



# **ORDER FORM**

# **Effective Date:**

This Order Form ("Order Form") is entered into and effective as of the above Effective Date, by and between PhotoniCare, Inc. ("PhotoniCare") with an address at 2800 Meridian Pkwy, Ste 175, Durham, NC 27713, and the Customer set forth below ("Customer"). This Order Form is made a part of, subject to, and governed by the Terms and Conditions attached hereto (the "Terms"). Capitalized terms not defined in this Order Form have the meaning given in the Terms.

Customer: Contact:	Customer Information		Billing Information			
Address: City/State/Zip:						
Telephone: E-Mail:						
PhotoniCare Re Product(s):	presentative:					
Product	Description	Quantity	List Price (Per Device)	Discount Amount	Total Price	
OS-20500	Subscription Contract for OtoSight Middle Ear Scope device with Welch Allyn adapter and battery included. Rolling stand included in box with a USB drive, power cord, and IFU. NOTE: Unit Price is billed per month for the Subscription					
Subscription Te automatically re the then-curren	enew for additional <b>months</b> unless either Party provid			•		
The "Subscription	on Term" is, collectively, the Initial Term together with a	ny subseque	nt renewal period.			
Total Monthly Fee: \$		ment Terms: Net 30				
Notes / Comme	ents: \$ early adoption discount applied for "Initial"	Term"				
	s Order Form, Customer agrees it has read and understar and the Terms between PhotoniCare and Customer.	nds the Tern	ns and this Order Fo	orm, and agrees to be bou	nd by the terms of	
This Order Form as of the Effectiv	is accepted and agreed to, by the authorized representage Date.	tive of each	Party, and made ef	fective between Custome	r and PhotoniCare	
	PHOTONICARE, INC.			Customer		
Signature:		Sign	Signature:			
Print Name:		Prin	Print Name:			
Print Title:		Prin	Print Title:			
Date:		Date	Date:			





### **TERMS AND CONDITIONS**

These Terms and Conditions (these "Terms") are effective as of the Effective Date set forth on the Order Form to which they are attached ("Order Form") and are entered into by and between PhotoniCare, Inc., a Delaware corporation with an address at 2800 Meridian Pkwy, Ste 175, Durham, NC 27713 ("PhotoniCare"), and the customer identified in the Order Form ("Customer"). Customer and PhotoniCare are referred to each as a "Party" and collectively as the "Parties." These Terms, together with any attachments, schedules, exhibits, and all documents referenced herein and the Order Form to which these Terms are attached constitute the agreement (the "Agreement"). Any capitalized terms herein that are not otherwise defined shall have the meaning given to such terms in the Order Form (if any). These Terms prevail over any of Customer's terms and conditions that may be included in, attached to, or referenced in any document (including any order) submitted by Customer to PhotoniCare regardless of whether or when Customer has submitted such terms. Fulfillment of Customer's order does not constitute acceptance of any of Customer's terms and conditions and does not serve to modify or amend these Terms.

1. **SCOPE.** These Terms are the terms and conditions under which PhotoniCare provides for use to Customer during the Subscription Term the Device(s) and Accessories (collectively, "**Products**") as further described in the Order Form, and through which Customer commits to take possession of the Products. Subject to the terms and conditions of the Agreement, PhotoniCare hereby grants Customer the right to use the Products during the Subscription Term at Customer's facility identified in the Order Form.

### 2. TERM AND TERMINATION.

- **2.1. Term.** These Terms commence on the Effective Date and continue for the entirety of the Subscription Term. Except as set forth herein, these Terms expire on the expiration or earlier termination of the Subscription Term.
- 2.2. Termination. A Party may terminate the Agreement at any time upon written notice to the other Party in the event the other Party commits a material breach of the Agreement and does not remedy such breach within thirty (30) days after receipt of written notice of such breach. In addition, a Party may terminate the Agreement immediately upon written notice to the other Party in the event the other Party: (a) ceases operation without a successor; or (b) seeks protection under any bankruptcy, receivership, trust deed, creditors' arrangement, composition, or comparable proceeding, or if any such proceeding is instituted against that Party and not dismissed within sixty (60) days thereafter. PhotoniCare may also terminate the Agreement at any time, for any reason or no reason, without liability to Customer, upon not less than forty-five (45) days' prior written notice to Customer.
- 2.3. Effect of Termination. Upon expiration or termination of the Agreement, all fees and other amounts owed by Customer to PhotoniCare shall be immediately due and payable by Customer. In no event shall any expiration or termination of the Agreement relieve Customer of the obligation to pay any fees payable to PhotoniCare for the period prior to the effective date of termination. Upon expiration or termination of the Agreement, Customer may elect to either purchase the Products at fair market value on an "AS-IS / WHERE-IS" basis (subject to execution of a product purchase agreement between Customer and PhotoniCare), or Customer shall return the Products to PhotoniCare in good working order, normal wear and tear excepted, within thirty (30) days after the expiration or termination of the Agreement. If the Products are not returned to PhotoniCare or purchased by Customer upon expiration or termination of this Agreement as provided in this Section 2.3, PhotoniCare reserves the right to charge Customer PhotoniCare's then-current monthly subscription fee for the period of time that Customer retains the Products. If Products returned by Customer to PhotoniCare are not in good working order, normal wear and tear excepted, or are otherwise damaged due to (a) Customer's failure to fulfill any of its obligations under the Agreement; (b) any alteration or improper storage, handling, use, maintenance of the Products by anyone other than PhotoniCare or its authorized service contractor; and/or (c) anything beyond PhotoniCare's reasonable control, PhotoniCare reserves the right to charge Customer for such damage (up to the full List Price (defined below) of the Products). The termination or expiration of this Agreement shall not relieve either Party of its responsibility to comply in all material respects with any statutory or regulatory requirements associated with the Products.

### 3. DELIVERY; TITLE AND RISK OF LOSS.

- **3.1. Delivery.** PhotoniCare will deliver the Products to Customer at the Customer address(es) identified on the Order Form. Any time quoted for delivery is an estimate only; provided, however, that PhotoniCare will use reasonable efforts to ship the Products on the scheduled shipment date set forth in the Order Form (subject to availability). Customer shall inspect the Products and report any damage to PhotoniCare promptly upon delivery. In the absence of written notice from Customer in accordance herewith, the Products shall be deemed to have been delivered and accepted as complete and in satisfactory condition as to damage, defects, shortages and overages. Shipping and handling fees (if any) are as set forth on the Order Form.
- 3.2. Title. Customer understands and acknowledges that Customer is purchasing the Products on a subscription basis during the Subscription Term and Customer does not and shall not acquire any ownership interest in or with respect to the Products or any intellectual property rights related to the Products. Title to the Products remains with PhotoniCare at all times. Customer shall not attach or install anything on the Products or otherwise alter or modify the Products, or affix the Products in any way to Customer's facilities, or remove the Product(s) from Customer's facilities without the prior written consent of PhotoniCare. Customer shall keep the Products free and clear of all liens and other encumbrances. Customer shall not take any action to jeopardize, limit or interfere with PhotoniCare's intellectual property rights with respect to the Products.
- **3.3. Risk of Loss.** Except as otherwise set forth herein, Customer shall bear the risk of loss of the Products for so long as the Products are within Customer's possession or control. Customer is responsible for the "Purchased" list price of \$30,000.00 (per device) of the Products if they are lost, confiscated, or stolen during the Subscription Term and Customer will promptly report to PhotoniCare if the Products are lost, confiscated or stolen. If the Products are lost, confiscated, or stolen during the Subscription Term, subject to Customer's payment



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of the List Price for such lost, confiscated, or stolen Products, PhotoniCare shall provide a replacement Products to Customer (subject to availability). Customer shall promptly report any damage or operational issues related to the Products to PhotoniCare. If the Products are damaged or malfunction during the Subscription Term, PhotoniCare will repair or provide replacement Products to Customer (at PhotoniCare's discretion); provided that if such damage or malfunction is due to (a) Customer's failure to fulfill any of its obligations under the Agreement; (b) any alteration or improper storage, handling, use, maintenance of the Products by anyone other than PhotoniCare or its authorized service contractor; and/or (c) anything beyond PhotoniCare's reasonable control, then the Customer shall be responsible for the cost of the repair or replacement, as applicable.

3.4. Insurance. Customer shall cooperate fully with PhotoniCare and any insurance companies producing insurance for the Products in the investigation and defense of any claims and suits arising from the operation of the Products. Customer shall comply with and shall cause all persons operating the Products to comply with all insurance policy conditions and with all applicable laws and regulations regarding acquiring, titling, registering, leasing, insuring, using, operating of the Products, and the licensing of operators thereof. Customer shall, at its own expense, maintain insurance insuring Customer and covering (a) physical damage to and loss of the Products, and (b) liability for bodily injury and property damage resulting from the operation of the Products. In addition, Customer shall maintain a general public liability insurance policy. All such insurance shall be obtained in commercially adequate amounts and from reputable companies of nationally recognized standing. Upon reasonable request by PhotoniCare, Customer shall furnish to PhotoniCare certificates or other evidence of insurance acceptable to PhotoniCare.

### 4. MAINTENANCE AND SUPPORT SERVICES.

- **4.1. Maintenance.** During the Subscription Term, PhotoniCare will provide routine maintenance for the Products. Customer will make the Products available for inspection and maintenance by PhotoniCare when and as directed by PhotoniCare. Such maintenance will be provided at no cost to Customer except to the extent maintenance or support is required (in PhotoniCare's discretion) due to (a) Customer's failure to fulfill any of its obligations under the Agreement; (b) any alteration or improper storage, handling, use, maintenance of the Products by anyone other than PhotoniCare or its authorized service contractor and/or (c) anything beyond PhotoniCare's reasonable control.
- **4.2. Product Support.** During the Subscription Term, PhotoniCare will provide as-needed support services in accordance with its standard support offerings during PhotoniCare's regular business hours. Any support requested by Customer in excess of PhotoniCare's standard support offerings or outside of PhotoniCare's regular business hours may incur additional fees that will be billed to Customer pursuant to PhotoniCare's standard billing practices at PhotoniCare's then-current pricing. The Parties acknowledge and agree that PhotoniCare will have no obligation to provide support to Customer with respect to use of the Products other than according to the then-current documentation, including the current approved product labeling, for the Products ("**Documentation**") or the terms of the Agreement.
- **4.3. Responsibility.** Subject to the foregoing, during the Subscription Term, PhotoniCare agrees to assume all responsibility for maintenance and repair of the Products and Customer is not permitted (and shall not permit any third party) to undertake maintenance or repair of the Products.
- **4.4. Training Support.** Following delivery of the Products to Customer, PhotoniCare will provide training to representatives of Customer in accordance with PhotoniCare's standard training procedures during PhotoniCare's regular business hours. PhotoniCare shall provide user guides, training manuals, and other documentation/videos and directions to a single representative of Customer ("**Trainer**") and support Customer's Trainer throughout the Subscription Term. Customer's Trainer will be responsible for training any other staff of Customer who will operate the Products on proper use in accordance with PhotoniCare's directions and procedures. Any additional training requested by Customer will be addressed on a case-by-case basis and may incur additional fees that will be billed to Customer pursuant to PhotoniCare's standard billing practices at PhotoniCare's then-current pricing.
- **4.5. Disclaimer.** Notwithstanding any training or support provided by PhotoniCare, Customer understands and acknowledges that PhotoniCare does not engage in the practice of medicine. Customer's personnel have a personal and independent duty to professionally examine patients and determine the appropriateness of use of the Products. Documentation and other materials and training provided by PhotoniCare are not intended to, and shall not, be substituted for the professional skill and judgment of a health care professional, and it is Customer's sole responsibility to make final judgments in all instances regarding patient care.
- 5. RETURNS. Customer must retain the original shipping materials for the return of the Products. If Customer does not retain the original shipping materials, Customer must contact PhotoniCare to receive a return shipping kit and Customer may be charged for costs associated with the return shipping kit. Customer is responsible for the deletion of any Protected Health Information (as defined below) from the Products prior to returning the Products to PhotoniCare (whether at the end of the Subscription Term or if Customer is returning the Products to PhotoniCare for maintenance, repair or replacement). PhotoniCare will provide instructions with respect to deletion of Customer Data.

The Products shall be returned to:

PhotoniCare, Inc. 2800 Meridian Pkwy, Ste 175 Durham, NC 27713

# 6. FEES.

**6.1. Fees.** Customer agrees to pay all fees and charges specified in the Order Form. All prices, fees and charges quoted by PhotoniCare are exclusive of taxes. Customer is responsible for any sales, use, or other taxes of any kind applicable to the payments hereunder and any





duties or other charges related to the export/import or clearance of Products that may be applicable to shipment of the Products to, or performance of services for, Customer. Customer will be invoiced for any such charges where applicable.

- **6.2. Prices.** Customer acknowledges and agrees that PhotoniCare reserves the right to change prices for the Products at any time during the Term. PhotoniCare will provide Customer at least thirty (30) days' notice prior to changing any prices with respect to the Products. If Customer does not agree with such change to the prices for the Products, (a) Customer may terminate this Agreement upon written notice to PhotoniCare prior to the date that the change in price would take effect, and (b) Customer's sole recourse is to terminate the Agreement and return the Products to PhotoniCare as set forth herein.
- 6.3. Invoices. Customer agrees to pay all invoiced amounts within thirty (30) days from the invoice date. If PhotoniCare does not receive payment by the due date, then any such amounts may accrue late interest at a rate of one percent (1%) of the outstanding balance per month, or the maximum rate permitted by law, whichever is lower, from the date such amounts were due until the date paid (plus costs of collection). Customer is responsible for providing complete and accurate billing and contact information to PhotoniCare and notifying PhotoniCare of any changes to such information. Customer understands and agrees that payment obligations are non-cancelable, and fees paid are non-refundable (except as expressly set forth in these Terms).
- **6.4.** Payment Default. If Customer becomes delinquent in the payment of any amount due ("Payment Default"), PhotoniCare, at its option and upon notice to Customer, may take possession of and remove the Products from Customer's premises or terminate the Agreement, in each case without further liability to Customer.
- 7. REPORTING. It is the intention of the Parties that the Agreement be administered in accordance with the discount provisions of the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b). In accordance with the statute and the discount safe harbor regulations at 42 C.F.R. § 1001.952(h), Customer shall fully and accurately report all prices paid net of discounts as required by law and any payor policies, and provide information upon request to Medicare, Medicaid and other federal health care programs on all discounts and price reductions under the Agreement.
- 8. COMPLIANCE WITH LAWS. Each Party shall comply in all material respects with all applicable state and federal laws and regulations, including, without limitation, the federal Food Drug and Cosmetic Act (FDCA) and implementing Food and Drug Administration (FDA) regulations and guidance, the federal Anti-Kickback Statute, the federal False Claims Act, the fraud and privacy provisions of the Health Insurance Portability and Accountability Act of 1996, state fraud and abuse laws, each as may be amended and their implementing regulations, and, except as provided for herein, shall bear their own cost and expense of complying therewith. Termination of the Agreement does not relieve either Party of its responsibility to comply with any on-going regulatory requirements associated with the Products.
- 9. ADVERSE EVENT REPORTING. Customer shall keep a record of all customer complaints received by Customer relating to the Products, as such are defined at 21 CFR § 820.198, and promptly advise PhotoniCare in writing of all such complaints and shall notify PhotoniCare by telephone of all potential MDR reportable events related to the Products (MDRs), as such are defined in 21 CFR § 803.3, within 24 hours of knowledge thereof and in writing within two (2) working days of receipt of the preliminary details thereof. Customer shall cooperate fully with PhotoniCare in the investigation or reporting of any MDR resulting from such complaints. Customer shall make any MDR Customer proposes to provide to the FDA available to PhotoniCare for review not less than five (5) days before such report is submitted by Customer.

# 10. REPRESENTATIONS AND WARRANTIES.

- **10.1. Mutual Representations.** Each Party hereby represents and warrants to the other Party that such Party has the corporate power and authority and the legal right to enter into the Agreement and to perform its obligations hereunder and has taken all necessary corporate action to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder.
- 10.2. Product Warranty. Subject to PhotoniCare's right to access the Products to inspect and perform maintenance or to take possession of and remove the Products from Customer's premises in the event of a Payment Default or upon expiration or termination of this Agreement, PhotoniCare will not disturb Customer's quiet enjoyment of the Products during the Subscription Term. PhotoniCare warrants that, during the Subscription Term, the Products will: (a) be free from defects in material and workmanship, and (b) conform to the specifications set forth in the Documentation ("Specifications"), at the time of delivery ("Product Warranty"). The Product Warranty is provided only to the Customer and is not transferable. Customer's sole and exclusive remedy under the Product Warranty is that PhotoniCare will, at its option and without additional charge to Customer, repair or replace the Products, or if repair or replacement of the Products cannot be done on a basis that PhotoniCare finds commercially reasonable, then PhotoniCare may terminate the Agreement, and PhotoniCare will refund to Customer any fees that were pre-paid by Customer with respect to the period following the effective date of termination.
- 10.3. Customer Representations and Warranties. Customer represents and warrants that it is not purchasing the Products for intended resale and that Customer does not intend to export or re-export the Products. Further, Customer represents and warrants that Customer and any of its employees, agents and/or contractors using the Products: (a) is not currently excluded or otherwise ineligible to participate in Federal Healthcare Programs as that term is defined in 42 U.S.C. § 1320a-7b(f) (the "Federal Healthcare Programs"); (b) is not debarred by the FDA and has not been convicted of a criminal offence related to the provision of health care items or services; and (c) is not under investigation or otherwise aware of any circumstances which may result in its (or its agents, employees or any substitutes thereof performing any duties under this Agreement) being excluded from participation in Federal Healthcare Programs or debarred by the FDA.
- 10.4. No Implied Warranties. EXCEPT AS EXPRESSLY PROVIDED IN THESE TERMS, THE PRODUCTS AND SERVICES ARE PROVIDED AS-IS, AND PHOTONICARE MAKES NO REPRESENTATIONS OR WARRANTIES, AND HEREBY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE PRODUCTS AND SERVICES, INCLUDING WITHOUT LIMITATION, ANY IMPIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, QUIET ENJOYMENT, OR ACCURACY OF RESULTS, OR THAT OPERATION OF THE PRODUCTS WILL BE UNINTERRUPTED OR ERROR-FREE.



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10.5. No Liability. The Product Warranty is void and PhotoniCare disclaims any obligation under this article if: (a) the Products have not been stored, configured, installed, operated, or maintained in accordance with PhotoniCare's Specifications, Documentation, and instructions for the Products (including the installation of any updates to the Device made available by PhotoniCare); (b) the Products have been subjected to accident, disaster, neglect, abuse, misuse, damage (e.g. burned, cracked, etc.) repair, or modification in any respect, by anyone other than PhotoniCare or its authorized service representatives without PhotoniCare's prior written consent; (c) the Products' performance is adversely affected by materials, equipment, software or services provided by an entity other than PhotoniCare; (d) Customer is in breach of its obligations under the Agreement; or (e) anyone other than the Customer asserts the warranty rights.

### 11. CONFIDENTIAL INFORMATION; CUSTOMER DATA.

- 11.1. Definition. "Confidential Information" means any information disclosed by one Party (the "Disclosing Party") to the other (the "Receiving Party"), that should reasonably be understood by the Receiving Party because of legends or other markings, the circumstances of disclosure, or the nature of the information itself to be proprietary and confidential to the Disclosing Party. Each Party may use the Confidential Information disclosed by the other only as necessary to perform its obligations or exercise its rights under the Agreement.
- 11.2. Exceptions. The restrictions of this provision do not apply to information that (a) was in the Receiving Party's possession without confidentiality restriction before its disclosure, (b) is or becomes generally available to the public through no fault of the Receiving Party, (c) the Receiving Party independently develops without reference to any Confidential Information received from the Disclosing Party, or (d) the Receiving Party obtains without breach of any obligation of confidentiality owed to the Disclosing Party.
- 11.3. Non-Disclosure and Protection. The Receiving Party must treat the Disclosing Party's Confidential Information in the same manner that it treats its own information of similar importance, but with no less than reasonable care. The Receiving Party may not divulge the Disclosing Party's Confidential Information to any third person or make any use of it except as expressly authorized herein. The Receiving Party must limit disclosure of Confidential Information received from the Disclosing Party to the Receiving Party's employees, affiliates, suppliers, contractors, or agents who (a) need to use or access the Confidential Information to configure, modify or use the Products or to carry out the Receiving Party's obligations under the Agreement and (b) have agreed in writing to treat the Confidential Information in accordance with this Section 11.
- 11.4. Judicial or Governmental Order. If the Receiving Party is ordered to disclose the Disclosing Party's Confidential Information under a judicial or governmental request, requirement, or order, the Receiving Party must (a) promptly notify the Disclosing Party, (b) take reasonable actions and provide reasonable assistance to the Disclosing Party to secure confidential treatment of the Confidential Information, and (c) disclose only the Confidential Information that is required to comply with such judicial or governmental request, requirement, or order.
- 11.5. Limitation on Copying and Return of Information. The Receiving Party may not reproduce or copy any Confidential Information, except as reasonably needed to perform its obligations under the Agreement. Each copy or reproduction of Confidential Information authorized under this section must include all notices of patent rights, copyrights, trademark rights, or similar proprietary rights included on the original version furnished to the Receiving Party by the Disclosing Party. Upon termination of the Agreement, the Receiving Party's right to use the Confidential Information will immediately terminate (except to the extent the Receiving Party has a continuing license to use such Confidential Information). Upon termination or any earlier demand by the Disclosing Party, the Receiving Party will promptly return to the Disclosing Party or, at the Disclosing Party's option, confirm destruction of all of the Confidential Information of the Disclosing Party in its possession or control.

#### 11.6. Customer Data.

- 11.6.1. "Customer Data" means any data collected resulting from Customer's use of the Device. The Device may share certain Customer Data with PhotoniCare automatically when the Device is powered on and connected to the internet.
- 11.6.2. **Customer Use of Customer Data.** Customer agrees to use Customer Data solely for its own internal, non-commercial research, education and patient care purposes in Customer's medical practice.
- 11.6.3. **PhotoniCare Use of Customer Data.** Customer Data shall, as between the Parties, be owned by Customer, provided that PhotoniCare retains an irrevocable right to use de-identified Customer Data for commercial purposes.
- 11.6.4. **Protected Health Information.** Customer agrees not to share or disclose any Protected Health Information (as defined in the Health Insurance Portability and Accountability Act and its implementing regulations) with PhotoniCare in any Feedback. Protected Health Information PhotoniCare creates, receives, maintains or transmits in order to provide a service to, or perform a function for or on behalf of, Customer pursuant to this Agreement, shall be governed by the Business Associate Agreement executed by the Parties and incorporated herein by reference, the form of which is attached hereto as **Attachment A**.
- 11.6.5. **Disclaimer.** The Device is not intended for use as a data storage device. Customer is solely responsible for maintaining any data and records that Customer is required to maintain by applicable law. The Device does not include any functionality to backup data on the Device. Customer is encouraged to print any records that Customer may be required or desires to maintain. NOTWITHSTANDING ANYTHING TO THE CONTRARY HEREIN, PHOTONICARE IS NOT RESPONSIBLE AND HEREBY EXPRESSLY DISCLAIMS LIABILITY FOR ANY LOSS OF CUSTOMER DATA.

# 12. CUSTOMER RESPONSIBILITIES.

12.1. Permitted Use. As between the Parties, Customer shall be solely responsible for the proper use and deployment of the Products in Customer's medical practice. Customer agrees to follow all user guides, training manuals, and other documentation/videos and directions provided by PhotoniCare when using the Products. Customer shall: (a) use the Products only as provided in the Documentation and in accordance with the current approved labeling; (b) not transfer or remove the Products from Customer's facility without PhotoniCare's prior written consent; (c) permit only qualified and authorized personnel that have been trained to use the Products to have access to or





use the Products; (d) advise PhotoniCare of any issues discovered with the use of the Products promptly upon becoming aware of any issues; (e) comply with all applicable laws in connection with Customer's use of the Products; and (f) comply with the Documentation and labeling, as updated by PhotoniCare from time to time, as well as any other instructions, training, warnings guidance, or other recommendations as may be provided by PhotoniCare from time to time.

- 12.2. Use Restrictions. Customer shall not, at any time, directly or indirectly, (a) copy, modify, or create derivative works of any part of the Products or Documentation or any other associated documentation, in whole or in part; (b) rent, lease, lend sell, sublicense, assign, distribute, publish, transfer or otherwise make available any part of the Products to any third party; (c) reverse engineer, disassemble, decompile, decode, adapt or otherwise attempt to derive or gain access to the source code, techniques, algorithms or processes from the Products or permit or encourage any third party to do so; or (d) use the Products in any manner or for any purpose other than as expressly permitted by the Agreement or in a manner or for any purpose that infringes, misappropriates, or otherwise violates any intellectual property right or other right of any person, or that violates any applicable law. The restrictions set out in this Section 12.2 do not apply to the extent they conflict with mandatory applicable law.
- 12.3. Feedback. From time to time, Customer may provide feedback to PhotoniCare regarding Customer's use of the Products and experience seeking reimbursement with respect to such use. Feedback includes suggestions or recommended changes to the Products, Documentation, and/or training; information regarding any issues discovered with use of the Products (e.g. Device malfunctions); and other comments, questions, suggestions, and feedback, but shall not include any Protected Health Information (collectively, "Feedback"). Customer hereby assigns to PhotoniCare, on Customer's behalf and on behalf of its employees, contractors, and/or agents, all right, title, and interest in and to any Feedback, including all intellectual property rights therein.

#### 13. SOFTWARE.

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- 13.1. Software and Use Restrictions. Any software used or incorporated into the Products ("Software") is provided in object code form only and may only be used on the Product in which it was initially installed. PhotoniCare or its licensors retain title to and ownership of Software and PhotoniCare reserves all rights in the Products, including any Software therein, not expressly granted herein. Customer will not remove or circumvent any copyright or other proprietary rights notices on the Products or associated with the Software. Customer shall not attempt to defeat or circumvent any technological security measures, copyright protection measures, application enabling mechanisms, passwords, key codes, encryption or other security device(s)s on the Products. Customer will not use Software for the purpose of developing or enhancing any product that is competitive with the Products. The restrictions set out in this Section 13.1 do not apply to the extent they conflict with mandatory applicable law.
- **13.2. Third-Party Technology.** The Products may contain third-party technology, including open source software ("**Third-Party Technology**"). Third-Party Technology may be licensed by third parties under separate terms ("**Third-Party Terms**"). Third-Party Terms are specified in the Documentation and control solely with respect to Third-Party Technology.
- 13.3. Updates. Customer is not entitled to any updates or upgrades to the Products or the Software during the Subscription Term, however PhotoniCare may update the Device or Software from time to time in PhotoniCare's sole discretion, including pursuant to Section 4.1 or via download, over-the-air, or remote means. Customer shall promptly install any updates provided by PhotoniCare in accordance with PhotoniCare's instructions. The Device must be powered on and connected to the internet to receive remote updates. The Device, or certain features thereof, may not be available while updates are being installed. PhotoniCare will use reasonable efforts to notify Customer of any anticipated loss of functionality of the Device while updates are being installed.
- 13.4. Third-Party Platform. Customer may receive access to a third-party platform (the "Galen Platform") in connection with Customer's use of the Products. To the extent Customer requests to use the Galen Platform services, the Business Associate Agreement executed by the Parties shall govern the Galen Platform services. Customer understands and acknowledges that the Galen Platform is provided by a third party (Galen Data, Inc., "GALEN") and is not controlled by PhotoniCare. Customer's use of the Galen Platform is subject to separate terms and conditions between Customer and GALEN. Other than with respect to obligations under the Business Associate Agreement, PhotoniCare accepts no responsibility or liability for Customer's use of the Galen Platform or for any loss or damage that may arise from such use.

### 14. INDEMNIFICATION.

- 14.1. Indemnification by PhotoniCare. PhotoniCare shall indemnify, defend and hold Customer harmless from and against any and all amounts payable under any judgement, verdict, court order or settlement for third party claims of infringement of any US patent, trademark, copyright, or other proprietary right of a third party alleged to have occurred and arising from the Products, as delivered. PhotoniCare may, at its option: (a) procure for Customer the right to continue using the Products provided; or (b) replace or modify the Products to make use thereof non-infringing while yielding substantially equivalent results. If neither of the foregoing options are or would be available on a basis that PhotoniCare finds commercially reasonable, then PhotoniCare may terminate the Agreement, retrieve the Products, and PhotoniCare will refund to Customer any fees that were pre-paid by Customer with respect to the period following the effective date of termination. The foregoing infringement indemnity does not cover claims arising from use of the Products in a manner not permitted or contemplated under the Agreement. Without limiting Section 14.3, any claim subject to indemnification pursuant to this section will be contingent upon, Customer: (i) promptly after receiving notice of the claim notifying PhotoniCare of the claim and any action taken by Customer on it; (ii) giving PhotoniCare sole control of the claim's defense and any negotiations of its settlement; and (iii) cooperating with and assisting PhotoniCare as reasonably requested for the claim's defense.
- **14.2. Indemnification by Customer.** Customer shall indemnify, defend and hold PhotoniCare, and its and their respective officers, directors, employees, agents and representatives harmless from and against any and all amounts payable under any judgement, verdict, court order or settlement for third party claims arising or resulting from Customer, its affiliates, or their respective employees', representatives', or





agents' (a) breach of any provision of the Agreement; (b) violation of applicable laws; or (c) use of the Products during the Subscription Term, except to the extent such claims are due to the negligence of PhotoniCare.

- 14.3. Indemnification Procedure. If any claim is commenced against a Party entitled to indemnification under this Section (the "Indemnified Party"), the Indemnified Party will provide notice thereof to the Party that is obligated to provide indemnification (the "Indemnifying Party") as promptly as practicable; provided, however, that the failure to provide such notice will not relieve the Indemnifying Party of its obligations under this Section 14 except and only to the extent that the Indemnifying Party is materially prejudiced thereby. The Indemnifying Party shall have full authority to settle any such claims; provided however, it may not enter into any settlement without the Indemnified Party's advance written consent in which (a) a full and final release of such claim in favor of the Indemnified Party is not obtained as a result of the settlement or (b) any admission or affirmative obligation is required or placed upon the Indemnified Party.
- 15. LIMITATION OF LIABILITY. PhotoniCare assumes no liability or responsibility for how Customer uses the information provided pursuant to the Agreement, for any diagnosis or treatment made in reliance thereon, or for injury to persons or property arising from the use of such information. EXCEPT WITH RESPECT TO A PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT OR INDEMNIFICATION OBLIGATIONS UNDER SECTION 14, NO PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR: (A) CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, EXEMPLARY, PUNITIVE, OR OTHER SIMILAR DAMAGES ARISING OUT OF OR IN CONNECTION WITH THE AGREEMENT EVEN IF THE PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR LOSSES; OR (B) AN AGGREGATE AMOUNT IN EXCESS OF THE AMOUNTS PAID OR PAYABLE UNDER THE ORDER FORM. THIS ALLOCATION OF LIABILITY IS REFLECTED IN THE PRICING OF THE PRODUCTS AND IS AN ESSENTIAL ELEMENT OF THE BASIS OF THE BARGAIN BETWEEN THE PARTIES.

#### 16. MISCELLANEOUS.

- 16.1. Force Majeure. Except with respect to Customer's obligation to make payment for Product and/or services received, if the performance of any part of this Agreement by any Party shall be prevented, restricted, interfered with or affected for any length of time by fire or other casualty, government restrictions, war, riots, strikes or labor disputes, lock out, transportation delays, acts of God, large-scale pandemic, or any other causes that are beyond the reasonable control of such Party, such Party shall not be responsible for delay or failure of performance of the Agreement for such length of time; provided that, the affected Party: (i) promptly notifies the other Party of such circumstances; and (ii) uses best efforts to mitigate the impact of those circumstances and to promptly resume performance.
- **16.2. No Third Party Beneficiaries.** Nothing in the Agreement is intended to confer, or shall have the effect of conferring, benefits, rights, or remedies unto any person other than the Parties hereto and their respective successors and permitted assigns.
- **16.3. Independent Contractors.** In making and performing under the Agreement, the Parties are acting and shall act as independent contractors. Neither Party is, or will be deemed to be, an agent, legal representative, joint venturer, or partner of the other Party for any purpose. Neither Party shall have any authority to act for or to bind the other Party in any respect.
- **16.4. Entire Agreement and Modification.** The Agreement constitutes the entire agreement between the Parties relating to the subject matter hereof and supersedes all prior and simultaneous agreements of any type relating to the subject matter hereof, whether written or oral. No modification of the Agreement shall be binding upon either Party unless in writing and signed by authorized representatives of both
- 16.5. Waivers and Severability. A Party's failure or delay to exercise a power or right, regardless of the length of time, does not operate as a waiver of that power or right. A waiver is not effective unless it is in writing and signed by the Party against whom enforcement is sought. If a court or other competent authority having final jurisdiction determines that any provision of the Agreement is for any reason found to be invalid or unenforceable, such part shall be severed and the remainder of the Agreement will continue in full force and effect to the maximum extent permissible. If the invalid or unenforceable provision is essential to the interpretation of material rights or obligations of either Party, the Parties will make every reasonable effort to negotiate a valid and enforceable replacement as promptly as possible.
- **16.6. Survival.** All rights and obligations by which their nature should survive shall remain in full force and effect. In particular, without limitation, the provisions of Sections 2.3, 3.3, 3.4, 4.5, 5, 6.1, 6.3, 6.4, 7, 8, 9, 10.4, 10.5, 11, 14, 15, and 16 shall survive the termination or expiration of the Agreement.
- **16.7. Assignment.** Customer may not assign or transfer this Agreement without the prior written consent of PhotoniCare. PhotoniCare may, without Customer's consent, assign or transfer this Agreement to any of its affiliates or to a successor by purchase, merger, consolidation, or transfer of substantially all of its assets to which this Agreement relates. Subject to the foregoing, all of the terms and conditions of this Agreement shall be binding upon, and shall inure to the benefit of, the successors and permitted assigns of the respective Parties hereto. Any assignment, transfer, or delegation in contravention of this clause shall be null and void.
- **16.8. Governing Law.** The Agreement shall be governed by the laws of the State of North Carolina, exclusive of its conflicts of law rules or principles.
- **16.9. Notices.** Any notice required or permitted to be given hereunder by either Party shall be in writing, sent to the address set forth in the Order Form or such other address as provided pursuant to this section and shall be deemed given on the date received as evidenced by the courier's receipt if delivered personally or by reputable overnight delivery service, or on the return receipt if sent by registered or certified mail, return receipt requested, postage prepaid.
- **16.10. Counterparts.** The Agreement may be executed in any number of counterparts, each of which shall be an original as against any Party whose signature appears thereon, but all of which together shall constitute but one and the same instrument.



OtoSight

Middle Ear Scope

Attachment A
Business Associate Agreement

This Business Associate Agreement (this "B.A. Agreement"), dated <u>Date of Device Install</u> ("Effective Date") is entered into by and between PhotoniCare, Inc. with an address at 2800 Meridian Pkwy, Ste 175, Durham, NC 27713 (the "Business Associate") and \_\_\_\_\_\_ (the "Covered Entity") (each a "Party" and collectively the "Parties").

Business Associate provides certain services (the "Services") pursuant to one or more agreements (collectively, the "Agreement") for or on behalf of the Covered Entity which Services may involve the creation, receipt, maintenance or transmission of PHI (as defined in Section 1.4). The purpose of this B.A. Agreement is to set forth the obligations of Business Associate with respect to such PHI in accordance with applicable federal law. The terms of this B.A. Agreement are incorporated by and made part of the Agreement. In the event of a conflict between the Agreement and this B.A. Agreement, this B.A. Agreement controls with respect to the subject matter hereof.

The Parties hereby agree as follows:

# 1. **DEFINITIONS**

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- 1.1 Unless otherwise specified in this B.A. Agreement, all capitalized terms used in this B.A. Agreement not otherwise defined have the meanings established for purposes of the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (collectively, "HIPAA") and HITECH, as each is amended from time to time.
- 1.2 "Electronic Protected Health Information" ("ePHI") shall mean PHI as defined in Section 1.4 that is transmitted or maintained in Electronic Media.
- 1.3 "HITECH" shall mean Subtitle D of the Health Information Technology for Economic and Clinical Health Act provisions of the American Recovery and Reinvestment Act of 2009, 42 U.S.C. §§17921-17954, and its implementing regulations.
- 1.4 "PHI" shall mean Protected Health Information, as defined in 45 C.F.R. § 160.103, limited to the Protected Health Information received from, or received or created on behalf of, Covered Entity by Business Associate pursuant to the Agreement.
- 1.5 "Privacy Rule" shall mean the Privacy of Individually Identifiable Health Information regulations issued pursuant to HIPAA, 45 C.F.R. Parts 160 and 164, Subparts A and E, as amended from time to time.
- 1.6 "Security Rule" shall mean the Security Standards for the Protection of Electronic Protected Health Information regulations issued pursuant to HIPAA, 45 C.F.R. Parts 160 and 164, Subparts A and C, as amended from time to time.

### 2. RESPONSIBILITIES OF BUSINESS ASSOCIATE

- 2.1 With regard to its use and/or disclosure of PHI, Business Associate agrees to:
  - a) not use and/or disclose PHI except as permitted or required by this B.A. Agreement or as otherwise Required by Law, and to the
    extent that Business Associate is to carry out any of Covered Entity's obligations under the Privacy Rule, Business Associate will
    comply with the requirements of the Privacy Rule that apply to Covered Entity in the performance of those obligations;
  - implement and use appropriate technical, physical and administrative safeguards to prevent use and/or disclosure of PHI other than
    as permitted or required by this B.A. Agreement and comply with the applicable provisions of the Security Rule with respect to
    ePHI;
  - c) report without unreasonable delay to Covered Entity: (i) any use and/or disclosure of PHI of which it becomes aware that is not permitted by this B.A. Agreement; and/or (ii) any Security Incident of which Business Associate becomes aware. Notwithstanding the foregoing, Covered Entity acknowledges that Business Associate routinely experiences unsuccessful Security Incidents that do not result in unauthorized access to, or use or disclosure of, PHI, such as pings, port scans, phishing attempts and other unsuccessful Security Incidents. Business Associate hereby notifies Covered Entity of such unsuccessful Security Incidents, and the Parties acknowledge and agree that no further notice shall be required of such unsuccessful Security Incidents;
  - d) without unreasonable delay and in no case later than ten (10) calendar days after discovery, Business Associate shall notify Covered Entity of a Breach of any Unsecured PHI all in accordance with 45 C.F.R. § 164.410;
  - e) in accordance with 45 C.F.R. § 164.502(e)(1)(ii) and 45 C.F.R. § 164.308(b)(2), ensure that any of its Subcontractors that create, receive, maintain, or transmit PHI on behalf of Business Associate agree, in writing, to no less restrictive restrictions and conditions on the use and/or disclosure of PHI that apply to Business Associate; including to the extent that Business Associate provides ePHI to a Subcontractor, it shall require the Subcontractor in writing to, where applicable, comply with the Security Rule with respect to



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that ePHI; make available its internal practices, books, and records relating to the use and/or disclosure of PHI to the Secretary of the Department of Health and Human Services ("HHS") for purposes of determining Covered Entity's compliance with the Privacy Rule:

- within fifteen (15) calendar days after receiving a written request from Covered Entity, make available information necessary for Covered Entity to make an accounting of disclosures of PHI about an Individual as provided in 45 C.F.R. § 164.528 and when directed by Covered Entity, make that accounting directly to the Individual;
- mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use and/or disclosure of PHI by Business Associate that is not permitted by the requirements of this B.A. Agreement;
- in the event that Business Associate in connection with the Services maintains a Designated Record Set of information of or about an Individual on behalf of Covered Entity, then the Business Associate shall make available that information in accordance with 45 C.F.R. § 164.524, including providing an electronic copy of the PHI, to Covered Entity or, as directed by Covered Entity, to an Individual or a third party designated by the Individual, as applicable;
- in the event that Business Associate in connection with the Services maintains a Designated Record Set of information of or about an Individual on behalf of Covered Entity, then the Business Associate shall make available that information for amendment and incorporate any amendments in accordance with 45 C.F.R. § 164.526; and
- request, use and/or disclose only the minimum amount of PHI necessary to accomplish the purpose of the request, use or disclosure.

# **OTHER PERMITTED USES AND DISCLOSURES OF PHI**

- 3.1 Unless otherwise limited herein, in addition to any other uses and/or disclosures permitted or required by this B.A. Agreement, Business
  - use, and disclose to third parties, the PHI in its possession as necessary to perform the Services to Covered Entity pursuant to the Agreement;
  - use and disclose the PHI in its possession for its proper management and administration or to carry out the legal responsibilities of Business Associate, provided that any such disclosures are Required by Law or any third party to which Business Associate discloses PHI for those purposes provides assurances that:
    - the information will be held confidentially and used or further disclosed only as Required by Law or for the purposes for which it was disclosed to the third party; and
    - (ii) the third party will notify Business Associate of any instances of which it becomes aware in which the confidentiality of the information has been breached;
    - (iii) perform Data Aggregation for the Health Care Operations of Covered Entity, as permitted under 45 C.F.R. § 164.504(e)(2)(i)(B); and
    - (iv) de-identify the PHI in accordance with 45 C.F.R. § 164.514.

# **RESPONSIBILITIES OF COVERED ENTITY**

- 4.1 With regard to the use and/or disclosure of PHI by Business Associate, Covered Entity agrees to:
  - a) notify Business Associate 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 Business Associate's use or disclosure of PHI;
  - notify Business Associate of any changes in, or revocation of, permission by an Individual to use or disclose PHI, to the extent that such changes may affect Business Associate's use or disclosure of PHI;
  - notify Business Associate of any restriction on the use or disclosure of PHI that Covered Entity has agreed to in accordance with 45 C.F.R. § 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of PHI.

#### **TERM AND TERMINATION**

5.1 Term. The Term of this B.A. Agreement shall be effective as of the Effective Date, and shall terminate upon the final expiration or termination of the Agreement unless earlier terminated in accordance with Section 5.2 of this B.A. Agreement.



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- 5.2 <u>Termination</u>. If Covered Entity knows of a pattern of activity or practice of Business Associate that constitutes a material breach or violation of this B.A. Agreement then Covered Entity shall provide notice thereof to Business Associate. Such notice shall clearly specify the nature of the breach or violation. If, after a reasonable time period following the notice to Business Associate, Covered Entity reasonably determines that Business Associate has not cured the breach or ended the violation, Covered Entity may terminate this B.A. Agreement.
- 5.3 Effect of Termination or Expiration. Within thirty (30) days after the termination or expiration of this B.A. Agreement, Business Associate shall return or destroy all PHI, if feasible to do so, including all PHI in possession of Business Associate's subcontractors. If return or destruction of the PHI is not feasible, Business Associate shall extend the protections contained in this B.A. Agreement to Business Associate's use and/or disclosure of any PHI retained after the termination or expiration of this B.A. Agreement, and limit any further uses and/or disclosures solely to the purposes that make return or destruction of the PHI infeasible.

# 6. MISCELLANEOUS

- 6.1 <u>Construction of Terms</u>. To the extent they are not clear, the terms of this B.A. Agreement shall be construed to allow for compliance by the Parties with HIPAA or HITECH and implementing regulations as applicable and as promulgated and amended from time to time.
- 6.2 <u>No Third Party Beneficiaries</u>. Nothing in this B.A. Agreement shall confer upon any person other than the Parties and their respective successors or assigns, any rights, remedies, obligations, or liabilities whatsoever.
- 6.3 Survival. Sections 5.3, 6.1, 6.2, and this Section 6.3 shall survive the termination for any reason or expiration of this B.A. Agreement.
- 6.4 <u>Counterparts</u>. This B.A. Agreement may be executed in counterparts, each of which will constitute an original and all of which will be one and the same document.

IN WITNESS WHEREOF, each of the undersigned has caused this B.A. Agreement to be duly executed in its name and on its behalf effective as of the date of the last party to sign this Agreement below.

PHOTONICARE, INC.	Customer (Covered Entity)
Signature:	Signature:
Print Name:	Print Name:
Print Title:	Print Title:
Date:	Date: