Integrating the Healthcare Enterprise

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IHE Radiology
Technical Framework Supplement

Digital Breast Tomosynthesis
(DBT)

10

Trial Implementation

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25   **Please verify you have the most recent version of this document.** See here for Trial Implementation and Final Text versions and here for Public Comment versions.

Foreword

This is a supplement to the IHE Radiology Technical Framework V12.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into
30   the volumes of the Technical Frameworks.

This supplement is published on May 30, 2014 for trial implementation and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the Radiology Technical Framework. Comments are invited and can be submitted at
35   http://www.ihe.net/Radiology_Public_Comments.

This supplement describes changes to the existing technical framework documents.

"Boxed" instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume.

Amend Section X.X by the following:

40   Where the amendment adds text, make the added text **bold underline**. Where the amendment removes text, make the removed text **bold strikethrough**. When entire new sections are added, introduce with editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.

45   General information about IHE can be found at: www.ihe.net.

Information about the IHE Radiology domain can be found at: ihe.net/IHE_Domains.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at: http://ihe.net/IHE_Process and http://ihe.net/Profiles.

50   The current version of the IHE Radiology Technical Framework can be found at: http://www.ihe.net/Technical_Frameworks.

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Introduction to this Supplement

The Digital Breast Tomosynthesis (DBT) Profile specifies the creation, exchange and use of DBT images. It defines basic display capabilities that Image Displays are expected to provide, especially simultaneous review of DBT and conventional 2D mammography images (FFDM).

The Digital Breast Tomosynthesis Profile is designed to provide faithful storage and retrieval of DBT images. Furthermore, sufficient display functionality to allow adequate review of current and prior studies consisting of DBT and/or conventional 2D mammography images is defined. The support for CAD is out of the scope for this profile.

Open Issues and Questions

1. *Table 4.8.4.1.2.7-1 was copied from a pre-approved version of DICOM CP 1299. The final version of this CP does not include this table anymore. However I think information like this is necessary to distinguish DBT images based on how they were derived. Therefore I kept this table and we can discuss how to modify it, that it meets our needs.*

    We created an updated version of this table which matches DICOM CP 1342. When this CP is approved we need to make sure, that the table is aligned with the final version of that CP.

2. *Should the Evidence Creator participate in the For Processing Breast Projection X-Ray Images Option? If so what transactions and functionality should it be required to support?*

Closed Issues

1. *Should this supplement be a new profile or a named option for the Mammography Image Profile?*

    Due to the complexity of this supplement and possible options for it (e.g., flagging key images) and in order to keep it aligned with MAMMO and SMI it was decided to create a new profile rather than an option.

2. *Is support for the Breast Projection X-Ray Image SOP classes needed?*

    During our discussions with clinical users it was pointed out that due to the limited amount of time for reviewing screening mammography cases, the projection images are not reviewed; therefore their use will not be mandated in this supplement.

3. *Do we need to distinguish between generated 2D images and conventional 2D mammography images or can they be treated the same?*

    Since there will be a transition period until clinical users are confident to just use the generated 2D images, it was decided to keep those separated for now.

4. *Should export to media and basic image reviewing be in the scope of this profile?*

No, there should not be any specific behavior defined in this profile, however in the section for Cross Profile Considerations some explanation should be given.

5. *Should this profile address 3D visualization (Volume Rendering, Multiplanar Reformatting …)?*

175   No, this is a broader problem, which impacts multiple other modalities as well, and therefore, if necessary should be addressed in a general profile on 3D.

6. *Should the profile support flagging of key images?*
According to clinical users, this would be a helpful feature. Therefore two uses cases should be taken into account:

180   a) Screening review, when the user wants to start scrolling through the case and not directly go to the key images.
b) Review of key images only.

7. *Should lossless compression be supported?*

185   In order to fulfill performance requirements Acquisition Modalities, Evidence Creators and Image Display Actors should be free to decide whether they create/display images with lossless compression. However the Image Manager/Archive needs to support both, compressed and uncompressed images and needs to be able to convert on the fly when sending to the Image Display.

8. *How do we address different reconstructions of DBT images (e.g., slabs)?*

190   It was decided to add an Evidence Creator Actor, which can generate different reconstructions of the DBT image. It is possible to either group the Acquisition Modality or the Image Display with this actor. Furthermore, this actor can be a standalone workstation. For the latter scenario it is out of scope to define, how this workstation accesses the images.

195   9. *Are there use cases for printing DBT images?*

Clinical users are interested in printing key images only, not the complete DBT data set. True size, same size and printing of annotated images shall be supported.

10. *Do contrast adjustments need to be performed on a per frame basis or for the complete DBT data set?*

200   Window/Level and VOI LUTs can be applied on a frame by frame basis; therefore those attributes can either be in the Shared or the Per Frame Functional Groups Sequence.

11. *Are partial views relevant to tomosynthesis?*

Yes, they will be treated the same way as for conventional 2D mammography images.

12. *Is there a use case, which mandates the use of DICOM Concatenation?*

205   No, all images are needed prior to starting the review (e.g., in order to evaluate asymmetries), therefore splitting up data sets in order to allow for faster review is not necessary.

13. How is this supplement best documented, using the current template (e.g., as done in the SMI Profile) or should it be defined as a pure content profile?

210   Current decision is to follow the approach that was taken in the SMI Profile, however in future, if there is a template for DICOM Content Profiles this supplement may be re-written to follow that template.

14. Shall Storage of Breast Projection X-Ray Images be a named option, or should we just reference it as an optional SOP Class?

215   It was decided to make support for Breast Projection X-Ray Images a named option in order to address use cases for creating additional reconstructions based on these images, for review, for tomosynthesis CAD and for use in technical problem solving.

15. What is a good name for synthetic images?

It was decided to use generated 2D images.

220   *16. Do we need to add additional procedure codes for tomosynthesis studies to the [Rad 5] Query Modality Worklist Transaction? Or are studies including DBT still classified as "Screening Mammography"*

It was decided to add exam codes for combined 2D and 3D acquisitions:

- Bilateral FFDM combined with tomosynthesis diagnostic

225   - Bilateral FFDM combined with tomosynthesis screening

- Left FFDM combined with tomosynthesis diagnostic

- Left FFDM combined with tomosynthesis screening

- Right FFDM combined with tomosynthesis diagnostic

- Right FFDM combined with tomosynthesis screening

230   *17. Since the Breast Tomosynthesis Image IOD and the Breast Projection X-Ray Image IOD are well defined with regards to Attribute Type requirements, should we list those tables in Transaction [Rad-8] Modality Images Stored?*

It was decided to keep the detailed tables and list attribute requirements that are relevant in the context of the 1999 ACR Quality Control Manual for Mammography.

235   *18. How do we potentially address performance requirements?*

Some informative text was added in the use case section to state the importance of performance and what the goal would be (instantaneous scrolling/switching, between slices, images and cases)

19. For the section on Image Orientation and Justification: Does the DBT image always
240   *consist of parallel slices or can they have different Image Orientation (Patient)(0020, 0037) in the Plane Orientation Sequence (0020,9116) values. If they are always parallel should we mandate the Plane Orientation Sequence to part of the Shared Functional Groups Sequence?*

245 Limit to just parallel slices for now and therefore mandate, that this information is stored in the Shared Functional Groups Sequence.

20. *What do we need to say about CAD? In theory one could perform CAD on DBT images and encode the results using SCOORD and the Referenced Frame number in the IMAGE in the existing Mammography CAD SR. Is this the way that tomosynthesis CAD will be defined or would it rather be done on the Projection Images and then 'translated' to the*
250 *DBT image coordinate system using SCOORD3D and a reference Coordinate System?*

CAD is out of the scope of this profile. 2D CAD is addressed in the MAMMO Image Profile and therefore all references to CAD will be removed in this supplement

21. *Mammography Acquisition Workflow depends on Mammo Image for Content Creation and display. Should it depend on Mammo Image, DBT, or both?*

255 Since MAWF is still in Trial Implementation and not very well adapted, we stay silent about this issue at the moment

22. *We decided to allow storage of generated 2D images in both SOP Classes (Tomosynthesis and MG). Do we need to know, that two images are the same, if so, which attributes do we need to mandate, in order to make sure, that two images*
260 *represent the same content, what values do they need to have?* (Section 4.8.4.1.2.7)

Both images will reference each other using the Reference Image Sequence and using Purpose of Reference Code Sequence (0040, A170) item shall have a value of ("121326, DCM, Alternate SOP Class Instance").

After additional discussions it was decided to only mandate storage using the Breast
265 Tomosynthesis Image Storage SOP Class. Therefore nothing will be said about MG and potential references.

23. *What is the relationship between Image Type and Frame Type in the X-Ray 3D Frame Type Sequence (see Table 4.8.4.1.2.7-2)? Which one should we use: Image Type or Frame Type, if Frame Type should this be a shared value or a per frame value. If both*
270 *are used should we state that they need to have the same value?*

We decided not to allow for different Frame Type values within one image instance and therefore to just use Image Type values to distinguish between different reconstruction types for tomosynthesis images.

24. *Should we add the table that defines the values of Image Type/Volumetric*
275 *Properties/Volume Based Calculation Technique (Table 4.8.4.1.2.7-2) to be used for the various types of reconstructions in this chapter, currently it is in Section 4.16.4.2.2.1.3.5.2?*

An updated version of that table was generated and moved to Section 4.8.4.1.2.7. The table is solely based on Image Type values; Volumetric Properties and Volume Based
280 Calculation Technique are not used.

25. *In Table 4.8.4.1.2.7-2 is the Relative X-Ray Exposure in the Per Projection Acquisition Sequence needed, or will we just display cumulative dose information and therefore remove this Sequence and the item?*

It was decided to just use the cumulative values for tomosynthesis images.

285 26. *Since additional breast tomosynthesis images can be derived from either the FOR PROCESSING breast projection X-Ray images or from a thin slice breast tomosynthesis image, do we need to annotate them differently depending on the object type that was used to generate them? How would those be distinguished in the DICOM header (another item in the Contributing Sources Sequence, differences in the Image Type*
290 *attribute)? Can it be done based on Value 1 of Image Type (e.g., using ORIGINAL vs DERIVED)?*

It was decided that this is not relevant.

27. *In Section 4.16.4.2.2.1.3.5.2: Is the Primary Positioner Scan Start Angle what is really clinically relevant or would it rather be the 'middle'- angle of the tomosynthesis*
295 *acquisition? If so, how would this be derived, since this information is not in the DBT image?*

We decided to additionally mandate the use of the Primary Positioner Scan Arc so that the relevant angles can be calculated.

28. *In Table 4.8.4.1.2.7-2.1: Do we need Image Type/Frame Type for Breast Projection X-*
300 *Ray Images at all? Do we make use of it, or should we just remove it, since we don't use it in this profile?*

We decided to use Image Type Value 3 to mark images as projection images

29. *In Section 4.16.4.2.2.1.3: If a generated 2D image is available as both (tomosynthesis image and MG image), which one should be displayed, I assumed it would be the*
305 *tomosynthesis images, is that true?*

The Image Display shall display one of the two images, it can decide which one.

Later it was decided to use only the Breast Tomosynthesis Image SOP Class for this profile.

30. *How should this profile be named?*

310 For now we decided on Digital Breast Tomosynthesis (DBT).

31. *We need to think about what to say about measurements and its accuracy on DBT images.*

Measurements performed on a 2D MG image based on Imager Pixel Spacing and Estimated Radiographic Magnification Factor slightly differ depending on where the
315 measured object is located (next to the detector or next to the paddle) due to projection characteristics.
Measurements performed on a DBT slice based on Pixel Spacing are accurate and

independent of the location of the measured object. (Pixel Spacing is the distance in the patient!)

320   *32. Are there any MQSA or other regulatory requirements that need to be taken into account? Are there any other international regulatory requirements?*

No additional requirements have been identified.

33. To simplify the task of the image display and to provide sufficient technique information for DBT images to the users we decided to require the information that is common to all
325   *projections (e.g., aggregate exposure values) be encoded by the modality and not to require per projection acquisition information for display purposes. Is this okay for all modality vendors?*

Accumulated values are sufficient.

34. In Table 4.8.4.1.2.7-4: Should JPEG-LS be supported by this profile. We also added
330   *support for lossy transfer syntaxes (JPEG 2000 lossy, JPEG Extended (Process 2 & 4) to this table. Is it appropriate to keep these?*

Support for JPEG-LS is not needed in this profile; the other transfer syntaxes will be supported in this profile.

35. Should we allow multi-pass perfusion studies in one tomosynthesis image instance or
335   *should we limit each tomosynthesis image instance to a single pass (i.e., should it be possible to have multiple slices at the same location within an image instance)?Closed only single pass*

Only single pass studies are supported.

36. Section 4.16.4.2.2.1.3.10 addresses display features for Projection images. Are all these
340   *features needed for use cases relevant to projection images?*

All features are supported except automatic scrolling (cine).

37. Section 4.16.4.2.2.1.3.10: what do we need to say about scrolling, I assume mostly the Section 4.16.4.2.2.1.3.9 applies but it may have to be extended to address simultaneous scrolling between projection images and tomosynthesis slices, I assume this should be
345   *disabled. Is there anything specific that needs to be said to parallel display of tomosynthesis slices with Projection Images?*

Simultaneous scrolling between projection images and tomosynthesis slices and automatic scrolling (cine) of projection images are not supported by this profile. Otherwise the scrolling behavior is the same.

350   *38. Should the User Annotation Option/use case subsume key image use cases? Would a user flag a key image/frame without performing an annotation?*

Both use cases have to be supported according to clinical user feedback.

39. Should the functionality to flag key images/frames be an option or should it be baseline functionality?

355   It was decided to keep it as an option based on public comment feedback.

40. *We need a better term for „generated 2D images" as a name for mathematically derived 2D images from a tomosynthesis acquisition. Any suggestions?*

We decided to use "generated 2D".

41. *How do we best document support for specific transfer syntaxes?*

360   Current text is okay, no changes are needed.

42. *In Table 4.8.4.1.2.7-2.1: For Breast Projection X-Ray Images dose information is stored in the X-Ray Dose Acquisition Sequence on a per frame basis as well as in the Enhanced Mammography Image Module as cumulative values. Do we need the per- frame information or do we just need the cumulative values?*

365   The decision was to use the information on a per frame basis.

43. *In Table 4.5-5 a set of codes for combination studies (tomosynthesis and conventional mammography) have been added. Do we also need codes for just tomosynthesis studies? Should we also transition to SNOMED or other standard codes rather than IHE specific codes?*

370   Table was updated to use LOINC or RadLex codes where available.

44. *Currently the Media Creator Option mandates that viewers copied on media need to provide display capabilities described in this supplement. However this might be too much for viewers on extern media. Shall we define a minimal set of requirements needed for these viewers?*

375   Section 4.16.4.2.2.1.3.11 was added to address a set of minimal viewer requirements.

General Introduction

Update the following appendices to the General Introduction as indicated below. Note that these are not appendices to Volume 1.

Appendix A – Actor Summary Definitions

380 *Add the following actors to the IHE Technical Frameworks General Introduction list of actors:*

There are no new actors in this supplement.

Appendix B – Transaction Summary Definitions

Add the following transactions to the IHE Technical Frameworks General Introduction list of Transactions:

385 There are no new transactions in this supplement.

Glossary

Add the following glossary terms to the IHE Technical Frameworks General Introduction Glossary:

Glossary Term	Definition
CAD	Computer Aided Detection
Conventional 2D mammography	Refers to mammography images that have been acquired using FFDM
DBT	Digital Breast Tomosynthesis
FFDM	Full Field Digital Mammography
Slab	A thick slice tomosynthesis reconstruction (e.g., greater than 1mm)

Volume 1 – Profiles

390

Add the following to the IHE Technical Frameworks General Introduction Copyright Section:

NA

Domain-specific additions

None

395

Add Section 37 …

37 Digital Breast Tomosynthesis (DBT)

The Digital Breast Tomosynthesis (DBT) Profile specifies the creation, exchange and use of DBT images. It defines basic display capabilities that Image Displays are expected to provide, especially simultaneous review of DBT and conventional 2D mammography images (FFDM).

The Digital Breast Tomosynthesis Profile is designed to provide faithful storage and retrieval of DBT images. Furthermore, sufficient display functionality to allow adequate review of current and prior studies consisting of DBT and/or conventional 2D mammography images is defined. The support for CAD is out of the scope for this profile.

37.1 DBT Actors, Transactions, and Content Modules

This section defines the actors, transactions, and/or content modules in this profile.

Figure 37.1-1 shows the actors directly involved in the Digital Breast Tomosynthesis Profile and the relevant transactions between them. If needed for context, other actors that may be indirectly involved due to their participation in other related profiles are shown in dotted lines. Actors which have a mandatory grouping are shown in conjoined boxes.
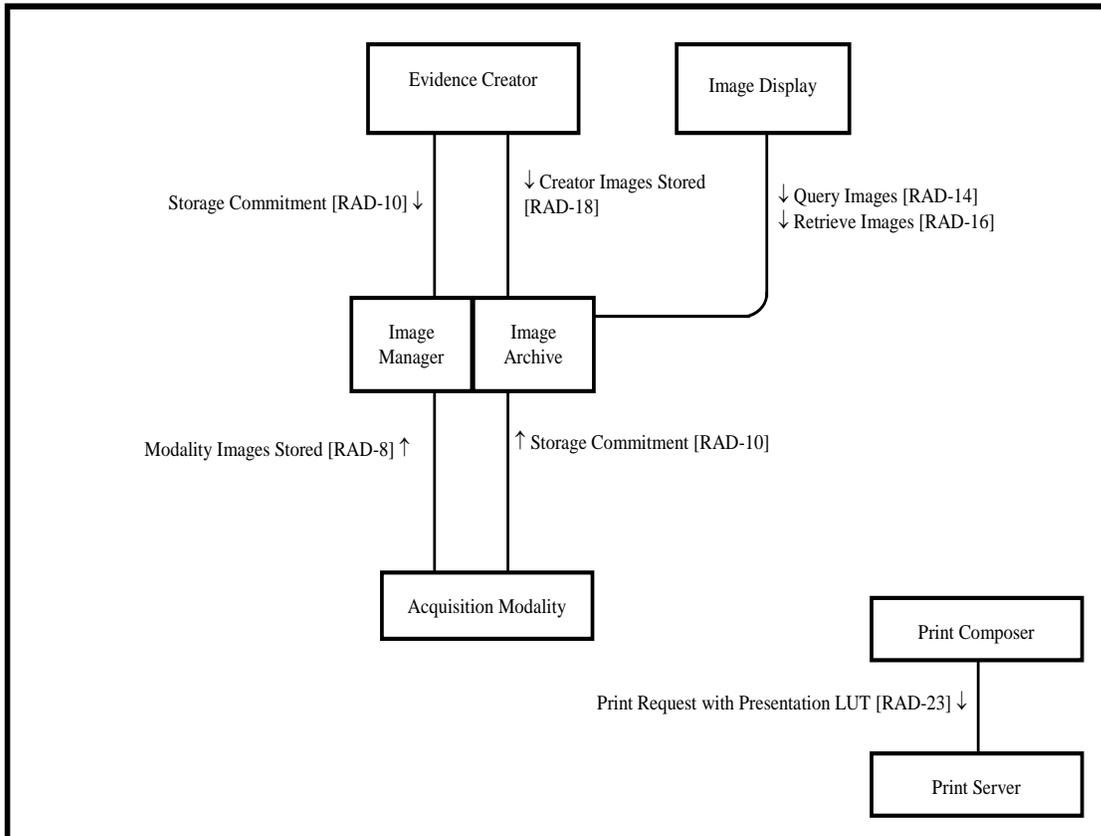
Figure 37.1-1: DBT Actor Diagram

415

Table 37.1-1 lists the transactions for each actor directly involved in the Digital Breast Tomosynthesis Profile. To claim compliance with this profile, an actor shall support all required transactions (labeled "R") and may support the optional transactions (labeled "O").

420   **Table 37.1-1: DBT Profile - Actors and Transactions**

Actors	Transactions	Option-ality	Reference
Acquisition Modality	Modality Images Stored [RAD-8]	R	RAD TF-2: 4.8
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
Evidence Creator	Creator Images Stored [RAD-18]	R	RAD TF-2: 4.18
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
Image Manager/Archive	Modality Images Stored [RAD-8]	R	RAD TF-2: 4.8
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
	Query Images [RAD-14]	R	RAD TF-2: 4.14
	Retrieve Images [RAD-16]	R	RAD TF-2: 4.16
	Creator Images Stored [RAD-18]	R	RAD TF-2: 4.18

Actors	Transactions	Option-ality	Reference
Image Display	Query Images [RAD-14]	R	RAD TF-2: 4.14
	Retrieve Images [RAD-16]	R	RAD TF-2: 4.16
Print Composer	Print Request with Presentation LUT [RAD-23]	R	RAD TF-2: 4.23
Print Server	Print Request with Presentation LUT [RAD-23]	R	RAD TF-2: 4.23

37.1.1 Actor Descriptions and Actor Profile Requirements

Most requirements are documented in Transactions (Volume 2 and 3). This section documents any additional requirements on this profile's actors.

37.1.1.1 Acquisition Modality

The Acquisition Modality Actor acquires breast projection X-Ray images and generates tomosynthesis images. Storage of the breast projection X-Ray images for tomosynthesis is optional.

The Acquisition Modality can optionally acquire conventional 2D mammography images or generate a 2D image mathematically from tomosynthesis data. Creation and storage of conventional 2D mammography images is facilitated by grouping the Acquisition Modality in the DBT Profile with an Acquisition Modality from the Mammography Image Profile (see RAD TF-1: 19).

In order to generate and store additional derived tomosynthesis reconstructions (e.g., slabs), the Acquisition Modality can be grouped with an Evidence Creator Actor.

37.1.1.2 Image Manager/Archive

The Image Manager/Archive Actor receives breast tomosynthesis images, conventional 2D mammography images, 2D images generated mathematically from tomosynthesis data, and optionally breast projection X-Ray images for tomosynthesis from the Acquisition Modality or an Evidence Creator Actor, responds to query requests, and stores requested image data to an Image Display.

37.1.1.3 Image Display

The Image Display Actor retrieves breast tomosynthesis images as well as 2D images generated mathematically from tomosynthesis data and/or conventional 2D mammography images from the current and prior exams and displays them. The Image Display can be grouped with an Evidence Creator Actor in order generate derived tomosynthesis reconstructions (e.g., slabs).

37.1.1.4 Evidence Creator

Evidence Creator Actors generate derived tomosynthesis reconstructions (e.g., slabs). The Evidence Creator can be grouped with the Acquisition Modality or the Image Display in order to access the images. If the Evidence Creator is a stand-alone system, the workflow to get access to the images is out of scope for this profile. The Evidence Creator uses the Creator Images Stored transaction [RAD-18] to store these reconstructions.

37.1.1.5 Print Composer

Print Composer Actors assemble film sheets of the selected key images and send print requests to a Print Server. A Print Composer can be grouped with an Image Display in order to get access to the key images. If the Print Composer is a stand-alone system, the workflow to get access to the key images is out of scope for this profile.

37.1.1.6 Print Server

The Print Server Actor processes the print requests from a Print Composer Actor.

37.2 DBT Actor Options

Table 37.2-1: DBT - Actors and Options

Actor	Option Name	Reference
Acquisition Modality	Partial View	RAD TF-1:37.2.2
	For Presentation Breast Projection X-Ray Images	RAD TF-1:37.2.3
	For Processing Breast Projection X-Ray Images	RAD TF-1:37.2.4
	Media Creation	RAD TF-1:37.2.6
Evidence Creator	No options defined	--
Image Manager/Archive	Key Images	RAD TF-1:37.2.1
	For Presentation Breast Projection X-Ray Images	RAD TF-1:37.2.3
	For Processing Breast Projection X-Ray Images	RAD TF-1:37.2.4
	User Annotation	RAD TF-1:37.2.5
Image Display	Key Images	RAD TF-1:37.2.1
	Partial View	RAD TF-1:37.2.2
	For Presentation Breast Projection X-Ray Images	RAD TF-1:37.2.3
	User Annotation	RAD TF-1:37.2.5
	Media Creation	RAD TF-1:37.2.6
Print Composer	No options defined	--

Actor	Option Name	Reference
Print Server	No options defined	--

37.2.1 Key Images Option

465   The Key Images Option enables users to mark key images or frames of a breast tomosynthesis image by attaching a Key Image Note and provide them for display. The functionality is defined in the Key Image Note Profile (RAD TF-1:8); therefore this functionality is achieved by grouping with relevant actors from the Key Image Note Profile:

- Image Displays that support creation of Key Image Notes shall be grouped with an
470   Evidence Creator in the Key Image Note Profile and shall be able to create and store Key Image Notes for one or more of the SOP classes in RAD TF-2: Table 4.16.4.1.3.7-1.

- Image Displays that support rendering of Key Image Notes shall be grouped with an Image Display Actor in the Key Image Note Profile and shall be able to query, retrieve and render Key Image Notes for one or more of the SOP classes in RAD TF-2: Table
475   4.16.4.1.3.7-1.

- Image Manager/Archives that support storage and retrieval of Key Image Notes shall be grouped with an Image Manager/Archive Actor in the Key Image Note Profile to enable storage/retrieval of the Key Object Selection Document.

37.2.2 Partial View Option

480   The Partial View Option addresses the creation and display of mosaic images.

It defines additional attributes which the Acquisition Modality includes in the image headers in order to indicate whether an image is part of a mosaic and which part of the set the image represents as defined in RAD TF-2: 4.8.4.1.2.7.1 Partial View Option.

Furthermore, it defines how Image Display Actors make use of this information to annotate the
485   images in the viewport as defined in RAD TF-2: 4.16.4.2.2.1.3.7 Partial View Option.

37.2.3 For Presentation Breast Projection X-Ray Images Option

The For Presentation Breast Projection X-Ray Images Option addresses the creation, retrieval and display of breast projection X-Ray images acquired for the purpose of tomosynthesis to identify the source of image quality issues, such as patient motion.

490   Acquisition Modalities and Image Manager/Archives that support this option shall implement the requirements for creation and storage of breast projection X-Ray images as defined in RAD TF-2: 4.8.4.1.2.7.2 Breast Projection X-Ray Images Options.

Image Displays that support this option shall implement the requirements for retrieval and display of breast projection X-Ray images as defined in RAD TF 2: 4.16.4.2.2.1.3.10.

495 **37.2.4 For Processing Breast Projection X-Ray Images Option**

The For Processing Breast Projection X-Ray Images Option addresses the creation and retrieval of breast projection X-Ray images acquired for the purpose of tomosynthesis in order to create retrospective reconstructions of tomosynthesis slices from projection images.

500 Acquisition Modalities and Image Manager/Archives that support this option shall implement the requirements for creation and storage of breast projection X-Ray images as defined in RAD TF-2: 4.8.4.1.2.7.2 Breast Projection X-Ray Images Options.

37.2.5 User Annotation Option

The User Annotation Option allows users to perform annotation on key images or frames of a breast tomosynthesis image, store it as a Grayscale Softcopy Presentation State, and provide it
505 for display. The functionality is defined in the Consistent Presentation of Images Profile (RAD TF-1:5); therefore this functionality is achieved by grouping with relevant actors from the Consistent Presentation of Images Profile:

- Image Displays that support creation of Grayscale Softcopy Presentation State objects shall be grouped with an Evidence Creator in the Consistent Presentation of Images
510 Profile and shall be able to create and store GSPS objects for one or more of the SOP Classes in RAD TF-2: Table 4.16.4.1.3.7-1.

- Image Displays that support rendering of Grayscale Softcopy Presentation State objects shall be grouped with an Image Display Actor in the Consistent Presentation of Images Profile and shall be able to query, retrieve and render GSPS objects for one or more of
515 the SOP Classes in RAD TF-2: Table 4.16.4.1.3.7-1.

- Image Manager/Archives that support storage and retrieval of Grayscale Softcopy Presentation State objects shall be grouped with an Image Manager/Archive Actor in the Consistent Presentation of Images Profile to enable storage/retrieval of the Grayscale Softcopy Presentation State objects.

520 **37.2.6 Media Creation Option**

The Media Creation Option allows users to export breast tomosynthesis studies to external media. The functionality is defined in the Portable Data for Imaging Profile (Rad TF-1:15); therefore this functionality is achieved by grouping with relevant actors from the Portable Data for Imaging Profile:

525 - Acquisition Modalities or Image Displays that support creation of external media shall be grouped with a Portable Media Creator Actor in the Portable Data for Imaging Profile.

- The Portable Media Creator shall be capable of encoding on the media all of the SOP Classes that are required to be supported by the Digital Breast Tomosynthesis Profile (which are defined in the Modality Images Stored and Retrieve Images transactions).

530   •   If the Key Images Option is also supported, the Portable Media Creator shall be capable of encoding on the media instances of the Key Object Selection Document Storage SOP Class.

•   If the User Annotation Option is also supported, the Portable Media Creator shall be capable of encoding on the media instances of the Grayscale Softcopy Presentation State
535   Storage SOP Class.

If a viewer is added to the media in addition to the breast tomosynthesis study, the viewer shall fulfill the Image Display requirements defined in RAD TF-2: 4.16.4.2.2.1.3.11.

37.3 DBT Required Actor Groupings

An actor from this profile (Column 1) shall implement all of the required transactions and/or
540 content modules in this profile in addition to all of the transactions required for the grouped actor (Column 2).

If this is a content profile, and actors from this profile are grouped with actors from a workflow or transport profile, the Content Bindings reference column references any specifications for mapping data from the content module into data elements from the workflow or transport
545 transactions.

In some cases, required groupings are defined as at least one of an enumerated set of possible actors; this is designated by merging column one into a single cell spanning multiple potential grouped actors. Notes are used to highlight this situation.

Section 37.5 describes some optional groupings that may be of interest for security
550 considerations and Section 37.6 describes some optional groupings in other related profiles.

Table 37.3-1: DBT - Required Actor Groupings

DBT Actor	Actor to be grouped with	Reference	Content Bindings Reference
Image Manager/Archive	Image Manager/Archive in the Mammography Image Profile	RAD TF-1:19.1	--
Image Display	Image Display in the Mammography Image Profile	RAD TF-1:19.1	--
Acquisition Modality (see Note 1)	Acquisition Modality in the Mammography Image Profile	RAD TF-1:19.1	--

Note 1: Acquisition Modalities that generate conventional 2D mammography images shall be grouped with an Acquisition Modality in the Mammography Image Profile.

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555 **37.4 DBT Overview**

The Digital Breast Tomosynthesis (DBT) Profile specifies the creation, exchange and use of DBT images. It defines basic display capabilities that Image Displays are expected to provide, especially simultaneous review of DBT and conventional 2D mammography images (FFDM).

560 The Digital Breast Tomosynthesis Profile is designed to provide faithful storage and retrieval of DBT images. Furthermore, sufficient display functionality to allow adequate review of current and prior studies consisting of DBT and/or conventional 2D mammography images is defined. The support for CAD is out of the scope for this profile.

37.4.1 Concepts

The Mammography Image Profile provides functionality for faithful storage, retrieval and
565 display of conventional 2D mammography images and associated CAD results. The DBT Profile extends this functionality to support breast tomosynthesis images and images derived from them.

37.4.2 Use Cases

37.4.2.1 Use Case #1: DBT Screening

This use case addresses the basic mammography screening workflow, which includes creation,
570 storage and retrieval of breast tomosynthesis images and optionally conventional 2D mammography images.

37.4.2.2.1 DBT Screening Use Case Description

This use case encompasses a group of scenarios which vary in the number and type of images that are created at the modality and whether a current study only or a current and a prior are
575 reviewed. Each study, current or prior can include one or multiple views of each breast, where one view may contain a set of:

- Tomosynthesis slices

- Tomosynthesis projection images

- Tomosynthesis slabs

580 - Conventional 2D mammography images

- Generated 2D images derived from tomosynthesis data

During the review of a study the radiologist can utilize the available display options, such as contrast adjustments, image sizing changes, etc.

The goal for this use case is to support fast reading of the data, which includes:

585 - Instantaneous scrolling through slices

- Instantaneous switching between images (different views, different image types, prior images)

- Instantaneous switching to the next case.

590 **37.4.2.1.2 DBT Screening Process Flow**
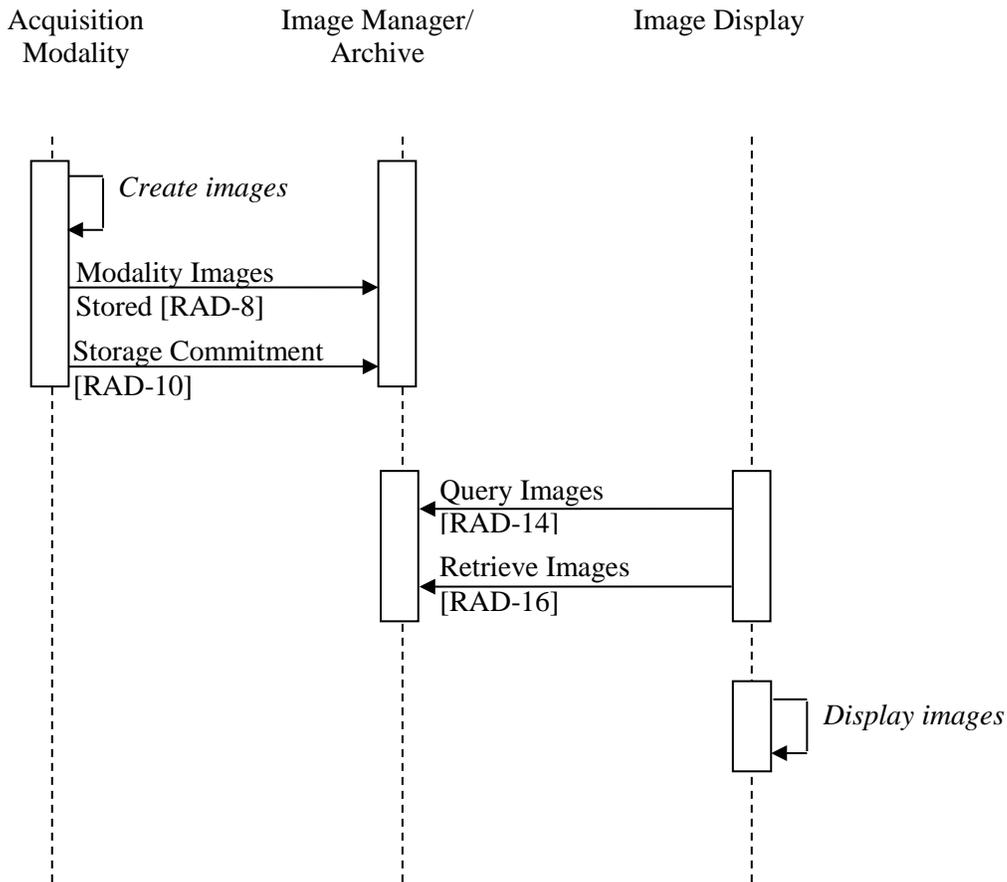
Figure 37.4.2.1.2-1: Process Flow in DBT Screening Use Case

595 **37.4.2.2 Use Case #2: Additional reconstructions**

During review of a study, the radiologist requests another DBT image (reconstruction). This may result in a complete volume or a sub-volume of the acquired DBT data.

37.4.2.2.1 Additional Reconstructions Use Case Description

While reviewing the study, the radiologist identifies the need for additional DBT images using 600 different reconstruction parameters. This can be triggered by the lesion type, by the character of the breast tissue (e.g., fatty or dense), any other clinical information (medication, hormone

status), or just by the image impression of the first DBT image. Using the functionality of their workstation the radiologist creates the additional DBT image(s) (e.g., using a different slice thickness for reconstruction) either covering the complete volume or a sub-volume. The additional images are stored in the PACS.

37.4.2.2.2 Additional Reconstructions Process Flow
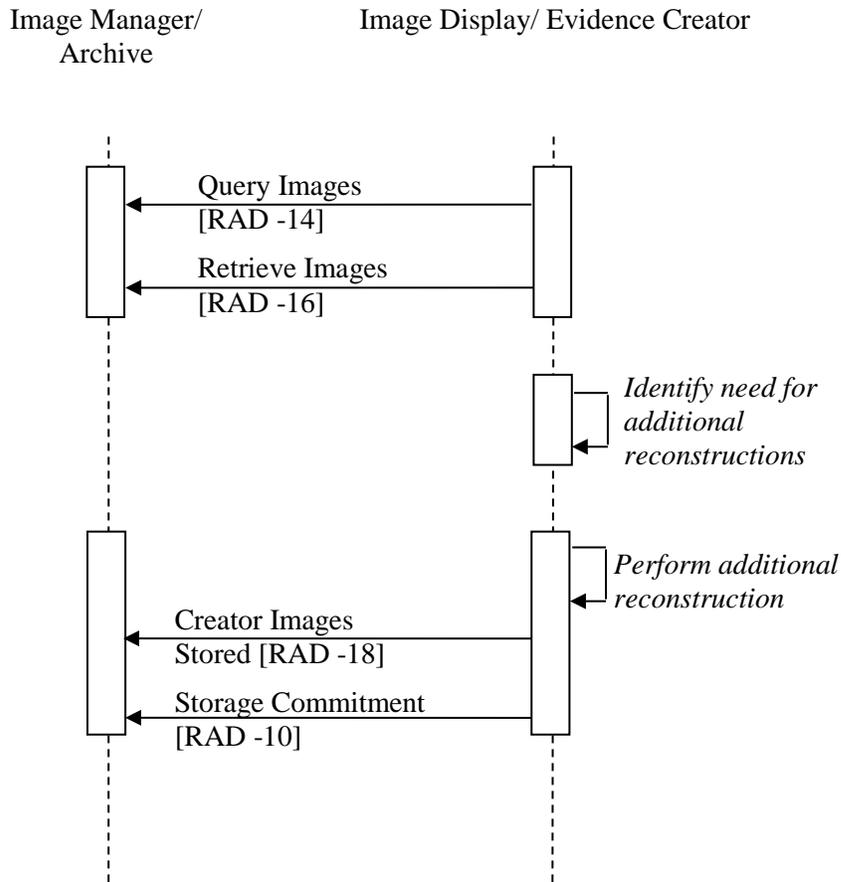
Figure 37.4.2.2.2-1: Process Flow in Additional Reconstructions Use Case

37.4.2.3 Use Case #3: DBT in Diagnostic Mammography

This use case describes acquisition and display of additional DBT images for diagnostic purposes based on the findings in the screening exam.

37.4.2.3.1 DBT in Diagnostic Mammography Use Case Description

Based on findings (e.g., suspected mass, asymmetry) in a conventional 2D mammography or DBT screening study or a palpable finding in the patient, a DBT diagnostic study may be ordered. Exaggerated, rolled, 90-degree (LM, ML) and/or spot compression views are acquired using DBT acquisition or combination 2D/DBT acquisition.

The diagnostic study may contain one or more diagnostic views of a single breast or both breasts, each of which may include a set of:

- Tomosynthesis slices
- Tomosynthesis projection images
- Tomosynthesis slabs
- Conventional 2D mammography images
- Generated 2D images derived from tomosynthesis data

During the review of a study the radiologist can utilize the available display options, such as contrast adjustments, image sizing changes, etc.

37.4.2.3.2 DBT in Diagnostic Mammography Process Flow
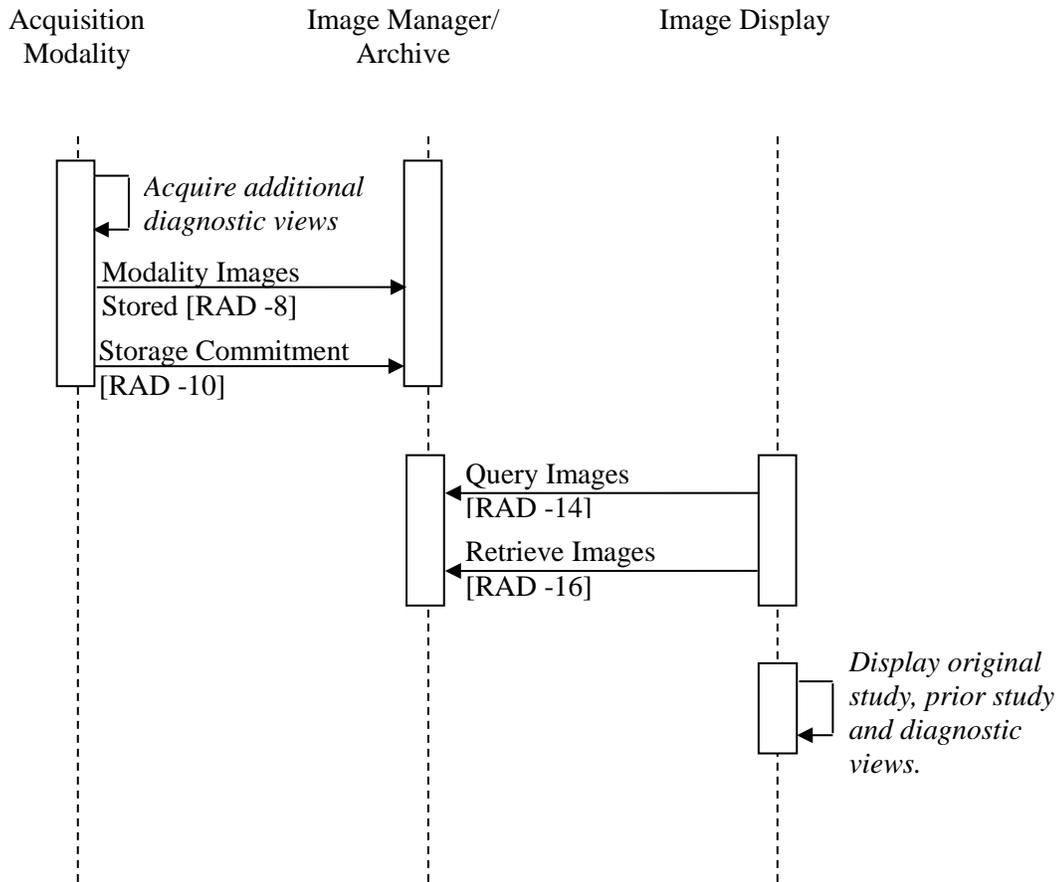
Figure 37.4.2.3.2-1: Process Flow in DBT for Diagnostic Mammography Use Case

630

37.4.2.4 Use Case #4: Key Images in DBT Screening

This use case addresses flagging of key images or frames in the DBT image for further review (e.g., by the referring physician or when asking for a second opinion).

37.4.2.4.1 Key Images in DBT Screening Use Case Description

635 Due to the size of the DBT image, it is helpful to flag key frames for subsequent reviews (e.g., for a second opinion, for a referring physician or even when reviewed as a prior) in order to find relevant frames faster and not miss key frames while scrolling rapidly.

While reviewing a screening exam, the radiologist identifies a lesion that she/he would like a second opinion on. She/he flags the frame which best represents the finding for a secondary

640   review by a colleague. She/he stores the information about the key frame in the Key Image Note and sends it to the PACS.

The second reader retrieves the images and the Key Image Note on the workstation and opens them. By selecting the Key Image Note, the relevant frame is displayed right away for review. Starting from the flagged images she/he reviews surrounding frames and provides feedback to

645   the other radiologist.

37.4.2.4.2. Key Images in DBT Screening Process Flow
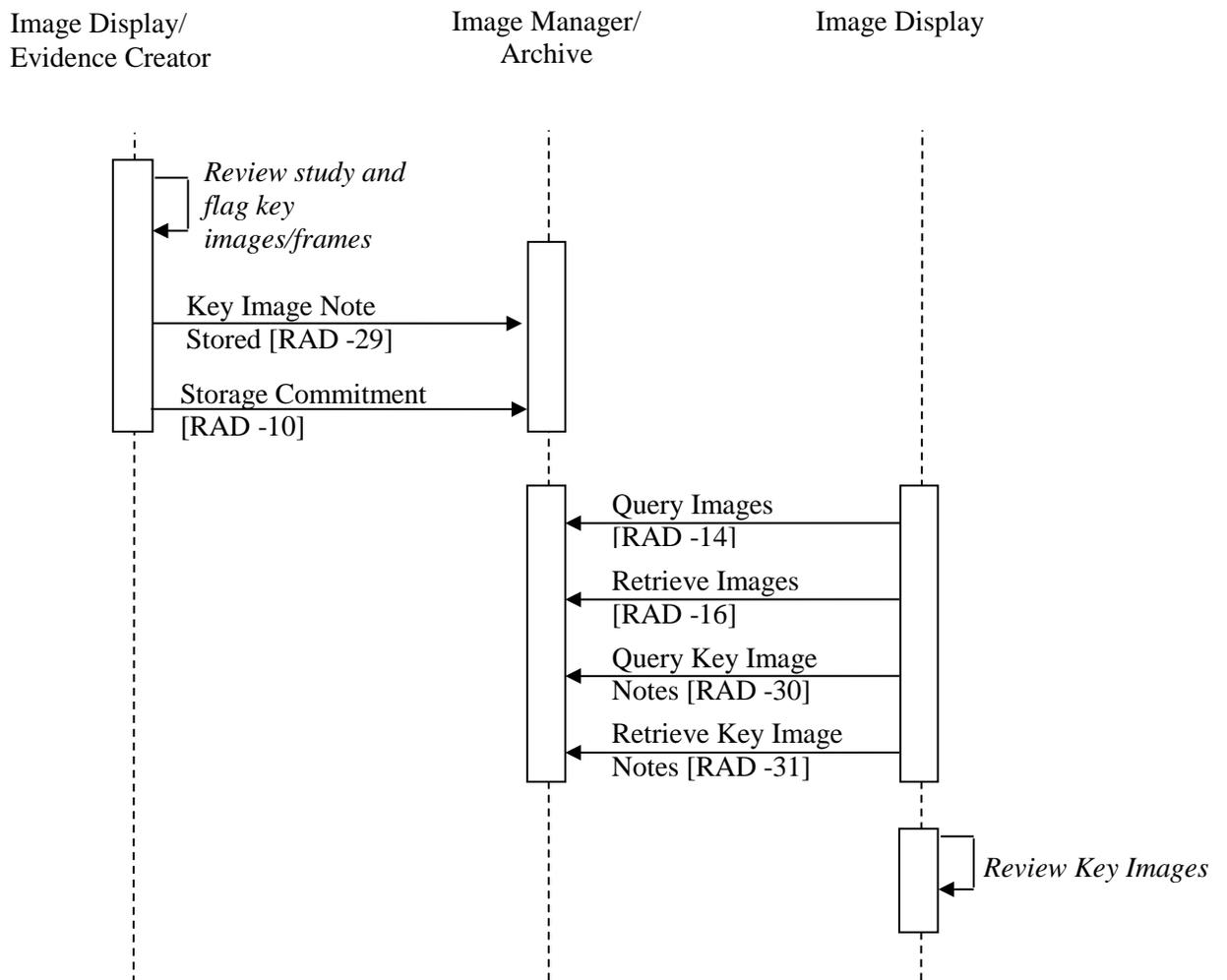
Figure 37.4.2.4.2-1: Process Flow in Key Images in DBT Screening Use Case

650 37.4.2.5 Use Case #5: User annotation in DBT studies

This use case addresses how to store user annotations on DBT images and make them available for review at a later point in time.

37.4.2.5.1 User annotation in DBT studies Use Case Description

While reviewing a DBT image, the radiologist identifies a lesion that she/he would like a second
655 opinion on. She/he marks the region on the relevant frame for review by a colleague. She/he stores the user annotation information in a Grayscale Softcopy Presentation State object and sends it to the PACS.

The second reader retrieves the images and the Grayscale Softcopy Presentation State object on the workstation and opens them. By selecting the user annotation, the annotated frame is
660 displayed right away for review showing the marks of the initial reader also applying any zoom and window/level settings stored in the Grayscale Softcopy Presentation State object.

37.4.2.5.2 User annotation in DBT studies Process Flow
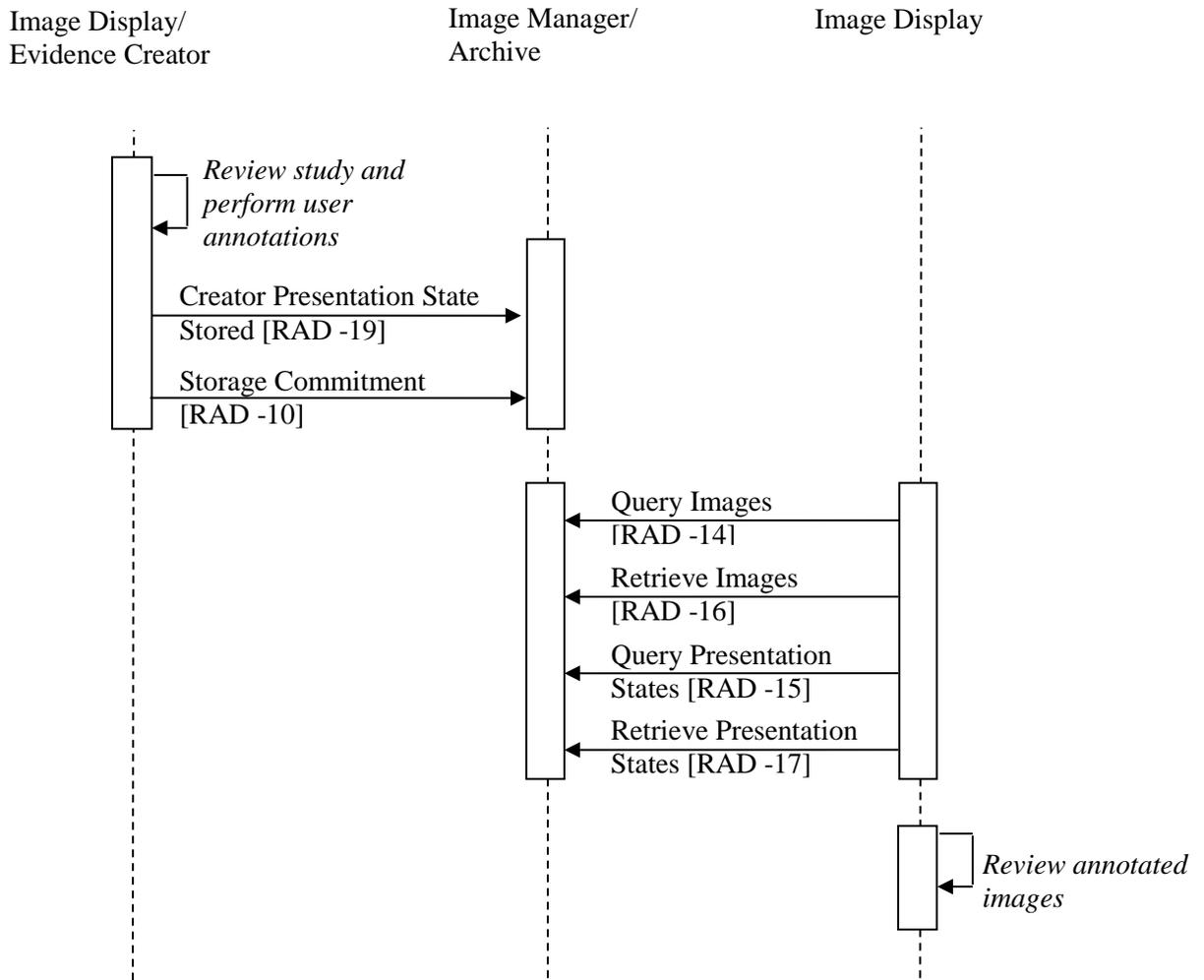
Figure 37.4.2.5.2-1: Process Flow in User Annotation in DBT studies Use Case

665

37.4.2.6 Use Case #6: Printing of selected DBT Frames

This use case addresses printing of selected frames from a DBT study.

37.4.2.6.1 Printing of selected DBT Frames Use Case Description

During reviewing a DBT study, the clinician selects particular frames (with or without
670 annotation) and wants to format them for printing. Options for printing are either in True Size or
in Same Size.

37.4.2.6.2 Printing of selected DBT Frames Process Flow
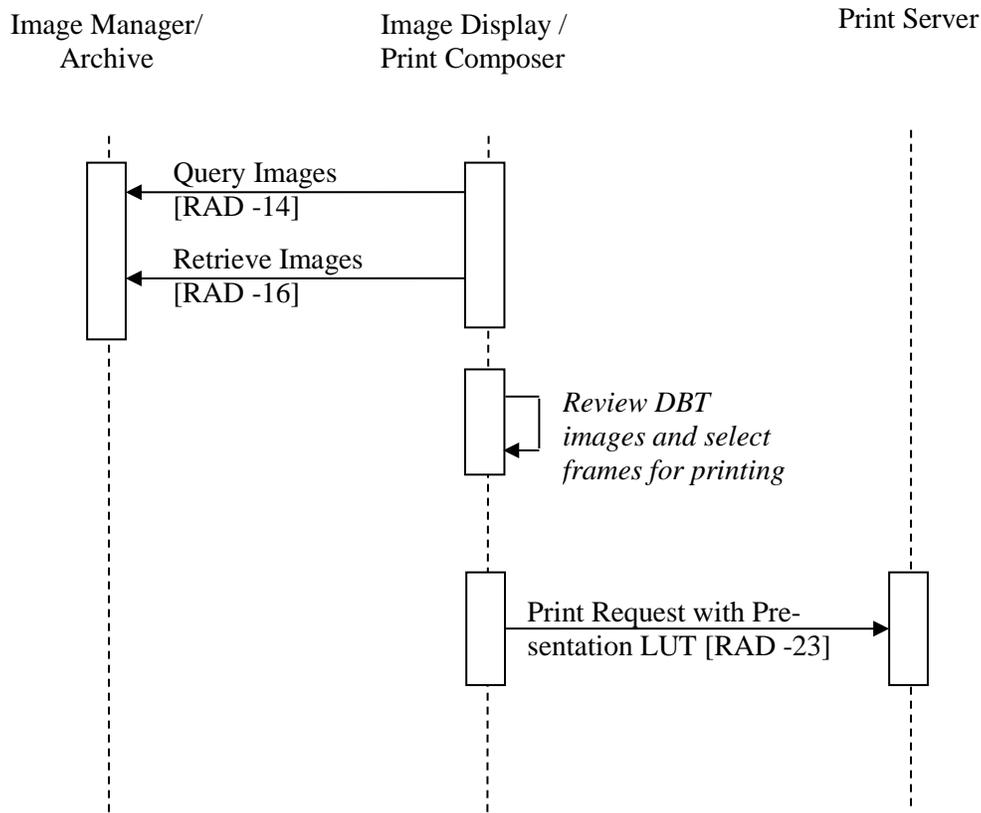
Figure 37.4.2.6.2-1: Process Flow in Printing of Selected DBT Frames Use Case

675

37.4.2.7 Use Case #7: Additional reconstructions based on Projection Images

This use case addresses the workflow to generate additional tomosynthesis reconstructions based on breast projection X-Ray images for tomosynthesis, for systems supporting both Breast Projection X-Ray Images Options.

680 **37.4.2.7.1 Additional reconstructions based on Projection Images Description**

The radiologist reviews the tomosynthesis images at a workstation and detects technical problems with the reconstruction. Therefore she/he loads the source breast projection X-Ray images (For Presentation) and reviews them. She/he decides that the problem could be solved by using different reconstruction parameters. The Evidence Creator which is grouped with the
685 Image Display performs the additional reconstruction, provides the images for display and stores them to the Image Manager/Archive.

Note: Handling rejection of previous reconstructions is addressed in Section 37.6 Cross Profile Consideration in the context of the Mammography Acquisition Workflow Profile.

690 **37.4.2.7.2 Additional reconstructions based on Projection Images Process Flow**
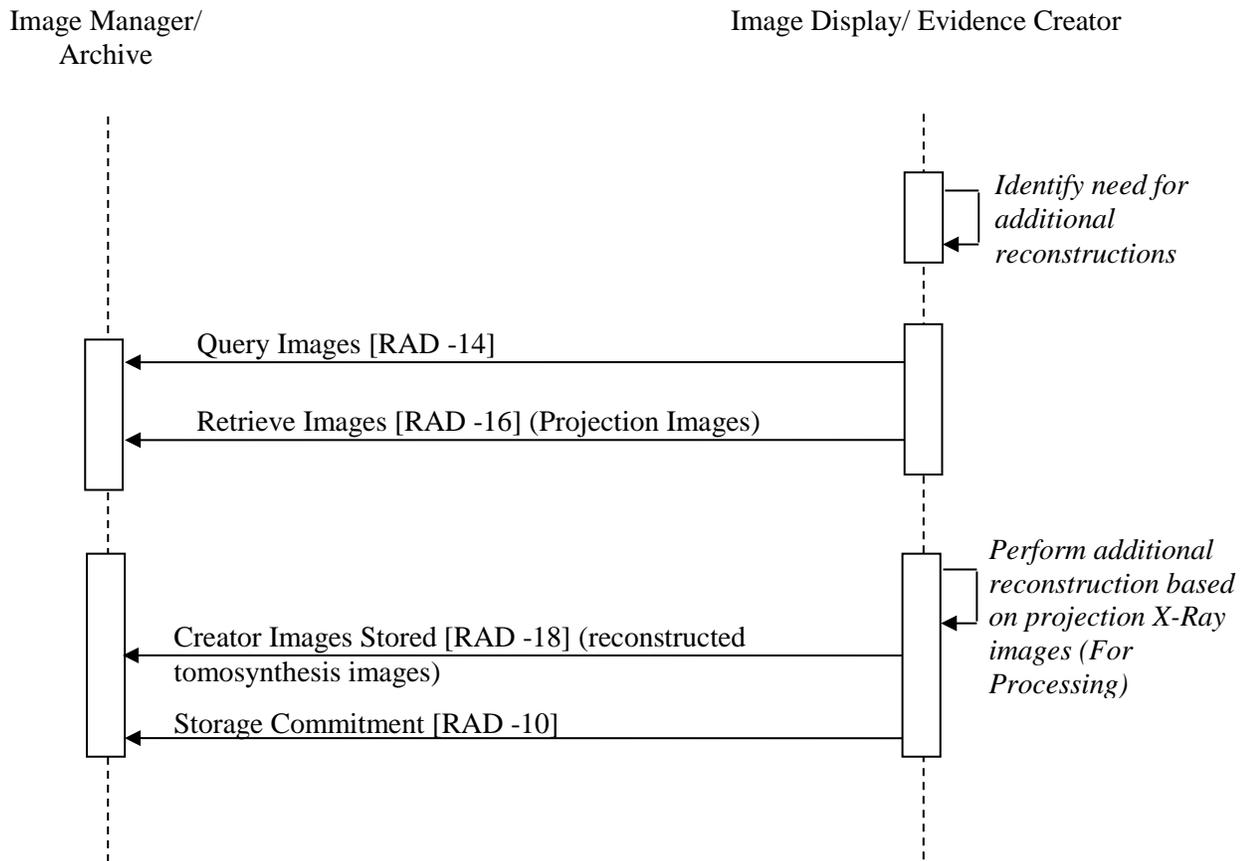
Figure 37.4.2.7.2-1: Process Flow in Additional Reconstructions based on Projection Images Use Case

695 **37.4.2.8 Use Case #8: Review of Projection Images**

This use case addresses reviewing the breast projection X-Ray images for tomosynthesis in addition to the tomosynthesis reconstructions and the conventional 2D mammography images for systems supporting the For Presentation Breast Projection X-Ray Images Option.

37.4.2.8.1 Review of Projection Images Use Case Description

700   The radiologist reviews the breast tomosynthesis images at a workstation and detects some problems with the images. Therefore she/he loads the source breast projection X-Ray images (For Presentation) and reviews them for diagnostic purposes or to check for quality issues such as patient motion.

37.4.2.8.2 Review of Projection Images Use Case Process Flow
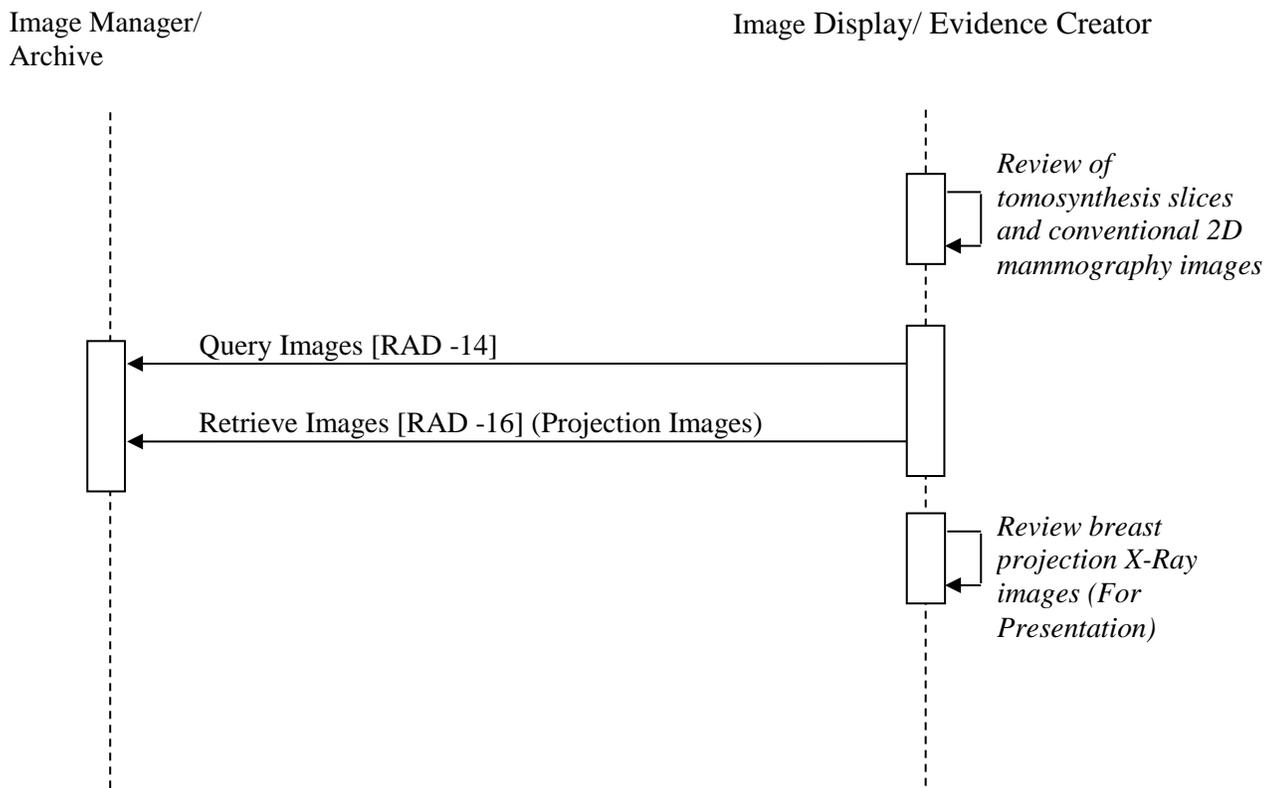
705

Figure 37.4.2.8.2-1: Process Flow in Review of Projection Images Use Case

37.5 DBT Security Considerations

N/A

710   ## 37.6 DBT Cross Profile Considerations

SWF – Scheduled Workflow

The main focus of the Digital Breast Tomosynthesis Profile is to define creation and review of digital breast tomosynthesis studies including DBT images, conventional 2D mammography images and breast projection X-Ray images. The scheduling workflow is addressed in the Scheduled Workflow Profile.

MAWF - Mammography Acquisition Workflow

The main focus of the Digital Breast Tomosynthesis Profile is to define creation and review of digital breast tomosynthesis studies including DBT images, conventional 2D mammography images and breast projection X-Ray images. The workflows addressing exception handling scenarios, e.g., converting a screening procedure into a diagnostic procedure, are defined in the Mammography Acquisition Workflow Profile. The workflows defined in that profile are independent of the type of images acquired and therefore apply to studies including DBT images as well.

BIR - Basic Image Review

The Basic Image Review Profile clearly states that specialty viewing (like Mammography) is outside the scope of that profile. Therefore review of DBT images in the BIR Profile is confined to partial (display – only) support. Specific viewer requirements are addressed in Section 37.2.6.

Appendices

730   No new appendices.

Volume 2 – Transactions

Modify Section 4.5 in the Mammography Acquisition Workflow Profile as indicated below

4.5 Query Modality Worklist

…

735 ### 4.5.4.2.2.2 Codes and References in Procedures (Mammography Acquisition Workflow)

…

Table 4.5-5: Codes for Procedures (informative)

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
~~99IHERADTF~~ **LN**	~~MAWF0001~~ **42174-3**	~~Screening Mammography, bilateral~~ **Breast - bilateral FFD mammogram screening**
~~99IHERADTF~~ **LN**	~~MAWF0002~~ **46355-4**	~~Screening Mammography, left~~ **Breast - left FFD mammogram screening**
~~99IHERADTF~~ **LN**	~~MAWF0003~~ **46354-7**	~~Screening Mammography, right~~ **Breast - right FFD mammogram screening**
~~99IHERADTF~~ **LN**	~~MAWF0004~~ **39154-0**	~~Diagnostic Mammography, bilateral~~ **Breast - bilateral FFD mammogram diagnostic**
~~99IHERADTF~~ **LN**	~~MAWF0005~~ **42169-3**	~~Diagnostic Mammography, left~~ **Breast - left FFD mammogram diagnostic**
~~99IHERADTF~~ **LN**	~~MAWF0006~~ **42168-5**	~~Diagnostic Mammography, right~~ **Breast - right FFD mammogram diagnostic**
~~99IHERADTF~~ **LN**	~~MAWF0007~~ **38096-4**	~~Mammary Ductogram, Single Duct, left~~ **Breast duct - left Mammogram W contrast intra duct**
~~99IHERADTF~~ **LN**	~~MAWF0008~~ **38825-6**	~~Mammary Ductogram, Single Duct, right~~ **Breast duct - right Mammogram W contrast intra duct**
~~99IHERADTF~~ **LN**	~~MAWF0009~~ **39145-8**	~~Mammary Ductogram, Multiple Ducts, left~~ **Breast duct - left Mammogram W contrast intra multiple ducts**
~~99IHERADTF~~ **LN**	~~MAWF0010~~ **39147-4**	~~Mammary Ductogram, Multiple Ducts, right~~ **Breast duct - right Mammogram W contrast intra multiple ducts**
99IHERADTF	MAWF0011	Mammogram for marker placement, left
99IHERADTF	MAWF0012	Mammogram for marker placement, right
~~99IHERADTF~~ **LN**	~~MAWF0013~~ **26316-0**	~~Needle Localization, Image Guided, Mammography, left~~ **Mammogram Guidance for needle localization of mass of Breast - left**
~~99IHERADTF~~ **LN**	~~MAWF0014~~ **26317-8**	~~Needle Localization, Image Guided, Mammography, right~~ **Mammogram Guidance for needle localization of mass of Breast - right**
~~99IHERADTF~~ **LN**	~~MAWF0015~~ **26293-1**	~~Stereotactic Biopsy, Image Guidance, left~~ **Mammogram Guidance stereotactic for biopsy of Breast - left**

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
~~99IHERADTF~~ **LN**	~~MAWF0016~~ **26294-9**	~~Stereotactic Biopsy, Image Guidance, right~~ **Mammogram Guidance stereotactic for biopsy of Breast - right**
~~99IHERADTF~~ **LN**	~~MAWF0017~~ **38080-8**	~~Breast Specimen Mammography, left~~ **Breast specimen - left Mammogram**
~~99IHERADTF~~ **LN**	~~MAWF0018~~ **38821-5**	~~Breast Specimen Mammography, right~~ **Breast specimen - right Mammogram**
99IHERADTF	MAWF0019	Quality Control, Mammography
~~99IHERADTF~~ **RADLEX**	~~MAWF0020~~ **RPID5608**	~~Additional Mammography Views~~ Mammography Breast Additional Views
LN	**72139-9**	**Breast - bilateral FFD mammogram-tomosynthesis diagnostic**
LN	**72142-3**	**Breast - bilateral FFD mammogram-tomosynthesis screening**
LN	**72138-1**	**Breast - left FFD mammogram-tomosynthesis diagnostic**
LN	**72141-5**	**Breast - left FFD mammogram-tomosynthesis screening**
LN	**72137-3**	**Breast - right FFD mammogram-tomosynthesis diagnostic**
LN	**72140-7**	**Breast - right FFD mammogram-tomosynthesis screening**
99IHERADTF	**MAWF0021**	**Bilateral FFDM combined with Tomosynthesis diagnostic**
99IHERADTF	**MAWF0022**	**Bilateral FFDM combined with Tomosynthesis screening**
99IHERADTF	**MAWF0023**	**Left FFDM combined with Tomosynthesis diagnostic**
99IHERADTF	**MAWF0024**	**Left FFDM combined with Tomosynthesis screening**
99IHERADTF	**MAWF0025**	**Right FFDM combined with Tomosynthesis diagnostic**
99IHERADTF	**MAWF0026**	**Right FFDM combined with Tomosynthesis screening**

…

740 *Modify Section 4.8 as indicated below*

4.8 Modality Images Stored

…

Add a new Section 4.8.4.1.2.7

4.8.4.1.2.7 Storage of Digital Breast Tomosynthesis Images

745 The Acquisition Modality in the Digital Breast Tomosynthesis Profile shall support the DICOM Breast Tomosynthesis Image Storage SOP Class and the additional attributes specified in Table 4.8.4.1.2.7-2 and Table 4.8.4.1.2.7-3.

If conventional 2D mammography images are acquired, the Acquisition Modality shall support the Digital Mammography X-Ray Image Storage - For Presentation and For Processing SOP
750 Classes and the additional attributes specified in Table 4.8.4.1.2.3-1.

The Acquisition Modality that supports the For Presentation Breast Projection X-Ray Images Option shall support the Breast Projection X-Ray Image For Presentation SOP Class and the additional attributes specified in Table 4.8.4.1.2.7-2 and Table 4.8.4.1.2.7.2-1.

755 The Acquisition Modality that supports the For Processing Breast Projection X-Ray Images Option shall support the Breast Projection X-Ray Image For Processing SOP Class and the additional attributes specified in Table 4.8.4.1.2.7-2 and Table 4.8.4.1.2.7.2-1.

> Note 1: These requirements are consistent with those for conventional 2D mammography images defined in Table 4.8.4.1.2.3-
> 1, but specialized to account for the encoding of multiple frames in a single image instance and the use of multi-frame
> 760 functional groups. The convention used in the CT/MR Perfusion Imaging with Contrast (PERF) Profile is used to
> indicate nesting within a functional group sequence.
>
> Note 2: Unlike the Digital Mammography X-Ray Image IOD, the Breast Tomosynthesis Image and Breast Projection X-Ray
> Image IODs use the Enhanced General Equipment Module, which already makes various equipment-related attributes
> mandatory, but these are repeated here for clarity.
>
> Note 3: Since support for the Breast Projection X-Ray Image IOD is optional, additional requirements to include acquisition
> 765 information in the Breast Tomosynthesis Image instances are to preserve the technique information for quality control.

Acquisition Modalities capable of creating generated 2D images mathematically from tomosynthesis data (e.g., by Maximum Intensity Projection) shall encode them using the Breast Tomosynthesis Image Storage SOP Class.

770 The Acquisition Modality is not required to use Stacks, or the Multi-frame Dimensions Module, but is not prohibited from doing so. Concatenations are forbidden. In order to distinguish the different types of tomosynthesis images, the Image Type (0008,0008) attribute shall be populated according to Table 4.8.4.1.2.7-1.

Table 4.8.4.1.2.7-1: Image Type in Breast Tomosynthesis Images

Type of tomosynthesis image	Image Type Value 1	Image Type Value 3	Image Type Value 4
Thin Slices	ORIGINAL/DERIVED	TOMOSYNTHESIS	NONE
Thick Slices (Slabs)	DERIVED	TOMOSYNTHESIS	e.g., MAXIMUM, MEAN
Tomosynthesis Generated 2D	DERIVED	TOMOSYNTHESIS	GENERATED_2D

775 Note: This table is adapted from DICOM CP 1342 and will be finalized after CP 1342 is approved.

Table 4.8.4.1.2.7-2: Required additional attributes common to DBT Reconstruction and Projection Images

Attribute	Tag	Tomo	Proj	Rationale
Patient's Name	(0010,0010)	R+	R+	Used for identification during display
Patient ID	(0010,0020)	R+	R+	Used for identification during display
Patient's Birth Date	(0010,0030)	R+	R+	Used for identification during display
Patient's Age	(0010,1010)	R+	R+	Used for identification during display
Operators' Name	(0008,1070)	R+	R+	Used for identification during display
Manufacturer	(0008,0070)	R	R	Used for quality control display
Institution Name	(0008,0080)	R+	R+	Used for identification during display

Attribute	Tag	Tomo	Proj	Rationale
Institution Address	(0008,0081)	R+	R+	Used for quality control display
Manufacturer's Model Name	(0008,1090)	R	R	Used for quality control display
Device Serial Number	(0018,1000)	R	R	Used for quality control display
Station Name	(0008,1010)	R+	R+	Used for identification of the system that acquired the images during display

780 **Table 4.8.4.1.2.7-3: Required Additional Attributes for DBT Reconstruction Images (Breast Tomosynthesis Image SOP Class)**

Attribute	Tag	Tomo	Rationale
Image Type	(0008,0008)	R	Used for display in order to distinguish between different reconstructions
Number of Frames	(0028,0008)	R	Used for display during scrolling
X-Ray 3D Reconstruction Sequence	(0018,9530)	RC+	Type 1 in Type U X-Ray 3D Reconstruction Module. Required if the image represents an additional reconstruction (e.g., slabs) Note: If the X-Ray 3D Reconstruction Sequence is sent, all other mandatory attributes need to be sent as well
>Reconstruction Description	(0018,9531)	RC+	Used to display the way how reconstructed images were generated. Shall be required for additional reconstructions (e.g., slabs)
Pixel Padding Value	(0028,0120)	RC+	Required if background air suppression has been performed by replacing the pixels with a value not used within the breast tissue, so that pixels with this value can be excluded from contrast transformations. May be present otherwise. See Section 4.8.4.1.2.3.2
Pixel Padding Range Limit	(0028,0121)	RC+	Required if Pixel Padding Value (0028,0120) is present and the padding values are a range rather than a single value. See Section 4.8.4.1.2.3.2
Breast Implant Present	(0028,1300)	R	Used to control hanging and processing; not identical to Implant Displaced value for View Modifier Code Sequence, since an implant may be present but not displaced
Frame VOI LUT With LUT Functional Macro (could either be in Per-frame Functional Groups Sequence (5200,9230) or in Shared Functional Groups Sequence (5200,9229))			
Frame VOI LUT Sequence	(0028,9132)	R	
>VOI LUT Sequence	(0028,3010)	C	Required if Window Center and Width not present

Attribute	Tag	Tomo	Rationale
>>LUT Explanation	(0028,3003)	RC+	Required if more than one sequence item or at least one sequence item and window center/width pair is present in order to allow Image Display to present to the user a selection of LUTs or windows described by the explanation
>Window Center	(0028,1050)	C	Required if VOI LUT Sequence is not present
>Window Width	(0028,1051)	C	Required if VOI LUT Sequence is not present
>Window Center and Width Explanation	(0028,1055)	RC+	Required if more than one VOI LUT Sequence item or window center/width pair and at least one VOI LUT Sequence item is present in order to allow Image Display to present to the user a selection of LUTs or windows described by the explanation
>VOI LUT Function	(0028,1056)	RC+	Required if Window Center and Width are not intended to be interpreted as parameters of a linear function in order to allow Image Display to perform appropriate contrast transformation. Enumerated Values LINEAR or SIGMOID
Pixel Measures Functional Macro (could either be in Per-frame Functional Groups Sequence (5200,9230) or in Shared Functional Groups Sequence (5200,9229))			
Pixel Measures Sequence	(0028,9110)	R	
>Pixel Spacing	(0028,0030)	RC	Required in order to perform measurements and annotations
>Slice Thickness	(0018,0050)	RC	Used for display
Plane Position (Patient) Functional Group Macro (may be in the Shared Functional Groups Sequence (5200,9229) if only a single frame is present, otherwise will be in the Per-frame Functional Groups Sequence (5200,9230))			
Plane Position Sequence	(0020,9113)	R	
>Image Position (Patient)	(0020,0032)	R	Used to identify location of slice in volume Shall be different for every frame (i.e., one traversal of the volume)
Plane Orientation (Patient) Functional Group Macro (shall be in Shared Functional Groups Sequence (5200,9229))			
Plane Orientation Sequence	(0020,9116)	R	
>Image Orientation (Patient)	(0020,0037)	R	Used for determination of the direction of rows and columns relative to the patient instead of Patient Orientation (0020,0020)
Frame Anatomy Functional Group Macro (shall be in Shared Functional Groups Sequence (5200,9229))			
Frame Anatomy Sequence	(0020,9071)	R	

Attribute	Tag	Tomo	Rationale
>Frame Laterality	(0020,9072)	R	Used to describe which breast is imaged; all frames share the same value
Information related to the acquisition of the source projection images			
Breast Tomosynthesis Contributing Sources			
Contributing Sources Sequence	(0018,9506)	R+	Type 1 in Type U Breast Tomosynthesis Contributing Sources Module
>Detector ID	(0018,700A)	R	Used for quality control display
>Date of Last Detector Calibration	(0018,700C)	R	Used for quality control display
>Acquisition DateTime	(0008,002A)	R+	Used for identification during display
Breast Tomosynthesis Acquisition			
X-Ray 3D Acquisition Sequence	(0018,9507)	R+	Type 1 in Type U Breast Tomosynthesis Acquisition Module
>Source Image Sequence	(0008,2112)	RC	Used to identify breast projection X-Ray images that were used to generate this image
>KVP	(0018,0060)	R	Used for display of the kVp technical factor
>X-Ray Tube Current in mA	(0018,9330)	R	Used for display of the mA technical factor
>Filter Material	(0018,7050)	R	Used for display of the filter technical factor
>Anode Target Material	(0018,1191)	R	Used for display of the target technical factor
>Compression Force	(0018,11A2)	R	Used for display of the compression force technical factor
>Body Part Thickness	(0018,11A0)	R	Used for display of the compressed breast thickness technical factor
>Primary Positioner Scan Start Angle	(0018,9510)	R	Used for display of the degree of obliquity technical factor
>Primary Positioner Scan Arc	(0018,9508)	R	Used for display of the degree of obliquity technical factor
>Exposure in mAs	(0018,9332)	R	Used for display of the mAs technical factor
>Exposure Time in ms	(0018,9328)	R	Used for display of the exposure time technical factor
>Entrance Dose in mGy	(0040,8302)	R+	Used for display of the estimated skin dose technical factor Note: This attribute is added in DICOM CP 1285 (final text)
>Organ Dose	(0040,0316)	R+	Used for the display of the estimated mean glandular dose technical factor Note: This attribute is added in DICOM CP 1285 (final text)

> Note: This table is not an exhaustive list of all attributes that are required by DICOM, but highlights those that are referred to elsewhere in the DBT Profile.

Acquisition Modalities participating in the Digital Breast Tomosynthesis Profile may support the following transfer syntaxes as listed in Table 4.8.4.1.2.7-4 for all supported SOP Classes.

Table 4.8.4.1.2.7-4: Compression Transfer Syntaxes in Digital Breast Tomosynthesis Profile

Transfer Syntax UID	Name
1.2.840.10008.1.2.4.51	JPEG Extended (Process 2 & 4): Default Transfer Syntax for Lossy JPEG 12 Bit Image Compression (Process 4 only)
1.2.840.10008.1.2.4.57	JPEG Lossless, Non-Hierarchical (Process 14)
1.2.840.10008.1.2.4.70	JPEG Lossless, Non-Hierarchical, First-Order Prediction (Process 14)
1.2.840.10008.1.2.4.90	JPEG 2000 Image Compression (Lossless Only)
1.2.840.10008.1.2.4.91	JPEG 2000 Image Compression

4.8.4.1.2.7.1 Partial View Option

Acquisition Modalities supporting the Partial View Option in the Digital Breast Tomosynthesis Profile shall fulfill all requirements listed in Section 4.8.4.1.2.3.1 for tomosynthesis reconstructions, 2D images generated mathematically from tomosynthesis data, and projection images (if the one of the Breast Projection X-Ray Images Options is supported).

4.8.4.1.2.7.2 Breast Projection X-Ray Images Options

The Acquisition Modality and Image Manager/Archive supporting the For Presentation Breast Projection X-Ray Images Option of the Digital Breast Tomosynthesis Profile shall additionally support the Breast Projection X-Ray Image For Presentation SOP Class as specified in Table 4.8.4.1.2.7-2 and in Table 4.8.4.1.2.7.2-1.

The Acquisition Modality and Image Manager/Archive supporting the For Processing Breast Projection X-Ray Images Option of the Digital Breast Tomosynthesis Profile shall additionally support the Breast Projection X-Ray Image For Processing SOP Class as specified in Table 4.8.4.1.2.7-2 and in Table 4.8.4.1.2.7.2-1.

Table 4.8.4.1.2.7.2-1: Required Additional Attributes for Breast Projection X-Ray Images

Attribute	Tag	Proj	Rationale
Acquisition DateTime	(0008,002A)	R	Used for identification during display
Image Type	(0008,0008)	R	Used to indicate projection images
Detector ID	(0018,700A)	R+	Used for quality control display

Attribute	Tag	Proj	Rationale
Date of Last Detector Calibration	(0018,700C)	R+	Used for quality control display
Number of Frames	(0028,0008)	R	Used for display during scrolling
Patient Orientation	(0020,0020)	RC	Used for hanging protocol configuration- Pixel data orientation of the most representative frame
KVP	(0018,0060)	R	Used for display of the kVp technical factor
X-Ray Tube Current in mA	(0018,9330)	R+	Used for display of the mA technical factor
Exposure in mAs	(0018,9332)	R+	Used to display cumulative Exposure parameters
Exposure Time in ms	(0018,9328)	R+	Used to display cumulative Exposure parameters
Entrance Dose in mGy	(0040,8302)	R	Used for display of the collective total skin dose technical factor
Organ Dose	(0040,0316)	R	Used for the display of the collective total glandular dose technical factor
Anode Target Material	(0018,1191)	R	Used for display of the target technical factor
Compression Force	(0018,11A2)	R	Used for display of the compression force technical factor
Body Part Thickness	(0018,11A0)	R	Used for display of the compressed breast thickness technical factor
Pixel Padding Value	(0028,0120)	RC+	Required if background air suppression has been performed by replacing the pixels with a value not used within the breast tissue, so that pixels with this value can be excluded from contrast transformations. May be present otherwise. See Section 4.8.4.1.2.3.2
Pixel Padding Range Limit	(0028,0121)	RC+	Required if Pixel Padding Value (0028,0120) is present and the padding values are a range rather than a single value. See Section 4.8.4.1.2.3.2
Breast Implant Present	(0028,1300)	R	Used to control hanging and processing; not identical to Implant Displaced value for View Modifier Code Sequence, since an implant may be present but not displaced
X-Ray Filter Macro (could either be in Per-frame Functional Groups Sequence (5200,9230) or in Shared Functional Groups Sequence (5200,9229))			
X-Ray Filter Sequence	(0018,9556)	R+	Type 1 in Type U X-Ray Filter Macro
>Filter Material	(0018,7050)	R+	Used for display of the filter technical factor
Breast X-Ray Acquisition Dose Macro (could either be in Per-frame Functional Groups Sequence (5200,9230) or in Shared Functional Groups Sequence (5200,9229))			
X-Ray Acquisition Dose Sequence	(0018,9542)	R	
>Exposure in mAs	(0018,9332)	R	Used for display of the mAs technical factor
>Exposure Time in ms	(0018,9328)	R	Used for display of the exposure time technical factor

Attribute	Tag	Proj	Rationale
>Relative X-Ray Exposure	(0018,1405)	R+	Used for the display of the relative exposure technical factor
>Entrance Dose in mGy	(0040,8302)	R	Used for display of the estimated skin dose technical factor
>Organ Dose	(0040,0316)	R	Used for the display of the estimated mean glandular dose technical factor
Frame VOI LUT With LUT Functional Macro (could either be in Per-frame Functional Groups Sequence (5200,9230) or in Shared Functional Groups Sequence (5200,9229))			
Frame VOI LUT Sequence	(0028,9132)	R	
>VOI LUT Sequence	(0028,3010)	C	Required if Window Center and Width not present
>>LUT Explanation	(0028,3003)	RC+	Required if more than one sequence item or at least one sequence item and window center/width pair is present in order to allow Image Display to present to the user a selection of LUTs or windows described by the explanation
>Window Center	(0028,1050)	C	Required if VOI LUT Sequence is not present
>Window Width	(0028,1051)	C	Required if VOI LUT Sequence is not present
>Window Center and Width Explanation	(0028,1055)	RC+	Required if more than one VOI LUT Sequence item or window center/width pair and at least one VOI LUT Sequence item is present in order to allow Image Display to present to the user a selection of LUTs or windows described by the explanation
>VOI LUT Function	(0028,1056)	RC+	Required if Window Center and Width are not intended to be interpreted as parameters of a linear function in order to allow Image Display to perform appropriate contrast transformation. Enumerated Values LINEAR or SIGMOID
Breast X-Ray Positioner Macro (could either be in Per-frame Functional Groups Sequence (5200,9230) or in Shared Functional Groups Sequence (5200,9229))			
Positioner Position Sequence	(0018,9405)	R	
>Positioner Primary Angle	(0018,1510)	R	Used for display of the degree of obliquity technical factor
>Positioner Primary Angle Direction	(0018,9559)	R	Used for display of the degree of obliquity technical factor
Breast X-Ray Geometry Functional Macro (could either be in Per-frame Functional Groups Sequence (5200,9230) or in Shared Functional Groups Sequence (5200,9229))			
X-Ray Geometry Sequence	(0018, 9476)	R	
>Estimated Radiographic Magnification Factor	(0018,1114)	R	Used to adjust Imager Pixel Spacing (0018,1164) to account for geometric magnification for normal and magnified views when making distance measurements and displaying or printing calipers

Attribute	Tag	Proj	Rationale
X-Ray Frame Pixel Data Properties Functional Group Macro (could either be in Per-frame Functional Groups Sequence (5200,9230) or in Shared Functional Groups Sequence (5200,9229))			
Frame Pixel Data Properties Sequence	(0018,9443)	R	
>Imager Pixel Spacing	(0018,1164)	R+	Used for measurements
Frame Anatomy Functional Group Macro (shall be in Shared Functional Groups Sequence (5200,9229))			
Frame Anatomy Sequence	(0020,9071)	R	
>Frame Laterality	(0020,9072)	R	Used to describe which breast is imaged; all frames share the same value
Derivation Image Macro could either be in Per-frame Functional Groups Sequence (5200,9230) or in Shared Functional Groups Sequence (5200,9229))			
Derivation Image Sequence	(0008,9124)	RC	Type 2 in Type C Derivation Image Macro
>Source Image Sequence	(0008,2112)	RC+	Used in "For Presentation" images to reference the corresponding "For Processing" images; shall have item(s) if "For Processing" images are produced as DICOM SOP instances

The Acquisition Modality shall be capable of sending all supported SOP Classes to multiple destinations.

The Breast Projection X-Ray Image "For Presentation" instances shall contain a reference to the
810   SOP Instance UID of the corresponding "For Processing" image in Source Image Sequence
(0008,2112), if any.

Amend Section 4.8.4.1.3.1:

4.8.4.1.3.1   DICOM Image Storage SOP Classes

815   The DICOM Standard (2007) defines a number of image specific storage SOP classes. It is
expected that Image Archive will support multiple storage SOP classes as defined in Table 4.8-1
below.

Table 4.8-1: Suggested Image SOP Classes

SOP Class UID	SOP Class Name
1.2.840.10008.5.1.4.1.1.1	Computed Radiography Image Storage
1.2.840.10008.5.1.4.1.1.2	CT Image Storage
1.2.840.10008.5.1.4.1.1.4	MR Image Storage

SOP Class UID	SOP Class Name
1.2.840.10008.5.1.4.1.1.20	Nuclear Medicine Image Storage
1.2.840.10008.5.1.4.1.1.128	Positron Emission Tomography Image Storage
1.2.840.10008.5.1.4.1.1.481.1	RT Image Storage
1.2.840.10008.5.1.4.1.1.7	Secondary Capture Image Storage
1.2.840.10008.5.1.4.1.1.6.1	Ultrasound Image Storage
1.2.840.10008.5.1.4.1.1.3.1	Ultrasound Multi-frame Image Storage
1.2.840.10008.5.1.4.1.1.12.1	X-Ray Angiographic Image Storage
1.2.840.10008.5.1.4.1.1.12.2	X-Ray Radiofluoroscopic Image Storage
1.2.840.10008.5.1.4.1.1.1.1	Digital X-Ray Image Storage – For Presentation
1.2.840.10008.5.1.4.1.1.1.1.1	Digital X-Ray Image Storage – For Processing
1.2.840.10008.5.1.4.1.1.1.2	Digital Mammography **X-Ray** Image Storage – For Presentation
1.2.840.10008.5.1.4.1.1.1.2.1	Digital Mammography **X-Ray** Image Storage – For Processing
1.2.840.10008.5.1.4.1.1.13.1.3	**Breast Tomosynthesis Image Storage**
1.2.840.10008.5.1.4.1.1.13.1.4	**Breast Projection X-Ray Image Storage – For Presentation**
1.2.840.10008.5.1.4.1.1.13.1.5	**Breast Projection X-Ray Image Storage – For Processing**
1.2.840.10008.5.1.4.1.1.1.3	Digital Intra-oral X-Ray Image Storage – For Presentation
1.2.840.10008.5.1.4.1.1.1.3.1	Digital Intra-oral X-Ray Image Storage – For Processing
1.2.840.10008.5.1.4.1.1.77.1.1	VL Endoscopic Image Storage
1.2.840.10008.5.1.4.1.1.77.1.2	VL Microscopic Image Storage
1.2.840.10008.5.1.4.1.1.77.1.3	VL Slide-Coordinates Microscopic Image Storage
1.2.840.10008.5.1.4.1.1.77.1.4	VL Photographic Image Storage

820   …

Table 4.8-4: Mammography SOP Classes for Acquisition and Archival

SOP Class UID	SOP Class Name
1.2.840.10008.5.1.4.1.1.1.2	Digital Mammography X-Ray Image Storage – For Presentation
1.2.840.10008.5.1.4.1.1.1.2.1	Digital Mammography X-Ray Image Storage – For Processing

Film digitizers are only required to create "For Presentation" images. All other Acquisition
Modalities claiming the Mammography Image Profile shall be capable of sending both "For
825   Presentation" and "For Processing" images for every image stored, though not necessarily to the
same target (e.g., "For Processing" images may be sent to the actor corresponding to the CAD
device and "For Presentation" images or both to the Image Manager/Archive).

The "For Presentation" images shall contain a reference to the SOP Instance UID of the
corresponding "For Processing" image in Source Image Sequence (0008,2112).

830 The Image Manager/ Image Archive Actor shall be able to accept both "For Processing" and "For Presentation" images from the Acquisition Modality, and make both available for retrieval, but is not required to be able to make "For Processing" images "presentable".

…

Add the following text and table to the end of Section 4.8.4.1.3.1 DICOM Image Storage SOP
835 *Classes.*

Acquisition Modalities and Image Manager/Image Archives participating in the Digital Breast Tomosynthesis Profile shall support the SOP classes with the optionality listed in Table 4.8-5.

840 **Table 4.8-5: Digital Breast Tomosynthesis SOP Classes for Acquisition and Archival**

SOP Class UID	SOP Class Name	Optionality (Acq. Mod)	Optionality (IM/IA)
1.2.840.10008.5.1.4.1.1.13.1.3	Breast Tomosynthesis Image Storage	R	R
1.2.840.10008.5.1.4.1.1.1.2	Digital Mammography X-Ray Image Storage – For Presentation	O	R
1.2.840.10008.5.1.4.1.1.1.2.1	Digital Mammography X-Ray Image Storage – For Processing	O	R
1.2.840.10008.5.1.4.1.1.13.1.4	Breast Projection X-Ray Image Storage – For Presentation (Note 1)	O	O
1.2.840.10008.5.1.4.1.1.13.1.5	Breast Projection X-Ray Image Storage – For Processing (Note 2)	O	O

Note 1: The Breast Projection X-Ray Image Storage – For Presentation SOP Class is required for Acquisition Modalities and Image Manager/Archives if the For Presentation Breast Projection X-Ray Image Option is supported.

Note 2: The Breast Projection X-Ray Image Storage – For Processing SOP Class is required for Acquisition Modalities
845 and Image Manager/Archives if the For Processing Breast Projection X-Ray Image Option is supported.

Image Manager/ Image Archives participating in the Digital Breast Tomosynthesis Profile shall support the compression transfer syntaxes as listed in Table 4.8.4.1.2.7-4.

850 | *Amend Section 4.16 Retrieve Images* |

4.16 Retrieve Images

...

| *Add Section 4.16.4.1.3.7 and subsections* |

4.16.4.1.3.7 Digital Breast Tomosynthesis Profile

855 Image Display and Image Manager/Image Archive Actors in the Digital Breast Tomosynthesis Profile shall support retrieval of the SOP Classes with the optionality specified in Table 4.16.4.1.3.7-1.

Table 4.16.4.1.3.7-1: DBT SOP Classes for Retrieval

SOP Class UID	SOP Class Name	Optionality (Image Display)	Optionality (IM/IA)
1.2.840.10008.5.1.4.1.1.13.1.3	Breast Tomosynthesis Image Storage	R	R
1.2.840.10008.5.1.4.1.1.1.2	Digital Mammography X-Ray Image Storage – For Presentation	R	R
1.2.840.10008.5.1.4.1.1.1.2.1	Digital Mammography X-Ray Image Storage – For Processing	O	R
1.2.840.10008.5.1.4.1.1.13.1.4	Breast Projection X-Ray Image Storage – For Presentation (Note 1)	O	O
1.2.840.10008.5.1.4.1.1.13.1.5	Breast Projection X-Ray Image Storage – For Processing (Note 2)	-	O

860 Note 1: Support for Breast Projection X-Ray Image Storage – For Presentation SOP Class is required if the For Presentation Breast Projection X-Ray Image Option is supported.

Note 2: Support for Breast Projection X-Ray Image Storage –For Processing SOP Classes is required if the For Processing Breast Projection X-Ray Image Option is supported.

Image Displays may support the transfer syntaxes listed in Table 4.8.4.1.2.7-4.

865 Image Displays are only expected to support a single traversal of a volume stored in a Breast Tomosynthesis Image Storage instance (i.e., Image Position (Patient) (0020, 0032) has a different value for each frame).

Image Manager/ Image Archives participating in the Digital Breast Tomosynthesis Profile shall support the compression transfer syntaxes as listed in Table 4.8.4.1.2.7-4 for retrieval.

870

| *Modify Section 4.16.4.2 as indicated below* |

4.16.4.2   View Images

This transaction relates to the "View Images" event of the above interaction diagram.

4.16.4.2.1 Trigger Events

875 The Image Display or Imaging Document Consumer is requested to be capable to display the images.

4.16.4.2.2 Invocation Semantics

This is a local invocation of functions at the Image Display or Imaging Document Consumer.

4.16.4.2.2.1 Display of Digital X-Ray, Mammo, **DBT** and Intra-Oral Images

880 For **the Breast Tomosynthesis Image,** the "For Presentation" variant of the Digital X-Ray Image, the Digital Mammography **X-Ray** Image, **the Breast Projection X-Ray Image,** and the Digital Intra-oral X-Ray Image, the Image Display or Imaging Document Consumer Actor shall have both the capability to apply all the transformations specified by the VOI LUT Sequence (0028,3010) and the capability to apply all the transformations specified by the Window Width

885 (0028,1051)/Window Center (0028,1050)/VOI LUT Function (0028,1056) attributes ~~in the DX Image Module~~ as selected by the user from the choices available (e.g., guided by Window Center/Width Explanation (0028,1055) or LUT Explanation(0028, 3003))**. These attributes may be nested in a Functional Groups Sequence depending on the SOP Class**,

If VOI LUT Function (0028, 1056) is absent, then Window Width (0028, 1051)/Window Center
890 (0028,1050) shall be assumed to be the parameters of a linear window operation. VOI LUT Function (0028, 1056) values of "SIGMOID" and "LINEAR" shall be supported.

The Image Display or Imaging Document Consumer shall support the application of LUT Data (0028,3006) in items of the VOI LUT Sequence (0028,3010) regardless of the Value Representation (i.e., the DICOM standard allows either OW or US Value Representation).

895 The Image Display or Imaging Document Consumer Actor must also support pixel rendering according to the Grayscale Standard Display Function (GSDF) defined in DICOM ~~2011~~ PS 3.14, because the output values of these images are always P-Values.

If the DICOM image is referenced by other DICOM composite objects, such as Grayscale Softcopy Presentation States, it is optional for the Image Display or Imaging Document
900 Consumer to actually retrieve and display/apply these objects.

…

Add the following Section 4.16.4.2.2.1.3 and sub-sections:

4.16.4.2.2.1.3 Display of DBT Images

Image Display Actors participating in the Digital Breast Tomosynthesis Profile shall fulfill all
905 requirements listed in Section 4.16.4.2.2.1.1 for the display of Digital Mammography X-Ray Image instances in addition to requirements listed in this section.

In the Digital Breast Tomosynthesis Profile, since current and prior studies may be performed with either conventional 2D mammography or DBT or both, and since DBT images may consist of tomosynthesis reconstructions alone, or together with either the projection images (if the For

910   Presentation Breast Projection X-Ray Images Option is supported) or generated 2D images or both, the Image Display shall be capable of displaying combinations of screening views (typically left and right CC and MLO) from a current and prior set of a pair of any of the following types of acquisition:

- Tomosynthesis slices

915
- Tomosynthesis projection images (if the For Presentation Breast Projection X-Ray Images Option is supported)

- Tomosynthesis slabs

- Conventional 2D mammography images

- Generated 2D images derived from tomosynthesis data

920   I.e., Assuming an eight viewport layout, Image Displays shall be at minimum capable of displaying the following combinations based on the user preferences:

- Up to four views of current and prior study of the same acquisition type (e.g., current and prior DBT slices, or current and prior conventional 2D mammography images).

925
- Up to four views of current study of one acquisition type compared with the same views of current exam of a different acquisition type (e.g., current conventional 2D mammography images and current DBT slices).

- Up to four views of current study of one acquisition type compared with the same views of a prior of a different acquisition type (e.g., current DBT slices with prior conventional 2D mammography images).

930   Furthermore, the user shall be provided with a means to toggle between the available conventional 2D mammography images, tomosynthesis slices, tomosynthesis projection images (if the For Presentation Breast Projection X-Ray Images Option is supported) and generated 2D image for the views currently displayed without affecting the display layout.

Image Displays shall support calibration as described in the DICOM Grayscale Standard Display
935   Function (GSDF). The minimum and maximum luminance of the display shall be configurable by the site, within the gamut of the device, for the purpose of conforming to local, regional or national regulatory and other requirements for luminance settings throughout the organization. For example, a site may require that all Image Displays used for consultation be calibrated to the same minimum and maximum luminance.

940   4.16.4.2.2.1.3.1 Background Air Suppression

Image Displays shall apply background air suppression to tomosynthesis slices and generated 2D images as defined in Section 4.16.4.2.2.1.1.1.

4.16.4.2.2.1.3.2 Image Orientation and Justification

Image Displays shall apply image orientation and justification requirements as described in
945   4.16.4.2.2.1.1.2 to tomosynthesis slices, and generated 2D images.

950

For images encoded with the Breast Tomosynthesis Image IOD, the orientation information is stored within the Image Orientation (Patient) (0020,0037) attribute in the Plane Orientation Sequence (0020,9116) of the Shared Functional Groups Sequence (5200,9229), and consideration of this pair of unit vectors describing the orientation of the image rows and columns with respect to the patient-relative 3D coordinate system is required to determine the orientation of the image, since Patient Orientation (0020,0020) is not present in the Breast Tomosynthesis Image IOD. The Image Display shall not assume that Patient Orientation (0020,0020), if present, is reliable, and shall not assume that the pixels are encoded with any particular or expected orientation.

955

For images encoded with the Breast Tomosynthesis Image IOD, the Image Display shall use the View Code Sequence (0054,0220), View Modifier Code Sequence (0054,0222) and Frame Laterality (0020,9072) in the Frame Anatomy Sequence (0020,9071) of the Shared Functional Groups Sequence (5200,9229) together with Image Orientation (Patient) (0020,0037) to display images according to the preferred hanging protocol of the current user.

960 **4.16.4.2.2.1.3.3 Image Size**

The physical size of the pixels in an image encoded with the Breast Tomosynthesis Image IOD for the purposes of distance measurements and the display of a distance caliper shall be approximated by using the values of Pixel Spacing (0028,0030) since geometric effects will have been accounted for during reconstruction.

965

Pixel Spacing (0028,0030) within the Pixel Measures Sequence (0028,9110) may either be part of the Shared Functional Groups Sequence (5200,9229) or the Per-frame Functional Groups Sequence (5200,9230).

4.16.4.2.2.1.3.3.1 Same Size

Image Displays shall be capable of displaying multiple single frame or multi-frame images such that all images are at the same relative physical size, regardless of whether they have the same values of Pixel Spacing (0028,0030) or not.

970

Further, within a single Breast Tomosynthesis Image instance, the Image Display shall be capable of displaying multiple frames of the image such that all frames are at the same relative physical size, regardless of whether they have the same values of Pixel Spacing (0028,0030) or not.

975

This means that as the user scrolls through each frame, the encoded pixel data for each frame may need to be interpolated with a different magnification factor than adjacent frames.

The location about which the frame pixel data is interpolated shall be chosen for successive slices such that the displayed image remains centered vertically at the middle of the vertical extent of the viewport and centered horizontally at the chest wall side of the viewport, until/if the user explicitly pans or zooms the displayed image to establish a new extent of pixels to be displayed.

980

The initial state (magnification factor relative to the physical size of the patient) is at the discretion of the implementer, but since multiple images (different views and prior images) are

985   required to be at the same size, whether or not a particular tomosynthesis slice is used to establish the initial size is not of importance, since the variation in spatial extent (how much of the breast tissue occupies a particular frame or image) is likely to vary more between sides, views and priors than within a set of frames for one image.

The Same Size display behavior as described in Section 4.16.4.2.2.1.1.3.1 shall be applicable
990   during display of any supported combination of conventional 2D mammography images, tomosynthesis slices and generated 2D images.

4.16.4.2.2.1.3.3.2 True Size

Image Displays shall be capable of displaying multiple single frame or multi-frame images such that all images are true size, regardless of whether they have the same values of Pixel Spacing
995   (0028,0030) or not.

Further, within a single Breast Tomosynthesis Image instance, the Image Display shall be capable of displaying multiple frames of the image such that all frames are at true size, regardless of whether they have the same values of Pixel Spacing (0028,0030) or not.

The True Size display behavior as described in Section 4.16.4.2.2.1.1.3.2 shall be applicable
1000   during display of any supported combination of conventional 2D mammography images, tomosynthesis slices and generated 2D images.

4.16.4.2.2.1.3.3.3 View Actual Pixels

For Image Displays, the view actual pixels display as described in Section 4.16.4.2.2.1.1.3.3 shall be applicable during display of any supported combination of conventional 2D
1005   mammography images, tomosynthesis slices and generated 2D images.

4.16.4.2.2.1.3.4 Image Contrast Adjustments

For Image Displays, the image contrast adjustment requirements in Section 4.16.4.2.2.1.1.4 shall be applied during the display of any combination of conventional 2D mammography images, tomosynthesis slices and generated 2D images.

1010   VOI LUT Sequence (0028,3010), Window Center (0028,1050) and Window Width (0028,1051) within the Frame VOI LUT Sequence (0028,9132) may either be part of the Shared Functional Groups Sequence (5200,9229) or the Per-frame Functional Groups Sequence (5200,9230).

4.16.4.2.2.1.3.5 Annotation of Image Information

For Image Displays the annotation requirements in Section 4.16.4.2.2.1.1.5 and all its sub-
1015   sections shall be applied during the display of any combination of conventional 2D mammography images, tomosynthesis slices, and generated 2D images except that, for images encoded with the Breast Tomosynthesis Image IOD the chest wall determination shall be based on Image Orientation (Patient) (0020,0037) in the Plane Orientation Sequence (0020,9116) of the Shared Functional Groups Sequence (5200,9229) rather than Patient Orientation (0020,0020) to
1020   avoid covering of breast tissue with annotations.

4.16.4.2.2.1.3.5.1 Annotation of Identification Information

Image Displays shall fulfill the requirements defined in Section 4.16.4.2.2.1.1.5.1 for the attributes listed in Table 4.16.4.2.2.1.3.5.1-1.

1025

Table 4.16.4.2.2.1.3.5.1-1: Identification Attributes for Display

Attribute	Tag	Requirement
Patient's Name	(0010,0010)	Clinical
Patient ID	(0010,0020)	Clinical
Patient's Birth Date	(0010,0030)	Clinical
Patient's Age	(0010,1010)	Clinical
Operators' Name	(0008,1070)	Clinical
Manufacturer	(0008,0070)	Investigative
Institution Name	(0008,0080)	Clinical
Institution Address	(0008,0081)	Investigative
Manufacturer's Model Name	(0008,1090)	Investigative
Device Serial Number	(0018,1000)	Investigative
Software Versions	(0018,1020)	Investigative
Station Name	(0008,1010)	Clinical
Contributing Sources Sequence	(0018,9506)	
>Acquisition DateTime	(0008,002A)	Clinical
>Detector ID	(0018,700A)	Investigative
>Date of Last Detector Calibration	(0018,700C)	Investigative

4.16.4.2.2.1.3.5.2 Annotation of Technical Factor Information

Image Displays shall fulfill the requirements defined in Section 4.16.4.2.2.1.1.5.2 for the attributes in Table 4.16.4.2.2.1.3.5.2-1:

1030

Table 4.16.4.2.2.1.3.5.2-1: Technique Attributes for Display

Attribute	Tag	Notes
X-Ray 3D Acquisition Sequence	(0018,9507)	
>KVP	(0018,0060)	
>Exposure in mAs	(0018,9332)	
>Exposure Time in ms	(0018,9428)	
>Filter Material	(0018,7050)	
>Anode Target Material	(0018,1191)	
>Compression Force	(0018,11A2)	

Attribute	Tag	Notes
>Body Part Thickness	(0018,11A0)	
>Primary Positioner Scan Start Angle	(0018,9510)	Used to derive the angle of the center of the arc.
>Primary Positioner Scan Arc	(0018,9508)	For additional information on angles see also DICOM CP 1282 (final text).
>Entrance Dose in mGy	(0040,8302)	
>Organ Dose	(0040,0316)	
Image Type	(0008,0008)	Used to display a human readable value of Value 4 for a derived image, e.g., if Value 4 is GENERATED_2D, a string such as "Generated 2D" might be displayed.
X-Ray 3D Reconstruction Sequence	(0018,9530)	
>Reconstruction Description	(0018,9531)	

4.16.4.2.2.1.3.5.3 Annotation of View Information

Image Displays shall provide a mechanism to annotate view information as described in Section 4.16.4.2.2.1.1.5.3, except that the orientation information shall be obtained from Image
1035   Orientation (Patient) (0020, 0037), see Section 4.16.4.2.2.1.3.2 Image Orientation and Justification.

For images encoded using the Breast Tomosynthesis Image IOD the Image Display shall derive the abbreviations displayed in the viewport from View Code Sequence (0054,0220), View Modifier Code Sequence (0054,0222) and Frame Laterality (0020,9072) in the Frame Anatomy
1040   Sequence (0020,9071) of the Shared Functional Groups Sequence (5200,9229).

4.16.4.2.2.1.3.5.4 Annotation of Frame Information

Image Displays shall fulfill the following annotation requirements:

- Frames shall be numbered from 1 to Number of Frames (0028,0008) corresponding to the encoded order of the Frames in Pixel Data (7FE0,0010). For each frame the annotation
1045   shall show the current frame number and the number of frames.

- For tomosynthesis frames, the thickness in mm of the frame based on the Slice Thickness (0018,0050) within Pixel Measures Sequence (0028,9110) of the Shared Functional Groups Sequence (5200,9229) or Per-frame Functional Groups Sequence (5200,9230) shall be displayed.

1050
- For tomosynthesis frames the position within the stack of frames shall be displayed. The position shall be computed from the Image Position (Patient) (0020,0032) distance along the normal to the Image Orientation (Patient) (0020,0037) with an indication of the patient-relative direction along that normal (e.g., lateral to medial, head to foot).

4.16.4.2.2.1.3.6 Annotation of Size Information

1055 For the purpose of this section, physical pixel size is as defined in Section 4.16.4.2.2.1.3.3. Image Displays shall fulfill requirements defined in Section 4.16.4.2.2.1.1.6.

> Note: For tomosynthesis frames, the reported distance measured will be based on actual size within the patient estimated during the reconstruction process, and may not be directly comparable with size measured from conventional 2D mammography images or generated 2D images.

1060 ### 4.16.4.2.2.1.3.7 Partial View Option

Image Displays supporting the Partial View Option in the Digital Breast Tomosynthesis Profile shall fulfill all requirements listed in Section 4.16.4.2.2.1.1 for tomosynthesis slices, projection images (if the For Presentation Breast Projection X-Ray Images Option is supported) and generated 2D images.

1065 ### 4.16.4.2.2.1.3.8 Accidental Reading of Prior Studies

Requirements defined in Section 4.16.4.2.2.1.1.10 shall apply to Image Displays in the Digital Breast Tomosynthesis Profile as well. The Acquisition DateTime (0008,002A) attribute in the Contributing Sources Sequence (0018,9506) (see Table 4.8.4.1.2.7-3) shall be used to determine the display of a warning message, if no studies are within a configurable period from the current 1070 real time.

4.16.4.2.2.1.3.9 Scrolling through Multi-frame Tomosynthesis Images

Image Displays shall be able to present tomosynthesis images in the viewport as a similar conventional 2D mammography view might be displayed. The tomosynthesis images are multi-frame. Accordingly, the user shall be provided with a means to scroll through the frames (such as 1075 one might scroll through a set of CT or MR slices).

Two modes of scrolling, manual and automatic (cine), shall be provided. For the automatic mode, the user shall be provided with control over the cine speed (frame rate) and the initial speed shall be configurable.

> Note: It is recommended that the maximum speed of scrolling be rapid so as to take advantage of the human visual system's 1080 sensitivity to motion in order to detect subtle abnormalities. It is beyond the scope of this transaction to specify a hardware performance target, but a maximum scrolling rate of at least 25 frames per second for an entire 5 MP display is desirable.

The user shall have control over the cine playback sequencing such that they may choose looping, sweeping or stopping (see definitions in DICOM PS 3.3 Preferred Playback Sequencing 1085 (0018,1244), even though this attribute is not used).

The Image Display shall not skip slices during manual or automatic scrolling.

Note: I.e., if the Image Display is unable to keep up with the user's requested frame rate, then the display will show all slices rather than scrolling faster.

1090 Scrolling between tomosynthesis frames shall be available regardless of the arrangement of the display and the combination with other views, whether the other views are tomosynthesis slices, conventional 2D mammography images or generated 2D images.

Scrolling shall be in spatial sequence according to Image Position (Patient) (0020,0032).

Scrolling shall be controllable using both a pointing device and the keyboard.

1095 Vertical movement of a conventional pointing device (such as a mouse) upward shall scroll toward the paddle (i.e., away from the detector). Touch screen pointing devices should scroll in the opposite direction.

4.16.4.2.2.1.3.10 For Presentation Breast Projection X-Ray Images Option

Image Displays supporting the For Presentation Breast Projection X-Ray Images Option shall fulfill the requirements defined in the following subsections for breast projection X-Ray images:

1100 • Section 4.16.4.2.2.1.3.1 Background Air Suppression

• Section 4.16.4.2.2.1.3.2 Image Orientation and Justification
For breast projection X-Ray images, the Image Display shall use the View Code Sequence (0054,0220), View Modifier Code Sequence (0054,0222) and Frame Laterality (0020,9072) in the Frame Anatomy Sequence (0020,9071) of the Shared Functional

1105 Groups Sequence (5200,9229) together with Image Orientation (Patient) (0020,0037) in the Plane Orientation Sequence (0020,9116) of the Shared Functional Groups Sequence (5200,9229) to display images according to the preferred hanging protocol of the current user.

• Section 4.16.4.2.2.1.3.3 Image Size

1110 For breast projection X-Ray images, size information shall be obtained from Imager Pixel Spacing (0018,1164) and Estimated Radiographic Magnification Factor (0018,1114).

• Section 4.16.4.2.2.1.3.4 Image Contrast Adjustments

• Section 4.16.4.2.2.1.3.5 Annotation of Image Information including section 4.16.4.2.2.1.3.5.3 Annotation of View Information

1115 • Section 4.16.4.2.2.1.1.5.1 Annotation of Identification Information, using Acquisition DateTime (0008,002A)

• Section 4.16.4.2.2.1.1.5.2 Annotation of Technical Factor Information using the attributes defined in Table 4.16.4.2.2.1.3.10-1:

1120 **Table 4.16.4.2.2.1.3.10-1: Technique Attributes for Display**

Attribute	Tag	Note
KVP	(0018,0060)	
X-Ray Acquisition Dose	(0018,9542)	Located either in Per-frame

Attribute	Tag	Note
Sequence		Functional Groups Sequence (5200,9230) or in Shared Functional Groups Sequence (5200,9229)
>Exposure in mAs	(0018,9332)	
>Exposure Time in ms	(0018,9428)	
>Entrance Dose in mGy	(0040,8302)	
>Organ Dose	(0040,0316)	
X-Ray Filter Sequence	(0018,9556)	Located either in Per-frame Functional Groups Sequence (5200,9230) or in Shared Functional Groups Sequence (5200,9229)
>Filter Material	(0018,7050)	
Anode Target Material	(0018,1191)	
Compression Force	(0018,11A2)	
Body Part Thickness	(0018,11A0)	
Positioner Position Sequence	(0018, 9405)	Located either in Per-frame Functional Groups Sequence (5200,9230) or in Shared Functional Groups Sequence (5200,9229)
>Positioner Primary Angle	(0018,1510)	
>Positioner Primary Angle Direction	(0018,9559)	
Image Type	(0008,0008)	Used to display a human readable value of Value 3 to indicate projection images.

- Section 4.16.4.2.2.1.3.5.4 Annotation of Frame Information

- Section 4.16.4.2.2.1.3.6 Annotation of Size Information
  For breast projection X-Ray images, size information shall be obtained from Imager Pixel
  Spacing (0018,1164) in the Frame Pixel Data Properties Sequence (0018,9443) of the
  Shared Functional Groups Sequence (5200,9229) or Per-frame Functional Groups
  Sequence (5200,9230) and Estimated Radiographic Magnification Factor (0018,1114) in
  the X-Ray Geometry Sequence (0018,9476) of the Shared Functional Groups Sequence
  (5200,9229) or Per-frame Functional Groups Sequence (5200,9230).

1130 Breast projection X-Ray images are multi-frame rather than single-frame and therefore the user
shall be provided with manual scrolling as defined in Section 4.16.4.2.2.1.3.9 Scrolling through
Multi-frame Tomosynthesis Images; automatic scrolling (cine) is not required. Scrolling through
breast projection X-Ray images shall be independent from scrolling through tomosynthesis
frames.

4.16.4.2.2.1.3.11 Display of DBT Images by the Viewer on the Media (Media Creation Option)

The Media Creation Option of the Digital Breast Tomosynthesis (DBT) Profile groups an Acquisition Modality or Image Display with a Portable Media Creator Actor in the Portable Data for Imaging (PDI) Profile, and allows for a viewer to be recorded on the media. That viewer is considered an Image Display for the purposes of this section and, the contents of this section are required for all such viewers recorded on media by actors claiming the Media Creation Option of the Digital Breast Tomosynthesis (DBT) Profile.

The Image Display shall be capable of displaying all SOP instances recorded on the media that are of the SOP Classes specified in Section 4.16.4.1.3.7. In addition, the Key Object Selection Document Storage SOP Class and Grayscale Softcopy Presentation State Storage SOP Class shall be supported if such instances are present on the media.

The Media Creation Option of the Digital Breast Tomosynthesis (DBT) Profile defines a simplified set of functions for the Image Display Actor to make available to the user with the intent of being able to perform basic review of individual or pairs of images encoded in any of the SOP Classes supported by the Digital Breast Tomosynthesis (DBT) Profile, as well as Key Image Notes and annotations, grayscale contrast and spatial transformations in Presentation States. Additional features may be present.

The Image Display shall provide a means of selecting a single patient to display when more than one patient's studies are recorded on the media. When only a single patient is recorded, there is no need for a patient selection mechanism.

The Image Display shall provide some means of selecting which images to display.

The Image Display shall allow at least two images of any of the supported SOP Classes for the same or different studies to be compared side by side in separate viewports (to allow for comparison of different images of the current or prior studies). The Image Display shall allow display of only a single image in a single viewport (in order to take advantage of limited screen space).

The Image Display shall fulfill all requirements listed in Section 4.16.4.2.2.1.1 related to the application of window/level and VOI LUTs present in the images and any Presentation States present on the media. Contrast adjustments as described in Section 4.16.4.2.2.1.3.4 shall be supported.

Background air suppression as defined in 4.16.4.2.2.1.3.1 shall be supported.

Image Displays shall apply image orientation and justification requirements as described in 4.16.4.2.2.1.3.2.

The physical size of pixels for the purpose of annotations and measurements shall be obtained as described in Sections 4.16.4.2.2.1.3.3 and 4.16.4.2.2.1.1.3.

There is no requirement for Same Size, True Size or View Actual Pixels display, but the Image Display shall provide continuous (not stepped) zooming and panning of an image displayed in a viewport.

The Image Display shall provide scrolling through multi-frame images as described in Section
1175 4.16.4.2.2.1.3.9, except that only manual, not automatic, scrolling is required.

The Image Display shall provide annotation of the displayed images as described in Section
4.16.4.2.2.1.3.5 and its subsections, and annotation of size information as described in Section
4.16.4.2.2.1.3.6.

There is no requirement for specific behavior for partial view images.

1180 The Image Display shall provide a tool to measure distance in a straight line between two user-
defined points. There is no requirement to be able to save such measurements.

The Image Display shall provide the user with the ability to select Key Images if Key Image
Notes are present on the media, as defined in the Key Image Note Profile.

The Image Display shall provide the user with the ability to select and apply Presentation States
1185 if Grayscale Softcopy Presentation State Storage instances are present on the media, as defined
in the Consistent Presentation of Images (CPI) Profile, except that calibration of the display to
the GSDF is not required since the Portable Media Creator that records the Image Display on the
media has no control over the viewing environment in which the Image Display will be used.

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1190 | *Modify Section 4.19 and subsections as indicated below* |

4.19 Creator Presentation State Stored

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4.19.4.1.2 Message Semantics

The Evidence Creator uses the DICOM C-STORE message to store Grayscale Softcopy
1195 Presentation States. All grayscale processing operations, and all spatial and graphical operations,
that are relevant to the resulting presentation of the referenced image have to be recorded in the
presentation state. This will preserve the "as-last-seen" view of the image, with for example the
contrast setting, rotation, flip and text annotation. The image operations in the presentation state
override whatever is recorded in the image itself, even in the case that no attributes for a specific
1200 operation (e.g., Window Width/Window Level operation) are present in the presentation state.
The latter case by definition specifies an identity operation. The full message semantics are
defined in the Grayscale Softcopy Presentation State Storage SOP Class behavior section of
DICOM ~~2011~~ PS 3.4.

The Evidence Creator derives images and Grayscale Softcopy Presentation State objects from
1205 source images that may include Modality Performed Procedure Step relationship information.
This information will include Scheduled Procedure Step information for the procedure
performed at an Acquisition Modality. When present in the source images, the Evidence Creator
shall extract appropriate Scheduled Procedure Step information and include it with PPS
information produced by the Evidence Creator.

1210 **Grayscale Softcopy Presentation States that reference multi-frame images shall populate the Referenced Frame Number (0008,1160) in each applicable occurrence of the Referenced Image Sequence (0008,1140) in the Grayscale Softcopy Presentation State, unless the presentation state applies to all the frames in the image.**

1215 *Modify Section 4.23 and subsections as indicated below*

4.23 Print Request with Presentation LUT

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4.23.4.2 DICOM Presentation LUT N-CREATE

The Presentation LUT data specified by this N-CREATE will be used to transform the image
1220 data at the film box level to realize specific image display characteristics suitable to the Print Composer. In addition, this message can use the Presentation LUT Shape Attribute to specify a pre-defined Presentation LUT Shape (The Presentation LUT Shape value of "LIN OD" will not be supported for the IHE Technical Framework, except for the Mammography Image Profile (see 4.23.4.8)). Presentation LUT information will only be specified and applied at the Film Box
1225 level.

> Note: In the event a Print Composer chooses to specify a Presentation LUT Shape of IDENTITY instead of a Presentation LUT then the image data will be sent to the Print Server in the form of P-values for interpretation by the Print Server according to the GSDF.

> Note: Print composers are encouraged to refer to Appendix B of DICOM Part 14 for calibration measurements
1230 requirements. Where these data are not available or when it is uncertain on which viewbox the film will be viewed, Print Composers may use the suggested default values specified in Part 14 of the DICOM standard for the attributes of Illumination (2010,015E) and Reflected Ambient Light (2010,0160) for conventional images (for Mammography Image Requirements, see Section 4.23.4.8). For transmissive hardcopy printers the standard recommends 2000 cd/m² for Illumination and 10 cd/m² for reflected ambient light. For reflective hardcopy printers the standard recommends
1235 150 cd/m² for Illumination (maximum luminance obtainable from diffuse reflection of the illumination present.) These values are also consistent with those used in the illustrative examples in Annex D of Part 14 of the standard.

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4.23.4.8 Mammography Image and Digital Breast Tomosynthesis Profile

Requirements specific to print are specified for mammography since there are regulatory
1240 requirements in many jurisdictions with respect to the need to provide the patient with images of primary diagnostic quality that are appropriately annotated.

Print Composers participating in the Mammography Image Profile **or the Digital Breast Tomosynthesis Profile** shall:

- Be capable of true size printing of all the pixels of a single view per sheet of film based
1245 on the value stored in Imager Pixel Spacing (0018,1164) in the Mammography Image SOP Instances being printed, so that distance measurements made optically on the printed film will be approximately equivalent to those made on a film-screen mammography exposure, and shall use Requested Image Size (2020,0030) to command the Print Server

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1250 to use the correct image size. Note that the Imager Pixel Spacing (0018,1164) should not be corrected by Estimated Radiographic Magnification Factor (0018,1114), since doing so for magnified views would not only exceed the size of the available print area, but would deviate from the accepted film-screen practice.

- **For Breast Tomosynthesis Image SOP Instances, be capable of true size printing of all the pixels of a selected frame per sheet of film based on the value stored in Pixel**
1255 **Spacing (0020,0030), and shall use Requested Image Size (2020,0030) to command the Print Server to use the correct image size. When printing selected frames of a magnified view, if printing the entire field of view, the Print Composer shall not send Requested Image Size (2020,0030).**

- Be capable of justifying the images in the print request such that the chest wall will be
1260 printed as close to the edge of the film as the Print Server is capable.

- Be capable of sending the Maximum Density attribute (2010,0130)

- **For Digital Mammography X-Ray Image SOP instances, be capable of b**urning into the pixel data sent to the Print Server all the annotations defined in the clinical set for Image Displays in **Section** 4.16.4.2.2.1.1.5.1 Annotation of Identification Information,
1265 and additionally Institution Address (0008,0081), 4.16.4.2.2.1.1.5.2 Annotation of Technical Factor Information and 4.16.4.2.2.1.1.5.3 Annotation of View Information.

- **For Breast Tomosynthesis Image SOP instances, be capable of burning into the pixel data sent to the Print Server all the annotations defined in the clinical set for Image Displays in Section 4.16.4.2.2.1.3.5.1 Annotation of Identification Information**
1270 **and additionally Institution Address (0008,0081), Section 4.16.4.2.2.1.3.5.2 Annotation of Technical Factor Information and Section 4.16.4.2.2.1.3.5.3 Annotation of View Information.**

- Be capable of burning a ruler, caliper or other form of distance scale into the pixel data sent to the Print Server

1275 - Be capable of transmitting a pixel data bit depth of 12 bits to the Print Server (i.e., an 8 bit path is not sufficient for mammography)

- Be capable of burning into the pixel data sent to the Print Server a VOI LUT transformation (linear, sigmoid or tabular) as selected by the user from those available in the original image or as otherwise provided by the user

1280 Print Servers participating in the Mammography Image Profile **or the Digital Breast Tomosynthesis Profile** shall:

- Print on transmissive media
- Be capable of true size printing based on the Requested Image Size (2020,0030) and shall attain the requested size with a precision of a maximum 2% error in linear distance
1285 (this precision requirement is chosen based not any implied or required accuracy of measurements from film or projection radiography, but rather because current electrical, mechanical and optical technology readily allows for this precision, and deviation beyond this value indicates a fundamental flaw in the implementation of the protocol or logic)

1290
- Be capable of printing with a border between the chest wall edge of the digital mammography image and the physical edge of the film no greater than 5mm, so that the printed films can be hung on a light box with the chest wall edges of corresponding views directly abutted.
- Be capable of applying the Maximum Density attribute (2010,0130) in the request, and
1295 printing with a maximum optical density no less than 3.5
- Be capable of receiving a pixel data bit depth of 12 bits from the Print Composer (i.e., an 8 bit path is not sufficient for mammography).
- Be capable of using a Presentation LUT Shape value of "IDENTITY" and "LIN OD" and the Presentation LUT Sequence (2050,0010)

1300 Note that support for a Presentation LUT Shape value of "LIN OD" by Print Servers is specified for Mammography since the expected transmitted illumination of mammography view boxes on which printed film may be hung exceeds the range of illumination for which the Barten model is defined, and hence it may be difficult to achieve consistency between prints, and between prints and displays. It allows the Print Composer to use "LIN OD" to have greater control over the
1305 optical density of the printed film, and to take what action is necessary to result in consistency of appearance for the anticipated viewing conditions.

Add additional text to Section 4.29.4.1.2 as indicated below

4.29 Key Image Note Stored

1310 …

4.29.4.1.2 Message Semantics

The Acquisition Modality or the Evidence Creator uses the DICOM C-STORE message to store Key Image Notes. Message semantics are defined in the Key Object Selection Storage SOP Class definition and Behavior section of DICOM PS3.3 and PS3.4.

1315 **Key Object Selection Documents that reference multi-frame images shall populate the Referenced Frame Number (0008,1160) in each applicable occurrence of the Referenced SOP Sequence (0008,1199) in the Key Object Selection Document, unless the Key Object Selection Document applies to all the frames in the image.**