

Change request

Medical Device

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Dataset Release	2024.1	Consulted expert	-

1 Change request input / rationale

Medical devices can use software for specific tasks. The software might be different between devices. We suggest for better specification the composedOf *software*.

2 Comparison to other standards/data models

2.1 SNOMED CT

The composedOf software is defined in SNOMED CT as follows: 706689003 | Application program software (physical object) |.

2.2 NCI Thesaurus

In the NCI Thesaurus, there is the following definition for software “A set of coded instructions, which a computer follows in processing data, performing an operation, or solving a logical problem, upon execution of the program.” Source: [NCI Thesaurus \(nih.gov\)](https://ncit.nci.nih.gov/)

3 Change content

3.1 Currently released concept

Concept or concept compositions or inherited	General concept name	General description	Contextualized concept name	Contextualized description	Type	Standard	Value set or subset	Meaning binding
concept	Medical Device	product intended for medical use when the main effect is not achieved by a medicinal product; medical devices include, but are not limited to, implants, instruments, devices, in vitro diagnostics	Medical Device	product intended for medical use when the main effect is not achieved by a medicinal product; medical devices include, but are not limited to, implants, instruments, devices, in vitro diagnostics				SNOMED CT: 63653004 Biomedical device (physical object)

composedOf	type code	code, name, coding system and version describing the type of the concept	type identifier	code, name, coding system and version used to describe the medical device type	Code	SNOMED CT or other	for SNOMED CT : descendant of: 272181003 Clinical equipment and/or device (physical object)	LOINC: 66464-9 Medical device type [PhenX]
composedOf	product code	code, name, coding system and version describing the product of the concept	product identifier	code, name, coding system and version used to describe the medical device product	Code			

3.2 Proposed new concept

Concept or concept compositions or inherited	General concept name	General description	Contextualized concept name	Contextualized description	Type	Standard	Value set or subset	Meaning binding	Cardinality for composed Of
concept	Medical Device	product intended for medical use when the main effect is not achieved by a medicinal product; medical devices include, but are not	Medical Device	product intended for medical use when the main effect is not achieved by a medicinal product; medical devices include, but are not				SNOMED CT: 63653004 Biomedical device (physical object)	

		limited to, implants, instruments, devices, in vitro diagnostics		limited to, implants, instruments, devices, in vitro diagnostics					
composedOf	type code	coded information specifying the type of the concept	type identifier	code, name, coding system and version used to describe the medical device type	Code	SNOMED CT or other	for SNOMED CT : descendant of: 272181003 Clinical equipment and/or device (physical object)	LOINC: 66464-9 Medical device type [PhenX]	0:1
composedOf	product code	coded information specifying the product of the concept	product identifier	code, name, coding system and version used to describe the medical device product	Code				0:1
composedOf	software	software associated to the concept	software	software pertaining to the operation of the medical device	Software				0:1

General Concept name	Cardinality for concept to Administrative Case	Cardinality for concept to Data Provider Institute	Cardinality for concept to Subject Pseudo Identifier
Medical Device	-	-	-

4 Pros and cons

4.1 Advantages

The concept *Software* is a new proposed concept. This is used in the Medical Device concept as a composedOf to provide holistic information of the used medical device.

4.2 Disadvantages

n.a.

5 Impact on SPHN Dataset

This is a change request on an existing concept. All concepts using *Medical Device* as a composedOf will be affected.

6 Discussion

The composedOf *software* captures additional information of a medical device. A new concept *Software* is suggested. We think the implementation of this concept as a composedOf in the *Medical Device* improves data interpretation.

7 Example

Medical Device

type code:

identifier: 468143004

name: Diagnostic spirometer (physical object)

coding system and version: SNOMED-CT-2023-03-10

product code:

identifier: -

name: -

coding system and version: -

software:

name: Sentry suite

description: -

url: -

version: 3.20.3