## Appendix B: UDI Organizer template from C-CDA Supplemental Templates for UDI

d. This code **MAY** contain zero or one [0..1] **@displayName=**"Expiration Date" (CONF:4437-3401).

The value of the Expiration Date as a time stamp.

3. **SHALL** contain exactly one [1..1] **value** with @xsi:type="TS" (CONF:4437-3395). Note: Expiration Date as a time stamp

Expiration Date as a time stamp.

a. This value **SHALL** contain exactly one [1..1] **@value** (CONF:4437-3402).

## Figure 7: Expiration Date

## 2.7 Implantable Device Status Observation

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.20.22.4.305:2019-06-21 (open)]

Table 15: Implantable Device Status Observation Contexts

Contained By:	Contains:
<u>UDI Organizer</u> (optional)	

This template is intended to be used in addition to the **Product Instance** template urn:oid:2.16.840.1.113883.10.20.22.4.37 to augment the parsed data from the a Unique Device Identifier (UDI). This template is used to exchange the status of the patient's implantable medical device. This status is only relevant to medical devices implanted in the patient's body.

Table 16: Implantable Device Status Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7	'ii:2.16.840.1.	113883.10.2	0.22.4.30	5:2019-06-2	21)
templateId	11	SHALL		4437- 3502	
@root	11	SHALL		4437- 3505	2.16.840.1.113883.10.20.22.4 .305
@extension	11	SHALL		4437- 3506	2019-06-21
code	11	SHALL		<u>4437-</u> <u>3503</u>	
@code	11	SHALL		<u>4437-</u> <u>3507</u>	urn:oid:2.16.840.1.113883.3.2 6.1.1 (NCI Thesaurus (NCIt)) = C160939
@codeSystem	11	SHALL		4437- 3508	2.16.840.1.113883.3.26.1.1
@codeSystemName	01	MAY		4437- 3509	NCI Thesaurus
@displayName	01	MAY		<u>4437-</u> <u>3510</u>	Implantable Device Status
value	11	SHALL	CD	4437- 3504	urn:oid:2.16.840.1.113883.3.2 6.1.1 (NCI Thesaurus (NCIt))
@code	01	SHALL		<u>4437-</u> <u>3511</u>	
@codeSystem	11	SHALL		<u>4437-</u> <u>3512</u>	2.16.840.1.113883.3.26.1.1
@sdtc:valueSet	01	SHOULD		<u>4437-</u> <u>3539</u>	2.16.840.1.113762.1.4.1021.4 8

- 1. **SHALL** contain exactly one [1..1] **templateId** (CONF:4437-3502).
  - a. This templateId **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.305" (CONF:4437-3505). Note: template oid

Revision from "2018-05-01".

- b. This templateId **SHALL** contain exactly one [1..1] **@extension=**"2019-06-21" (CONF:4437-3506).
- 2. **SHALL** contain exactly one [1..1] **code** (CONF:4437-3503). Note: Code for "Implantable Device Status"

Code used to specify the **Implantable Device Status**.

a. This code **SHALL** contain exactly one [1..1] **@code**="C160939" Implantable Device Status (CodeSystem: NCI Thesaurus (NCIt) urn:oid:2.16.840.1.113883.3.26.1.1 **STATIC**) (CONF:4437-3507).

- b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.3.26.1.1" (CONF:4437-3508).
- c. This code **MAY** contain zero or one [0..1] @codeSystemName="NCI Thesaurus" (CONF:4437-3509).

Implantable Device Status

d. This code **MAY** contain zero or one [0..1] **@displayName**="Implantable Device Status" (CONF:4437-3510).

The status of the device in the body of the patient. This status augments the overall status of the device active/inactive specified in the UDI organizer.

3. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD", where the code **SHALL** be selected from CodeSystem NCI Thesaurus (NCIt) (urn:oid:2.16.840.1.113883.3.26.1.1) (CONF:4437-3504).

Allowed values specified on value set 2.16.840.1.113762.1.4.1021.48:

Active (C45329)

Inactive (C154407)

Malfunctioning (C122711)

Reduced Function (C160942)

- a. This value **SHALL** contain zero or one [0..1] @code (CONF:4437-3511).
- b. This value **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.3.26.1.1" (CONF:4437-3512).
- c. This value **SHOULD** contain zero or one [0..1] @sdtc:valueSet=" 2.16.840.1.113762.1.4.1021.48" (CONF:4437-3539).

## Figure 8: Implantable Device Status