas the 3.X relates to the document and ANSI\HIBC standards numbering. Changes made to the standard may affect the internal version number and parsers should read the version number and process records and fields according to the internal version number.

Following is a summary of the changes made to the standard and the internal version number. Unless otherwise noted, records and fields not changed are forwards and backwards compatible across versions.

ANSI\HIBC 3.1 Positive Identification for Patient Safety: Part 1 Medication Delivery Change Summary

The internal version number is incremented to 1.2

DTI – Dose Tracking Information

The field OrderDoseSequenceNumber is added.

DDA and DDV – Drug Delivery Information by Amount (DDA) and Volume (DDV)

The MultiComponentDose field changes to a decimal field to express fractional amounts. MultiComponentDoseUnitsOfMeasure, DeliveryDate and DeliveryTime fields are added.

OLI – Order Lifetime Information

The StabilityEndDate and StabilityEndTime fields are removed.

DSL – Dose Stability Lifetime – New Record added

This record is added and contains DrugAlias, TrackingNumber, StabilityEndDate, StabilityEndTime, StabilityStartDate and StabilityStartTime fields to express the stability and useable lifetime of the dose.

The StabilityEndDate and StabilityEndTime fields are removed from the OLI record.

DXA – Drug Component Ingredient Information Amount – New Record added

This record is added and contains UDI, DrugAlias, UNII, UNIISource,, DrugName, StrengthAmount, StrengthAmountUnitsOfMeasure, CarrierAmount, CarrierAmountUnitsOfMeasure, GenericEquivalenceNumber, and GenericEquivalenceSource. The record conveys information about an ingredient in a drug consisting of a combination of drugs or ingredients. This is the absolute amount form where the strength and carrier fields represent the total amount of each ingredient in the package or container.

DXC – Drug Component Ingredient Information Concentration – New Record added

This record is added and contains UDI, DrugAlias, UNII, UNIISource,, DrugName, StrengthAmount, StrengthAmountUnitsOfMeasure, CarrierAmount, CarrierAmountUnitsOfMeasure, GenericEquivalenceNumber, GenericEquivalenceSource, TotalDrugAmount and TotalDrugAmountUnitsOfMeasure. The record conveys information about an ingredient in a drug consisting of a combination of drugs or ingredients.
This is the concentration form where the strength and carrier fields represent the concentration of each ingredient in the package or container. The optional TotalDrugAmount and TotalDrugAmountUnitsOfMeasure fields convey the total amount of each ingredient in the package or container.

SDI – Set Device Identifier

A field DeviceIdentifierType is added to the record to indicate the type of identifier carried in the DeviceIdentifier field such as EUI64.

DEI – Device Identification – New Record added

This record is added and contains DeviceIdentifier and DeviceIdentifierType fields.

All numeric date elements of the form 999999.9999 with a length of 11 have been expanded to 99999999.9999 with a length of 13.

The MultiComponentDose data element has been expanded to 99999999.9999 with a length of 13.

Data Dictionary and Record Implementation sections are updated to reflect these changes.

Added sample 2D symbols for Aztec, Data Matrix, and QR Code symbologies.

APPENDIX 1. Data Dictionary for Drug Package Types in accordance with FDA Centre for Drug Evaluation and Research (CDER) Data Standards Manual

NAME	DEFINITION	FDA CODE	NCI CONCEPT ID
AMPULE	A container capable of being hermetically sealed, intended to hold sterile materials.	AMP	C43165
APPLICATOR	A pre-filled non-injectable pipette, syringe or tube.	AP	C43166
BAG	A sac or pouch.	BAG	C43167
BLISTER PACK	A package that consists of molded plastic or laminate that has indentations (viewed as “blisters” when flipped) into which a dosage form, is placed. A covering, usually of laminated material, is then sealed to the molded part. A strip pack is a specialized type of blister pack where there are no pre-formed or molded parts; in this case there are two flexible layers that are sealed with the dosage form in between. Suppositories that are strip packed between two layers of foil are also considered a blister pack.	BLPK	C43168
BOTTLE	A vessel with a narrow neck designed to accept	BOT	C43169

	a specific closure.		
BOTTLE, WITH APPLICATOR	A bottle which includes a device for applying its contents.	BOTAP	C43177
BOTTLE, DISPENSING	A bottle that is used by the pharmacist to dispense the prescribed medication. It includes preparations for which a dropper accompanies the bottle.	BOTDIS	C43170
BOTTLE, DROPPER	A bottle that has a device specifically intended for the application of a liquid in a drop by drop manner, or a device intended for the delivery of an exact dose (e.g., calibrated dropper for oral medications).	BOTDR	C43171
BOTTLE, GLASS	A glass vessel with a narrow neck designed to accept a specific closure.	BOTGL	C43172
BOTTLE, PLASTIC	A plastic vessel with a narrow neck designed to accept a specific closure.	BOTPL	C43173
BOTTLE, PUMP	A bottle that is fitted with a pumping mechanism for the administration of drug product.	BOTPU	C43174
BOTTLE, SPRAY	A bottle that is fitted with an atomizer or a device which produces finely divided liquid carried by air.	BOTSPR	C43175

BOTTLE, UNIT-DOSE	A bottle that contains a single whole dose of a non-parenteral drug product.	BOTUD	C43176
BOX	A square or rectangular vessel, usually made of cardboard or plastic.	BOX	C43178
BOX, UNIT-DOSE	A box that contains a single dose of a non-parenteral drug product. [Note: Boxes that contain 100 unit dose blister packs should be classified under blister pack, since this is the immediate container into which the dosage form is placed.]	BOXUD	C43179
CAN	A cylindrical vessel, usually made of metal.	CAN	C43180
CANISTER	A type of can for holding a drug product.	CSTR	C43181
CARTON	A cardboard box or container which is usually considered a secondary packaging component.	CRTN	C43182
CARTRIDGE	A container consisting of a cylinder with a septum at one end, and a seal at the other end, which is inserted into a device to form a syringe which contains a single dose of a parenteral drug product.	CTG	C43183
CASE	A receptacle for holding something (e.g., that into which some oral	CASE	C43184

	contraceptive blister packs are placed).		
CELLO PACK	A plastic "clamshell" [thin plastic pre-formed structure for a device].	CELLO	C43185
CONTAINER	A receptacle designed to hold a specific dosage form.	CTR	C43186
CUP	A bowl-shaped container.	CUP	C43187
CUP, UNIT-DOSE	A cup intended to hold a single dose of a non-parenteral drug product.	CUPUD	C43188
CYLINDER	A container designed specifically to hold gases.	CYL	C43189
DEWAR	A container, usually made of glass or metal, that has at least two walls with the space between each wall evacuated so as to prevent the transfer of heat. The inside of the container often has a coating (as silvering) on the inside to reduce heat transfer, and is used especially for storing liquefied gases or for experiments at low temperatures. The size can vary from that of a small thermos bottle up to that which may be mounted upon a large truck (also known as a “cryogenic truck”).	DEW	C43190
DIALPACK	A dose pack container	DLPK	C43191

	designed to assist with patient compliance. The patient turns a dial to the correct day and the correct dose is made available and the container indicates that the dose has been removed.		
DOSE PACK	A container in which a preselected dose or dose regimen of the medication is placed.	DSPK	C43192
DRUM	A straight-sided cylindrical shipping container with flat ends; one of which can be opened/closed.	DRUM	C43193
INHALER	A device by means of which a medicinal product can be administered by inspiration through the nose or the mouth.	INHL	C16738
INHALER, REFILL	A container of medication intended to refill an inhaler.	INHLRE	C43194
JAR	A rigid container having a wide mouth and often no neck which typically holds solid or semisolid drug products.	JAR	C43195
JUG	A large, deep container that has a narrow mouth, is typically fitted with a handle, and is used to hold liquids.	JUG	C43196
KIT	A package which includes a container of	KIT	C43197

	drug product(s) and the equipment and supplies used with it.		
NOT STATED	The package type is not stated or is unavailable.	NS	C48626
PACKAGE	The drug product container with any accompanying materials or components. This may include the protective packaging, labeling, administration devices, etc.	PKG	C43233
PACKAGE, COMBINATION	A package in which two or more drug products that are normally available separately are now available together.	PKGCOM	C43198
PACKET	An envelope into which only one dose of a drug product, usually in the form of granules or powder, has been directly placed. An example includes glassine powder paper containing aspirin. Other examples include aluminum foil packets into which alcohol swabs and pledgets are placed.	PKT	C43199
POUCH	A flexible container used to protect or hold one or more doses of a drug product (e.g. a pouch into which oral contraceptive blister packs are inserted, and an overwrap pouch for large volume	POU	C43200

	parenterals).		
SUPERSACK	A multilayer paper bag for shipping some solid bulk excipients, usually in the form of powder or granules.	SUPSACK	C43201
SYRINGE	A device for the administration of parenteral drug products that consists of a rigid barrel fitted with septum with a plunger at one end and a seal or needle at the other end. The needle assembly may be part of the device or separate.	SYR	C43202
SYRINGE, GLASS	A device for the administration of parenteral drug products that consists of a rigid glass barrel fitted with septum with a plunger at one end and a seal or needle at the other end. The needle assembly may be part of the device or separate.	SYRGL	C43203
SYRINGE, PLASTIC	A device for the administration of parenteral drug products that consists of a rigid plastic barrel fitted with septum with a plunger at one end and a seal or needle at the other end. The needle assembly may be part of the device or separate.	SYRPL	C43204

TABMINDER	A specialized package; it registers each time it is opened and is used for checking patient compliance to prescribed medication regimens.	TABMIND	C43205
TANK	A large receptacle used for holding, transporting, or storing liquids or gases, and often referred to as a reservoir.	TANK	C43206
TRAY	A shallow flat receptacle, with a raised edge or rim, used for carrying, holding, or displaying finished drug product in its primary or market package. A tray and its contents may be encased in shrink-wrapped plastic for shipping, or with a cover or an overwrap as part of a unit of use package or kit.	TRAY	C53438
TUBE	A flexible container for semisolid drug products which is flattened and crimped or sealed at one end and has a reclosable opening at the other.	TUBE	C42794
TUBE, WITH APPLICATOR	A tube which is provided with a device (the applicator) for administering the dosage form. The applicator may be part of the tube closure or be separate.	TUBEAP	C43207

VIAL	A container designed for use with parenteral drug products.	VIAL	C43226
VIAL, DISPENSING	A vial that is used by the pharmacist to dispense the prescribed medication.	VIALDIS	C43208
VIAL, GLASS	A glass container designed for use with parenteral drug products.	VIALGL	C43209
VIAL, MULTI-DOSE	A vial intended to contain more than one dose of the drug product.	VIALMD	C43210
VIAL, PATENT DELIVERY SYSTEM	A vial that has a patented delivery system.	VIALPAT	C43211
VIAL, PHARMACY BULK PACKAGE	A container of a sterile preparation whose contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes.	VIALPHR	C43212
VIAL, PIGGYBACK	A vial that contains a parenteral preparation that can be attached directly to the tubing of a parenterally administered fluid.	VIALPIG	C43213
VIAL, PLASTIC	A plastic container designed for use with parenteral drug	VIALPL	C43214

	products.		
VIAL, SINGLE-DOSE	A vial containing a single unit of a parenteral drug product.	VIALSD	C43215
VIAL, SINGLE-USE	A vial where a single dose of a parenteral drug product can be removed, and then the vial and its remaining contents can be disposed.	VIALSU	C43216

APPENDIX 2. Data Dictionary for Route of Administration in accordance with Centre for Drug Evaluation and Research (CDER) Data Standards Manual

NAME	DEFINITION	SHORT NAME	FDA CODE	NCI CONCEPT ID
AURICULAR (OTIC)	Administration to or by way of the ear.	OTIC	013	C38192
BUCCAL	Administration directed toward the cheek, generally from within the mouth.	BUCCAL	030	C38193
CONJUNCTIVAL	Administration to the conjunctiva, the delicate membrane that lines the eyelids and covers the exposed surface of the eyeball.	CONJUNC	068	C38194
CUTANEOUS	Administration to the skin.	CUTAN	130	C38675
DENTAL	Administration to a tooth or teeth.	DENTAL	038	C38197
ELECTRO-OSMOSIS	Administration of through the diffusion of substance through a membrane in an electric field.	EL-OSMOS	357	C38633
ENDOCERVICAL	Administration within the canal of the cervix uteri.	E-CERVIC	131	C38205

	Synonymous with the term intracervical..			
ENDOSINUSIAL	Administration within the nasal sinuses of the head.	E-SINUS	133	C38206
ENDOTRACHEAL	Administration directly into the trachea.	E-TRACHE	401	C38208
ENTERAL	Administration directly into the intestines.	ENTER	313	C38209
EPIDURAL	Administration upon or over the dura mater.	EPIDUR	009	C38210
EXTRA-AMNIOTIC	Administration to the outside of the membrane enveloping the fetus	X-AMNI	402	C38211
EXTRACORPOREAL	Administration outside of the body.	X-CORPOR	057	C38212
HEMODIALYSIS	Administration through hemodialysate fluid.	HEMO	140	C38200
INFILTRATION	Administration that results in substances passing into tissue spaces or into cells.	INFIL	361	C38215
INTERSTITIAL	Administration to or in the interstices of a tissue.	INTERSTIT	088	C38219
INTRA-ABDOMINAL	Administration within the abdomen.	I-ABDOM	056	C38220
INTRA-AMNIOTIC	Administration within the	I-AMNI	060	C38221

	amnion.			
INTRA-ARTERIAL	Administration within an artery or arteries.	I-ARTER	037	C38222
INTRA-ARTICULAR	Administration within a joint.	I-ARTIC	007	C38223
INTRABILIARY	Administration within the bile, bile ducts or gallbladder.	I-BILI	362	C38224
INTRABRONCHIAL	Administration within a bronchus.	I-BRONCHI	067	C38225
INTRABURSAL	Administration within a bursa.	I-BURSAL	025	C38226
INTRACARDIAC	Administration with the heart.	I-CARDI	027	C38227
INTRACARTILAGINOUS	Administration within a cartilage; endochondral.	I-CARTIL	363	C38228
INTRACAUDAL	Administration within the cauda equina.	I-CAUDAL	413	C38229
INTRACAVERNOUS	Administration within a pathologic cavity, such as occurs in the lung in tuberculosis.	I-CAVERN	132	C38230
INTRACAVITARY	Administration within a non-pathologic cavity, such as that of the cervix, uterus, or penis, or such as that which is formed as the result of a wound.	I-CAVIT	023	C38231
INTRACEREBRAL	Administration	I-CERE	404	C38232

	within the cerebrum.			
INTRACISTERNAL	Administration within the cisterna magna cerebellomedularis.	I-CISTERN	405	C38233
INTRACORNEAL	Administration within the cornea (the transparent structure forming the anterior part of the fibrous tunic of the eye).	I-CORNE	406	C38234
INTRACORONAL, DENTAL	Administration of a drug within a portion of a tooth which is covered by enamel and which is separated from the roots by a slightly constricted region known as the neck.	I-CORONAL	117	C38217
INTRACORONARY	Administration within the coronary arteries.	I-CORONARY	119	C38218
INTRACORPORUS CAVERNOSUM	Administration within the dilatable spaces of the corporus cavernosa of the penis.	I-CORPOR	403	C38235
INTRADERMAL	Administration within the dermis.	I-DERMAL	008	C38238
INTRADISCAL	Administration	I-DISCAL	121	C38239

	within a disc.			
INTRADUCTAL	Administration within the duct of a gland.	I-DUCTAL	123	C38240
INTRADUODENAL	Administration within the duodenum.	I-DUOD	047	C38241
INTRADURAL	Administration within or beneath the dura.	I-DURAL	052	C38242
INTRAEPIDERMAL	Administration within the epidermis.	I-EPIDERM	127	C38243
INTRAESOPHAGEAL	Administration within the esophagus.	I-ESO	072	C38245
INTRAGASTRIC	Administration within the stomach.	I-GASTRIC	046	C38246
INTRAGINGIVAL	Administration within the gingivae.	I-GINGIV	307	C38247
INTRAILEAL	Administration within the distal portion of the small intestine, from the jejunum to the cecum.	I-ILE	365	C38249
INTRALESIONAL	Administration within or introduced directly into a localized lesion.	I-LESION	042	C38250
INTRALUMINAL	Administration within the lumen of a tube.	I-LUMIN	310	C38251
INTRALYMPHATIC	Administration within the lymph.	I-LYMPHAT	352	C38252

INTRAMEDULLARY	Administration within the marrow cavity of a bone.	I-MEDUL	408	C38253
INTRAMENINGEAL	Administration within the meninges (the three membranes that envelope the brain and spinal cord).	I-MENIN	409	C38254
INTRAMUSCULAR	Administration within a muscle.	IM	005	C28161
INTRAOCULAR	Administration within the eye.	I-OCUL	036	C38255
INTRAOVARIAN	Administration within the ovary.	I-OVAR	354	C38256
INTRAPERICARDIAL	Administration within the pericardium.	I-PERICARD	314	C38257
INTRAPERITONEAL	Administration within the peritoneal cavity.	I-PERITON	004	C38258
INTRAPLEURAL	Administration within the pleura.	I-PLEURAL	043	C38259
INTRAPROSTATIC	Administration within the prostate gland.	I-PROSTAT	061	C38260
INTRAPULMONARY	Administration within the lungs or its bronchi.	I-PULMON	414	C38261
INTRASINAL	Administration within the nasal or periorbital sinuses.	I-SINAL	010	C38262
INTRASPINAL	Administration within the vertebral column.	I-SPINAL	022	C38263

INTRASYNOVIAL	Administration within the synovial cavity of a joint.	I-SYNOV	019	C38264
INTRATENDINOUS	Administration within a tendon.	I-TENDIN	049	C38265
INTRATESTICULAR	Administration within the testicle.	I-TESTIC	110	C38266
INTRATHECAL	Administration within the cerebrospinal fluid at any level of the cerebrospinal axis, including injection into the cerebral ventricles.	IT	103	C38267
INTRATHORACIC	Administration within the thorax (internal to the ribs); synonymous with the term endothoracic.	I-THORAC	006	C38207
INTRATUBULAR	Administration within the tubules of an organ.	I-TUBUL	353	C38268
INTRATUMOR	Administration within a tumor.	I-TUMOR	020	C38269
INTRATYMPANIC	Administration within the aurus media.	I-TYMPAN	366	C38270
INTRAUTERINE	Administration within the uterus.	I-UTER	028	C38272
INTRAVASCULAR	Administration within a vessel or vessels.	I-VASC	021	C38273
INTRAVENOUS	Administration within or into a	IV	002	C38276

	vein or veins.			
INTRAVENOUS BOLUS	Administration within or into a vein or veins all at once.	IV BOLUS	138	C38274
INTRAVENOUS DRIP	Administration within or into a vein or veins over a sustained period of time.	IV DRIP	137	C38279
INTRAVENTRICULAR	Administration within a ventricle.	I-VENTRIC	048	C38277
INTRAVESICAL	Administration within the bladder.	I-VESIC	128	C38278
INTRAVITREAL	Administration within the vitreous body of the eye.	I-VITRE	311	C38280
IONTOPHORESIS	Administration by means of an electric current where ions of soluble salts migrate into the tissues of the body.	ION	055	C38203
IRRIGATION	Administration to bathe or flush open wounds or body cavities.	IRRIG	032	C38281
LARYNGEAL	Administration directly upon the larynx.	LARYN	364	C38282
NASAL	Administration to the nose; administered by way of the nose.	NASAL	014	C38284
NASOGASTRIC	Administration through the	NG	071	C38285

	nose and into the stomach, usually by means of a tube.			
NOT APPLICABLE	Routes of administration are not applicable.	NA	312	C48623
OCCLUSIVE DRESSING TECHNIQUE	Administration by the topical route which is then covered by a dressing which occludes the area.	OCCLUS	134	C38286
OPHTHALMIC	Administration to the external eye.	OPHTHALM	012	C38287
ORAL	Administration to or by way of the mouth.	ORAL	001	C38288
OROPHARYNGEAL	Administration directly to the mouth and pharynx.	ORO	410	C38289
OTHER	Administration is different from others on this list.	OTHER	135	C38290
PARENTERAL	Administration by injection, infusion, or implantation.	PAREN	411	C38291
PERCUTANEOUS	Administration through the skin.	PERCUT	113	C38676
PERIARTICULAR	Administration around a joint.	P-ARTIC	045	C38292
PERIDURAL	Administration to the outside of the dura mater of the spinal cord..	P-DURAL	050	C38677

PERINEURAL	Administration surrounding a nerve or nerves.	P-NEURAL	412	C38293
PERIODONTAL	Administration around a tooth.	P-ODONT	040	C38294
RECTAL	Administration to the rectum.	RECTAL	016	C38295
RESPIRATORY (INHALATION)	Administration within the respiratory tract by inhaling orally or nasally for local or systemic effect.	RESPIR	136	C38216
RETROBULBAR	Administration behind the pons or behind the eyeball.	RETRO	034	C38296
SOFT TISSUE	Administration into any soft tissue.	SOFT TIS	109	C38198
SUBARACHNOID	Administration beneath the arachnoid.	S-ARACH	066	C38297
SUBCONJUNCTIVAL	Administration beneath the conjunctiva.	S-CONJUNC	096	C38298
SUBCUTANEOUS	Administration beneath the skin; hypodermic. Synonymous with the term SUBDERMAL.	SC	003	C38299
SUBLINGUAL	Administration beneath the tongue.	SL	024	C38300
SUBMUCOSAL	Administration beneath the mucous membrane.	S-MUCOS	053	C38301
TOPICAL	Administration	TOPIC	011	C38304

	to a particular spot on the outer surface of the body. The E2B term TRANSMAMMARY is a subset of the term TOPICAL.			
TRANSDERMAL	Administration through the dermal layer of the skin to the systemic circulation by diffusion.	T-DERMAL	358	C38305
TRANSMUCOSAL	Administration across the mucosa.	T-MUCOS	122	C38283
TRANSPLACENTAL	Administration through or across the placenta.	T-PLACENT	415	C38307
TRANSTRACHEAL	Administration through the wall of the trachea.	T-TRACHE	355	C38308
TRANSTYMPANIC	Administration across or through the tympanic cavity.	T-TYMPAN	124	C38309
UNASSIGNED	Route of administration has not yet been assigned.	UNAS	400	C38310
UNKNOWN	Route of administration is unknown.	UNKNOWN	139	C38311
URETERAL	Administration into the ureter.	URETER	112	C38312
URETHRAL	Administration into the urethra.	URETH	017	C38271

VAGINAL	Administration into the vagina.	VAGIN	015	C38313

APPENDIX 3. Data Dictionary for Dosage Form in accordance with Centre for Drug Evaluation and Research (CDER) Data Standards Manual

NAME	DEFINITION	USE RESTRICTIONS	SHORT NAME	FDA CODE	NCI CONCEPT ID
AEROSOL	A product that is packaged under pressure and contains therapeutically active ingredients that are released upon activation of an appropriate valve system; it is intended for topical application to the skin as well as local application into the nose (nasal aerosols), mouth (lingual aerosols), or lungs (inhalation aerosols).	a,b,c	AER	246	C42887
AEROSOL, FOAM	A dosage form containing one or more active ingredients, surfactants,	a,b,c	AER FOAM	800	C42888

	aqueous or nonaqueous liquids, and the propellants; if the propellant is in the internal (discontinuous) phase (i.e., of the oil-in-water type), a stable foam is discharged, and if the propellant is in the external (continuous) phase (i.e., of the water-in-oil type), a spray or a quick-breaking foam is discharged.				
AEROSOL, METERED	A pressurized dosage form consisting of metered dose valves which allow for the delivery of a uniform quantity of spray upon each activation.	a,b,c	AER MET	339	C42960

AEROSOL, POWDER	A product that is packaged under pressure and contains therapeutically active ingredients, in the form of a powder, that are released upon activation of an appropriate valve system.	a,b	AER PWD	801	C42971
AEROSOL, SPRAY	An aerosol product which utilizes a compressed gas as the propellant to provide the force necessary to expel the product as a wet spray; it is applicable to solutions of medicinal agents in aqueous solvents.	a,b	AER SPRAY	247	C42889
BAR, CHEWABLE	A solid dosage form usually in the form of a rectangle that is meant to be chewed.	a,b,c	BAR CHEW	347	C42892
BEAD	A solid	a,b	BEAD	317	C42890

	dosage form in the shape of a small ball.				
BEAD, IMPLANT, EXTENDED RELEASE	A small sterile solid mass consisting of a highly purified drug intended for implantation in the body which would allow at least a reduction in dosing frequency as compared to that drug presented as a conventional dosage form.	a	BEAD IMP ER	802	C43451
BLOCK	Solid dosage form, usually in the shape of a square or rectangle.	a,b	BLOCK	803	C42891
CAPSULE	A solid dosage form in which the drug is enclosed within either a hard or soft soluble container or "shell" made from a suitable form of gelatin.	a,b,c	CAP	600	C25158
CAPSULE, COATED	A solid dosage form in which the	a,b	CAP COATED	602	C42895

	drug is enclosed within either a hard or soft soluble container or "shell" made from a suitable form of gelatin; additionally, the capsule is covered in a designated coating.				
CAPSULE, COATED PELLETS	A solid dosage form in which the drug is enclosed within either a hard or soft soluble container or "shell" made from a suitable form of gelatin; the drug itself is in the form of granules to which varying amounts of coating have been applied.	a,b,c	CAP COATED PELLETS	603	C42896
CAPSULE, COATED, EXTENDED RELEASE	A solid dosage form in which the drug is enclosed within either a hard or soft soluble container or "shell" made from a	a,b	CAP COATED ER	611	C42917

	suitable form of gelatin; additionally, the capsule is covered in a designated coating, and which releases a drug (or drugs) in such a manner to allow at least a reduction in dosing frequency as compared to that drug (or drugs) presented as a conventional dosage form.				
CAPSULE, DELAYED RELEASE	A solid dosage form in which the drug is enclosed within either a hard or soft soluble container made from a suitable form of gelatin, and which releases a drug (or drugs) at a time other than promptly after administratio n. Enteric-coated	a,b,c	CAP DR	620	C42902

	articles are delayed release dosage forms.				
CAPSULE, DELAYED RELEASE PELLETS	A solid dosage form in which the drug is enclosed within either a hard or soft soluble container or "shell" made from a suitable form of gelatin; the drug itself is in the form of granules to which enteric coating has been applied, thus delaying release of the drug until its passage into the intestines.	a,b,c	CAP DR PELLETS	621	C42904
CAPSULE, EXTENDED RELEASE	A solid dosage form in which the drug is enclosed within either a hard or soft soluble container made from a suitable form of gelatin, and which releases a drug (or drugs) in	a,b,c	CAP ER	610	C42916

	such a manner to allow a reduction in dosing frequency as compared to that drug (or drugs) presented as a conventional dosage form.				
CAPSULE, FILM COATED, EXTENDED RELEASE	A solid dosage form in which the drug is enclosed within either a hard or soft soluble container or "shell" made from a suitable form of gelatin; additionally, the capsule is covered in a designated film coating, and which releases a drug (or drugs) in such a manner to allow at least a reduction in dosing frequency as compared to that drug (or drugs) presented as a	a	CAP FILM COATED ER	612	C42928

	conventional dosage form.				
CAPSULE, GELATIN COATED	A solid dosage form in which the drug is enclosed within either a hard or soft soluble container made from a suitable form of gelatin; through a banding process, the capsule is coated with additional layers of gelatin so as to form a complete seal.	a,b	CAP GELATIN COATED	605	C42936
CAPSULE, LIQUID FILLED	A solid dosage form in which the drug is enclosed within a soluble, gelatin shell which is plasticized by the addition of a polyol, such as sorbitol or glycerin, and is therefore of a somewhat thicker consistency than that of a	a,b	CAP LIQ FILLED	606	C42954

	hard shell capsule; typically, the active ingredients are dissolved or suspended in a liquid vehicle.				
CEMENT	A substance that serves to produce solid union between two surfaces.	a	CEMENT	252	C45414
CIGARETTE	A narrow tube of cut tobacco (or other similar material) enclosed in paper and designed for smoking.	a,b	CIGARETTE	253	C42678
CLOTH	A large piece of relatively flat, absorbent material that contains a drug. It is typically used for applying medication or for cleansing.	a,b,c	CLOTH	845	C60884
CONCENTRATE	A liquid preparation of increased strength and reduced volume which is usually diluted prior to administratio	a,b,c	CONC	280	C60891

	n.				
CONE	A solid dosage form bounded by a circular base and the surface formed by line segments joining every point of the boundary of the base to a common vertex. A cone (usually containing antibiotics) is normally placed below the gingiva after a dental extraction.	a,b	CONE	049	C42900
CORE, EXTENDED RELEASE	An ocular system placed in the eye from which the drug diffuses through a membrane at a constant rate over a specified period.	a,b	CORE ER	804	C42919
CREAM	An emulsion, semisolid[3] dosage form, usually containing > 20% water and volatiles[5] and/or < 50% hydrocarbons	a,b,c	CREAM	805	C28944

	, waxes, or polyols as the vehicle. This dosage form is generally for external application to the skin or mucous membranes.				
CREAM, AUGMENTED	A cream dosage form that enhances drug delivery. Augmentation does not refer to the strength of the drug in the dosage form. NOTE: CDER has decided to refrain from expanding the use of this dosage form due to difficulties in setting specific criteria that must be met to be considered "augmented".	a,b,c	CREAM AUG	365	C60897
CRYSTAL	A naturally produced angular solid of definite form in which the ultimate units from which it is	a	CRYSTAL	051	C42901

	built up are systematically arranged; they are usually evenly spaced on a regular space lattice.				
CULTURE	The propagation of microorganisms or of living tissue sells in special media conducive to their growth.	a	CULTURE	281	C45415
DIAPHRAGM	A device usually dome-shaped, worn during copulation over the cervical mouth for prevention of conception or infection.	a	DIAPHRAGM	255	C47890
DISC	A circular plate-like organ or structure.	a,b,c	DISC	256	C43525
DOUCHE	A liquid preparation, intended for the irrigative cleansing of the vagina, that is prepared from	a	DOUCHE	838	C42679

	powders, liquid solutions, or liquid concentrates and contains one or more chemical substances dissolved in a suitable solvent or mutually miscible solvents.				
DRESSING	The application of various materials for protecting a wound.	a,b,c	DRESSING	285	C42763
DRUG DELIVERY SYSTEM	Modern technology, distributed with or as a part of a drug product that allows for the uniform release or targeting of drugs to the body.	a	DDS	259	C17423
ELIXIR	A clear, pleasantly flavored, sweetened hydroalcoholic liquid containing dissolved medicinal agents; it is intended for oral use.	a,b,c	ELIXIR	807	C42912

EMULSION	A dosage form consisting of a two-phase system comprised of at least two immiscible liquids[1], one of which is dispersed as droplets (internal or dispersed phase) within the other liquid (external or continuous phase), generally stabilized with one or more emulsifying agents. (Note: Emulsion is used as a dosage form term unless a more specific term is applicable, e.g. cream, lotion, ointment.)	a,b,c	EMULSION	052	C42913
ENEMA	A rectal preparation for therapeutic, diagnostic, or nutritive purposes.	a,b,c	ENEMA	286	C42915
EXTRACT	A concentrated	a,b	EXTRACT	287	C42929

	preparation of vegetable or animal drugs obtained by removal of the active constituents of the respective drugs with a suitable menstrua, evaporation of all or nearly all of the solvent, and adjustment of the residual masses or powders to the prescribed standards.				
FIBER, EXTENDED RELEASE	A slender and elongated solid thread-like substance that delivers drug in such a manner to allow a reduction in dosing frequency as compared to that drug (or drugs) presented as a conventional dosage form.	a,b,c	FIBER ER	847	C60926
FILM	A thin layer	a,b	FILM	061	C42932

	or coating.				
FILM, EXTENDED RELEASE	A drug delivery system in the form of a film that releases the drug over an extended period in such a way as to maintain constant drug levels in the blood or target tissue.	a,b,c	FILM ER	810	C42920
FILM, SOLUBLE	A thin layer or coating which is susceptible to being dissolved when in contact with a liquid.	a,b	FILM SOLUBLE	063	C42984
FOR SOLUTION	A product, usually a solid, intended for solution prior to administratio n.	a,c	FOR SOL	848	C60927
FOR SUSPENSION	A product, usually a solid, intended for suspension prior to administratio n.	a,c	FOR SUSP	849	C60928
FOR SUSPENSION, EXTENDED RELEASE	A product, usually a solid, intended for	a,c	FOR SUSP ER	850	C60929

	suspension prior to administration; once the suspension is administered, the drug will be released at a constant rate over a specified period.				
GAS	Any elastic aeriform fluid in which the molecules are separated from one another and so have free paths.	a,b,c	GAS	064	C42933
GEL	A semisolid[3] dosage form that contains a gelling agent to provide stiffness to a solution or a colloidal dispersion.[4] A gel may contain suspended particles.	a,b,c	GEL	066	C42934
GEL, DENTIFRICE	A combination of a dentifrice (formulation intended to clean and/or polish the teeth, and which may	a,b	GEL DENT	806	C42906

	contain certain additional agents), and a gel. It is used with a toothbrush for the purpose of cleaning and polishing the teeth.				
GEL, METERED	A gel preparation, with metered dose valves, which allow for the delivery of a uniform quantity of gel upon each activation.	a,b,c	GEL MET	851	C60930
GENERATOR	An apparatus for the formation of vapor or gas from a liquid or solid by heat or chemical action. The term GENERATOR also applies to radioactive columns from which radionuclides are provided.	a,b	GENERATOR	289	C48193
GLOBULE	Also called pellets or pilules, are	a,b	GLOBULE	808	C42937

	made of pure sucrose, lactose, or other polysaccharides. They are formed into small globular masses of various sizes, and are medicated by placing them in a vial and adding the liquid drug attenuation in the proportion not less than one percent (v/w). After shaking, the medicated globules are dried at temperatures not to exceed 40 degrees Centigrade.				
GRAFT	A slip of skin or of other tissue for implantation.	a,b	GRAFT	290	C45416
GRANULE	A small particle or grain.	a,b,c	GRAN	078	C42938
GRANULE, DELAYED RELEASE	A small medicinal particle or grain to which an enteric or other coating	a,c	GRAN DR	820	C42903

	has been applied, thus delaying release of the drug until its passage into the intestines.				
GRANULE, EFFERVESCENT	A small particle or grain containing a medicinal agent in a dry mixture usually composed of sodium bicarbonate, citric acid, and tartaric acid which, when in contact with water, has the capability to release gas, resulting in effervescence.	a,b,c	GRAN EFFRV	080	C42909
GRANULE, FOR SOLUTION	A small medicinal particle or grain made available in its more stable dry form, to be reconstituted with solvent just before dispensing; the granules are so prepared to	a,b	GRAN F/SOL	809	C42939

	contain not only the medicinal agent, but the colorants, flavorants, and any other desired pharmaceutic ingredient.				
GRANULE, FOR SUSPENSION	A small medicinal particle or grain made available in its more stable dry form, to be reconstituted with solvent just before dispensing to form a suspension; the granules are so prepared to contain not only the medicinal agent, but the colorants, flavorants, and any other desired pharmaceutic ingredient.	a,b	GRAN F/SUSP	819	C42940
GRANULE, FOR SUSPENSION, EXTENDED RELEASE	A small medicinal particle or grain made available in its more stable dry form, to be reconstituted	a	GRAN F/SUSP ER	811	C42921

	with solvent just before dispensing to form a suspension; the extended release system achieves slow release of the drug over an extended period of time and maintains constant drug levels in the blood or target tissue.				
GUM	A mucilaginous excretion from various plants.	a,b	GUM	084	C42941
GUM, CHEWING	A sweetened and flavored insoluble plastic material of various shapes which when chewed, releases a drug substance into the oral cavity.	a,b,c	GUM CHEWING	085	C42894
GUM, RESIN	Natural mixture of gum and resin, usually obtained as exudations	a,b	GUM RESIN	087	C42978

	from plants.				
IMPLANT	A material containing drug intended to be inserted securely of deeply in a living site for growth, slow release, or formation of an organic union.	a,b,c	IMP	715	C42942
INHALANT	A special class of inhalations consisting of a drug or combination of drugs, that by virtue of their high vapor pressure can be carried by an air current into the nasal passage where they exert their effect; the container from which the inhalant generally is administered is known as an inhaler.	a,b,c	INHALANT	293	C42944
INJECTABLE, LIPOSOMAL	An injection, which either consists of or forms liposomes (a lipid bilayer	a,c	INJ LIPOS	852	C60931

	vesicle usually composed of phospholipids which is used to encapsulate an active drug substance).				
INJECTION	A sterile preparation intended for parenteral use; five distinct classes of injections exist as defined by the USP.	a,b	INJ	700	C42946
INJECTION, EMULSION	An emulsion consisting of a sterile, pyrogen-free preparation intended to be administered parenterally.	a,b	INJ EMULSION	701	C42914
INJECTION, LIPID COMPLEX	[definition pending]	a	INJ LIPID COMPLEX	716	C42950
INJECTION, POWDER, FOR SOLUTION	A sterile preparation intended for reconstitution to form a solution for parenteral use.	a,b	INJ PWD F/SOL	702	C42974
INJECTION, POWDER, FOR SUSPENSION	A sterile preparation intended for reconstitution to form a	a,b	INJ PWD F/SUSP	703	C42976

	suspension for parenteral use.				
INJECTION, POWDER, FOR SUSPENSION, EXTENDED RELEASE	A dried preparation intended for reconstitution to form a suspension for parenteral use which has been formulated in a manner to allow at least a reduction in dosing frequency as compared to that drug presented as a conventional dosage form (e.g., as a solution).	a,b	INJ PWD F/SUSP ER	710	C42977
INJECTION, POWDER, LYOPHILIZED, FOR LIPOSOMAL SUSPENSION	A sterile freeze dried preparation intended for reconstitution for parenteral use which has been formulated in a manner that would allow liposomes (a lipid bilayer vesicle usually composed of phospholipids which is used to	a,b	INJ PWD LYO F/LS	713	C42959

	encapsulate an active drug substance, either within a lipid bilayer or in an aqueous space) to be formed upon reconstitution.				
INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	A dosage form intended for the solution prepared by lyophilization ("freeze drying"), a process which involves the removal of water from products in the frozen state at extremely low pressures; this is intended for subsequent addition of liquid to create a solution that conforms in all respects to the requirements for Injections.	a,b	INJ PWD LYO F/SOL	705	C42957
INJECTION, POWDER,	A liquid preparation,	a,b	INJ PWD LYO	706	C42958

LYOPHILIZED, FOR SUSPENSION	intended for parenteral use that contains solids suspended in a suitable fluid medium and conforms in all respects to the requirements for Sterile Suspensions; the medicinal agents intended for the suspension are prepared by lyophilization ("freeze drying"), a process which involves the removal of water from products in the frozen state at extremely low pressures.		F/SUSP		
INJECTION, POWDER, LYOPHILIZED, FOR SUSPENSION, EXTENDED RELEASE	A sterile freeze dried preparation intended for reconstitution for parenteral use which has been formulated in a manner to	a,b	INJ PWD LYO F/SUSPER	712	C42956

	allow at least a reduction in dosing frequency as compared to that drug presented as a conventional dosage form (e.g., as a solution).				
INJECTION, SOLUTION	A liquid preparation containing one or more drug substances dissolved in a suitable solvent or mixture of mutually miscible solvents that is suitable for injection.	a,b	INJ SOL	708	C42945
INJECTION, SOLUTION, CONCENTRATE	A sterile preparation for parenteral use which, upon the addition of suitable solvents, yields a solution conforming in all respects to the requirements for Injections.	a,b	INJ SOL CONC	709	C42899
INJECTION, SUSPENSION	A liquid preparation, suitable for	a,b	INJ SUSP	704	C42995

	injection, which consists of solid particles dispersed throughout a liquid phase in which the particles are not soluble. It can also consist of an oil phase dispersed throughout an aqueous phase, or vice-versa.				
INJECTION, SUSPENSION, EXTENDED RELEASE	A sterile preparation intended for parenteral use which has been formulated in a manner to allow at least a reduction in dosing frequency as compared to that drug presented as a conventional dosage form (e.g., as a solution or a prompt drug-releasing, conventional solid dosage form).	a,b	INJ SUSP ER	711	C42926
INJECTION, SUSPENSION, LIPOSOMAL	A liquid preparation, suitable for	a,b	INJ SUSP LIPOS	714	C42951

	injection, which consists of an oil phase dispersed throughout an aqueous phase in such a manner that liposomes (a lipid bilayer vesicle usually composed of phospholipids which is used to encapsulate an active drug substance, either within a lipid bilayer or in an aqueous space) are formed.				
INJECTION, SUSPENSION, SONICATED	A liquid preparation, suitable for injection, which consists of solid particles dispersed throughout a liquid phase in which the particles are not soluble. In addition, the product is sonicated while a gas is bubbled	a	INJ SUSPSON	840	C42988

	through the suspension, and this results in the formation of microspheres by the solid particles.				
INSERT	A specially formulated and shaped solid preparation (e.g. ring, tablet, or stick) intended to be placed in the body, where drug is released, generally for localized effects.	a,c	INSERT	853	C60933
INSERT, EXTENDED RELEASE	A specially formulated and shaped solid preparation (e.g., ring, tablet, or stick) intended to be placed in the vagina by special inserters, where the medication is released, generally for localized effects; the extended release preparation is	a,b,c	INSERT ER	812	C42922

	designed to allow a reduction in dosing frequency.				
INTRAUTERINE DEVICE	A device inserted and left in the uterus to prevent effective conception.	a,b,c	IUD	260	C47915
IRRIGANT	A sterile solution intended to bathe or flush open wounds or body cavities; they're used topically, never parenterally.	a,b	IRRIGANT	830	C42947
JELLY	A class of gels, which are semisolid systems that consist of suspensions made up of either small inorganic particles or large organic molecules interpenetrated by a liquid--in which the structural coherent matrix contains a high portion of liquid,	a,b,c	JELLY	072	C42948

	usually water.				
KIT	A packaged collection of related material.	a,b	KIT	261	C47916
LINER, DENTAL	A material applied to the inside of the dental cavity, for protection or insulation of the surface.	a,b	LINER DENTAL	316	C45413
LINIMENT	A solution or mixture of various substances in oil, alcoholic solutions of soap, or emulsions intended for external application.	a,b	LINIMENT	298	C42949
LIPSTICK	A waxy solid, usually colored cosmetic, in stick form for the lips.	a,b	LIPSTICK	265	C42952
LIQUID	A dosage form consisting of a pure chemical in its liquid[1] state. This dosage form term should not be applied to solutions.	a,b,c	LIQ	299	C42953
LIQUID,	A liquid that	a,b,c	LIQ ER	854	C60934

EXTENDED RELEASE	delivers a drug in such a manner to allow a reduction in dosing frequency as compared to that drug (or drugs) presented as a conventional dosage form.				
LOTION	An emulsion, liquid[1] dosage form. This dosage form is generally for external application to the skin.[2]	a,b,c	LOTION	300	C29167
LOTION, AUGMENTED	A lotion dosage form that enhances drug delivery. Augmentation does not refer to the strength of the drug in the dosage form. NOTE: CDER has decided to refrain from expanding the use of this dosage form due to difficulties in setting specific criteria that	a,b,c	LOTION AUG	364	C60957

	must be met to be considered "augmented".				
LOTION/SHAMPOO	A lotion dosage form which has a soap or detergent that is usually used to clean the hair and scalp; it is often used as a vehicle for dermatologic agents.	a,b,c	LOTION SHAMPOO	855	C60958
LOZENGE	A solid preparation containing one or more medicaments, usually in a flavored, sweetened base which is intended to dissolve or disintegrate slowly in the mouth. A lollipop is a lozenge on a stick.	a,b	LOZENGE	831	C42955
MOUTHWASH	An aqueous solution which is most often used for its deodorant, refreshing, or antiseptic effect.	a,b	MOUTHWASH	832	C29269
NOT APPLICABLE	The use of a dosage form	a,b,c	NOT APPLICABL	313	C48624

	term is not relevant or appropriate.		E		
OIL	An unctuous, combustible substance which is liquid, or easily liquefiable, on warming, and is soluble in ether but insoluble in water. Such substances, depending on their origin, are classified as animal, mineral, or vegetable oils.	a,b,c	OIL	098	C42965
OINTMENT	A suspension or emulsion, semisolid[3] dosage form, usually containing < 20% water and volatiles[5] and > 50% hydrocarbons, waxes, or polyols as the vehicle. This dosage form is generally for external application to the skin or mucous membranes.	a,b,c	OINTMENT	101	C42966

OINTMENT, AUGMENTED	An ointment dosage form that enhances drug delivery. Augmentation does not refer to the strength of the drug in the dosage form. NOTE: CDER has decided to refrain from expanding the use of this dosage form due to difficulties in setting specific criteria that must be met to be considered "augmented".	a,b,c	OINTMENT AUG	366	C60984
PACKING	A material, usually covered by or impregnated with a drug that is inserted into a body cavity or between the tooth enamel and the gingival margin.	a,b	PACKING	839	C47887
PASTE	A semisolid[3] dosage form, containing a large proportion (20 – 50%) of	a,b,c	PASTE	103	C42967

	solids finely dispersed in a fatty vehicle. This dosage form is generally for external application to the skin or mucous membranes.				
PASTE, DENTIFRICE	A paste formulation intended to clean and/or polish the teeth, and which may contain certain additional agents.	a,b	PASTE DENT	104	C42907
PASTILLE	An aromatic preparation, often with a pleasing flavor, usually intended to dissolve in the mouth.	a,c	PASTILLE	341	C60985
PATCH	A drug delivery system that often contains an adhesive backing that is usually applied to an external site on the body. Its ingredients either	a,b,c	PATCH	843	C42968

	passively diffuse from, or are actively transported from, some portion of the patch. Depending upon the patch, the ingredients are either delivered to the outer surface of the body or into the body. A patch is sometimes synonymous with the terms ‘extended release film’ and ‘system’.				
PATCH, EXTENDED RELEASE	A drug delivery system in the form of a patch that releases the drug in such a manner that a reduction in dosing frequency compared to that drug presented as a conventional dosage form (e.g., a solution or a	a,b	PATCH ER	813	C42923

	prompt drug-releasing, conventional solid dosage form).				
PATCH, EXTENDED RELEASE, ELECTRICALLY CONTROLLED	A drug delivery system in the form of a patch which is controlled by an electric current that releases the drug in such a manner that a reduction in dosing frequency compared to that drug presented as a conventional dosage form (e.g., a solution or a prompt drug-releasing, conventional solid dosage form).	a,b	PATCH ER ELCON	814	C42911
PELLET	A small sterile solid mass consisting of a highly purified drug (with or without excipients) made by the formation of granules, or by	a,b,c	PELLET	105	C42969

	compression and molding.				
PELLET, IMPLANTABLE	A small sterile solid mass consisting of a highly purified drug (with or without excipients) made by the formation of granules, or by compression and molding; they are intended for implantation in the body (usually subcutaneously) for the purpose of providing continuous release of the drug over long periods of time.	a	PELLET IMP	844	C42943
PELLETS, COATED, EXTENDED RELEASE	A solid dosage form in which the drug itself is in the form of granules to which varying amounts of coating have been applied, and which releases a drug (or drugs) in such a	a	PELLETS COATED ER	842	C42918

	manner to allow a reduction in dosing frequency as compared to that drug (or drugs) presented as a conventional dosage form				
PILL	A small, round solid dosage form containing a medicinal agent intended for oral administratio n.	a,b	PILL	107	C25394
PLASTER	Substance intended for external application made of such materials and of such consistency as to adhere to the skin and attach to a dressing; plasters are intended to afford protection and support and/or to furnish an occlusion and macerating action and to bring	a,b	PLASTER	108	C42970

	medication into close contact with the skin.				
POULTICE	A soft, moist mass of meal, herbs, seed, etc., usually applied hot in cloth that consists of gruel-like consistency.	a,b	POULTICE	109	C47913
POWDER	An intimate mixture of dry, finely divided drugs and/or chemicals that may be intended for internal or external use.	a,b,c	PWD	110	C42972
POWDER, DENTIFRICE	A powder formulation intended to clean and/or polish the teeth, and which may contain certain additional agents.	a,b	PWD DENT	115	C42908
POWDER, FOR SOLUTION	An intimate mixture of dry, finely divided drugs and/or chemicals, which, upon the addition of suitable vehicles,	a,b	PWD F/SOL	833	C42973

	yields a solution.				
POWDER, FOR SUSPENSION	An intimate mixture of dry, finely divided drugs and/or chemicals, which, upon the addition of suitable vehicles, yields a suspension (a liquid preparation containing the solid particles dispersed in the liquid vehicle).	a,b	PWD F/SUSP	834	C42975
POWDER, METERED	A powder dosage form that is situated inside a container that has a mechanism to deliver a specified quantity.	a,c	PWD MET	841	C42961
RING	A small circular object with a vacant circular center that is usually intended to be placed in the body by special inserters,	a,b,c	RING	856	C60988

	where the medication is released, generally for localized effects.				
RINSE	A liquid used to cleanse by flushing.	a,b	RINSE	303	C42979
SALVE	A thick ointment or cerate (a fat or wax based preparation with a consistency between an ointment and a plaster).	a,b	SALVE	137	C42980
SHAMPOO	A liquid soap or detergent used to clean the hair and scalp and is often used as a vehicle for dermatologic agents.	a,b,c	SHAMPOO	304	C42981
SHAMPOO, SUSPENSION	A liquid soap or detergent containing one or more solid, insoluble substances dispersed in a liquid vehicle that is used to clean the hair and scalp and is often used as a vehicle for dermatologic agents.	a,b	SHAMPOO SUSP	193	C42982

SOAP	Any compound of one or more fatty acids, or their equivalents, with an alkali; soap is detergent and is much employed in liniments, enemas, and in making pills. It is also a mild aperient, antacid and antiseptic.	a,b,c	SOAP	305	C42983
SOLUTION	A clear, homogeneous liquid[1] dosage form that contains one or more chemical substances dissolved in a solvent or mixture of mutually miscible solvents.	a,b,c	SOL	138	C42986
SOLUTION, CONCENTRATE	A liquid preparation (i.e., a substance that flows readily in its natural state) that contains a drug dissolved in a suitable solvent or mixture of	a,b	SOL CONC	835	C42898

	mutually miscible solvents; the drug has been strengthened by the evaporation of its nonactive parts.				
SOLUTION, FOR SLUSH	A solution for the preparation of an iced saline slush, which is administered by irrigation and used to induce regional hypothermia (in conditions such as certain open heart and kidney surgical procedures) by its direct application.	a,c	SOL F/SLUSH	321	C42987
SOLUTION, GEL FORMING / DROPS	A solution, which after usually being administered in a drop-wise fashion, forms a gel.	a,c	SOL GF DROPS	858	C60994
SOLUTION, GEL FORMING, EXTENDED RELEASE	A solution that forms a gel when it comes in contact with ocular fluid,	a	SOL GF ER	717	C42935

	and which allows at least a reduction in dosing frequency				
SOLUTION/ DROPS	A solution which is usually administered in a drop-wise fashion.	a,b,c	SOL DROPS	857	C60992
SPONGE	A porous, interlacing, absorbent material that contains a drug. It is typically used for applying or introducing medication, or for cleansing. A sponge usually retains its shape.	a,b,c	SPONGE	271	C47912
SPRAY	A liquid minutely divided as by a jet of air or steam.	a,b,c	SPRAY	272	C42989
SPRAY, METERED	A non-pressurized dosage form consisting of valves which allow the dispensing of a specified quantity of spray upon each activation.	a,b,c	SPRAY MET	345	C42962

SPRAY, SUSPENSION	A liquid preparation containing solid particles dispersed in a liquid vehicle and in the form of coarse droplets or as finely divided solids to be applied locally, most usually to the nasal-pharyngeal tract, or topically to the skin.	a,b	SPRAY SUSP	195	C42990
STICK	A dosage form prepared in a relatively long and slender often cylindrical form.	a,b	STICK	273	C42991
STRIP	A long narrow piece of material.	a,b	STRIP	274	C47914
SUPPOSITORY	A solid body of various weights and shapes, adapted for introduction into the rectal, vaginal, or urethral orifice of the human body; they usually melt, soften,	a,b,c	SUPP	173	C42993

	or dissolve at body temperature.				
SUPPOSITORY, EXTENDED RELEASE	A drug delivery system in the form of a suppository that allows at least a reduction in dosing frequency.	a,b,c	SUPP ER	815	C42924
SUSPENSION	A liquid[1] dosage form that contains solid particles dispersed in a liquid vehicle.	a,b	SUSP	177	C42994
SUSPENSION, EXTENDED RELEASE	A liquid preparation consisting of solid particles dispersed throughout a liquid phase in which the particles are not soluble; the suspension has been formulated in a manner to allow at least a reduction in dosing frequency as compared to that drug presented as a conventional dosage form	a,b	SUSP ER	816	C42925

	(e.g., as a solution or a prompt drug-releasing, conventional solid dosage form).				
SUSPENSION/ DROPS	A suspension which is usually administered in a dropwise fashion.	a,c	SUSP DROPS	859	C60995
SUTURE	A strand or fiber used to hold wound edges in apposition during healing.	a	SUTURE	275	C47889
SWAB	A small piece of relatively flat absorbent material that contains a drug. A swab may also be attached to one end of a small stick. A swab is typically used for applying medication or for cleansing.	a,b,c	SWAB	276	C47898
SYRUP	An oral solution containing high concentrations of sucrose or other sugars; the term has also	a,b,c	SYRUP	307	C42996

	been used to include any other liquid dosage form prepared in a sweet and viscid vehicle, including oral suspensions.				
TABLET	A solid dosage form containing medicinal substances with or without suitable diluents.	a,b,c	TAB	500	C42998
TABLET, CHEWABLE	A solid dosage form containing medicinal substances with or without suitable diluents that is intended to be chewed, producing a pleasant tasting residue in the oral cavity that is easily swallowed and does not leave a bitter or unpleasant after-taste.	a,b,c	TAB CHEW	501	C42893
TABLET, COATED	A solid dosage form that contains medicinal	a,b	TAB COATED	502	C42897

	substances with or without suitable diluents and is covered with a designated coating.				
TABLET, COATED PARTICLES	A solid dosage form containing a conglomerate of medicinal particles that have each been covered with a coating.	a,c	TAB COATED PART	860	C60997
TABLET, DELAYED RELEASE	A solid dosage form which releases a drug (or drugs) at a time other than promptly after administration. Enteric-coated articles are delayed release dosage forms.	a,b,c	TAB DR	520	C42905
TABLET, DELAYED RELEASE PARTICLES	A solid dosage form containing a conglomerate of medicinal particles that have been covered with a coating	a,b	TAB DR PARTICLES	521	C42997

	which releases a drug (or drugs) at a time other than promptly after administration. Enteric-coated articles are delayed release dosage forms.				
TABLET, DISPERSIBLE	A tablet that, prior to administration, is intended to be placed in liquid, where its contents will be distributed evenly throughout that liquid. Note: The term 'tablet, dispersible' is no longer used for approved drug products, and it has been replaced by the term 'tablet, for suspension'.	a,c	TAB DISP	491	[Note: The concept has been entered as a synonym for the dosage form term TABLET, FOR SUSPENSION.]
TABLET, EFFERVESCENT	A solid dosage form containing mixtures of acids (e.g., citric acid,	a,b,c	TAB EFFRV	503	C42910

	tartaric acid) and sodium bicarbonate, which release carbon dioxide when dissolved in water; it is intended to be dissolved or dispersed in water before administration.				
TABLET, EXTENDED RELEASE	A solid dosage form containing a drug which allows at least a reduction in dosing frequency as compared to that drug presented in conventional dosage form.	a,b,c	TAB ER	510	C42927
TABLET, FILM COATED	A solid dosage form that contains medicinal substances with or without suitable diluents and is coated with a thin layer of a water-insoluble or water-soluble polymer.	a,b	TAB FILM COATED	504	C42931

TABLET, FILM COATED, EXTENDED RELEASE	A solid dosage form that contains medicinal substances with or without suitable diluents and is coated with a thin layer of a water-insoluble or water-soluble polymer; the tablet is formulated in such manner as to make the contained medicament available over an extended period of time following ingestion.	a,b	TAB FILM COATED ER	511	C42930
TABLET, FOR SOLUTION	A tablet that forms a solution when placed in a liquid.	a,c	TAB FOR SOL	523	C61004
TABLET, FOR SUSPENSION	A tablet that forms a suspension when placed in a liquid (formerly referred to as a ‘dispersible tablet’).	a,c	TAB FOR SUSP	524	C61005
TABLET, MULTILAYER	A solid dosage form containing medicinal	a,b	TAB MULTILAYER	505	C42964

	substances that have been compressed to form a multiple-layered tablet or a tablet-within-a-tablet, the inner tablet being the core and the outer portion being the shell.				
TABLET, MULTILAYER, EXTENDED RELEASE	A solid dosage form containing medicinal substances that have been compressed to form a multiple-layered tablet or a tablet-within-a-tablet, the inner tablet being the core and the outer portion being the shell, which, additionally, is covered in a designated coating; the tablet is formulated in such manner as to allow at least a reduction in	a,b	TAB MULTILAYER ER	512	C42963

	dosing frequency as compared to that drug presented as a conventional dosage form.				
TABLET, ORALLY DISINTEGRATING	A solid dosage form containing medicinal substances which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue.	a,b,c	TAB ORALLY DIS	522	C42999
TABLET, ORALLY DISINTEGRATING, DELAYED RELEASE	A solid dosage form containing medicinal substances which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue, but which releases a drug (or drugs) at a time other than promptly after administration.	a,c	TAB ORALLY DIS DR	526	C61006

TABLET, SOLUBLE	A solid dosage form that contains medicinal substances with or without suitable diluents and possesses the ability to dissolve in fluids.	a,b	TAB SOLUBLE	507	C42985
TABLET, SUGAR COATED	A solid dosage form that contains medicinal substances with or without suitable diluents and is coated with a colored or an uncolored water-soluble sugar.	a,b	TAB SUGAR COATED	508	C42992
TAMPON	A plug made of cotton, sponge, or oakum variously used in surgery to plug the nose, vagina, etc., for the control of hemorrhage or the absorption of secretions.	a,b,c	TAMPON	277	C47892
TAPE	A narrow woven fabric, or a narrow	a,b,c	TAPE	278	C47897

	extruded synthetic (such as plastic), usually with an adhesive on one or both sides.				
TINCTURE	An alcoholic or hydroalcoholic solution prepared from vegetable materials or from chemical substances.	a,b	TINCTURE	837	C43000
TROCHE	A discoid-shaped solid containing the medicinal agent in a suitably flavored base; troches are placed in the mouth where they slowly dissolve, liberating the active ingredients.	a,b	TROCHE	363	C43001
UNASSIGNED	A dosage form has yet to be assigned.	a,b	UNASSIGNED	900	C43002
WAFER	A thin slice of material containing a medicinal agent.	a,b	WAFER	245	C43003

APPENDIX 4. Data Dictionary for Potency Units Of Measure in accordance with Centre for Drug Evaluation and Research (CDER) NDC Directory TBLUNITS.TXT

Code	Description
%VV	PERCENT VOL./VOL.
%WV	PERCENT WT./VOL.
%WW	PERCENT WT./WT.
AMP	AMPULE
BAG	BAG
BOL	BOLUS
BOT	BOTTLE
BOX	BOX
CAN	CAN
CAP	CAPSULE
CC	CUBIC CENTIMETER
CMM	CUBIC MILLIMETER
CNT	COUNT
CTG	CARTRIDGE
CTR	CONTAINER
DIS	DISK
DRM	DRUM
FLD	FLUID DRAM
FLO	FLUID OUNCE
FTC	FEET, CUBIC
FTS	FEET, SQUARE
GAL	GALLON
GM	GRAM
GR	GRAIN
IN	INCH
INC	INCH, CUBIC
JAR	JAR

KG	KILOGRAM
KIT	KIT
L	LITER
LB	POUND
LOZ	LOZENGE
MCG	MICROGRAM
MCL	MICROLITER
MMO	MICROMOLE
MCN	MICRON
MEQ	MILLIEQUIVALENT
MG	MILLIGRAM MIC MICROCURIE
MIL	MILLICURIE
MIN	MINIM
MIS	MISCELLANEOUS
ML	MILLILITER
MM	MILLIMETER
MCM	MILLIMOLE
MOL	MOLAR
NL	NORMAL
NMG	NANOGRAM, MILLIMICROGRAM
NMO	NANOMOLE, MILLIMICROMOLE
OZ	OUNCE
PEL	PELLET
PKG	PACKAGE
TES	TEST
PNU	PROTEIN UNIT
PPM	PART PER MILLION
PT	PINT
QS	QUANTITY SUFFICIENT
QT	QUART
SAT	SATURATED

SPR	SPRAY
SQC	SQUARE CENTIMETER
STP	STRIP
SUP	SUPPOSITORY
SYR	SYRINGE
TAB	TABLET
TBL	TABLESPOON
TON	TON
TPN	TAMPON
TRC	TRACE
TRO	TROCHE
TSP	TEASPOON
TUB	TUBE
UMG	UNITS PER MILLIGRAM
UNT	UNITS
VIL	VIAL
VPR	VARIES PER REGIMEN
WAF	WAFER
X	HOMEOPATHIC DILUTION (DECIMAL 1/10)
YDL	YARD, LINEAR
YDS	YARD, SQUARE
NS	NOT STATED
MG/ML	MILLIGRAMS PER MILLILITER
C	HOMEOPATHIC DILUTION (CENTESIMAL 1/100)
LM	HOMEOPATHIC DILUTION (FIFTY MILLESIMAL 1/50,000)