

## **Professional Services Agreement**

Customer Name: THE COUNTY OF MONTEREY on behalf of NATIVIDAD MEDICAL CENTER Customer Account #: 10647

Ship To: NATIVIDAD MEDICAL CENTER 1441 CONSTITUTION BLVD SALINAS, CA 93906 US Bill To: NATIVIDAD MEDICAL CENTER PO BOX 81611 SALINAS, CA 93912 US **Proposal #:** Q-218346 **Proposal Date:** 12/9/2020

Hologic Representative: Garth Herrington Contract Type: Data Conversion Services

ATTN: Peter Mccormack Marsh Phone: 831-772-7616 Fax: Email: mccormackp@natividad.com

Description	List Price per Item	Discount Amount per Item	Number of Units	Services Price
Fee for initial installation, licensing, and configuration of the RDC server - This fee is applied for every conversion.	\$8,000.00	0.00	1	\$8,000.00

	Agreement Total Term Price:	USD 8,000.00
--	-----------------------------	--------------

The services quoted hereunder are provided pursuant to the Digital Breast Tomosynthesis Data Conversion Statement of Work between the Parties, attached hereto as Exhibit A and incorporated herein.

Customer Acceptance: By signing below, Customer indicates acceptance of this Professional Services Agreement proposal and agrees to be bound by the Hologic Professional Services Terms and Conditions attached hereto and incorporated herein. This Professional Services Agreement proposal supersedes all previous proposals for the services quoted herein. Upon execution, this Professional Services Agreement proposal, along with the Hologic Professional Services Terms and Conditions and any supporting documentation and attachments executed by the Parties, shall constitute the complete and entire agreement between the Parties (collectively referred to herein as the "Agreement").

This offer shall remain open for sixty (60) days after the Proposal Date stated above unless otherwise specified, and is subject to change or withdrawal by Hologic prior to acceptance by both Parties.

CUSTOMER: THE COUNTY OF MONTEREY on behalf of NATIVIDAD MEDICAL CENTER	HOLOGIC, INC.
Authorized Signature:Name:	Authorized Signature: Authorized Signature: Name: Keith Reed
Title:Date:	Title: Vice President, BSH Sales Date:
Natividad Medical Center	Name: Garth Herrington  Email: garth herrington@hologic.com

THIS IS NOT AN INVOICE. INVOICE(S) WILL BE GENERATED COMPLETION OF THE SERVICES, WHICH SHALL BE SCHEDULED AND PERFORMED FOLLOWING RECEIPT OF A FULLY EXECUTED AGREEMENT AND CUSTOMER'S PURCHASE ORDER.

Hologic is required by law to collect state and local taxes on all sales. Final invoices will include these amounts unless a valid exemption certificate is provided.

Attn: Contracts Division 1441 Constitution Blvd Salinas, CA 93906

#### HOLOGIC DATA CONVERSION TERMS AND CONDITIONS

1. TERMS AND CONDITIONS. These Hologic Data Conversion Terms and Conditions ("Terms") set forth the conditions under which Hologic, Inc. ("Hologic") shall perform the Data Conversion for and between the County of Monterey, a political subdivision of the State of California, on behalf of Natividad Medical Center, an acute care hospital (hereinafter, "Customer") per the Professional Services Agreement Proposal ("Quote") to which these Terms are attached. The Data Conversion shall be further detailed in the Digital Breast Tomosynthesis Data Conversion Statement of Work ("SOW"), attached hereto as Exhibit A and incorporated herein. Any capitalized terms not defined herein shall have the meaning ascribed to them in the SOW.

These Terms, together with the Quote, the SOW, and any supporting documentation attached hereto or referenced herein, constitutes the entire agreement between the Parties with respect to the Data Conversion (the "Agreement"). This Agreement supersedes all other proposals, quotations, agreements, understandings, warranties and representations (whether written or oral) between the Parties with respect to the subject matter set forth herein. Any variation in the terms and conditions contained in this Agreement (including, but not limited to the inclusion of Customer's own terms and conditions in any purchase order or other document issued by Customer in response to and/or referencing Hologic's proposal or quotation for service or the Agreement) is hereby rejected and of no effect unless specifically agreed to in writing and signed by both Parties. In the event of any conflict or inconsistency between the provisions of this Agreement and the Provisions of any exhibit or other attachment to this Agreement, the provisions of this Agreement shall prevail and control.

- 2. TERM OF AGREEMENT; the term of this Agreement is from November 1, 2021 through October 31, 2022 unless sooner terminated pursuant to the terms of this Agreement. This Agreement is of no force or effect until signed by both Hologic and Customer and with Customer signing last and Hologic may not commence work before Customer signs this Agreement.
- 3. REMOTE ACCESS. Customer will provide Hologic with remote access through Hologic Connect™ to enable Hologic to deliver and monitor the Data Conversion remotely. .
- 4. NO GUARANTEE OF COMPLETION. Hologic will use its best efforts to meet the projected timeframes in the SOW for completion of the Data Conversion. Further, Hologic will use its best commercial efforts to complete the Data Conversion pursuant to the SOW. However, Customer acknowledges that a variety of factors, such as tool limitations, Customer's existing equipment and software, Customer's prior system operating procedures and data retention and data storage policies may cause delays or make it impossible to complete the Data Conversion. In the event that Hologic concludes that it is impossible to complete the Data Conversion in accord with the SOW specifications, it will promptly notify Customer and the Parties will terminate this Agreement without further liability, provided that the Customer will pay to Hologic the setup, configuration and licensing fee pursuant to the Quote and, if applicable, the per Exam rate based on the Actual Exams through the effective date of termination.
- 5. DATA BACKUP. Customer acknowledges its responsibility to have a commercially appropriate backup of any and all Customer Data prior to and after Conversion, and if applicable, during the Data Conversion. Hologic shall not be liable for loss, corruption, recovery, storage, or backup of Customer Data.
- 6. LICENSE. Hologic grants Customer a non-exclusive, non-assignable software license solely for the Data Conversion ("License"). Use of the License for any other purpose or delegation to anyone other than Customer is expressly prohibited without the prior written agreement of Hologic. This Agreement grants Customer no title or right of ownership in the License. The License is agreed to contain and shall be treated as confidential information. Customer agrees not to remove or destroy any proprietary markings, copyright notices or other restrictions placed upon or contained within the License or any related materials. Customer agrees not to distribute copies of the License or to sell or sub-license any other derivative product containing any of the content of the License.
- 7. PRICING. To the extent the Quote includes a per Exam rate, the Quote provides the best guess cost estimate for the Data Conversion to be provided based on Estimated Exams as stated by the Customer in the Enterprise Survey. Customer acknowledges and agrees that the initial invoice sent to Customer for payment will be based on the Estimated Exams, and if, upon completion of the Data Conversion, the Actual Exams exceed the Estimated Exams, both parties shall execute an amendment to add any additional exams not already included in the Estimated Exams. Hologic will then provide Customer with an additional, final invoice based on Actual Exams. Accordingly, Customer may need to amend its purchase order to reflect the actual cost of the Data Conversion.
- 8. PAYMENT TERMS. Hologic shall remit invoice(s) to Customer pursuant to the Quote following receipt of the Customer's purchase order and full execution of the Quote and SOW by the Parties. Customer shall review the invoice for accuracy and certify the accuracy within fifteen (15) days of receipt. Thereafter, payment shall be made net thirty (30) days of receipt of the Customer-certified invoice by the County of Monterey Auditor-Controller.
- 9. TAXES. Customer shall be responsible for all such taxes for the purchase or use of products or services provided hereunder. Hologic shall be responsible for all other taxes, including, but not limited to, Hologic's net income taxes and excise taxes imposed on Hologic. The Customer shall be responsible for all taxes due unless Customer is tax exempt from such taxes as evidenced by a valid tax exempt certificate, which shall be provided to Hologic prior to the commencement of services. If Hologic is required to charge any taxes, Hologic shall invoice Customer for any such taxes.
- 10.LIMITED WARRANTIES AND EXCEPTIONS. Hologic warrants that the Data Conversion will be performed by trained individuals in a professional workman-like manner. Hologic will promptly re-perform any non-conforming services for no charge as long as Customer provides reasonably prompt written notice to Hologic (not to exceed thirty (30) days from the date Customer obtains, pursuant to the SOW, the final report listing the SCO Data that was Converted, the BTO Data that was created, and any remaining instances in which the SCO Data failed to Convert). The foregoing remedy is Customer's exclusive remedy and Hologic's sole liability for warranty claims. ALL WARRANTIES ARE EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, WHICH ARE EXPRESSLY DISCLAIMED AND THOSE IMPLIED WARRANTIES ARISING FROM COURSE OF DEALING OR USAGE OR TRADE. THESE WARRANTIES AND EXCLUSIONS OF WARRANTIES SHALL APPLY TO THE CUSTOMER AND TO ANY END-USER PURCHASING OR USING THE SERVICES.
- 11. LIMITATION OF LIABILITY. Hologic's entire liability and Customer's exclusive remedy for any damages incurred by Customer from any cause whatsoever, regardless of the form of action, whether liability in contract or in tort, arising from the services furnished hereunder or from any cause related thereto, shall not exceed an amount equal to the amount of the price, fee, or charge paid by Customer for the Data Conversion. The foregoing limitation of liability shall not apply to claims by Customer or third parties for bodily injury or damage to real property or tangible personal property caused solely and directly by the gross negligence or willful misconduct of Hologic or its authorized representatives. IN NO EVENT SHALL HOLOGIC BE LIABLE TO THE CUSTOMER OR ANY OTHER PERSON FOR ANY INCIDENTAL, SPECIAL, OR CONSEQUENTIAL DAMAGES, INCLUDING LOSS OF GOOD WILL, LOSS OF PROFIT, LOSS OF USE, LOSS OF DATA, LOSS OF IMAGES, LOSS OF BUSINESS INFORMATION, INTERRUPTION OF BUSINESS, LOSS OF MEDICAL INFORMATION, CORRUPTION OF MEDICAL INFORMATION, MISDIAGNOSIS OF A MEDICAL CONDITION, LOSS OF IMAGE QUALITY, LOSS OF IMAGE FIDELITY OR ANY OTHER LOSS, OR FOR ANY CLAIMS MADE MORE THAN ONE (1) YEAR AFTER THE CAUSE OF ACTION OCCURRED. THESE EXCLUSIONS OF WARRANTIES AND LIMITATION OF LIABILITIES SHALL APPLY TO THE CUSTOMER AND TO ANY END-USER PURCHASING OR USING THE SERVICES.

- 12. DISCLOSURES. Each Party agrees that any information furnished by the other Party, including without limitation, , software, manuals, devices, information or data about patients, clients, or associated institutions, and all other materials which are identified as confidential information or the like ("Confidential Information"), contains valuable information and will hold such Confidential Information in confidence and not disclose, use, reproduce or distribute it except to its employees (and agents who agree to this provision and are subject to applicable confidentiality or non-disclosure agreements) on a need to know basis to meet its obligations hereunder, or to the extent such disclosure is required by applicable law. If either Party ("Receiving Party") is required by law to disclose any Confidential Information, it will promptly notify the other Party ("Disclosing Party") prior to making such disclosure. However, Confidential Information does not include information that: (a) is now, or subsequently becomes generally available to the public through no fault or breach on the part of the Receiving Party; (b) Receiving Party can demonstrate to have rightfully had in its possession without an obligation of confidentiality prior to disclosure by the Disclosing Party to the Receiving Party; (c) independently developed by the Receiving Party without the use of any Confidential Information, as evidenced by contemporaneous written documentation; (d) Receiving Party rightfully obtains from a third party who has the right to transfer or disclose it and who provides it without a confidentiality obligation; or (e) is available to the Receiving Party by lawful analysis of commercially available products. Confidential Information of Hologic does not include information that is or becomes publicly known or available as a result of Customer's proper compliance with the California Public Records Act. In the event any information becomes available in the California Public Records, Customer will notify Hologic prior to suc
- 13. HIPAA COMPLIANCE. Both Parties agree to comply with the applicable provisions of the privacy regulations within the Health Insurance Portability and Accountability Act of 1996, as enacted in 45 C.F.R. Parts 160, 162, and 164 and as codified at 42 U.S.C. §1320d, as amended from time to time ("HIPAA"). Hologic agrees that if it directly or indirectly gains access to Protected Health Information ("PHI") during any interaction with Customer, it will keep the PHI confidential under the terms of this Agreement. Any ambiguity in this Agreement shall be resolved to permit compliance with the Privacy Regulations of HIPAA and other federal or state laws or regulations.

#### 14. TERMINATION.

- (a) Customer's payments to Hologic under this Agreement are funded by local, state and federal governments. If funds from local, state and federal sources are not obtained and continued at a level sufficient to allow for Customer's purchase of the indicated quantity of services, then Customer may give written notice of this fact to Hologic, and the obligations of the parties under this Agreement shall terminate immediately, or on such date thereafter, as the Customer may specify in its notice, unless in the meanwhile the parties enter into a written amendment modifying this Agreement.
- (b) Either Party may terminate this Agreement upon written notice to the other party, if the other party has breached a material provision of this Agreement and has failed to cure the breach within thirty (30) days of receipt of notice, provided that the Customer will pay to Hologic the setup, configuration and licensing fee pursuant to the Quote and, if applicable, the per Exam rate based on the Actual Exams through the effective date of termination. The foregoing shall in no way limit or eliminate a Party's ability to seek any remedy available at law or in equity.
- 15. FORCE MAJEURE. Hologic's obligations hereunder are subject to force majeure, including but not limited to, civil insurrection, terrorism, fire, flood, labor disputes, shortages, delays of Customer, delays of suppliers or contractors, or government priority systems, actions taken or threatened by any governmental agencies, acts of God, or other contingencies or acts not within the sole control of Hologic. Hologic will not be liable for any loss, damage, delay, or penalty due to causes beyond its reasonable control. In the event a force majeure event preventing Hologic's performance hereunder continues for a period of five (5) business days, Customer may terminate this Agreement, without payment of termination fee or penalty, by providing written notice to Hologic. For the avoidance of doubt, in the event Hologic's performance hereunder is the subject of a force majeure event, the fees to be paid by Customer shall be credited back to Customer and services have not been performed.
- 16. ASSIGNMENT. Neither party may assign, delegate, or subcontract any portion of its rights, duties, or obligations under the Agreement without the prior written consent from the other party. Notwithstanding any such subcontract, both Parties shall continue to be liable for the performance of all requirements of this Agreement.
- 17. MODIFICATION. This Agreement may be modified only by a written instrument duly executed by an authorized representative of Hologic and Customer. Any additional terms and conditions accompanying a Customer purchase order or other documentation must be agreed upon in writing by both parties in order to be valid.
- 18. WAIVER AND SEVERABILITY. If either Party fails to perform its obligations under the Agreement, such nonperformance shall not affect the other Party's right to enforce performance at any time. Waiver of any remedy or material breach of any subject matter contained in this Agreement shall not be viewed as a waiver unless agreed to by the Parties in writing. Each provision of the Agreement is separate and independent of one another, and the unenforceability of any provision will not affect the enforceability of any other provision. If any provision is held to be excessively broad or unenforceable, such provision shall be modified accordingly so that it is enforceable to the fullest extent possible by law.
- 19. SUCCESSORS. Nothing in the Agreement shall confer upon any person other than the parties and their respective successors or assigns, any rights, remedies, obligations, or liabilities whatsoever.
- 20. COMPLIANCE WITH LAWS. Hologic and Customer shall comply with all federal and applicable California state laws that govern the enforceability and performance of this Agreement.
- 21. GOVERNING LAW. Upon execution, this Agreement shall be considered to be a California contract, entered into in California, and shall be governed and viewed under the laws of the State of California without reference to its conflict of laws provisions. The Parties specifically agree that any action relating to the relationship between the Parties, the Agreement, or the services provided, purchased or licensed hereunder, shall be brought and tried in State or Federal Courts located in California. Hologic hereby waives all objections to, and consents to the venue and personal jurisdiction of such Courts.

#### 22. INSURANCE:

#### 23.1 Evidence of Coverage:

Prior to commencement of this Agreement, Hologic shall provide a "Certificate of Insurance" certifying that coverage as required herein has been obtained. Individual endorsements executed by the insurance carrier shall accompany the certificate. In addition, Hologic upon request shall provide a certified copy of the policy or policies,.

This verification of coverage shall be sent to CUSTOMER's Contracts/Purchasing Department, unless otherwise directed. Hologic shall not receive a "Notice to Proceed" with the work under this Agreement until it has obtained all insurance required and CUSTOMER has approved such insurance. This approval of Professional Services Quote #: Q-218346

insurance shall neither relieve nor decrease the liability of Hologic.

- 23.2 Qualifying Insurers: All coverage's except surety, shall be issued by companies which hold a current policy holder's alphabetic and financial size category rating of not less than A-VII, according to the current Best's Key Rating Guide or a company of equal financial stability that is approved by CUSTOMER's Contracts/Purchasing Director.
- 23.3 Insurance Coverage Requirements: Without limiting Hologic's duty to indemnify, Hologic shall maintain in effect throughout the term of this Agreement a policy or policies of insurance with the following minimum limits of liability:
- 23.4 Commercial General Liability Insurance, including but not limited to premises and operations, including coverage for Bodily Injury and Property Damage, Personal Injury, Contractual Liability, Broad form Property Damage, Products and Completed Operations, with a combined single limit for Bodily Injury and Property Damage of not less than \$1,000,000 per occurrence.

(Note: any proposed modifications to these general liability insurance requirements shall be attached as an Exhibit hereto, and the section(s) above that are proposed as not applicable shall be lined out in blue ink. All proposed modifications are subject to County approval.)

Exemption/Modification (Justification attached; subject to approval)

23.5 Business Automobile Liability Insurance, covering all motor vehicles, including owned, leased, non-owned, and hired vehicles, used in providing services under this Agreement, with a combined single limit for Bodily Injury and Property Damage of not less than \$500,000 per occurrence.

(Note: any proposed modifications to these general liability insurance requirements shall be attached as an Exhibit hereto, and the section(s) above that are proposed as not applicable shall be lined out in blue ink. All proposed modifications are subject to County approval.)

Exemption/Modification (Justification attached; subject to approval)

23.6 Workers' Compensation Insurance, If Hologic employs other in the performance of this Agreement, in accordance with California Labor Code section 3700 and with Employer's Liability limits not less than \$1,000,000 each person, \$1,000,000 each accident and \$1,000,000 each disease.

(Note: any proposed modifications to these general liability insurance requirements shall be attached as an Exhibit hereto, and the section(s) above that are proposed as not applicable shall be lined out in blue ink. All proposed modifications are subject to County approval.)

Exemption/Modification (Justification attached; subject to approval)

23.7 Professional Liability Insurance, if required for the professional services being provided, (e.g., those persons authorized by a license to engage in a business or profession regulated by the California Business and Professions Code), in the amount of not less than \$1,000,000 per claim and \$2,000,000 in the aggregate, to cover liability for malpractice or errors or omissions made in the course of rendering professional services. If professional liability insurance is written on a "claims-made" basis rather than an occurrence basis, Hologic shall, upon the expiration or earlier termination of this Agreement, obtain extended reporting coverage ("tail coverage") with the same liability limits. Any such tail coverage shall continue for at least three years following the expiration or earlier termination of this Agreement.

(Note: any proposed modifications to these general liability insurance requirements shall be attached as an Exhibit hereto, and the section(s) above that are proposed as not applicable shall be lined out in blue ink. All proposed modifications are subject to County approval.)

Exemption/Modification (Justification attached; subject to approval)

- 24. Other Insurance Requirements:
- 24.1 All insurance required by this Agreement shall be with a company acceptable to CUSTOMER and issued and executed by an admitted insurer authorized to transact insurance business in the State of California. Unless otherwise specified by this Agreement, all such insurance shall be written on an occurrence basis, or, if the policy is not written on an occurrence basis, such policy with the coverage required herein shall continue in effect for a period of three years following the date Hologic completes its performance of services under this Agreement.
- 24.2 Each liability policy shall provide that CUSTOMER shall be given notice in writing within a commercially reasonable timeframe of any endorsed reduction in coverage or limit, cancellation, or intended non-renewal thereof. Each policy shall provide coverage for Hologic and additional insured with respect to claims arising from each subcontractor, if any, performing work under this Agreement, or be accompanied by a certificate of insurance from each subcontractor showing each subcontractor has identical insurance coverage to the above requirements.
- 24.3 Commercial general liability policies shall provide an endorsement naming the County of Monterey, its officers, agents, and employees as Additional insureds with respect to liability arising out of the Hologic's work, including ongoing and completed operations, and shall further provide that such insurance is primary insurance to any insurance or self-insurance maintained by the County and that the insurance of the Additional Insureds shall not be called upon to contribute to a loss covered by Hologic's insurance.
- 24.4 Prior to the execution of this Agreement by CUSTOMER, Hologic shall file certificates of insurance with CUSTOMER's Contracts/Purchasing Department, showing that Hologic has in effect the insurance required by this Agreement. Hologic shall file a new or amended certificate of insurance within five calendar days after any change is made in any insurance policy, which would alter the information on the certificate then on file. Acceptance or approval of insurance shall in no way modify or change the indemnification clause in this Agreement, which shall continue in full force and effect.
- 24.5 Hologic shall at all times during the term of this Agreement maintain in force the insurance coverage required under this Agreement and shall send, without demand by CUSTOMER, annual certificates to CUSTOMER's Contracts/Purchasing Department. If the certificate is not received by the expiration date, CUSTOMER shall notify Hologic and Hologic shall have a commercially reasonable timeframe to send in the certificate, evidencing no lapse in coverage during the interim. Failure by Hologic to maintain such insurance is a default of this Agreement, which entitles CUSTOMER, at its sole discretion, to terminate the Agreement immediately.

25. Notices: Notices required under this Agreement shall be delivered personally or by first-class, postage per-paid mail to Customer and Hologic's contract administrators at the addresses listed below.

## **CUSTOMER:**

Natividad Medical Center Attn: Contracts Division Natividad Medical Center 1441Constitution Blvd Salinas, CA. 93906 FAX: 831-757-2592

HOLOGIC:	
Name: Hologic, Inc	
Attn: Hologic Contracting Department	
Address: 250 Campus Drive	
City, State, Zip: Marlborough MA 01752FAX:	
Email: Contracts@Hologic.com	

Reviewed and approved as to form.

Chief Deputy County Counsel 12/20/2021

Reviewed and approved as to fiscal provisions

Property Tax Manager 12/21/2021

## **EXHIBIT B**

## **Justification for Exemption to Auto Insurance Requirements**

Both Customer and Hologic agree that because there is no driving associated with providing the services as per this Agreement and its Scope of Services, Hologic is not required to comply with the auto insurance requirements as stated herein.

Should the scope of services change at any time during the term of this Agreement, this exemption may be revoked.



## Digital Breast Tomosynthesis ("DBT") Data Conversion Statement of Work

Between Hologic, Inc.

and NATIVIDAD MEDICAL CENTER

Date: 9/17/2021

This DBT Data Conversion Statement of Work ("SOW") is subject to the Professional Services Proposal # Q-218346 dated 12/9/2020 by and between Hologic, Inc. and NATIVIDAD MEDICAL CENTER, including the Professional Services Terms and Conditions contained therein ("Quote").

#### 1.0 Introduction

**Hologic, Inc.**, together with its subsidiaries and affiliates ("**Hologic**") is offering a service to convert DBT image data created by the Selenia Dimensions from the SCO format to the BTO format. This Statement of Work outlines the scope of and the process associated with this service, which service shall be referred to as the "Data Conversion". The Data Conversion may be provided by Hologic's authorized distributor.

This Statement of Work ("SOW") serves as a binding agreement between **NATIVIDAD MEDICAL CENTER**, with a place of business at 1441 CONSTITUTION BLVD., SALINAS CA 93906 ("**Customer**") and **Hologic**, with a usual place of business at 250 Campus Drive, Marlborough, MA 01752, for the implementation, execution, and completion of the Data Conversion. Either the Customer or Hologic may be individually and separately identified as a "Party" or both collectively referred to as the "Parties."

This SOW is subject to the Professional Services Proposal # Q-218346 dated 12/9/2020 by and between Hologic and Customer, including the Hologic Data Conversion Services Terms and Conditions contained therein ("Quote").

#### 2.0 Definitions

- 2.1 Breast Tomosynthesis image Object or BTO means the DICOM standard format for the storage of DBT image data.
- 2.2 **BTO Data** means DBT image data in the BTO format, and refers specifically to the Customer's DBT image data that was Converted from the SCO format under this SOW.
- 2.3 Conversion, Convert, Converted, or Converting means to alter the format of DBT image data generated by the Customer's Selenia Dimensions from the DICOM supported SCO format to the DICOM standard BTO format.
- 2.4 Customer Data shall mean collectively all of the Customer's data, particularly DBT image data and any related GSPS Data, subject to the services provided under this SOW.
- 2.5 Data Conversion means the services provided under this SOW to Convert the Customer's DBT image data from the SCO format to the BTO format.
- 2.6 Destination Archive means the Customer's DICOM archive device or space which will store the Customer's BTO Data and any related GSPS Data following Conversion. The Destination Archive may, but does not have to, be the same device or space as the Source Archive.
- 2.7 DICOM means Digital Imaging and Communications in Medicine, and is the industry standard for the communication and management of medical imaging information and related data. This standard facilitates the interoperability of medical imaging equipment by enabling the review and storage of medical images and related information regardless of the data's equipment of origin.
- 2.8 Digital Breast Tomosynthesis or DBT means three-dimensional (3D) mammography used in breast cancer screening.
- 2.9 DBT image data means the reconstructed slices comprising the image(s) created by a DBT modality, whether in the SCO format or the BTO format, and refers specifically to the reconstructed slices subject to the services provided under this SOW.
- 2.10 **Enterprise Survey** means Appendix I of this SOW, to be completed by the Customer in order to enable Hologic to determine the feasibility of the Data Conversion.
- 2.11 Exams refers to the number of studies comprised of Customer's DBT image data that is to be Converted under this SOW.
  - (i) **Estimated Exams** means the estimated number of studies to be Converted based on information provided by the Customer in its completed Enterprise Survey.
  - (ii) Actual Exams means the actual number of studies Converted.
- 2.12 **GSPS Data** means annotations or associated presentation state objects created on a SecurView workstation with at least one reference to DBT image data in SCO format. At Customer's option, as indicated by Customer on the Enterprise Survey, an annotation's referenced image object(s) and

- graphic coordinates may be updated once all associated DBT image data has been Converted as part of the Data Conversion. Annotations without any reference to DBT image data in SCO format will not be updated.
- 2.13 **Hologic Connect** shall mean the Hologic Connect SSL remote access solution used by Hologic to monitor the progress of the Data Conversion.
- 2.14 Milestone or Milestones refers to specific points during the Data Conversion that are marks of project progress and/or phase completion which require signature by the Parties' authorized representative in order to proceed to the following phase.
- Other Related Connected Devices means the Customer's equipment and modalities that interact with the Selenia Dimensions and which may be affected by the Data Conversion.
- 2.16 Picture Archiving and Communication System or PACS means the Customer's medical imaging technology which provides storage of and access to, among other things, DBT image data generated by the Customer's DBT modalities.
- 2.17 RosettaDC™ means the Hologic® RosettaDC™ software, and is the tool used primarily to Convert archived DBT image data from SCO format to the BTO format and to update the referenced image objects and graphic coordinates of the GSPS Data during the Conversion. The RosettaDC™ may be provided to the Customer in one of two methods:
  - (i) as a server running the RosettaDC™ software; or
  - (ii) as a compact disc containing the RosettaDC™ software, along with the RosettaDC™ software license dongle.
- 2.18 Secondary Capture Image Object or SCO means the DICOM supported format for the storage of DBT image data containing Hologic proprietary compression encoding of the pixel data.
- 2.19 SCO Data means DBT image data in the SCO format and refers specifically to the Customer's DBT image data created by the Customer's Selenia Dimensions to be Converted to the BTO format under this SOW.
- 2.20 SecurView is a reference to the Hologic-manufactured SecurView™DX and SecurView™RT diagnostic workstations. In this SOW, it specifically refers to such workstations owned by the Customer.
- 2.21 Selenia Dimensions refers to the Hologic-manufactured DBT modality. In this SOW, it specifically refers to such DBT modality(ies) owned by the Customer.
- 2.22 **Source Archive** means the Customer's DICOM archive device or space which stores the Customer's SCO Data and any associated GSPS Data prior to the start of the Data Conversion. The Source Archive may, but does not have to, be the same device or space as the Destination Archive.

#### 3.0 Scope

The scope of this SOW is to define:

- the DBT image data to be Converted and, if applicable, GSPS Data to be updated; and
- the Data Conversion process; and
- any requirements prior to the start of each Milestone and projected timeframes for the completion of each Milestone; and
- the responsibilities of each Party.

The scope of the Data Conversion is to Convert, to the extent possible with Hologic's reasonable and best effort, the Customer's DBT image data stored in the SCO format to the BTO format for storage and optional display on the Customer's PACS, and if applicable, to update the reference image objects and graphic coordinates of any GSPS Data related to such DBT image data.

It is not in the scope of this SOW nor the Data Conversion to provide data recovery or repair services for any Customer Data that could not be retrieved from the Source Archive or displayed by the Destination Archive. Customer is solely

responsible for ensuring that all Customer Data is appropriately backed up prior to the provision of any services hereunder; Hologic is not responsible for the loss, corruption, recovery, storage, or backup of Customer Data.

#### 4.0 Contacts for Data Conversion

#### 4.1. Hologic Contact:

Michael Banden	
Conversion Project Lead	
250 Campus Drive	
Marlborough, MA 01752	
314.603.9045	
Michael.Banden@hologic.com	
	Conversion Project Lead 250 Campus Drive Marlborough, MA 01752 314.603.9045

#### 4.2. Customer Contact:

Peter McCormach Marsh	
Diagnostic Imaging Manager	
1441 Constitution Blvd.	
Salinas, CA 93906	
831.772.7616	
mccormackp@natividad.com	
	1441 Constitution Blvd. Salinas, CA 93906 831.772.7616

#### 5.0 Data Conversion Process and Milestones

#### 5.1. Phase 1: Commencement

- 5.1.1. Enterprise Survey is provided to Customer for completion.
- 5.1.2. Customer will complete the Enterprise Survey and send completed survey to BTOSurvey@hologic.com. Hologic personnel is available to assist with the completion of the Enterprise Survey.
- 5.1.3. Upon receipt of the Customer's completed Enterprise Survey, Hologic will work with the Customer, and if necessary, Customer's third party vendors such as Customer's PACS vendor, to assess the feasibility of the Data Conversion.
- 5.1.4. A Professional Services proposal ("Quote") with an estimated cost for the Data Conversion, as well as the SOW, will be provided to Customer. To the extent a per Exam rate applies, such estimated cost is based on Estimated Exams. The Quote and SOW must be fully executed and Customer must provide a valid purchase order in order to proceed to Phase 2.
- 5.1.5. Customer will be invoiced for the Data Conversion pursuant to the Quote following Hologic's receipt of Customer's purchase order and the Parties' execution of the Quote and SOW.

#### 5.2. Phase 2: Site Preparation

- 5.2.1. The RosettaDC™ shall be shipped FOB Destination to Customer site. Following delivery, (i) a Hologic Field Engineer will be scheduled for an on-site visit to install the RosettaDC™ server; or (ii) Customer will install the RosettaDC™ software and license dongle.
- 5.2.2. The Parties will exchange configuration requirements for the Selenia Dimensions, SecurView, and Other Related Connected Devices.
  - 5.2.2.1. The Selenia Dimensions will be configured and operational in storing BTO Data to the Destination Archive, SecurView, and any Other Related Connected Devices. Customer is responsible for validating configuration.
  - 5.2.2.2. Any Other Related Connected Devices that will store, display, or transmit BTO Data will be configured and validated by Customer.

- 5.2.3. Customer will inform Hologic Contact listed in Section 4.1 that the configuration of equipment is complete.
- 5.2.4. Hologic will perform a trial implementation using test samples of DBT image data.
  - 5.2.4.1. Customer will load the test samples of DBT image data in SCO format to the Source Archive or test equivalent.
  - 5.2.4.2. Using the RosettaDC™ remotely, Hologic will obtain the test samples of DBT image data in SCO format from the Source Archive or test equivalent, Convert the test samples of DBT image data, and send the test samples of DBT image data in BTO format to the Destination Archive or test equivalent.
  - 5.2.4.3. The Parties will review the results of the trial implementation. The Customer is responsible for reviewing the storage, access, display, performance, and impact of the Converted test samples of DBT image data in BTO format within their PACS, network, SecurView workstations, and Other Related Connected Devices.
- 5.2.5. If any conditions are found during Phase 2 that differ from predicted conditions, the Parties will discuss and assess whether the Data Conversion may proceed with such conditions or, if not, whether such conditions may be remedied to allow the Data Conversion to proceed. Should any such conditions prevent Hologic from proceeding with the Data Conversion, the Parties will terminate this SOW and the Data Conversion.
- 5.2.6. Customer will indicate agreement or disagreement to proceed to Phase 3 by email confirmation to the Hologic Contact listed in Section 4.1.

#### 5.3. Phase 3: Conversion

- 5.3.1. The SCO Data, and any optional GSPS Data, will be obtained by the RosettaDC™ from the Source Archive.
- 5.3.2. A best effort attempt will be made to Convert the SCO Data to BTO Data and to update any optional GSPS Data.
- 5.3.3. Hologic personnel will monitor the Conversion process and provide periodic updates on the progress of the Data Conversion in the form of email, electronic documents, or physical paper to the Customer Contact listed in Section 4.2.
  - 5.3.3.3. If remote network access via Hologic Connect is granted to Hologic by Customer, Hologic personnel will monitor the Conversion process remotely. If remote network access via Hologic Connect is not granted by Customer, the Conversion process will need to be monitored on-site by Hologic personnel, resulting in additional fees to Customer.
- 5.3.4. The BTO Data, and any optional GSPS Data, will be sent to the Destination Archive.

#### 5.4. Phase 4: Validation and Termination

- 5.4.1. The Customer will obtain and review a report listing the SCO Data that was Converted, the BTO Data that was created, and any instances in which the SCO Data failed to Convert.
  - 5.4.1.3. With Customer's reasonable cooperation, and if necessary, Customer's third party vendors such as Customer's PACS vendor, Hologic will make a best effort attempt to Convert any SCO Data that failed to Convert in Phase 3. Upon Converting any such SCO Data or exhaustion of best effort attempts, Customer will obtain a final report listing the SCO Data that was Converted, the BTO Data that was created, and any remaining instances in which the SCO Data failed to Convert.
- 5.4.2. Within thirty (30) days of the earlier of Data Conversion completion or exhaustion of best effort attempts, Customer will:

- (i) review the report and verify that the Data Conversion has been completed in accordance with the specifications of this SOW and acknowledge completion of the Data Conversion services by executing the Completion of Conversion sign-off document located in Appendix II and providing a copy of such executed document to Hologic.
- (ii) ship the RosettaDC™ server or software license dongle back to Hologic.
- 5.4.3. RosettaDC™ will be cleared of Customer Data prior to Customer shipping the RosettaDC™ to Hologic upon Hologic's receipt of the Customer-executed Completion of Conversion signoff document.
- 5.4.4. If applicable, a final invoice for the Data Conversion based on the Actual Exams will be sent to the Customer.

#### 5.5. Data Conversion Milestones

#### 5.5.1. Phase 1: Commencement

Estimated Date	Milestone
12/2020	Enterprise Survey sent to Customer
12/2020	Quote and SOW sent to Customer
9/2021	Fully executed Quote and SOW, Customer to provide purchase order
9/2021	Invoice sent to Customer based on Quote

#### 5.5.2. Phase 2: Site Preparation

Estimated Date	Milestone
10/2021	Ship/install RosettaDC™ to/at Customer site
10/2021	Exchange of configuration information
10/2021	Trial implementation of Conversion
10/2021	Customer approval to proceed to Phase 3

#### 5.5.3. Phase 3: Conversion

Estimated Date	Milestone	
10/2021	Estimated Conversion start date	
11/2021	Estimated Conversion completion date	

#### 5.5.4. Phase 4: Validation and Termination

Estimated Date	Milestone
11/2021	Report detailing Conversion sent to Customer
11/2021	Customer validation of Conversion and report
11/2021	Hologic receipt of executed Completion of Conversion document
11/2021	Clear Customer Data from RosettaDC™
11/2021	Return of RosettaDC™ to Hologic
11/2021	Final invoice sent to Customer (if applicable)

#### 6.0 Data Conversion Details

6.1. Certain technical conditions are required for the performance of the Data Conversion. By signing this SOW, Customer acknowledges and warrants that the conditions stated in this Section will exist during the performance of the Data Conversion. In the event the Customer does not meet such conditions, Hologic shall be excused from any further performance, and shall not be liable for any delay or non-

performance resulting from a lack of such conditions. The technical conditions to be met are as follows:

6.1.1. Network Recommendations

(i) Recommended: 1 Gbps (ii) Supported (Marginal Performance): 100 Mbps

6.1.2. Remote Access Requirements

(i) Hologic Connect version 3.2 or higher

- 6.2. The Conversion will only operate during standard business hours (Monday to Friday, 8am to 5pm, EST) at mutually agreed upon times.
- 6.3. Estimated Exams: 8,736 Date estimate provided: 12/3/2020
- 6.4. Estimated timeframe required to complete Conversion: 1 month once started
- 6.5. The Quote contains the cost of the Data Conversion. To the extent a per Exam rate applies, the Quote and invoice prior to the commencement of the Data Conversion is based on Estimated Exams. Customer acknowledges and agrees an additional final invoice may be sent to Customer upon completion of the Data Conversion in the event the Actual Exams exceed the Estimated Exams.

#### 7.0 Responsibilities

#### 7.1. Customer Responsibilities

- 7.1.1. Complete the Enterprise Survey and return to Hologic.
- 7.1.2. Customer acknowledges its responsibility to have a commercially appropriate backup of any and all Customer Data prior to and after the Data Conversion, and if applicable, during the provision of the services pursuant to this SOW. Customer acknowledges and agrees that Hologic is not responsible for the loss, corruption, recovery, storage, or backup of Customer Data.
- 7.1.3. The Customer will validate that all Selenia Dimensions are configured and operational in storing and/or transmitting BTO Data to the Destination Archive, any SecurView, and any Other Related Connected Devices prior to Conversion.
- 7.1.4. Customer is responsible for ensuring Hologic is provided accurate configuration information.
- 7.1.5. Customer is solely responsible for ensuring that the Destination Archive is capable of storing and optionally displaying BTO Data, and that Other Related Connected Devices will perform adequately upon introduction of BTO Data. Customer acknowledges that archive systems vary in their ability to reclaim storage space for data that is no longer needed, that workstations and other related connected devices may vary in their ability to perform with the presence of two (2) versions of the same DBT image data, and that Customer is responsible for considerations and actions to address resulting enterprise conditions.
- 7.1.6. Customer is solely responsible for any charges related to environment preparation to meet appropriate or required performance standards when BTO Data is introduced into PACS, Customer's network, SecurView workstations, and Other Related Connected Devices. This includes, but is not limited to, PACS software or hardware upgrades or additions, component software or hardware upgrades, licensing for necessary connections, network upgrades, storage volume charges, and data transfer volume changes.
- 7.1.7. Archives vary in their ability to reclaim storage space for data no longer needed. Workstations and other connected devices vary in their ability to perform with two versions of the same DBT view present. The Customer is responsible for considerations and actions to address resulting enterprise conditions.

- 7.1.8. If the Source Archive is not compatible with RosettaDC™'s ability to query for SCO Data, the Customer will be responsible for pushing the SCO Data to the RosettaDC™ for Conversion.
- 7.1.9. Provide remote network access via Hologic Connect to the RosettaDC™, Selenia Dimensions, and Securview. If Customer does not grant remote network access via Hologic Connect, Customer will be subject to additional fees for travel time and labor costs for onsite monitoring of the Data Conversion.
- 7.1.10. Monitor the Conversion and promptly communicate any issues to the Hologic Contact listed in Section 4.1.
- 7.1.11. Review Customer Data prior to, during, and following the conclusion of its movement, copying, or Conversion to confirm that all of Customer Data has been appropriately moved, copied and/or Converted. Within thirty (30) days of the conclusion of the Data Conversion, Customer will carefully inspect the Conversion report and results of the Conversion to verify that the Conversion has been completed in accordance with the specifications of this SOW.
- 7.1.12. Within thirty (30) days of completion of the Data Conversion, execute the Completion of Conversion sign-off document located in Appendix II and provide a copy of such executed document to Hologic.
- 7.1.13. Within thirty (30) days of completion of the Data Conversion, ship the RosettaDC™ server or software license dongle back to Hologic.
- 7.1.14. Submit payment for the Data Conversion.

#### 7.2. Hologic Responsibilities

- 7.2.1. Provide the Enterprise Survey to Customer and reasonable support to enable the Customer to complete it.
- 7.2.2. If applicable, document the feasibility of the Data Conversion and required technical details, both known and assumed.
- 7.2.3. Ensure proper configuration of Selenia Dimensions, SecurView, and RosettaDC™ to interface with the Source and Destination Archives.
- 7.2.4. Perform the trial implementation and review results and performance with the Customer prior to proceeding to the next Phase.
- 7.2.5. Provide reasonable training to the Customer Contact listed in Section 4.2 on how to appropriately monitor the Data Conversion.
- 7.2.6. Monitor the Data Conversion, either remotely if remote network access is granted via Hologic Connect, or on-site, and promptly communicate any issues to the Customer Contact listed in Section 4.2.
- 7.2.7. Provide Customer with access to report(s) listing the SCO Data that was Converted, the BTO Data that was created, and any instances in which the SCO Data failed to Convert.
- 7.2.8. Clear the RosettaDC™ of Customer Data following receipt of Customer-executed Completion of Conversion sign-off document located in Appendix II and prior to shipment of RosettaDC™ back to Hologic by Customer.
- 7.2.9. Invoice Customer for the Data Conversion in accordance with the Quote. To the extent a per Exam rate applies, an additional, final invoice may be issued based on Actual Exams upon completion of the Data Conversion.

#### 8.0 List of Appendices

Appendix I Enterprise Survey

Appendix II Confirmation of Completion

## 9.0 Signatures

By signing below, the duly authorized representative of each Party acknowledges receipt of this SOW and agrees to the Data Conversion services pursuant to this SOW and the Quote.

Customer: NATIVIDAD MEDICAL CENTER	Hologic, Inc.  (25 %) feet Reed 2021.09.17 13:37:50	
Name:	Name:Keith Reed	
Title:	Title: VP, BSH Sales	
Date:	Date: 909/17/2021	



# Appendix I DBT Data Conversion: Enterprise Survey

- 1. Site Name (Primary facility):
- 2. Site Address:
- 3. Site Contact (Contact Name, Address, Phone Number, Email Address):

## **BTO Enterprise Information**

Acquisition Equipment and Data		
Number of 3D Selenia Dimensions AWS:		
Serial Numbers [optional]:		
Minimum Equipment requirements: 3D Selenia Dimensions AWS: Software: 1.6.0 Hardware: rev. 6		
Storage and PACS Environment		
PACS Manufacturer(s) and model:		
PACS version:		
PACS vendor representative name(s) and contact information:		
Minimum Equipment requirements: Consult PACS representative for DICOM Breast Tomosynthesis Image Object support		
Reading Environment		
Target Diagnostic Workstation for 3D Tomosynthesis exams using DICOM BTO:		
☐ SecurViewox ☐ PACS Workstation		
☐ Other (specify manufacturer, model, rev)		
Data to be used in 3D reading environment:		
☐ GSPS Annotations (PR)		
Secondary Capture Annotations (PR-SC)		
☐ 3D projection images		
Existing SecurView <sub>DX</sub> Workstations:		
Number Client or Standalone Workstations:		
Network bandwidth available to Workstation(s):		
Network Environment		
Enterprise network bandwidth available for mammography traffic:		
Full remote support requires Hologic Connect™ remote access technology (Internet/DNS/Port 443 with https/SSL). Is this available? Yes ☐ No ☐		
Other Connected Devices		
Please list any other Enterprise-connected devices and their functionality related to Breast Tomosynthesis data or workflow (such as image viewing distribution through PACS, reporting, EMR's, and other medical information systems)		

## **SCO to BTO Conversion Information**

Exam Volume and Data							
Total number of 3D exams to convert:							
Selected Compression Method (check one):							
None		Average 2D	Average 2D/3D study size is 2.6 GB				
JPEG 2000		Average 2D/3D study size is 330 MB					
JPEG Lossless .70		Average 2D/3D study size is 660 MB					
Expected compressed* disk space required GB							
*Data compression is governed by: (1) how the data is sent from RosettaDC to the PACS; and (2) how the PACS archives the data. A conversation with the PACS vendor may be appropriate to determine how the PACS archives the data.							
		Storage En	vironment				
Once converted, will the 3D slice data (in BTO format) be archived on the same PACS where it is stored prior to the conversion (in SCO format)? Yes   No							
If no, please provide information on the Source Archive (data storage location prior to conversion) and Destination Archive (data storage location after conversion):							
Source Archive							
Manufacturer(s) and	d model:	Version:					
Manufacturer representative name(s) and contact information:							
Syste	ems	Locations	AE Title	IP Address	Port#		
PACS (make	and model)						
		Destinatio	n Archive				
Manufacturer(s) and	d model:	Version:					
Manufacturer repres							
		Locations	AE Title	IP Address	Port#		
PACS (make		Locations	AL IIde	II Addiess	1 olen		
1,7,55 (mails							
		Deletion					
☐ Customer will keep the original SCO Tomosynthesis object, and GSPS if applicable, on PACS (preferred)							
Customer will delete the original SCO Tomosynthesis object, and GSPS if applicable, from PACS Only select this option based upon Customer request and ensure feasibility with PACS vendor.							
Data Transmission							
	Does PACS support Series Level Query/Retrieve? Yes No No * If PACS supports Study Level only, a direct push from PACS will be required.						



## Appendix II DBT Data Conversion: Completion of Conversion

This Appendix II, Completion of Conversion, serves as acceptance of the Data Conversion services. By signing this Completion of Conversion, Customer's duly authorized representative acknowledges and confirms that:

- (i) the Data Conversion has been completed in accordance with the specifications and requirements of the SOW;
- (ii) Customer has received the final report of Conversion results;
- (iii) Customer has reviewed the results of the Data Conversion;
- (iv) Hologic may clear the RosettaDC of all Customer Data; and
- (v) Customer will promptly ship the RosettaDC™ back to Hologic.

**Customer: NATIVIDAD MEDICAL CENTER** 

Name:		
Title:		
Date:		

## BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement ("BAA") effective on the date of full execution ("Effective Date"), is entered into by and among between the County of Monterey, a political subdivision of the State of California, on behalf of Natividad Medical Center ("Covered Entity") and Hologic, Inc. ("Business Associate") (each a "Party" and collectively the "Parties").

#### **RECITALS**

- A. WHEREAS, Business Associate provides certain Services for Covered Entity that may involve the Use and Disclosure of Protected Health Information ("PHI") that is created, received, transmitted, or maintained by Business Associate for or on behalf of Covered Entity.
- B. WHEREAS, The Parties are committed to complying with the Health Insurance Portability and Accountability Act of 1996 ("HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act (the "HITECH Act"), and their implementing regulations, including the Standards for the Privacy of Individually Identifiable Health Information, 45 C.F.R. Part 160 and Part 164, Subparts A and E (the "Privacy Rule"), the Breach Notification Standards, 45 C.F.R. Part 160 and 164 subparts A and D (the "Breach Notification Rule"), and the Security Standards, 45 C.F.R. Part 160 and Part 164, Subpart C (the "Security Rule"), (collectively "HIPAA"), all as amended from time to time.
- C. WHEREAS, The Parties are also committed to complying with the California Confidentiality Laws (defined below).
- D. WHEREAS, To the extent that Business Associate is performing activities in connection with covered accounts for or on behalf of Covered Entity, the Parties are also committed to complying with applicable requirements of the Red Flag Rules issued pursuant to the Fair and Accurate Credit Transactions Act of 2003 ("Red Flag Rules").
- E. WHEREAS, The Privacy and Security Rules require Covered Entity and Business Associate to enter into a business associate agreement that meets certain requirements with respect to the Use and Disclosure of PHI. This BAA, sets forth the terms and conditions pursuant to which PHI, and, when applicable, Electronic Protected Health Information ("EPHI") shall be handled, in accordance with such requirement.

NOW THEREFORE, in consideration of the mutual promises below and the exchange of information pursuant to this BAA, the Parties agree as follows:

#### **AGREEMENT**

## 1. <u>DEFINITIONS</u>

- 1.1 All capitalized terms used in this BAA but not otherwise defined shall have the meaning set forth in the Privacy Rule, the Breach Notification Rule, or the Security Rule.
- (a) "Breach" shall have the same meaning as "breach" as defined in 45 C.F.R. § 164.402 and shall mean the access, acquisition, Use, or Disclosure of PHI in a manner not permitted under the Privacy Rule that compromises the privacy or security of the PHI; the term "Breach" as used in this BAA shall also mean the unlawful or unauthorized access to, Use or Disclosure of a patient's "medical information" as defined under Cal. Civil Code § 56.05(j), for which notification is required pursuant to Cal. Health & Safety Code 1280.15, or a "breach of the security of the system" under Cal. Civil Code § 1798.29.
- (b) "California Confidentiality Laws" shall mean the applicable laws of the State of California governing the confidentiality of PHI or Personal Information, including, but not limited to, the California Confidentiality of Medical Information Act (Cal. Civil Code §56, et seq.), the patient access law (Cal. Health & Safety Code §123100 et seq.), the HIV test result confidentiality law (Cal. Health & Safety Code §120975, et seq.), the Lanterman-Petris-Short Act (Cal. Welf. & Inst. Code §5328, et seq.), and the medical identity theft law (Cal. Civil Code 1798.29).
- (c) "Protected Health Information" or "PHI" shall mean any information, whether oral or recorded in any form or medium: (i) that relates to the past, present or future physical or mental condition of an Individual; the provision of health care to an Individual or the past, present or future payment for the provision of health care to an Individual; (ii) that identifies the Individual or with respect to which there is a reasonable basis to believe the information that can be used to identify the Individuals, and (iii) is provided by Covered Entity to Business Associate or created, maintained, received, or transmitted by Business Associate on Covered Entity's behalf. **PHI includes EPHI**.
- (d) "Services" shall mean the services for or functions on behalf of Covered Entity performed by Business Associate pursuant to a written Services Agreement between Covered Entity and Business Associate to which this BAA applies.

## 2. PERMITTED USES AND DISCLOSURES OF PHI

Unless otherwise limited herein, Business Associate may:

- (a) Use or Disclose PHI to perform Services for, or on behalf of, Covered Entity, provided that such Use or Disclosure would not violate the Privacy or Security Rules, this BAA, or California Confidentiality Laws;
- (b) Use or Disclose PHI for the purposes authorized by this BAA or as otherwise Required by Law;
- (c) Use PHI to provide Data Aggregation Services for the Health Care Operations of Covered Entity, if required by the Services Agreement and as permitted by 45 C.F.R. § 164.504(e)(2)(i)(B);

- (d) Use PHI if necessary for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate as permitted by 45 C.F.R. § 164.504(e)(4)(i);
- (e) Disclose PHI for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate as permitted under 45 C.F.R. § 164.504(e)(4)(ii), provided that Disclosures are Required by Law, or Business Associate obtains reasonable assurances from the person to whom the information is Disclosed that it will remain confidential and be Used or further Disclosed only as Required by Law or for the purpose for which it was Disclosed to the person, and that such person will notify the Business Associate of any instances of which such person is aware that the confidentiality of the information has been Breached;
- (f) Use PHI to report violations of law to appropriate Federal and state authorities, consistent with 45 C.F.R. § 164.502(j)(1); and
- (g) De-identify any PHI obtained by Business Associate under this BAA in accordance with 45 C.F.R. § 164.514 and Use or Disclose such de-identified information only as required to provide Services pursuant to the a Services Agreement between the Parties, or with the prior written approval of Covered Entity.

## 3. RESPONSIBILITIES OF THE PARTIES WITH RESPECT TO PHI

- **3.1.** <u>Responsibilities of Business Associate</u>. With regard to its Use and/or Disclosure of PHI, Business Associate shall:
- (a) Notify the Privacy Officer of Covered Entity, in writing, of: (i) any Use and/or Disclosure of the PHI that is not permitted or required by this BAA; (ii) any Security Incident involving PHI of which Business Associate becomes aware; and (iii) any Breach. Such notice shall be provided within ten (10) business days of Business Associate's discovery of such unauthorized access, acquisition, Use and/or Disclosure. Notwithstanding the foregoing, the Parties acknowledge the ongoing existence and occurrence of attempted but ineffective Security Incidents that are trivial in nature, such as, but not limited to, pings and other broadcast service attacks on Business Associate's firewall, port scans, denials of service, unsuccessful log-in attempts and any combination of the above. The Parties acknowledge and agree that this Section 3.1(a) constitutes notice by Business Associate to Covered Entity of such ineffective Security Incidents and no additional notification to Covered Entity of such ineffective Security Incidents is required, provided that no such Security Incident results in a Breach. A ransomware attack that may affect PHI shall not be considered an ineffective Security Incident and shall be reported to Covered Entity, irrespective of whether such Security Incident results in a Breach. Business Associate shall investigate each Security Incident involving PHI or unauthorized access, acquisition, Use, or Disclosure of PHI, or Breach that it discovers and shall provide a summary of its investigation to Covered Entity, upon request. If Business Associate or Covered Entity determines that such Security Incident or unauthorized access, acquisition, Use, or Disclosure, or Breach constitutes a Breach, then Business Associate shall comply with the requirements of Section 3.1(a)(i) below;

- (i) Business Associate shall provide a supplemental written report in accordance with 45 C.F.R. § 164.410(c), which shall include, to the extent possible, the identification of each Individual whose PHI has been, or is reasonably believed by the Business Associate to have been, accessed, acquired, Used or Disclosed during the Breach, to Covered Entity without unreasonable delay, but no later than ten (10) business days after discovery of the Breach;
- (ii) Covered Entity shall have sole control over the timing and method of providing notification of such Breach to the affected Individual(s), the appropriate government agencies, and, if applicable, the media. Business Associate shall assist with the implementation of any decisions by Covered Entity to notify Individuals or potentially impacted Individuals;
- (b) In consultation with the Covered Entity, Business Associate shall mitigate, to the extent practicable, any harmful effect that is known to the Business Associate of such improper access, acquisition, Use, or Disclosure, Security Incident involving PHI, or Breach. Business Associate shall take prompt corrective action, including any action required by applicable State or federal laws and regulations relating to such Security Incident involving PHI or non-permitted access, acquisition, Use, or Disclosure caused by Business Associate. Business Associate shall reimburse Covered Entity for its reasonable and actual costs and expenses in providing any required notification to affected Individuals, appropriate government agencies, and, if necessary the media, including, but not limited to, any administrative costs associated with providing notice, printing and mailing costs, public relations costs, attorney fees, and costs of mitigating the harm (which may include the costs of obtaining up to one year of credit monitoring services and identity theft insurance) for affected Individuals whose PHI or Personal Information has or may have been compromised as a result of a Breach caused by Business Associate;
- (c) Implement reasonable and appropriate administrative, physical, and technical safeguards and comply with the Security Rule to prevent Use and/or Disclosure of EPHI other than as provided for by this BAA;
- (d) Obtain and maintain a written agreement with each of its Subcontractors that creates, maintains, receives, Uses, transmits or has access to PHI that requires such Subcontractors to adhere to the substantially the same restrictions and conditions with respect to PHI that apply to Business Associate pursuant to this BAA;
- (e) Make available all internal practices, records, books, agreements, policies and procedures and PHI relating to the Use and/or Disclosure of PHI received from, created, maintained, or transmitted by Business Associate on behalf of Covered Entity to the Secretary of the Department of Health and Human Services ("Secretary") in a time and manner designated by the Secretary for purposes of determining Covered Entity's or Business Associate's compliance with the Privacy Rule. In addition, Business Associate shall promptly make available to Covered Entity copies of any such books, records, or other information relating to the Use and Disclosure of PHI provided to the Secretary;

- (f) Document Disclosures of PHI and information related to such Disclosure and, within thirty (30) days of receiving a written request from Covered Entity, provide to Covered Entity such information as is requested by Covered Entity to permit Covered Entity to respond to a request by an Individual for an accounting of the Disclosures of the Individual's PHI in accordance with 45 C.F.R. § 164.528. At a minimum, the Business Associate shall provide the Covered Entity with the following information: (i) the date of the Disclosure; (ii) the name of the entity or person who received the PHI and if known, the address of such entity or person; (iii) a brief description of the PHI Disclosed; and (iv) a brief statement of the purpose of such Disclosure which includes an explanation of the basis for such Disclosure. In the event the request for an accounting is delivered directly to the Business Associate, the Business Associate shall, within ten (10) business days, forward such request to the Covered Entity. To the extent Business Associate maintains PHI on behalf of the Covered Entity, the Business Associate shall implement an appropriate recordkeeping process to enable it to comply with the requirements of this Section:
- (g) Subject to Section 4.4 below, return to Covered Entity within thirty (30) days of the termination of this BAA, the PHI in its possession and retain no copies, including backup copies;
- (h) Disclose to its Subcontractors or other third parties, and request from Covered Entity, only the minimum PHI necessary to perform or fulfill a specific function required or permitted hereunder;
  - (i) If all or any portion of the PHI is maintained in a Designated Record Set:
- (i) Upon ten (10) business days' prior written request from Covered Entity, provide access to the PHI to Covered Entity to meet a request by an Individual under 45 C.F.R. § 164.524. Business Associate shall notify Covered Entity within ten (10) business days of its receipt of a request for access to PHI from an Individual; and
- (ii) Upon ten (10) business days' prior written request from Covered Entity, make any amendment(s) to the PHI that Covered Entity directs pursuant to 45 C.F.R. § 164.526. Business Associate shall notify Covered Entity within ten (10) business days of its receipt of a request for amendment of PHI from an Individual;
- (j) If applicable, maintain policies and procedures to detect and prevent identity theft in connection with the provision of the Services, to the extent required to comply with the Red Flag Rules;
- (k) To the extent that Business Associate carries out one or more of Covered Entity's obligations under the Privacy Rule, Business Associate shall comply with the requirements of the Privacy Rule that apply to Covered Entity in the performance of such obligations;

- (l) Unless prohibited by law, notify the Covered Entity within ten (10) business days of the Business Associate's receipt of any request or subpoena for PHI. To the extent that the Covered Entity decides to assume responsibility for challenging the validity of such request, the Business Associate shall reasonably cooperate with the Covered Entity in such challenge; and
- (m) Maintain policies and procedures materially in accordance with State Confidentiality Laws and industry standards designed to ensure the security and integrity of the Covered Entity's data and protect against threats or hazards to such security.

## 3.2 **Business Associate Acknowledgment**.

- (a) Business Associate acknowledges that, as between the Business Associate and the Covered Entity, all PHI shall be and remain the sole property of the Covered Entity.
- (b) Business Associate further acknowledges that it is obligated by law to comply, and represents and warrants that it shall comply, with HIPAA and the HITECH Act. Business Associate shall comply with all California Confidentiality Laws, to the extent that such state laws are not preempted by HIPAA or the HITECH Act.
- (c) Business Associate further acknowledges that uses and disclosures of protected health information must be consistent with NMC's privacy practices, as stated in NMC's Notice of Privacy Practices, which are provided to Business Associate in writing.
- **3.3** Responsibilities of Covered Entity. Covered Entity shall, with respect to Business Associate:
- (a) Provide Business Associate in writing a copy of Covered Entity's notice of privacy practices ("Notice") currently in use;
- (b) Notify Business Associate in writing of any changes to the Notice that Covered Entity provides to Individuals pursuant to 45 C.F.R. § 164.520, to the extent that such changes may affect Business Associate's Use or Disclosure of PHI;
- (c) Notify Business Associate in writing of any changes in, or withdrawal of, the consent or authorization of an Individual regarding the Use or Disclosure of PHI provided to Covered Entity pursuant to 45 C.F.R. § 164.506 or § 164.508, to the extent that such changes may affect Business Associate's Use or Disclosure of PHI; and
- (d) Notify Business Associate in writing of any restrictions on Use and/or Disclosure of PHI as provided for in 45 C.F.R. § 164.522 agreed to by Covered Entity, to the extent that such restriction may affect Business Associate's Use or Disclosure of PHI.

## 4. <u>TERM AND TERMINATION</u>

- **4.1** Term. This BAA shall become effective on the Effective Date and shall continue in effect unless terminated as provided in this Section 4. Certain provisions and requirements of this BAA shall survive its expiration or other termination as set forth in Section 5 herein.
- **4.2** <u>Termination</u>. If Covered Entity determines in good faith that Business Associate has breached a material term of this BAA, Covered Entity may either: (i) immediately terminate this BAA and any underlying Services Agreement; or (ii) terminate this BAA and any underlying Services Agreement within thirty (30) days of Business Associate's receipt of written notice of such breach, if the breach is not cured to the satisfaction of Covered Entity.
- **4.3** <u>Automatic Termination</u>. This BAA shall automatically terminate without any further action of the Parties upon the termination or expiration of Business Associate's provision of Services to Covered Entity.
- 4.4 **Effect of Termination**. Upon termination or expiration of this BAA for any reason, Business Associate shall return all PHI pursuant to 45 C.F.R. § 164.504(e)(2)(ii)(J) if, and to the extent that, it is feasible to do so. Prior to returning the PHI, Business Associate shall recover any PHI in the possession of its Subcontractors. To the extent it is not feasible for Business Associate to return or destroy any portion of the PHI, Business Associate shall provide Covered Entity with a statement that Business Associate has determined that it is infeasible to return or destroy all or some portion of the PHI in its possession or in possession of its Subcontractors. In such event, Business Associate shall: (i) retain only that PHI which is necessary for Business Associate to continue its proper management and administration or carry out its legal responsibilities; (ii) return to Covered Entity the remaining PHI that the Business Associate maintains in any form; (iii) continue to extend the protections of this BAA to the PHI for as long as Business Associate retains PHI; (iv) limit further Uses and Disclosures of such PHI to those purposes that make the return or destruction of the PHI not feasible and subject to the same conditions as set out in Section 2 above, which applied prior to termination; and (vi) return to Covered Entity the PHI retained by Business Associate when it is no longer needed by Business Associate for its proper management and administration or to carry out its legal responsibilities.

## 5. <u>MISCELLANEOUS</u>

- **5.1** <u>Survival</u>. The respective rights and obligations of Business Associate and Covered Entity under the provisions of Sections 2.1, 4.4, 5.7, 5.8, 5.11, and 5.12 shall survive termination of this BAA until such time as the PHI is returned to Covered Entity or destroyed. In addition, Section 3.1(i) shall survive termination of this BAA, provided that Covered Entity determines that the PHI being retained pursuant to Section 4.4 constitutes a Designated Record Set.
- **5.2** <u>Amendments; Waiver</u>. This BAA may not be modified or amended, except in a writing duly signed by authorized representatives of the Parties. To the extent that any relevant provision of HIPAA, the HITECH Act, or California Confidentiality

Laws is materially amended in a manner that changes the obligations of the Parties, the Parties agree to negotiate in good faith appropriate amendment(s) to this BAA to give effect to the revised obligations. Further, no provision of this BAA shall be waived, except in a writing duly signed by authorized representatives of the Parties. A waiver with respect to one event shall not be construed as continuing, or as a bar to or waiver of any right or remedy as to subsequent events.

- **5.3** No Third Party Beneficiaries. Nothing express or implied in this BAA is intended to confer, nor shall anything herein confer, upon any person other than the Parties and the respective successors or assigns of the Parties, any rights, remedies, obligations, or liabilities whatsoever.
- **5.4** <u>Notices</u>. Any notices to be given hereunder to a Party shall be made via U.S. Mail or express courier to such Party's address given below.

If to Business Associate, to:

Hologic Inc. Attn: Office of the General Counsel 250 Campus Drive Marlboro MA 01752

If to Covered Entity, to:

Natividad Medical Center Attn: Compliance/Privacy Officer 1441 Constitution Blvd. Salinas, CA 93906

Phone: 831-755-4111 Fax: 831-755-6254

Each Party named above may change its address and that of its representative for notice by the giving of notice thereof in the manner hereinabove provided. Such notice is effective upon receipt of notice, but receipt is deemed to occur on next business day if notice is sent by FedEx or other overnight delivery service.

- **5.5** <u>Counterparts; Facsimiles</u>. This BAA may be executed in any number of counterparts, each of which shall be deemed an original. Facsimile copies hereof shall be deemed to be originals.
- **5.6** Relationship of Parties. Notwithstanding anything to the contrary in the Services Agreement, Business Associate is an independent contractor and not an agent of Covered Entity under this BAA. Business Associate has the sole right and obligation to supervise, manage, contract, direct, procure, perform, or cause to be performed all Business Associate obligations under this BAA.

- **5.7** Choice of Law; Interpretation. This BAA shall be governed by the laws of the State of California. Any ambiguities in this BAA shall be resolved in a manner that allows Covered Entity and Business Associate to comply with the Privacy Rule, the Security Rule, and the California Confidentiality Laws.
- 5.8 **Indemnification**. Business Associate shall indemnify, defend, and hold harmless the County of Monterey (the "County"), its officers, agents, and employees from any claim, liability, loss, injury, cost, expense, penalty or damage, including costs incurred by the County with respect to any investigation, enforcement proceeding, or third party action, arising out of a Use or Disclosure of PHI in violation of this BAA or a Breach by Business Associate and/or its agents, members, employees, or Subcontractors, excepting only loss, injury, cost, expense, penalty or damage caused by the negligence or willful misconduct of personnel employed by the County. This provision is in addition to, and independent of, any indemnification provision in any related or other written agreement between the Parties. Business Associate's obligations under this paragraph are conditioned on Covered Entity giving Business Associate: (i) written notice within thirty (30) days of Covered Entity's receipt of notice of any claim; and (ii) continuous reasonable cooperation in the defense; and (iii) complete and sole control over the defense and settlement of any such claim provided that, Business Associate agrees not to settle any claim or lawsuit that involves an admission of liability or wrongdoing by, or imposes any obligations on, Covered Entity, without Covered Entity's prior written consent, which consent shall not be unreasonably withheld or delayed.
- Agreements and written Business Associate relationships in which Business Associate creates, receives, transmits, or maintains any PHI for or on behalf of Covered Entity in any form whatsoever. This BAA shall automatically be incorporated in all subsequent written agreements between Business Associate and Covered Entity involving the Use or Disclosure of PHI whether or not specifically referenced therein. In the event of any conflict or inconsistency between a provision of this BAA and a provision of any other written agreement between Business Associate and Covered Entity with respect to the subject matter herein, the provision of this BAA shall control unless the provision in such other written agreement establishes additional rights for Business Associate or additional duties for or restrictions on Business Associate with respect to PHI, in which case the provision of such other written agreement will control.
- **5.10** <u>Insurance</u>. In addition to any general and/or professional liability insurance required of Business Associate, Business Associate agrees to obtain and maintain, at its sole expense, liability insurance on an occurrence basis. Such insurance coverage will be maintained for the term of this BAA, and a copy of such policy or a certificate evidencing the policy shall be provided to Covered Entity at Covered Entity's request.
- **5.11** <u>Legal Actions</u>. Promptly, but no later than five (5) business days after notice thereof, Business Associate shall advise Covered Entity of any actual action, proceeding, regulatory or governmental orders or actions that becomes known to it that may affect the interests of Covered Entity with respect to the subject matter herein or

jeopardize this BAA, and of any facts and circumstances that may be pertinent to the prosecution or defense of any such actual legal action or proceeding, except to the extent prohibited by law.

**5.12** <u>Audit or Investigations</u>. Promptly, but no later than five (5) business days after notice thereof, Business Associate shall advise Covered Entity of any audit, compliant review, or complaint investigation by the Secretary or other state or federal agency related to compliance with HIPAA, the HITECH Act, or the California Confidentiality Laws.

IN WITNESS WHEREOF, each of the undersigned has caused this BAA to be duly executed in its name and on its behalf as of the Effective Date.

BUSINESS ASSOCIATE	COVERED ENTITY		
By: See DW	D.		
Ву: _/	By:		
Print Name: Keith Reed	Print Name:		
Print Title: VP – Breast & Skeletal Health	Print Title:		
Date: 9/17/2021	Date:		