

PROVIZIO® SINGLE USE SENSOR PROGRAM
TERMS AND CONDITIONS

These terms and conditions (the "**Terms**") apply to and are incorporated into Customer's written agreement with BRUIN BIOMETRICS, LLC, a California limited liability corporation or BRUIN BIOMETRICS EUROPE, LTD, located and registered in the UK 8711483 (collectively "**BBI**"), and govern Customer's participation in BBI's Provizio® SEM Scanner Single Use Sensor program. BBI may change these Terms upon written notice to Customer at any time and any continued use of Devices and Consumables thereafter by Customer shall be deemed acceptance of any such changes to these Terms.

1. DEFINITIONS.

Terms that are capitalized in this document but are not defined in this Section 1 or these Terms shall have the meaning set forth in the Agreement.

- 1.1 "**Affiliate**" means any entity that, directly or indirectly, whether through one or more intermediaries, controls, is controlled by, or is under common control with such party, where "control" means the possession, directly or indirectly, of the power to direct or cause the direction of the management or the policies of an entity, whether through ownership of voting securities or by agreement or otherwise.
- 1.2 "**Applicable Law**" means, with respect to any party, any federal, state or local statute, law, ordinance, rule, administrative interpretation, regulation, regulatory approval, order, writ, injunction, directive, judgment, decree or other requirement of any international, federal, state or local court, administrative agency or commission or other governmental or regulatory authority or instrumentality, domestic or foreign, applicable to such party or any of its properties, assets or business operations or having jurisdiction over all or any part of the Devices, Consumables, and/or Services to be used hereunder, including of the U.S. Food and Drug Administration, the European Commission and the European Medicines Agency.
- 1.3 "**Authorized Personnel**" means Customer's healthcare practitioners who are authorized to access and use the Devices.
- 1.4 "**Confidential Information**" means each party's and its Affiliates' business and technical information in any form, including Data, business and marketing plans, strategies, sales, product and financial data and projections, formulas, processes, techniques, trade secrets, know-how, inventions, processes (business, technical or other), designs, algorithms, source code, customer lists and this Agreement.
- 1.5 "**Data**" has the meaning set forth in Section 8.1.
- 1.6 "**Documentation**" means the manuals, specifications and other written and electronic materials describing the functionality, features and operating characteristics, maintenance, operation and use of the Devices and/or Consumables as provided to Customer from time to time, including as may be indicated by BBI in a link to specific entries posted by BBI on BBI's website.

- 1.7 **"Functional Specifications"** means the features, functionality, configuration and other specifications and requirements for the Devices and/or Consumables that are set forth in the Documentation.
- 1.8 **"HIPAA Requirements"** means collectively the applicable provisions of the Administrative Simplification section of HIPAA - the Health Insurance Portability and Accountability Act of 1996 (as codified at 42 U.S.C. § 1320d-8), as amended by the Health Information Technology for Economic and Clinical Health Act, and any regulations promulgated thereunder, including the federal privacy regulations (45 CFR Parts 160 and 164) and the federal security standards (45 CFR Part 160 and 164), as may be amended from time to time.
- 1.9 **"Intellectual Property Rights"** means all intellectual property rights throughout the world, whether now existing or existing in the future, including (a) all patent rights, including any rights in pending patent applications and any related rights; (b) all copyrights and other related rights in works of authorship, including all registrations and applications therefor; (c) all trademarks, service marks, trade dress or other proprietary trade designations, including all registrations and applications therefor (d) all rights to proprietary know-how, trade secrets and other confidential information, whether arising by law or pursuant to any contractual obligation of non-disclosure; and (e) all rights covering intellectual property or technology recognized in any jurisdiction.
- 1.10 **"New Product"** means a release of Devices, Consumables or software with significant new features or capabilities that may or may not work with Customer's existing Devices or Consumables.
- 1.11 **"Personal Information"** means information that identifies, can be used to identify, or relates to an identifiable individual. An identifiable individual is one who can be identified, directly or indirectly, in particular by reference to an identifier, such as a name, an identification number, location data, an online identifier, or to one or more factors specific to the physical, psychological, genetic, mental, economic, cultural or social identity of that individual. Personal Information includes Protected Health Information.
- 1.12 **"Protected Health Information" or "PHI"** has the meaning given to such term by the HIPAA Requirements.

2. PURCHASE MODEL.

- 2.1 **Initial Purchase Order.** The parties will execute an initial Purchase Order for Devices, Consumables and Services, and designating the Facilities where the Devices will be used. The Purchase Order will also specify the pricing and minimum purchase commitments agreed by the parties.
- 2.2 **Additional Purchase Orders.** During the Term, the parties may execute one or more Purchase Orders for additional Devices, Consumables and/or Services or changes of Facilities. The purchase of each additional Device will be subject to the minimum purchase commitments set forth in the applicable Purchase Order. For clarity, Customer may purchase additional Consumables above the Minimum Order at the pricing set forth in the applicable Purchase Order. Each Purchase Order shall include at least the following: (a) an order number; (b) the quantity of Devices and/or Consumables purchased; (c) the

Facility and if different, the address for delivery; (d) the requested delivery date (subject to BBI's standard lead times); (e) any requested Services; and (f) any specific shipping instructions (non-standard shipping instructions may bear additional costs). Any terms in any Purchase Order submitted by Customer that are inconsistent with or in addition to the Agreement are hereby rejected and shall have no force or effect.

2.3 **Order Acceptance.** No Purchase Order received by BBI from Customer will be binding on BBI unless and until BBI expressly accepts the Purchase Order in writing. BBI agrees to use commercially reasonable efforts to accept Purchase Orders that comply with the Agreement.

2.4 **Cancellation and Reschedule.** No Purchase Order may be cancelled, rescheduled, or reconfigured without BBI's prior written consent, which shall not be unreasonably withheld, and in such event, Customer will be liable to BBI for any additional charges and expenses incurred by BBI. No cancellations, reschedules or reconfigurations are permitted within 30 days prior to the delivery date. Prices are subject to change by BBI upon Customer rescheduling or reconfiguration of orders.

3. **PRICE; PAYMENT.**

3.1 **Prices.** The prices for Consumables and Services are set forth in the Purchase Order. Prices are subject to change in response to supplier price increases, whereupon, Customer may cancel the undelivered portion of any affected order by delivering written notice to BBI prior to the shipment thereof and within ten days of its receipt of notice of the price increase. Unless otherwise agreed in advance, shipping will be Customer's responsibility.

3.2 **Payment.** Payment terms are net thirty (30) days from the date of BBI's invoice and prices do not include any freight, handling, shipping, insurance or other similar charges, payment of which will be the sole responsibility of Customer unless set forth otherwise in the applicable Purchase Order; *provided that* Customer may provide its contracted shipping information to BBI for direct billing. Any payments not paid by the due date will incur a late fee of one and one-half percent (1.5%) per month or the highest rate allowed by Applicable Law, whichever is lower, until the balance is fully paid. BBI reserves the right to modify terms prior to shipment, require payment in advance, or delay or cancel any shipment or order by reason of Customer's creditworthiness or should Customer fail to fulfill any obligation when due.

3.3 **Taxes.** All charges to Customer are calculated exclusive of any applicable taxes, duties, or similar liabilities. Customer will pay such charges unless Customer provides BBI with the appropriate and valid exemption documentations prior to BBI's provision of the applicable invoice to Customer.

4. **DELIVERY.**

4.1 **Delivery; Title and Risk of Loss.** BBI agrees to use commercially reasonable efforts to deliver the Devices and Consumables in accordance with the terms of the applicable Purchase Order, unless otherwise agreed in writing by the parties. BBI's responsibility for any loss or damage ends when products are delivered to the carrier for delivery to Customer or to Customer's agent. Title to Consumables will pass to Customer upon

delivery, *provided* that at no time will title to any Devices, software or firmware pass to Customer. All product purchases shall be deemed irrevocably accepted upon delivery.

5. UPDATES, UPGRADES, TRAINING AND SUPPORT; MAINTENANCE.

- 5.1 **Updates, Upgrades, and New Products.** BBI will provide to Customer at no additional charge any changes to the existing Devices that BBI makes generally available to its customers containing substantially only minor error corrections, security patches and/or performance improvements of existing functionality (collectively, "**Updates**"). Customer agrees to accept and allow the installation of any such Updates. A change to any existing Device, in each case, containing new features, functionality and/or performance improvements and/or extending the useful life of the Device ("**Upgrades**") released by BBI may be made available to Customer at an additional charge, *provided, however*, in the event such Upgrades are required for the safe operation of the Device or without such Upgrades, Customer cannot use the Device in accordance with Applicable Law, such Updates shall be provided to Customer at no additional charge. New Products may be made available to Customer under a new Purchase Order at the prices then in effect for such New Products. BBI will determine in its sole discretion what constitutes an Update, an Upgrade, or a New Product. In the event that BBI determines that a Consumable requires an Update for the safe operation of the Device, BBI shall promptly inform Customer and replace such Consumables with the appropriate updated Consumables. BBI shall provide a credit to Customer for the value of any such returned Consumables to be applied towards the value of the updated Consumables, if applicable, at the price of the updated Consumables.
- 5.2 **Provision of Services; Training and Support.** BBI may provide certain services, including training and support services, as set forth in the Agreement or in a Purchase Order.
- 5.3 **Maintenance.** Except for warranty repairs made pursuant to Section 10.1 below, maintenance services for the Devices are not covered by the Agreement. If Customer desires BBI to provide maintenance or assistance other than warranty repairs, Customer must contact BBI and enter into a separate maintenance agreement.

6. CUSTOMER OBLIGATIONS.

- 6.1 Customer is responsible for ensuring that only Authorized Personnel may access and use the Devices and Consumables, and that all uses of Devices and Consumables will be solely in the manner and in accordance with the procedures for which the Devices have been approved, and that such use complies with Applicable Law and BBI's instructions for use. Customer (a) may only use the Devices and Consumables during the Term and agrees to accept and implement all security and other Updates or required Upgrades made available by BBI, (b) may use the Consumables solely with the Devices in accordance with the Agreement during the Term, and (c) agrees to ensure that each Device is sufficiently connected and has access to the Internet to accept and install any Updates and required Upgrades.
- 6.2 Customer will promptly following receipt provide BBI with any communications (written or oral) it receives from any regulatory or governmental authority regarding the Device

or Consumable and shall give BBI reasonable notice of all meetings and telephone calls with any regulatory or governmental authority in relation to the same, and give BBI or its nominee a reasonable opportunity to attend and participate at each such meeting.

6.3 Customer shall immediately notify BBI of any complaint, product quality issue or adverse event associated with the use of any Device or Consumables in humans, whether or not considered product related, as soon as possible (and in any event within 24 hours) following receipt of the complaint or occurrence of the issue or adverse event, providing reasonable detail. Customer agrees to provide BBI with a copy of any adverse event report relating to any Device or Consumables at least three (3) days prior to filing it with the relevant regulator or governmental authority, or, if such notice would cause a violation of applicable law, as soon as practicable thereafter. On BBI's request, the Customer shall enter into a safety data exchange agreement with BBI.

6.4 **Use Restrictions.** Customer will not, and will not permit others to:

- (a) remove or modify any program markings or any notice of BBI's or its licensors' proprietary rights in the Documentation, or on the Device or Consumables;
- (b) modify, make derivative works of, disassemble, decompile, or reverse engineer any part of the Device (the foregoing prohibition includes review of data structures or similar materials produced by programs) or Consumables;
- (c) manufacture or alter the Device or Consumables or any of its components;
- (d) export, market, promote, lease or sell the Device or Consumables or any of their components, or access or use the Device or Consumables in order to build or support, and/or assist a third party in building or supporting, products or devices or Consumables competitive to BBI or use the Device or Consumables to create or develop any service, interface or software that competes with the Device or Consumables;
- (e) perform or disclose any benchmark or performance tests of the Device or Consumables without BBI's prior written consent;
- (f) perform or disclose any of the following security testing of the Device or Consumables or associated infrastructure without BBI's prior written consent: network discovery, port and service identification, vulnerability scanning, password cracking, remote access testing, or penetration testing;
- (g) disable or circumvent any security features of the Device or Consumables;
- (h) license, sell, rent, lease, transfer, assign, distribute, display, host, outsource, disclose, permit timesharing or service bureau use, or otherwise commercially exploit or make the Device or Consumables, or any data or materials made available to Customer through the Device, to any third party, other than as expressly permitted under the Agreement;
- (i) permit unauthorized third parties to use or access the Device or Consumables;

- (j) use the Device or Consumables in any manner that violates any Applicable Law; or
- (k) engage in (i) any use by Customer of the Device or Consumables (1) that does not conform to the Documentation, Functional Specifications or instructions provided by BBI from time to time, including using, operating or modifying the Device or Consumables with or by any components, parts or equipment other than those provided by BBI or its Affiliates; (2) at a location other than the Facility; or (3) for any procedures that are not otherwise approved for intended use in the jurisdiction by the applicable regulatory authority; and (ii) any use of the Device or Consumables by a person other than the Authorized Personnel (collectively (a)-(k), "**Unauthorized Uses**").

6.5 **Compliance with HIPAA.** Customer and BBI agree that for Customer to receive the Services from BBI, Customer may need to disclose to BBI PHI belonging to Customer's patients, and for BBI to provide the Services, BBI may need to access, store and process such PHI. As such, Customer and BBI agree to the terms of the Business Associate Addendum attached hereto as **Exhibit A** (the "**BAA**"). Customer represents and warrants that it has obtained and will obtain all releases and authorizations from Customer's patients before providing any PHI to BBI.

6.6 **Device Storage.** Customer is responsible for each Device while it is in Customer's possession and is responsible for proper storage, operation, maintenance and security of the Devices. The Devices must remain located at the Facility unless otherwise authorized by BBI in writing and shall be stored by Customer for use in accordance with its labeling.

7. INTELLECTUAL PROPERTY RIGHTS.

7.1 **License.** Subject to the terms of the Agreement, BBI hereby grants Customer a non-exclusive, non-transferable, non-sublicensable, revocable, right for Customer's Authorized Personnel to access and use the Devices, Consumables and the Services solely in connection with such Authorized Personnel's treatment and diagnosis of Customer's patients at the Facility or Facilities during the Term, subject to and in accordance with all instructions, guidelines, policies and other protocols regarding the use of the Devices and Consumables set forth in the Documentation. Under no circumstances may Customer reproduce, transfer, modify, transmit or distribute any software incorporated in the Device or any Documentation. Any software or firmware incorporated in or provided with the products is licensed, not sold to Customer. Except as specifically set forth in the Agreement, no license or right of any kind, express or implied, is granted to Customer in connection with the Devices, Consumables or the Services. All rights not expressly granted are reserved. Customer agrees to comply with BBI's requirements with regard to proprietary and similar rights in and to any third party software incorporated in the Device, Consumables or the Services (including any requirement to enter into a separate license agreement and prohibitions against duplicating or disclosing the same, even if the seal on any "shrink wrap" item has been broken by BBI).

7.2 **Ownership.** As between the parties, BBI and its Affiliates and licensors shall retain any and all right, title, and interest, in and to the Devices, Consumables and the Services,

including any and all improvements, updates and modifications, and technology related thereto, and any and all Intellectual Property Rights therein.

7.3 **Feedback.** To the extent Customer provides BBI with any feedback relating to BBI's or its Affiliates' business or the Devices, Consumables and Services (collectively, "**Feedback**"), Customer hereby grants (for itself and on behalf of its Authorized Personnel) to BBI and its Affiliates a non-exclusive, perpetual, worldwide, irrevocable, royalty-free, transferable, sublicensable license to (a) use, copy, prepare derivative works of, distribute, sell and license all or any portion of the Feedback; (b) incorporate Feedback in the design of the Devices, Consumables, and Services, or other products or services; and (c) modify, enhance, design, debug, display, publicly perform, copy and otherwise dispose of, document and support the Devices, Consumables, Services or other products and services.

8. DATA.

8.1 **Data.** As between BBI and Customer, Customer owns the specific data generated from its use of the Devices and/or Consumables that directly relates to Customer's patients and users, including PHI and Personal Data of Customer's patients ("**Data**").

8.2 **Aggregated Data License.**

(a) In addition to any other rights granted to the Data set forth in this Section 8, and subject to the BAA, Customer hereby grants BBI a perpetual, irrevocable, worldwide, royalty-free, fully-paid, transferable, non-exclusive, sublicensable right and license to certain de-identified Data in aggregate form ("**Aggregated Data**") for BBI and its affiliate's internal use, including improvement of the Devices, Consumables and the Services and, to the extent permitted by Applicable Law, any other legitimate business purposes pursued by BBI and its affiliates. As between the parties, BBI shall own any and all rights and interests in and under any work product based on or created from the Aggregated Data and any datasets compiled from the Aggregated Data, including any and all Intellectual Property Rights therein.

(b) To the extent the Data comprises Personal Data, Customer shall provide the fair processing language prepared by BBI detailing the anonymization and aggregation of Personal Data by or on behalf of BBI to create Aggregated Data and the subsequent use by BBI and its affiliates of such Aggregated Data [for BBI and its affiliate's internal use, including improvement of the Devices, Consumables and the Services and, to the extent permitted by Applicable Law, any other legitimate business purposes pursued by BBI and its affiliates] in the consents and/or notices required to be provided by Customer to permit the processing of data subject Personal Data under this Agreement in compliance with EU Data Protection Laws. Customer shall comply with BBI's reasonable requests, at BBI's cost and expense, regarding BBI's compliance with EU Data Protection Law in connection with the Aggregated Data.

8.3 **BBI Privacy Policy.** Customer acknowledges that from time to time, but in all instances no less than each time a Device is placed in its dock, the Device will transmit

to BBI certain Data from such Device in key-coded form. Terms regarding BBI's collection, storage and use of Data are set forth in BBI's Privacy Policy available at [SEM Scanner Privacy Policy](#) and BBI's Data Security Terms available at [SEM Scanner Data Security](#). The Privacy Policy and Data Security Terms are incorporated into these Terms by reference. BBI may update the Privacy Policy and Data Security Terms from time to time in its sole discretion and Customer acknowledges and agrees that its continued use of the Devices and the Consumables following such time as BBI updates the Privacy Policy or Data Security Terms shall be deemed Customer's acceptance of such updated Privacy Policy and Data Security Terms.

- 8.4 **Compliance with EU Data Protection Laws.** To the extent that BBI processes Personal Data on behalf of Customer, Customer and BBI shall each comply with their respective obligations as set out in **Exhibit B**.

For the purposes of this Section 8, "**EU Data Protection Laws**" means (i) Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (the "**GDPR**") and (ii) Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector and (iii) any Applicable Law which implements, replaces, adds to, amends, extends, reconstitutes or consolidates such laws from time to time, in each case as amended, consolidated, re-enacted or replaced from time to time, including for clarity, any implementing or supplementing law in the United Kingdom; and "**Personal Data**" means all Personal Data (as defined in EU Data Protection Laws) that is subject to EU Data Protection Laws, including Personal Data of individual patients or customers of Customer who are offered goods and services in the European Economic Area ("**EEA**"), the UK and Switzerland (the "**GDPR Countries**") or whose behaviour is monitored in the GDPR Countries.

9. **CONFIDENTIAL INFORMATION.**

- 9.1 **Disclosure.** Each party ("**Receiving Party**") acknowledges that in connection with the Agreement it may from time to time receive Confidential Information from the other party ("**Disclosing Party**") and/or its Affiliates. The parties agree that (a) the Receiving Party shall not disclose to others nor authorize any of its employees, agents, consultants or representatives to disclose to others any of the Disclosing Party's Confidential Information, except as expressly permitted under this Agreement, (b) the Receiving Party shall use the Disclosing Party's Confidential Information solely for the purpose of carrying out its responsibilities and obligations or exercising its rights under the Agreement, and (c) the Receiving Party shall use the same degree of care to protect the confidential nature of the Disclosing Party's Confidential Information that the Receiving Party takes to protect its own Confidential Information of a similar nature and value, but in no event less than reasonable care, including industry standard controls. The Receiving Party agrees that its own use and/or distribution of the Disclosing Party's Confidential Information will be limited to the Receiving Party's own employees on a "need to know" basis; *provided, however,* that the Receiving Party may disclose Confidential Information learned pursuant to the Agreement to its employees, including the employees of their respective Affiliates, and to consultants or other persons having a "need to know" in support of the purpose of

carrying out its responsibilities and obligations or exercising its rights under the Agreement, and who have been advised of the obligations of confidentiality and agreed to be bound by them or, alternatively, are under pre-existing obligations of confidentiality substantially as protective as those set forth in these Terms. The Receiving Party further acknowledges that the Disclosing Party's Confidential Information is and shall remain the sole property of the Disclosing Party (including any Intellectual Property Rights therein). The Receiving Party will not, without first obtaining the written consent of the Disclosing Party, or as otherwise permitted hereunder, disclose to any person, firm or enterprise, or use for its own benefit or the benefit of any third party, any of the Disclosing Party's Confidential Information except as permitted for the purpose of carrying out its responsibilities and obligations or exercising its rights under the Agreement. The Agreement shall be the Confidential Information of both parties.

- 9.2 **Limitations.** Notwithstanding the foregoing, the Receiving Party's obligation of confidentiality hereunder shall not extend to Confidential Information that the Receiving Party can document (a) is legally in the Receiving Party's possession or already known by the Receiving Party free of any confidentiality obligation prior to the time it is received from the Disclosing Party, (b) is or subsequently becomes legally and publicly available without restriction without breach of this Agreement, (c) is rightfully received by the Receiving Party from a third party without restriction and not in violation of any duty of non-disclosure on the part of such third party or (d) the Receiving Party independently developed, or had developed for it, without use or reference to the Disclosing Party's Confidential Information. The Receiving Party shall not be deemed in breach of this Section 9 if the Receiving Party must disclose the Disclosing Party's Confidential Information pursuant to a validly issued order of a court, administrative agency or other governmental body with jurisdiction over the parties hereto, or as required by law or regulation, or in response to an audit, inquiry, request or other investigation by a governmental agency, *provided* that to the extent that it may legally do so, the Receiving Party (i) first provides the Disclosing Party with prompt written notice of such disclosure and takes reasonable steps to allow the Disclosing Party, at its sole option and expense, to object to such disclosure, seek a protective order with respect to the confidentiality of the information to be disclosed or take such other action as it deems appropriate to protect its Confidential Information and (ii) discloses only reasonably related portions of the Disclosing Party's Confidential Information. Notwithstanding anything to the contrary herein, BBI may disclose Customer's Confidential Information to bona fide actual or potential investors, lenders, or partners, *provided* that each such investor, lender or partner executes a confidentiality agreement that includes provisions no less restrictive than those provided in this Section 9.
- 9.3 **Remedy.** Any use or disclosure of the Disclosing Party's Confidential Information in violation of this Agreement may cause immediate and irreparable injury, loss and/or damage to the Disclosing Party for which an adequate remedy at law may not exist. Therefore, in the event of an actual or threatened violation, through any means whatsoever, the Disclosing Party may seek to obtain from a court of competent jurisdiction specific performance and/or temporary or permanent injunctive relief without having to post a bond.
- 9.4 **Termination of Agreement; Return or Destruction of Confidential Information.** In the event of any termination or expiration of the Agreement or at any time upon written

request of the Disclosing Party (which request shall not apply to the Devices, any portion thereof or any other Confidential Information in which the Receiving Party has continuing rights that it may exercise) the Receiving Party shall destroy the other Party's Confidential Information and all full and partial copies thereof in its possession or the possession of any third party who received such Confidential Information from the Receiving Party. Nothing in this Section 9 shall require the destruction or alteration of computer back-up tapes or similar storage made in the ordinary course of the Receiving Party's business that contain Confidential Information, *provided* that such Confidential Information contained therein may not be disclosed or used by the Receiving Party for any purpose.

10. LIMITED REPRESENTATIONS AND WARRANTIES.

- 10.1 **Devices Warranty.** BBI represents and warrants to Customer that the loaned Devices provided under the Agreement will be manufactured in accordance with current good manufacturing practice, and will perform in all material respects in accordance with all Functional Specifications in effect at the time of shipment for the period specified in the Device's Instructions for Use (the "**Warranty Period**"), which can be accessed at [SEM Scanner Instructions for Use](#). Customer may notify BBI in writing of any material nonconformance during the Warranty Period. If BBI determines that the warranty applies, BBI will issue a return authorization ("**RMA**") for the nonconforming products, and Customer will return the nonconforming unit(s) to BBI's designated repair facility in accordance with the instructions set forth in the RMA. BBI shall, at its option, either (i) repair or replace nonconforming products, at BBI's cost, and return the conforming products to Customer, or (ii) credit Customer for any non-conforming products. Any such repair or replacement provided to Customer will not extend the original warranty period for the products in question. The foregoing sets forth BBI's sole and exclusive obligation and Customer's sole and exclusive remedy for any breach of the foregoing warranty. Customer shall bear all risk of loss or damage to returned goods while in transit. In the event no defect or breach of warranty is discovered by BBI upon receipt of any returned item, the item will be returned to Customer at Customer's expense and Customer will reimburse BBI for the transportation charges, labor, and associated charges incurred in testing the allegedly defective item.
- 10.2 **Exceptions.** With respect to the representations and warranties in this Section 10, BBI shall have no liability for: (a) any Device that has been repaired or altered without BBI's or its Affiliates' written consent; (b) any Device that has been subject to abuse, misuse, negligence, or accidents; (c) any Unauthorized Uses or (d) any Device that did not implement Updates or Upgrades in a timely manner. The installation of any software or software updates on the Device not authorized in writing by BBI shall relieve BBI of any further obligations under the Agreement with respect to the warranty. Warranty coverage does not include any defect or performance deficiency that is the result of (i) operation of the Device outside of any specified environmental, electrical, or performance requirements or standards; (ii) power fluctuation or failure at Customer's premises; (iii) fires, floods or other natural causes; or (iv) inadequate environmental conditions (including but not limited to temperature or humidity control, and power quality).
- 10.3 **Additional Representations and Warranties.** Each party represents and warrants to the other that: (a) it has the full right, power and authority to enter into and perform the obligations under the Agreement without the consent of any third party; (b) it has the

right to transmit and grant or receive the licenses, including rights relating to the Data and Feedback; and (c) the use, storage, and transmission of the Data, including the Aggregated Data, will comply with all Applicable Law.

10.4 **Disclaimer.** BBI DOES NOT GUARANTEE THAT (A) ANY DEVICE, CONSUMABLE OR SERVICE WILL BE ERROR-FREE OR UNINTERRUPTED, OR THAT BBI WILL CORRECT ALL DEVICE, CONSUMABLE OR SERVICE ERRORS, (B) THE DEVICE OR CONSUMABLES WILL OPERATE IN COMBINATION WITH CUSTOMER'S OTHER APPLICATIONS, OR WITH ANY OTHER EQUIPMENT, SOFTWARE, SYSTEMS OR DATA NOT PROVIDED BY BBI, OR (C) THE DEVICE, THE CONSUMABLES OR THE SERVICES WILL MEET CUSTOMER'S REQUIREMENTS, SPECIFICATIONS OR EXPECTATIONS OR ANY REQUIREMENTS, SPECIFICATIONS OR EXPECTATIONS OF CUSTOMER'S PATIENTS. BBI DISCLAIMS RESPONSIBILITY FOR ANY ACTIVITY OF CUSTOMER, ANY AUTHORIZED PERSONNEL, OR ANY OTHER THIRD PARTY. CUSTOMER ACKNOWLEDGES THAT BBI DOES NOT CONTROL THE TRANSFER OF DATA OVER COMMUNICATIONS FACILITIES, INCLUDING THE INTERNET, CUSTOMER'S OWN DATA SYSTEMS AND OR NETWORKS, THE DATA HOSTING AND STORAGE FACILITIES OF ANY HOSTING SERVICES PROVIDER, AND THAT THE DEVICES, CONSUMABLES OR SERVICES MAY BE SUBJECT TO LIMITATIONS, DELAYS, AND OTHER PROBLEMS INHERENT IN THE USE OF SUCH COMMUNICATIONS FACILITIES. BBI IS NOT RESPONSIBLE FOR ANY DELAYS, DELIVERY FAILURES, OR OTHER DAMAGE RESULTING FROM SUCH PROBLEMS. BBI IS NOT RESPONSIBLE FOR ANY ISSUES RELATED TO THE PERFORMANCE, OPERATION OR SECURITY OF THE DEVICES, CONSUMABLES OR SERVICES THAT ARISE FROM SYSTEM ACCESS OR THE DATA PROVIDED BY CUSTOMER. BBI DOES NOT MAKE ANY REPRESENTATION OR WARRANTY REGARDING THE RELIABILITY, ACCURACY, COMPLETENESS, CORRECTNESS, OR USEFULNESS OF THIRD-PARTY CONTENT, AND DISCLAIMS ALL LIABILITIES ARISING FROM OR RELATED TO THIRD PARTY CONTENT.

10.5 **General Disclaimer.** EXCEPT FOR THE EXPRESS REPRESENTATIONS AND WARRANTIES MADE BY EACH PARTY IN THESE TERMS, NEITHER PARTY MAKES AND EACH PARTY HEREBY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES OF ANY KIND, WHETHER EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, RELATING TO THE DEVICES OR THE AGREEMENT, INCLUDING ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, QUALITY, ACCURACY AND TITLE, AND ANY WARRANTIES ARISING OUT OF COURSE OF DEALING OR USAGE OF TRADE. CUSTOMER SHALL NOT MAKE TO ANY THIRD PARTY ANY WARRANTY OR REPRESENTATION IN THE NAME OF OR ON BEHALF OF BBI.

11. LIMITATION OF LIABILITY.

11.1 **LIMITATION OF LIABILITY.** TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, IN NO EVENT SHALL BBI BE LIABLE TO CUSTOMER OR TO ANY PARTY CLAIMING THROUGH OR UNDER CUSTOMER FOR ANY INDIRECT, INCIDENTAL, SPECIAL, OR CONSEQUENTIAL DAMAGES, OR FOR ANY LOSS OF REVENUE OR PROFITS, DATA, OR DATA USE, WHETHER SUCH LIABILITY ARISES FROM ANY CLAIM BASED UPON CONTRACT, WARRANTY, TORT (INCLUDING NEGLIGENCE), PRODUCT LIABILITY OR OTHERWISE, WHETHER OR NOT BBI HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS OR DAMAGE. IN THE EVENT THAT ANY LIABILITY IS IMPOSED ON BBI FOR ANY REASON WHATSOEVER UNDER OR AS A RESULT OF THE AGREEMENT, THE AGGREGATE

AMOUNTS PAYABLE BY BBI HEREUNDER SHALL NOT EXCEED THE FEES PAID OR PAYABLE BY CUSTOMER TO BBI UNDER THE AGREEMENT IN THE 12 MONTHS PRIOR TO THE EVENT GIVING RISE TO THE CLAIM. EACH PARTY AGREES THAT THESE LIMITATIONS WILL SURVIVE AND APPLY EVEN IF ANY LIMITED REMEDY SPECIFIED IN THE AGREEMENT IS FOUND TO HAVE FAILED ITS ESSENTIAL PURPOSE.

- 11.2 **BBI DOES NOT PROVIDE MEDICAL ADVICE THROUGH THE DEVICE OR THE SERVICES.** THE DEVICE MAY PROVIDE INFORMATION AND DATA TO CUSTOMER'S AUTHORIZED PERSONNEL IN ORDER TO ASSIST SUCH AUTHORIZED PERSONNEL IN THEIR ASSESSMENT AND MANAGEMENT OF THE CARE OF THEIR PATIENTS. HOWEVER, CUSTOMER ACKNOWLEDGES AND AGREES THAT ANY SUCH HEALTH CARE INFORMATION OR RELATED MEDICAL ADVICE IS PROVIDED BY CUSTOMER OR ITS AUTHORIZED PERSONNEL ONLY, AND NOT BY BBI, AND BBI IS NOT ENGAGED IN RENDERING MEDICAL, HEALTH CARE OR SIMILAR SERVICES OR ADVICE VIA THE DEVICE, CONSUMABLES OR THE SERVICES, AND THE INFORMATION PROVIDED BY BBI VIA THE DEVICE IS NOT INTENDED TO REPLACE MEDICAL, HEALTH CARE OR OTHER PROFESSIONAL ADVICE OFFERED BY A PHYSICIAN OR OTHER PROFESSIONAL HEALTHCARE PROVIDER. BBI IS NOT RESPONSIBLE FOR ANY HEALTH PROBLEMS THAT MAY RESULT FROM INFORMATION CUSTOMER OR ITS AUTHORIZED PERSONNEL RECEIVE THROUGH USING THE DEVICE, CONSUMABLES OR THE SERVICES. IF CUSTOMER RELIES ON ANY INFORMATION CUSTOMER RECEIVES OR LEARNS ABOUT THROUGH THE DEVICE OR THE SERVICES, CUSTOMER AGREES THAT IT DOES SO AT ITS OWN RISK AND IS VOLUNTARILY PARTICIPATING IN THESE ACTIVITIES AND BBI WILL HAVE NO LIABILITY FOR SUCH INFORMATION.

12. INDEMNIFICATION.

- 12.1 **Indemnification by BBI.** BBI shall defend Customer and its successors and permitted assigns (the "**Customer Indemnified Parties**") against any third party claims, demands, suits and proceedings (each, a "**Claim**") and indemnify the Customer Indemnified Parties from and against any liabilities, losses, damages, costs and expenses, including reasonable attorneys' fees (collectively, "**Losses**") actually incurred by Customer in connection with or arising out of the Device or Consumables as used by Customer in accordance with the Documentation infringes or misappropriates the Intellectual Property Rights of a third party, except to the extent Customer indemnifies BBI pursuant to Section 12.4.
- 12.2 **Exceptions.** Notwithstanding anything to the contrary herein, BBI will not indemnify Customer for any of the following:
- (a) if Customer (i) alters the Devices or Consumables, or uses the Devices or Consumables for any Unauthorized Uses or for any other uses outside the scope of Agreement, (ii) uses a version of any Device or Consumable which has been superseded or fails to install or implement any Updates or Upgrades when made available by BBI, or (iii) Customer continues to use the Devices or Consumables after the expiration or termination of the Agreement; and

- (b) any portion of a Claim that is based upon the unauthorized modification of the Device or Consumables, or combination of the Device or Consumables with any products or services not provided by BBI.

12.3 **Infringement Remedy.** If BBI believes that Customer is, or may become, prohibited from continued use of the Devices or Consumables by reason of an actual or anticipated infringement Claim, or if BBI believes that infringement Claims or allegations of infringement may be made regarding the Devices or Consumables, then, at BBI's option, BBI will use its commercially reasonable efforts to: (a) obtain for Customer the right to continue to use the Devices and Consumables as permitted hereunder, or (b) replace or modify the Devices or Consumables so that they are no longer subject to such infringement Claim, but perform the same functions in an equivalent manner. If the options described in clauses (a) and (b) are not reasonably available to BBI, BBI may terminate the Agreement with thirty (30) days' notice and refund Customer any pre-paid fees prorated for the unused time remaining in the then-current term, if applicable. The remedies in this Section 12.3, in addition to BBI's indemnity obligations in Section 12.1, shall be Customer's sole and exclusive remedy and BBI's sole and exclusive obligation for any Claim that the Devices or Consumables infringe or misappropriate the Intellectual Property Rights of a third party.

12.4 **Indemnification by Customer.** Customer shall defend BBI, its Affiliates and its successors and permitted assigns (the "**BBI Indemnified Parties**") against any and all Claims and indemnify and hold the BBI Indemnified Parties harmless from and against any Losses in connection with or arising out of the following: (a) any violation of Applicable Law by Customer in connection with the use of the Devices, Consumables, the Services or the Data, except in each case to the extent any obligation of indemnification arises under Section 12.1; (b) any breach by Customer of Section 6.3, Section 9 or Section 14.2; or (c) any Unauthorized Uses.

12.5 **Indemnification Procedures.** To be eligible for indemnification hereunder, the party seeking indemnification (the "**Indemnified Party**") shall (a) provide the other party (the "**Indemnifying Party**") with prompt written notice of the Claim giving rise to the indemnification obligation hereunder, but in no event later than thirty (30) days after receiving notice of the Claim, (b) reasonably cooperate with the Indemnifying Party in the defense of any such claim at the Indemnifying Party's cost, and (c) permit the Indemnifying Party to assume the defense of such Claim. The Indemnifying Party shall have the exclusive ability to defend or settle any such Claim; *provided* that an Indemnifying Party shall not enter into any settlement for damages, or that imposes upon the Indemnified Party any obligation or liability, without the Indemnified Party's prior written consent, such consent not to be unreasonably withheld, delayed or conditioned. The Indemnified Party shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any claim or suit that has been assumed by the Indemnifying Party.

13. GOVERNING LAW AND DISPUTE RESOLUTION.

13.1 **Governing Law.** The Agreement and these Terms are governed by and will be construed in accordance with the laws of the State of California, excluding any conflicts of law provisions. The (a) United Nations Convention on Contracts for the International Sale of

Goods or the United Nations Convention on the Limitation Period in the International Sale of Goods, as amended, and (b) Uniform Computer Information Transactions Act, as such model act is or may be enacted in any jurisdiction, will not govern any aspect of the Agreement or these Terms, including any of the parties' rights and obligations arising pursuant to the Agreement. Any dispute, controversy or claim arising out of or related to the Agreement, or the interpretation, application, breach, termination or validity thereof, including any claim of inducement by fraud or otherwise, will be resolved in accordance with this Section 13.

- 13.2 **Dispute Resolution.** Any controversy or claim arising out of or relating to the Agreement (including any controversy or claim involving BBI, Customer, or any of either party's Affiliates (a "**Dispute**") shall first be submitted to mediation according to the *International Mediation Procedures* of the International Institute for Conflict Prevention & Resolution ("**CPR**") (*see* www.cpradr.org). Such mediation shall be attended on behalf of each party for at least one session by a senior business person with authority to resolve the Dispute. Any period of limitations that would otherwise expire between the initiation of a mediation and its conclusion shall be extended until twenty (20) days after the conclusion of the mediation. Engaging in mediation will not preclude a party from seeking interim or provisional relief necessary to protect the rights or property of that party. By so doing, such party does not waive any right or remedy under this Agreement. Any Dispute that cannot be resolved by mediation within forty-five (45) days of notice by one party to the other of the existence of a Dispute (unless the parties agree to extend that period) shall be resolved by arbitration in accordance with the CPR Rules for Administered Arbitration of "**CPR Rules**") and the Federal Arbitration Act, 9 U.S.C. §1 et seq. The arbitrator shall follow the ICDR Guidelines for Arbitrators Concerning Exchanges of Information in managing and ruling on requests for discovery. The arbitrator, by accepting appointment, undertakes to exert best efforts to conduct the process so as to issue an award within eight (8) months of her or his appointment, but failure to meet that timetable shall not affect the validity of the award. The arbitration must be conducted in California by one arbitrator appointed in accordance with the CPR Rules. The arbitrator must interpret any dispute arising out of or relating to the Agreement in accordance with the laws of California, without giving effect to its choice of law principles. Any arbitration award, order, or judgment will be final and may be entered in any court of competent jurisdiction.

THE ARBITRATOR WILL NOT AWARD PUNITIVE, COVER, EXEMPLARY, MULTIPLIED OR CONSEQUENTIAL DAMAGES, PREJUDGMENT INTEREST OR ATTORNEYS' FEES OR COSTS, EXCEPT AS MAY BE REQUIRED BY STATUTE AND EACH PARTY IRREVOCABLY WAIVES ANY RIGHT TO SEEK OR COLLECT ANY SUCH DAMAGES, PREJUDGMENT INTEREST, FEES OR COSTS IN ARBITRATION OR ANY JUDICIAL PROCEEDING. EACH PARTY IRREVOCABLY WAIVES ITS RIGHT TO TRIAL OF ANY ISSUE BY JURY.

14. MISCELLANEOUS.

- 14.1 **Survival.** Section 1, Section 3.2, Section 6.2, Section 6.3, Section 7.2, Section 7.3, Section 8, Section 9, Sections 10.2 through 10.5, Section 11, Section 12, Section 13 and Section 14 shall survive the expiration or termination of the Agreement.
- 14.2 **Anti-Kickback; Anti-Corruption.** The federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b) prohibits certain activities in connection with referring or arranging for business paid

for by a federal healthcare program. BBI may provide Customer, as permitted by the “discount safe harbor” to the federal anti-kickback statute under 42 C.F.R. § 1001.952(h), with discounts on the Devices purchased under the Agreement if certain conditions are met. Neither party shall perform any actions that are prohibited by local and other anti-corruption laws that may be applicable to any party to the Agreement. Without limiting the foregoing, neither party shall make any payments, or offer or transfer anything of value, to any government official or government employee, to any political party official or candidate for political office or to any other third party related to the transaction in a manner that would violate any such anti-corruption laws.

- 14.3 **Relationship of the Parties.** For purposes of the Agreement, each party is an independent contractor. The Agreement does not create a partnership, association, or other business entity. Neither party has any authority to act for or to bind the other.
- 14.4 **Successors and Assigns.** Customer may not assign, directly or indirectly, the Agreement or any of its rights or obligations under the Agreement, either voluntarily or involuntarily (whether by merger, acquisition, consolidation, dissolution, change of control, operation of law, or otherwise), without the prior written consent of BBI. Any purported assignment in violation of the Agreement will be null and void from the beginning.
- 14.5 **Force Majeure.** BBI will not be liable for any failure or delay in its performance or in the delivery or shipment of products, or for any damages suffered by Customer by reason of such failure or delay, when such failure or delay is caused by, or arises in connection with, any fire, flood, accident, riot, pandemic, epidemic, earthquake, severe weather, war, act of terror, governmental interference or embargo, strike, shortage of labor, fuel, power, materials or supplies, delay in delivery by BBI’s suppliers, or any other cause(s) beyond BBI’s reasonable control. BBI reserves the right to cancel without liability any order, the shipment of which is or may be delayed for more than thirty (30) days by reason of any such cause. BBI and its Affiliates reserve the right to allocate products in its sole discretion among customers or potential customers, or defer or delay the shipment of any product, which is in short supply due to any such cause.
- 14.6 **Export.** Any or all products may be subject to export or resale restriction or regulation, and Customer acknowledges that it will comply with such regulations or restrictions. Any or all products may have been imported. Country of origin information is as provided to BBI by its suppliers and is, where applicable, located on the products themselves or the supplier’s innermost packaging thereof.
- 14.7 **Severability.** If any provision in the Agreement or these Terms is found or held to be invalid or unenforceable, then the meaning of said provision will be construed, to the extent feasible, so as to render the provision enforceable, and if no feasible interpretation would save such provision, it will be severed from the remainder of the Agreement, which will remain in full force and effect unless the severed provision is essential and material to the rights or benefits received by either party. In such event, the parties will negotiate, in good faith, a substitute, valid and enforceable provision or agreement which most nearly effects the parties’ intent in entering into the Agreement.
- 14.8 **No Third-Party Beneficiaries.** No one other than BBI, BBI’s Affiliates and Customer has any rights, or is entitled to any remedies, under the Agreement and any rights that any

third party may have as a third party beneficiary under Applicable Law are hereby expressly disclaimed.

- 14.9 **Waiver.** No provision of the Agreement may be waived except by a writing signed by the party against whom the waiver is sought to be enforced. No failure to enforce any provision of the Agreement constitutes a waiver of future enforcement of that provision or of any other provision of the Agreement. All waivers must be in writing.
- 14.10 **Headings and Construction.** The headings to the clauses, sub-clause and parts of the Agreement and these Terms are inserted for convenience of reference only and are not intended to be part of or to affect the meaning or interpretation of the Agreement. The parties agree that any rule of construction to the effect that ambiguities are to be resolved against the drafting party will not be applied in the construction or interpretation of the Agreement or these Terms. As used in the Agreement or these Terms, the words "include" and "including," and variations thereof, will be deemed to be followed by the words "without limitation."
- 14.11 **Entire Agreement.** These Terms, the Agreement, and all other attachments thereto and any document expressly incorporated by reference therein, constitute the full and entire understanding and agreement between the parties with regard to the subject matter hereof, and supersedes any prior communications, representations, understandings, and agreements, either oral or written, between the parties with respect to such subject matter. Customer, by accepting any products, making any payments, or ordering any products having previously received these Terms, will be deemed to have assented to these Terms notwithstanding any terms contained in any prior or later communication from Customer and whether or not BBI will specifically or expressly object to any of Customer's terms. BBI's failure to object to any document, communication or act of Customer will not be deemed a waiver of any of these Terms. A duly authorized officer of BBI must specifically agree to any addition or change to these Terms in writing before becoming binding on BBI.

EXHIBIT A

BUSINESS ASSOCIATE ADDENDUM

This Business Associate Agreement ("**BAA**") is entered into as of the effective date of the Terms entered into by and between BBI and Customer. BBI and Customer may be individually referred to as a "**Party**" and, collectively, the "**Parties**" in this BAA. Upon execution of the Terms, this BAA is incorporated by reference into the Terms.

RECITALS

- A. BBI is providing certain Services to Customer under the underlying Terms. To the extent that BBI creates, receives, maintains or transmits "**Protected Health Information**" or "**PHI**" (as defined below) on behalf of Customer in the course of providing the Services, and BBI is acting as a "**Business Associate**" (defined below) of Customer, the terms of this BAA shall apply with respect to such PHI.
- B. BBI may create, receive, maintain or transmit PHI on behalf of Customer only as set forth in this BAA and to the extent allowed under the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, as amended by the Health Information Technology for Economic and Clinical Health Act (collectively, "**HIPAA**"), and the Privacy Rule, Security Rule, Enforcement Rule and Breach Notification Rule set forth at 45 C.F.R. Parts 160 and 164 (jointly, the "**HIPAA Rules**") promulgated thereunder.
- C. Customer and BBI intend to protect the privacy and provide for the security of PHI in compliance with HIPAA and the HIPAA Rules.
- D. The purpose of this BAA is to satisfy certain standards and requirements of HIPAA and the HIPAA Rules, including, but not limited to, Title 45, §§ 164.314(a)(2)(i), 164.502(e) and 164.504(e) of the Code of Federal Regulations ("**C.F.R.**").

NOW, THEREFORE, in consideration of the mutual covenants and promises set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

SECTION 1: DEFINITIONS

Capitalized Terms. Capitalized terms used in this BAA and not otherwise defined herein shall have the meanings set forth in the HIPAA Rules and the Terms, which definitions are incorporated in this BAA by reference.

"**Business Associate**" shall have the same meaning given to such term in 45 C.F.R. § 160.103, and for purposes of this BAA shall refer to BBI.

"**Covered Entity**" shall have the same meaning given to such term in 45 C.F.R. § 160.103, and for purposes of this BAA shall refer to Customer.

“Protected Health Information” or **“PHI”** shall have the same meaning given to such term in 45 C.F.R. § 160.103, as applied to the information created, received, maintained or transmitted by BBI from or on behalf of Customer.

“Unsuccessful Security Incident” shall mean pings and other broadcast attacks on a firewall, port scans, unsuccessful log-on attempts, denials of service, or other similar attempted but unsuccessful Security Incident, or a combination thereof, so long as no such incident results in unauthorized access, use or disclosure of PHI.

SECTION 2: PERMITTED USES AND DISCLOSURES OF PHI

- 2.1 **Uses and Disclosures of PHI.** BBI shall not use or disclose PHI other than (a) as necessary to provide the Services, (b) as otherwise expressly permitted in this BAA or the Terms, or (c) as Required by Law, provided that such use or disclosure would not violate the Privacy Rule if done by Customer, except as set forth in Sections 2.2, 2.3 and 2.4. To the extent BBI is carrying out any of Customer’s obligations under the Privacy Rule to provide the Services or pursuant to the terms of this BAA, BBI shall comply with the requirements of the Privacy Rule that apply to Customer in the performance of such obligation(s).
- 2.2 **Permitted Uses of PHI by BBI.** Except as otherwise limited in this BAA, BBI may use PHI for the proper management and administration of BBI or to carry out the legal responsibilities of BBI.
- 2.3 **Permitted Disclosures of PHI by BBI.** Except as otherwise limited in this BAA, BBI may disclose PHI for the proper management and administration of BBI, provided that the disclosures are Required by Law, or BBI obtains reasonable assurances from the person to whom the information is disclosed that it shall remain confidential and will be used or further disclosed only as Required by Law or for the purpose for which it was disclosed to the person (which purpose must be consistent with the limitations imposed upon BBI pursuant to this BAA), and that the person agrees to notify BBI of any instances of which it is aware in which the confidentiality of the information has been breached. BBI may disclose PHI to report violations of law to appropriate federal and state authorities, consistent with 45 C.F.R. § 164.502(j)(1).
- 2.4 **Data Aggregation.** Except as otherwise limited in this BAA, BBI may use PHI to provide Data Aggregation services as permitted by 45 C.F.R. § 164.504(e)(2)(i)(B).
- 2.5 **De-identified Data.** BBI may de-identify PHI in accordance with the standards set forth in 45 C.F.R. § 164.514(b) and may use or disclose such de-identified data for any purpose.

SECTION 3: OBLIGATIONS OF BBI

- 3.1 **Appropriate Safeguards.** BBI shall use appropriate safeguards and shall comply with the Security Rule with respect to Electronic PHI, to prevent use or disclosure of such information other than as provided for by the Terms or this BAA.
- 3.2 **Reporting of Improper Use or Disclosure, Security Incident or Breach.** BBI shall report to Customer any use or disclosure of PHI not permitted under this BAA, Breach of Unsecured PHI or Security Incident, without unreasonable delay, and in any event no

more than ten (10) business days following discovery; provided, however, that the Parties acknowledge and agree that this Section constitutes notice by BBI to Customer of the ongoing existence and occurrence of Unsuccessful Security Incidents.

- 3.3 **BBI's Agents.** In accordance with 45 C.F.R. § 164.502(e)(1)(ii) and 45 C.F.R. § 164.308(b)(2), as applicable, BBI shall enter into a written agreement with any agent or subcontractor that creates, receives, maintains, or transmits PHI on behalf of BBI for services provided to Customer, providing that the subcontractor or agent agrees to substantially the same restrictions and conditions that apply to BBI through this BAA with respect to such PHI.
- 3.4 **Access to PHI.** To the extent BBI has PHI contained in a Designated Record Set, BBI agrees to make information available to Customer pursuant to 45 C.F.R. § 164.524, to respond to an Individual's request to Customer to review or copy the Individual's PHI; provided, however, that BBI is not required to provide such access where the PHI contained in a Designated Record Set is duplicative of the PHI contained in a Designated Record Set possessed by Customer. If an Individual makes a request for access pursuant to 45 C.F.R. § 164.524 directly to BBI, or inquires about his or her right to access, BBI shall either forward such request to Customer or direct the Individual to Customer.
- 3.5 **Amendment of PHI.** To the extent BBI has PHI contained in a Designated Record Set, BBI agrees to make such information available to Customer for amendment pursuant to 45 C.F.R. § 164.526. If an Individual submits a written request for amendment pursuant to 45 C.F.R. § 164.526 directly to BBI, or inquires about his or her right to amendment, BBI shall either forward such request to Customer or direct the Individual to Customer.
- 3.6 **Documentation of Disclosures.** BBI agrees to document such disclosures of PHI and information related to such disclosures as would be required for Customer to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. § 164.528. BBI shall document, at a minimum, the following information: (i) the date of the disclosure, (ii) the name and, if known, the address of the recipient of the PHI, (iii) a brief description of the PHI disclosed, (iv) the purpose of the disclosure that includes an explanation of the basis for such disclosure, and (v) any additional information required under HIPAA and any implementing regulations.
- 3.7 **Accounting of Disclosures.** BBI agrees to provide to Customer, upon receipt of a written request from Customer, information collected in accordance with Section 3.6 of this BAA to permit Customer to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. § 164.528. If an Individual submits a written request for an accounting of disclosures of PHI pursuant to 45 C.F.R. § 164.528 directly to BBI, or inquires about his or her right to an accounting of disclosures of PHI, BBI shall direct the Individual to Customer.
- 3.8 **Governmental Access to Records.** BBI shall make its internal practices, books and records relating to the use and disclosure of PHI received from, or created or received by BBI on behalf of, Customer available to the Secretary for purposes of the Secretary determining Customer's compliance with the Privacy Rule.

- 3.9 **Mitigation.** To the extent practicable, BBI will reasonably cooperate with Customer's efforts to mitigate a harmful effect that is known to BBI of a use or disclosure of PHI by BBI that is not permitted by this BAA.
- 3.10 **Minimum Necessary.** BBI shall request, use and disclose the minimum amount of PHI necessary to accomplish the purpose of the request, use or disclosure, in accordance with 45 C.F.R. § 164.514(d), and any amendments thereto.

SECTION 4: OBLIGATIONS OF CUSTOMER

- 4.1 **Notice of Privacy Practices.** Customer shall notify BBI of any limitation(s) in its notice of privacy practices in accordance with 45 C.F.R. § 164.520, to the extent that such limitation may affect BBI's use or disclosure of PHI.
- 4.2 **Notification of Changes Regarding Individual Permission.** Customer shall obtain any consent or authorization that may be required by the Privacy Rule, or applicable state law, prior to furnishing BBI with PHI. Customer shall notify BBI of any changes in, or revocation of, permission by an Individual to use or disclose PHI, to the extent that such changes may affect BBI's use or disclosure of PHI.
- 4.3 **Notification of Restrictions to Use or Disclosure of PHI.** Customer shall notify BBI of any restriction to the use or disclosure of PHI that Customer has agreed to in accordance with 45 C.F.R. § 164.522, to the extent that such restriction may affect BBI's use or disclosure of PHI.
- 4.4 **Permissible Requests by Customer.** Customer shall not request BBI to use or disclose PHI in any manner that would not be permissible under the HIPAA Rules if done by Customer, except as permitted pursuant to the provisions of Sections 2.2, 2.3 and 2.4 of this BAA.

SECTION 5: TERM AND TERMINATION

- 5.1 **Term.** The term of this BAA shall commence as of the BAA Effective Date, and shall terminate when all of the PHI provided by Customer to BBI, or created or received by BBI on behalf of Customer, is destroyed or returned to Customer. If it is infeasible to return or destroy PHI, BBI shall extend protections to such information in accordance with Section 5.3.
- 5.2 **Termination for Cause.** Upon either Party's knowledge of a material breach by the other Party of this BAA, such Party may terminate this BAA immediately if cure is not possible. Otherwise, the non-breaching Party shall provide written notice to the breaching Party detailing the nature of the breach and providing an opportunity to cure the breach within thirty (30) business days. Upon the expiration of such thirty (30) day cure period, the non-breaching Party may terminate this BAA if the breaching Party does not cure the breach or if cure is not possible.

5.3 Effect of Termination.

5.3.1 Except as provided in Section 5.3.2, upon termination of the Underlying Arrangement or this BAA for any reason, BBI shall return or destroy all PHI received from Customer, or created or received by BBI on behalf of Customer, and shall retain no copies of the PHI.

5.3.2 If it is infeasible for BBI to return or destroy the PHI upon termination of the Underlying Arrangement or this BAA, BBI shall: (a) extend the protections of this BAA to such PHI and (b) limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as BBI maintains such PHI.

SECTION 6: COOPERATION IN INVESTIGATIONS

The Parties acknowledge that certain breaches or violations of this BAA may result in litigation or investigations pursued by federal or state governmental authorities of the United States resulting in civil liability or criminal penalties. Each Party shall cooperate in good faith in all respects with the other Party in connection with any request by a federal or state governmental authority for additional information and documents or any governmental investigation, complaint, action or other inquiry.

SECTION 7: SURVIVAL

The respective rights and obligations of BBI under Section 5.3 of this BAA shall survive the termination of this BAA and the Terms.

SECTION 8: AMENDMENT

This BAA may be modified, or any rights under it waived, only by a written document executed by the authorized representatives of both Parties. In addition, if any relevant provision of the HIPAA Rules is amended in a manner that changes the obligations of BBI or Customer that are embodied in terms of this BAA, then the Parties agree to negotiate in good faith appropriate non-financial terms or amendments to this BAA to give effect to such revised obligations.

SECTION 9: EFFECT OF BAA

In the event of any inconsistency between the provisions of this BAA and the Terms, the provisions of this BAA shall control. In the event that a court or regulatory agency with authority over BBI or Customer interprets the mandatory provisions of the HIPAA Rules, in a way that is inconsistent with the provisions of this BAA, such interpretation shall control. Where provisions of this BAA are different from those mandated in the HIPAA Rules, but are nonetheless permitted by such rules as interpreted by courts or agencies, the provisions of this BAA shall control.

SECTION 10: GENERAL

This BAA is governed by, and shall be construed in accordance with, the laws of the State governing the Terms. Any action relating to this BAA must be commenced within one (1) year after the date upon which the cause of action accrued. Customer shall not assign this BAA without the prior written consent of BBI, which shall not be unreasonably withheld. If any part

of a provision of this BAA is found illegal or unenforceable, it shall be enforced to the maximum extent permissible, and the legality and enforceability of the remainder of that provision and all other provisions of this BAA shall not be affected. All notices relating to the Parties' legal rights and remedies under this BAA shall be provided in writing to a Party, shall be sent to its address set forth below, or to such other address as may be designated by that Party by notice to the sending Party, and shall reference this BAA. Nothing in this BAA shall confer any right, remedy, or obligation upon anyone other than Customer and BBI. This BAA is the complete and exclusive agreement between the Parties with respect to the subject matter hereof, superseding and replacing all prior agreements, communications, and understandings (written and oral) regarding its subject matter.

SECTION 11: INDEPENDENT CONTRACTOR

BBI will be considered, for all purposes, an independent contractor, and BBI will not, directly or indirectly, act as agent, servant or employee of Customer or make any commitments or incur any liabilities on behalf of Customer without its express written consent. Nothing in this BAA shall be deemed to create an employment, principal-agent or partner relationship between the Parties. BBI shall retain sole and absolute discretion in the manner and means of carrying out its activities and responsibilities under this BAA.

EXHIBIT B

EU DATA PROCESSING TERMS

1. DEFINITIONS

1.1 For the purposes of this Exhibit B, the following expressions bear the following meanings unless the context otherwise requires:

"Controller", **"Process"**, **"Processed"**, **"Processing"** and **"Processor"** have the meaning given in the GDPR;

"Data Subject" means the living individuals who are the subject of the Personal Data;

"EU Data Protection Laws" means (i) Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (the **"GDPR"**) and (ii) Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector and (iii) any Applicable Law which implements, replaces, adds to, amends, extends, reconstitutes or consolidates such laws from time to time, in each case as amended, consolidated, re-enacted or replaced from time to time, including for clarity, any implementing or supplementing law in the United Kingdom.

"Model Clauses" means, as applicable:

(a) the Standard Contractual Clauses (Controller to Processor) as set out in the Commission Decision of 5 February 2010 (C(2010) 593); or

(b) the Standard Contractual Clauses (Controller to Controller) as set out in Commission Decision of 27 December 2004 amending Decision 2001/497/EC;

in each case as amended, updated or replaced from time to time (or such other standard data protection clauses as may be adopted or approved by the UK Government or European Commission);

"Personal Data" means all Personal Data (as defined in EU Data Protection Laws) that is subject to EU Data Protection Laws, including Personal Data of individual patients or customers of Customer who are offered goods and services in the European Economic Area ("EEA"), the UK and Switzerland (the **"GDPR Countries"**) or whose behaviour is monitored in the GDPR Countries.

"Regulator" means the data protection supervisory authority which has jurisdiction over a Customer's Processing of Personal Data; and

"Third Countries" means all countries outside of the scope of the data protection laws of the European Economic Area ("EEA"), excluding countries approved as providing adequate protection for Personal Data by the European Commission from time to time,

which at the date of this Exhibit B include Andorra, Argentina, Canada, Faroe Islands, Guernsey, Isle of Man, Israel, Japan, Jersey, New Zealand, Switzerland and Uruguay.

2. CONDITIONS OF PROCESSING

- 2.1 This Exhibit B governs the terms under which BBI will Process Personal Data on behalf of Customer. The Parties agree that for the purposes of such Processing, BBI will be the Processor and Customer will be the Controller.

3. BBI'S OBLIGATIONS

- 3.1 BBI shall only Process Personal Data on behalf of Customer and in accordance with, and for the purposes set out in the documented instructions received from Customer from time to time (including, for clarity, in this Agreement, but excluding the anonymization or aggregation of such Personal Data for internal use or other business purposes, which is performed by BBI as a Controller); if BBI cannot provide such compliance for whatever reason (including if the instruction violates the EU Data Protection Laws), BBI agrees to inform Data Controller of its inability to comply as soon as reasonably practicable.
- 3.2 BBI shall implement appropriate technical and organisational security measures to protect the Personal Data belonging to Customer, taking into account the nature, scope, context and purposes of processing as well as the risks of varying likelihood and severity for the rights and freedoms of natural persons.
- 3.3 BBI shall notify Customer without undue delay of any breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, the Personal Data belonging to Customer.
- 3.4 BBI shall provide reasonable assistance in response to inquiries from Customer or its Regulator relating to BBI's Processing of Customer's Personal Data.
- 3.5 BBI shall upon written request from Customer from time to time provide Customer with all information necessary to demonstrate compliance with the obligations laid down in this Exhibit B.
- 3.6 BBI shall permit Customer at any time upon thirty (30) days' notice, to be given in writing, to have access to the appropriate part of BBI's premises, systems, equipment, and other materials and data Processing facilities to enable Customer to inspect or audit the same solely for the purposes of monitoring compliance with BBI's obligations under this Exhibit B.
- 3.7 Where:
- (a) a Data Subject exercises his or her rights under EU Data Protection Law in respect of Personal Data Processed by BBI on behalf of Customer; or
 - (b) Customer is required to deal or comply with any assessment, enquiry, notice or investigation by the Regulator; or

- (c) Customer is required under the EU Data Protection Laws to carry out a mandatory data protection impact assessment or consult with the Regulator prior to Processing Personal Data entrusted to the Data Processor under this Exhibit B,

then BBI will provide reasonable assistance to Customer, at Customer's cost and expense, to enable Customer to comply with obligations which arise as a result thereof.

- 3.8 BBI shall carry out a request from Customer to amend, correct, block, transfer or delete any of the Personal Data to the extent necessary to allow Customer to comply with its responsibilities as a Controller.
- 3.9 Where the BBI processes, accesses, and/or stores Personal Data in any Third Country, BBI shall comply with the data importer's obligations set out in the Model Clauses, which are hereby incorporated into and form part of this Exhibit B (with the Processing details set out in Schedule 1 (Processing Details) and the technical and organisational security measures set out in paragraph 3.2 above applying for the purposes of Appendix 1 and Appendix 2, respectively), and Customer will comply with the Data Exporter's obligations in such Model Clauses.
- 3.10 The Customer acknowledges and agrees that BBI may, or may appoint an affiliate or third party subprocessor to Process Customer's Personal Data in a Third Country, provided that it ensures that such Processing takes place in accordance with the requirements of EU Data Protection Laws. Customer hereby grants BBI a mandate to execute the Model Clauses with any relevant subcontractor (including affiliates) it appoints on behalf of Customer.

4. CUSTOMER'S OBLIGATIONS

- 4.1 Customer warrants that: (i) no Applicable Laws prevent BBI from fulfilling the instructions received from Customer and performing BBI's obligations under this Exhibit B; and (ii) Customer has complied and continues to comply with the EU Data Protection Laws, in particular it has obtained any necessary consents or given any necessary notices, and otherwise has a legitimate ground to disclose the data to BBI and enable the Processing of the Personal Data by the BBI as set out in this Exhibit B and as envisaged by the Agreement.
- 4.2 Customer shall indemnify, defend and hold harmless BBI on demand from and against all claims, liabilities, costs, expenses, loss or damage (including consequential losses, loss of profit and loss of reputation and all interest, penalties and legal and other professional costs and expenses) incurred by BBI arising directly or indirectly from a breach by the Customer of this Clause 4.

5. CHANGES IN EU DATA PROTECTION LAWS

- 5.1 The parties agree to negotiate in good faith modifications to this Exhibit B if changes are required for BBI to continue to Process the Personal Data belonging to Customer in compliance with the EU Data Protection Laws or to address the legal interpretation of the EU Data Protection Laws, including (i) to comply with the GDPR, any national legislation implementing it and any guidance on the interpretation of their respective provisions;

(ii) the Model Clauses or any other mechanisms or findings of adequacy are invalidated or amended, or (iii) if changes to the membership status of a country in the European Union or the European Economic Area require such modification.

6. SUB-PROCESSING

6.1 Customer hereby consents to the use of the subprocessors set out in Schedule 2 (*Authorised Subprocessors*) for the purposes further described in Schedule 2 (*Authorised Subprocessors*). If BBI intends to make any changes concerning an addition or replacement of the subprocessors set out in Schedule 2 (*Authorised Subprocessors*), it shall provide Customer with seven (7) days' prior written notice, during which Customer can object against the appointment or replacement. If Customer does not object, BBI may proceed with the appointment or replacement. BBI shall ensure that it has a written agreement in place with all subprocessors which contains obligations on the Subcontractor which are no less onerous on the relevant subprocessor than the obligations on BBI under this Exhibit B.

7. TERMINATION

7.1 Upon termination of the Agreement, BBI shall:

- (a) return or destroy all Personal Data it has Processed on behalf of Customer after the end of the provision of services relating to the Processing, and destroy all copies of the Personal Data unless Applicable Law requires ongoing storage of such Personal Data; and
- (b) cease Processing Personal Data on behalf of Customer.

SCHEDULE 1 PROCESSING DETAILS

Processing Operations

BBI will ensure that data processing is accurate, secure, credible and ready for analysis. Data should be traceable and an audit trail should be available. Privacy considerations and IT security should be safeguarded in all aspects of data management.

1. INTERPRETATION OF RULES AND REGULATIONS TO ENSURE PATIENT CONFIDENTIALITY

Collection of Personal Data

BBI's legal precedent for collecting personal data must be established using at least one of the six bases for data collection as per *Article 6* of GDPR and the HIPAA privacy rule.

Consent: the individual has given clear consent for you to process their personal data for a specific purpose.

Contract: the processing is necessary for a contract you have with the individual, or because they have asked you to take specific steps before entering into a contract.

Legal obligation: the processing is necessary for you to comply with the law (not including contractual obligations).

Vital interests: the processing is necessary to protect someone's life.

Public task: the processing is necessary for you to perform a task in the public interest or for your official functions, and the task or function has a clear basis in law.

Legitimate interests: the processing is necessary for your legitimate interests or the legitimate interests of a third party, unless there is a good reason to protect the individual's personal data which overrides those legitimate interests. (This cannot apply if you are a public authority processing data to perform your official tasks.)

All patient information must be collected on authorized Data Record Sheets (OTH-SEM-0117 Patient Data record Sheet). Obligations, roles and responsibilities in recording patient information must be clearly described in evaluation agreements and contracts. (OTH-SEM-0120 (UK) and OTH-SEM-0550 (US))

Roles

- For data collection, BBI will be considered as a joint controller to individual medical institutions/facilities and hospitals.
- Directive 95/46/EC of the EU regulations is a precursor to the GDPR. Authoritative interpretations of the Directive are applicable to the GDPR where the underlying obligations are similar.
- BBI interprets and assumes the role of a joint controller based on current laws and regulations. Additionally, reference is made to the Court of Justice of the European Union (CJEU) ruling of June 5, 2018 and the initial ruling by the German supervisory authority, Independent Data Protection Centre for the Land of Schleswig-Holstein, Germany (the "Supervisory Authority"), in November 3, 2011 between Facebook and a German company fan page.

- A detailed interpretation and justification for assuming joint controller responsibilities along with an example describing joint controllers in the context of engaging in research, surveys, or other collection and processing of Personal Data is provided in the document **OTH-SEM-0551**.

2. RESPONSIBILITY

Data Controller (and Joint Controller)

- The data controller has overall responsibility for ensuring that data management is carried out in compliance with national and international laws and this SOP.
- Data controller must provide information to all data subjects participating and obtain consent.
- BBI must be considered as a joint controller to individual medical institutions/facilities and hospitals.
- All agreed upon roles and responsibilities between data controllers must be outlined in the evaluation contract (**OTH-SEM-0120 (UK) and OTH-SEM-0552 (US)**) to be completed and executed by BBI prior to implementation.
- Only data controllers are allowed to collect personal data from data subjects. Data controllers are accountable for the collection, use, and disposal of personal data.
- Data controllers may only use processors that guarantee compliance with all applicable laws and regulations for patient confidentiality.
- Processors may be appointed only in the form of a binding written agreement.
- Patient data must be de-identified, pseudonymized and/or anonymized at all times.

Data Processor

- Must only act on the controller's documented instructions;
- Must impose confidentiality obligations on all personnel who process the relevant data;
- Must ensure the security of the personal data that it processes;
- abide by the rules regarding appointment of sub-processors;
- Must implement measures to assist the controller in complying with the rights of data subjects;
- Must assist the controller in obtaining approval from DPAs where required;
- Must, at the controller's election, either return or destroy the personal data at the end of the relationship (except as required by EU or Member State law); and
- Must provide the controller with all information necessary to demonstrate compliance with the GDPR.
- In the event that a processor believes that the controller's instructions conflict with patient confidentiality or applicable laws, the processor must immediately inform the controller.
- The processor must not appoint a sub-processor without the prior written consent of the controller
- Processors (and any sub-processors) shall not process personal data, except in accordance with the instructions of the controller, or the requirements of applicable laws.
- Each processor (and its representative, if any) must keep records of its processing activities performed on behalf of the controller

- Processors must implement appropriate technical and organizational security measures to protect personal data against accidental or unlawful destruction or loss, alteration, unauthorized disclosure or access.
- Processors must notify any data breach to the controller without undue delay.

3. PROCEDURE

Data Collection

BBI will provide comprehensive device use and data collection training to all agreed customer clinical staff as listed in respective contracts.

- Training records will be completed and signed by designated BBI employee.
- Protocol **OTH-SEM-0224** describes in detail, the data collection procedures for using the Provizio® SEM Scanner and the SEM Scanner 200.
- Any and all data relating to patients, or data that could be used to identify any particular patient will not be recorded on Data Record Sheets (OTH-SEM-0117).
- BBI will ensure completeness of data as agreed upon in the contract or at least on a bi-weekly basis during the data collection period.
- Customers will provide BBI with all completed Data Record Sheets by the end of each data collection period.
- BBI will ensure all necessary information is collected to complete the incidence form (**QT-0090**) by the end of each data collection period.

Data Entry

- BBI is responsible for ensuring only anonymized patient data is being captured at all times.
- Data provided by customers will be entered into site specific raw data forms using the raw data template form- **QT-0089**. Detailed instructions for data entry, storage and ensuring completeness of data are provided in work instructions **WI-37**.
- Data will be entered into form/template **QT-0089** by authorized personnel only.
- Self-Evident Corrections (SEC) will be clarified and closed in consultation with BBI Implementation team and customer team leads before finalizing the raw data for individual sites.

Data Storage and Security

- All documents and raw data will be kept secure, access restricted to authorized persons and will be stored in a shared cloud-based storage platform.
- Working raw data files for individual sites will be stored in a separate location until deemed complete by responsible BBI employee and a quality check has been performed as per work instructions **WI-38**.
- All files stored in the final folder as described in **WI-37** will be considered as locked files.
- Procedures required for securing and storage of data must be performed according to the current regulations.

- All data will be uploaded to a cloud-based storage platform to be cumulated into a relational database management system (DBMS) with access restricted to authorized persons only.
- All data imported into the DBMS will be considered final and locked for read only access to exported files.
- Any non-conformances, required changes, identified errors etc. to the data imported into the DBMS will require written authorization from the Head of Quality and Regulatory and changes will be made by notifying the statistician for updated analysis reports.
- All verified source data will be stored in a secure location by BBI for a period of 15 years or as agreed upon in the evaluation contract before being archived.

Quality Control and Quality Assurance

BBI's quality management of data aligns with the principles laid down in Article 5 of the GDPR and Article 4 of Regulation (EU) 2018/1725, namely:

1. Lawfulness, fairness and transparency
2. Purpose limitation
3. Data minimization
4. Accuracy
5. Storage limitation
6. Integrity and confidentiality

BBI is responsible for ensuring that there are procedures to ensure the quality at every step of the data management.

- Quality control procedures and ongoing data verification and validation will be carried out as described in work instructions **WI-38**.
- Manual verification (proof reading) of individual files will be performed to ensure that the data is accurate.
- Any questions, concerns, considerations and discrepancies will be raised immediately and must be clarified by designated BBI employee/personnel.
- QC reports for individual data files will be completed and documented using the form **QT-0091**.

Additionally, BBI as a joint controller of real-world data collected will ensure the following:

- Obtain documentation showing that the collected data meets the requirements for completeness, accuracy, reliability and stability (validation)
- Verify that changes to the data will not cause the original or previously entered data to be deleted (audit trail)
- Ensure that security systems exist to prevent unauthorized access
- Maintain a list of the people who have the authority to change the data.
- Ensure the adequate back-up of data
- Ensure that the data collected matches data record sheets provided by the customers and that the pooled data is consistent with the source data.

Database Export

Periodic data sets will be exported after data lock to the following:

- Data processors (Statisticians, PU Registry), for anonymized descriptive statistics and reports
- BBI implementation, marketing and sales teams for Customer evaluations
- BBI commentary and publications

The procedure for analysis including parameters derived from source data and anonymized descriptive statistics processed by BBI appointed 3rd party statisticians is described in work instruction **WI-39**.

Additional information on Data Collection can be obtained from your BBI Representative

SCHEDULE 2¹
AUTHORISED SUBPROCESSORS

Subprocessor	Services provided	Contact Details
[•]	[•]	[•]
[•]	[•]	[•]
[•]	[•]	[•]
[•]	[•]	[•]

¹ **Note to BBI:** To be completed with applicable subprocessor details, if relevant, e.g. AWS, Microsoft Azure, etc.