Equipment Loan Agreement

This Agreement between THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY ("Stanford"), an institution of higher education having corporate powers under the laws of the State of California, and Arnold & Richter Cine Technick GmbH & Co. Betriebs KG ("Company"), a corporation having a principal place of business at Turkenstr.89, D-080799, Muenchen, Germany, is effective on the 18 day of July 2018 ("Effective Date").

Whereas, Company manufactures equipment, as described in the attached Exhibit A ("Equipment"). Company explicit advice Stanford that the Equipment is not a commercial product eligible and available for sale and it is not a medical device. Nikolas Blevins ("Principal Investigator") of Stanford desires to have access to Equipment for research to be performed as set forth in Exhibit A ("Research Program"). Company desires to loan equipment to Stanford for research purposes.

Whereas, Stanford's Principal Investigator has developed the CardinalSim software as described in Docket No. 18-208 ("CardinalSim") and desires to use CardinalSim in conjunction with the Equipment as set forth in the Research Program.

The parties hereby agree as follows:

1. LOAN

1.1 **Loan.** Company will loan the Equipment to Stanford for Principal Investigator's use, subject to the terms and conditions of this Agreement.

1.2 **Loan Term.** The loan period will be from April 1, 2018 to December 31, 2019. The term may be extended only by advance written agreement of both parties.

1.3 **No Other Rights.** Notwithstanding the Section 1.1, this Agreement does not constitute, grant nor confer any license under any patents or proprietary interests from one party to the other.

1.4 **No Payment.** Stanford has no payment obligation to Company for the loan of the Equipment and no obligation to purchase the Equipment.

2. COMPANY EQUIPMENT

2.1 **Ownership.** The Equipment will at all times remain the property of Company. Company represents and warrants that it has clear title to the Equipment.

2.2 **Installation, Shipping and De-installation.** Company will ship and install the Equipment at Stanford. Company will also obtain and pay for any applicable export/import fees and insurance on the Equipment during shipment and installation.

When the loan period ends or this Agreement is terminated per Section 9.1, Company will de-install the Equipment at Stanford and pay for its return to Company. Company will also obtain and pay for any applicable export/import fees and insurance on the Equipment during such de-installation and shipment.

2.3 **Maintenance of Equipment.** Company will be responsible for service and maintenance on the Equipment during the loan period, at its own discretion. Company provides no warranty and/or guarantee regarding the Equipment, its use and/or its performance. The Equipment is delivered on an "as is" basis. Performance of service and maintenance is at sole discretion of Company.

2.4 **Value.** The value of the Equipment is 120.000 €.

3. STANFORD USE OF COMPANY EQUIPMENT

3.1 **No Clinical Use.** Stanford will not use the Equipment for clinical use.

3.2 **No Certification.** Company advises Stanford that the Equipment is a prototype without any kind of certification and/or registration, which may be needed for medical and/or other commercial use. Use of the Equipment is at the sole risk of Stanford. Stanford is obliged to obtain instructions given by Company with regard to the use of the Equipment and further is obliged to comply with existing regulatory, administrative, and/or statutory regulations regarding the use of the Equipment.

4. RESULTS

4.1 **Definition of Results.** "Results" means all data and information developed using the Equipment in the performance of the Research Program.

4.2 **Ownership and Use of Results.** Results generated by Stanford will be owned by Stanford and be made available to Company at no charge, subject to all applicable laws. Company will indemnify, defend and hold harmless Stanford for Company's use of Results.

5. INTELLECTUAL PROPERTY

5.1 **Definition of Technology.** "Technology" means all tangible materials, inventions, works of authorship, software, information, and data conceived or developed in the performance of the Research Program and funded under this Agreement.

5.2 **Ownership of Technology.** Stanford owns the entire right, title, and interest, including all patents, copyrights, and other intellectual property rights, in and to all Technology developed using Stanford facilities and by Stanford personnel under this Agreement ("Stanford Technology"). Company owns the entire right, title and interest, including all patents, copyrights, and other intellectual property rights, in and to all Technology developed using Company facilities and by Company personnel under this Agreement

("Company Technology"). Technology that is jointly developed by Stanford and Company personnel will be jointly owned ("Joint Technology").

5.3 **Patent Filing and Expenses.** Unless the parties agree in writing otherwise, the filing, prosecution, defense and maintenance of all patents for Joint Technology will be conducted jointly in the name of both parties and controlled by them jointly, acting reasonably and in good faith.

5.4 **Licensing.** Each party reserves the right to license its interest in its sole Technology or Joint Technology, and neither party will have any right to compensation in connection with any such license granted by the other.

5.5 **Assignment.** Stanford represents that all of its employees, students, and consultants who participate in the Research Program will be obligated to assign to Stanford all their rights in patentable or copyrightable Technology.

5.6 **Other Intellectual Property.** For the avoidance of doubt, all intellectual property developed outside of this Agreement shall remain the property of its owner. Except as explicitly provided in this Agreement, neither party receives any right to the other's intellectual property developed outside of this Agreement.

6. PUBLICATION

6.1 **Objective.** The basic objective of research activities at Stanford is the generation of new knowledge and its expeditious dissemination for the public's benefit. Company will cooperate with Stanford in meeting this objective.

6.2 **Confidential Information.** "Confidential Information" means Company-owned, confidential, scientific, business or financial information that is provided in written form and clearly marked as confidential, provided that such information:

(A) is not publicly known or available from other sources who are not under a confidentiality obligation to the source of the information;

(B) has not been made available by its owners to others without a confidentiality obligation;

(C) is not already known by or available to Stanford without a confidentiality obligation;

(D) is not independently developed by the receiving party; or

(E) does not relate to potential hazards or cautionary warnings associated with the performance of the Research Program, and is not required to be disclosed under operation of law.

6.3 **Review.** As a matter of basic academic policy, Stanford retains the right at its discretion to publish freely the results of the Research Program. Stanford will provide Company

with a copy of any manuscript or other publication at the time it is submitted for publication. Company may review the manuscript or publication:

(A) To ascertain whether Company's Confidential Information would be disclosed by the publication;

(B) To identify potentially patentable Technology so that appropriate steps may be taken to protect the Technology; and

(C) To confirm that the privacy rights of individuals are adequately protected.

6.4 **Comments.** Company will provide comments, if any, within 30 days of receiving the manuscript or publication. If patentable Technology is disclosed in the manuscript or publication, Company will promptly advise Stanford whether it requests Stanford to file and prosecute a patent application.

7. INDEMNITY

7.1 As used herein, "Claim" includes but is not limited to every phase of any lawsuit, claim, damage or liability for death, illness or personal injury of any person (including employees of Stanford or Company) and/or for property damage.

7.2 Company hereby agrees to indemnify, defend, and hold harmless Stanford, and its trustees, directors, employees, agents, students or volunteers from any Claim brought against Stanford by a third party arising out of or connected with this Agreement or the work done under this Agreement to the extent such Claim is caused by Company's gross negligence or willful misconduct. Stanford shall promptly notify Company of any such Claim and shall cooperate with Company and its insurance carrier in the defense of the Claim.

7.3 Stanford hereby agrees to indemnify, defend, and hold harmless Company, and its directors, employees, advisors, or agents from any Claim brought against Company by a third party arising out of or connected with this Agreement or the work done under this Agreement to the extent such Claim is caused by Stanford's gross negligence or willful misconduct. Company shall promptly notify Stanford of any such Claim and shall cooperate with Stanford and its insurance carrier in the defense of the Claim.

7.4 A party's indemnity shall be limited by the amount of the indemnifying party's insurance.

8. WARRANTIES AND LIABILITY LIMITS

8.1 **No Guarantee.** Company acknowledges that the Research Program is a scientific undertaking and, consequently, Stanford will not guarantee any particular outcome or specific yield.

8.2 **Disclaimer of Warranties.** Stanford provides Company the rights granted in this Agreement AS IS and WITH ALL FAULTS. Stanford makes no representations and

extends no warranties of any kind, either express or implied. Among other things, Stanford disclaims any express or implied warranty:

(A) of merchantability, of fitness for a particular purpose,

(B) of non-infringement or

(C) arising out of any course of dealing.

8.3 **No Damages.** NEITHER PARTY SHALL BE LIABLE FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL, OR INCIDENTAL DAMAGES SUFFERED BY THE OTHER PARTY, ANY LICENSEE, OR ANY OTHERS INCLUDING, BUT NOT LIMITED TO, DAMAGES ARISING FROM LOSS OF DATA OR DELAY OR TERMINATION OF THE RESEARCH PROGRAM, OR FROM THE USE OF THE RESULTS OF THE RESEARCH PROGRAM, THE USE OF ANY RESEARCH MATERIALS OR ANY SUCH TECHNOLOGY OR PRODUCT. EACH PARTY ACKNOWLEDGES AND AGREES THAT THIS EXCLUSION AND LIMITATION IS REASONABLE CONSIDERING THE EXPERIMENTAL NATURE OF THE RESEARCH PROGRAM AND THE NATURE AND TERMS OF THE PARTIES' RELATIONSHIP.

9. GENERAL PROVISIONS

9.1 **Termination.** Either party may terminate this Agreement at any time upon thirty (30) days' prior written notice. Sections 2.1, 3.1, and 9.2 will survive the termination or expiration of this Agreement.

9.2 **Notices.** All notices under this Agreement are deemed fully given when written, addressed, and sent as follows:

All notices to Company are mailed or emailed to:

ARRI Medical
Alexander Keerl
Tuerkenstrasse 89
80799 München
akeerl@arri.de

All notices to Stanford are e-mailed or mailed to:

Industrial Contracts Office
3000 El Camino Real
Building Five, Third Floor
Palo Alto, CA 94306-2100
ico@stanford.edu

9.3 **No Human Subjects Research.** The Parties acknowledge that no human subjects research is allowed or will be conducted under this Agreement.

9.4 **Publicity.** Neither party will use the name or trademark of the other party in any publicity, advertising or announcement related to this Agreement without the prior written consent of the other party.

9.5 **No Assignment.** This Agreement will inure to the benefit of and be binding upon the parties and their respective successors and assigns; provided, however, that no party will assign this Agreement or any interest herein without prior written notice to the other party.

9.6 **Integration.** This Agreement, including the attached Exhibits, supersedes all prior oral and written proposals and communications, if any, and sets forth the entire agreement of the parties with respect to its subject matter, and may not be altered or amended except in writing, signed by an authorized representative of each party.

9.7 **Choice of Law.** This Agreement is governed by the laws of the State of California without regard to its principles of conflict of laws.

9.8 **No Waiver.** No waiver of any default, condition, provision or breach of this Agreement will be deemed to imply or constitute a waiver of any other like default, condition, provision or breach of this Agreement.

9.9 **Severability.** If any paragraph, term, condition or provision of this Agreement should be found by a court of competent jurisdiction to be invalid or unenforceable, or if any paragraph, term, condition or provision is found to violate or contravene the substantive laws of the State of California, then the paragraph, term, condition or provision so found will be deemed severed from this Agreement, but all other paragraphs, terms, conditions and provisions will remain in full force and effect.

9.10 **Electronic Copy.** The parties agree that a copy of the original signature (including an electronic copy) may be used for any and all purposes for which the original signature may have been used. The parties further waive any right to challenge the admissibility or authenticity of this document in a court of law based solely on the absence of an original signature.

The duly authorized party representatives execute this Agreement.

THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY	COMPANY Arnold u. Richter Cine Technik GmbH u. Co. Betriebs KG
Signature: Jamie Kitano	Signature:
Name: Jamie Kitano	Name: Dr. Hans Kiening
Title: Industrial Contracts Officer	Title: Head of BU Medical
Date: 7/27/2018	Date: 7/31/2018

I acknowledge that I have read this Agreement in its entirety and will use reasonable efforts to uphold my obligations and responsibilities under this Agreement.

PRINCIPAL INVESTIGATOR

Signature:

Name: NIKOLAS H. BLEVINS MD

Title: PROFESSOR, STANFORD OHNS

Date: 7/26/18

Exhibit A

Description of Equipment and

ARRISCOPE LAB, Prototype 02

Research Program

Stanford PI: Nikolas Blevins, MD

Department of Otolaryngology – Head and Neck Surgery

Co-Investigators

Joyce Farrell PhD

Bernd Girod PhD

Kenneth Salisbury PhD

Date of Initiation: May, 2018

Introduction

Our Stanford research team is undertaking a project using an investigational imaging device provided by the ARRI Medical company (http://www.arrimedical.com). ARRI Medical will provide a laboratory digital surgical microscope (the ARRIscope) that will be central to the success of this investigation. By leveraging the technology provided by the ARRIscope, our team will explore methods to improve surgical imaging with the ultimate goal of improving surgical outcomes. The project is focused on 2 major areas: (1) The use of real-time multispectral imaging in a surgical environment, and (2) The development of a mixed-reality environment for surgery, with the incorporation of virtual models derived from a surgical rehearsal platform. The research will be carried out by our multidisciplinary team from the Stanford departments of Otolaryngology, Electrical Engineering, and Computer Science.

The ARRIscope provides enabling technology for these goals. It provides an all-digital image pathway, through which the surgeon sees high-resolution stereoscopic digital representation of the surgical field rather than an optical image. The image sensor was developed by ARRI for high-end motion picture cameras, and provides an image quality and dynamic range that makes

this approach feasible. Access to the raw digital video allows real-time image processing, alteration, and volumetric reconstructions that would be otherwise impossible.

Research Plan

Multispectral Imaging

Complex head and neck anatomy, especially when altered by disease, creates challenges to identify and isolate target tissues safely, while avoiding injury to critical structures. Examples in our field include the differentiation of tumor from normal tissue, parathyroid glands from fat, nerves from blood vessels, and residual cholesteatoma from granulation tissue. Recent advances in intraoperative imaging using fluorescent probes, and multispectral analysis provide new ways to identify structures not visible with the unaided eye. Many of these techniques are hampered by use of exogenous contrast agents or need for radiation exposure. Multispectral imaging avoids both of these limitations by differentiating tissues based on their characteristic light scatter and absorption. While the technology holds great promise in research settings, at present there are no clinically validated models for delivering real-time multispectral imaging during surgery. With the integration of the ARRIscope, our team is equipped to develop and validate a novel multispectral digital 3D stereoscopic operating microscope for clinical use. Optimizing the use of this technology for surgical care and trainee education has the potential to decrease surgical complications, reduce radiation and contrast agent exposure, and increase surgical success and efficiency.

We will first characterize the ability of multispectral imaging with the ARRIscope to differentiate clinically-relevant tissue types during surgery. We will systematically compare multiple pairings of background and target tissues (e.g., nerve, muscle, fat, tumor, bone) to identify (i) target tissue types for which multispectral imaging most improves identification; and (ii) the optimal spectral frequency and image processing techniques to enhance each type of target tissue. For this, we will image the tissue pairings with the ARRIscope, collect the stereoscopic images, process them optimally to enhance apparent contrast, and test the ability for surgical trainees to identify the margins between tissue types.

Our next effort will be to assess the feasibility, benefits, and limitations of real-time multispectral imaging in real-time during surgical dissection. This will require a formative phase to determine ideal real-time multispectral image processing methods and preferred user workflow, incorporating best practices from human-computer interaction and human factors engineering. Using this knowledge, we will complete a validation phase, including a mixed methods study of use in a simulated surgical task, incorporating (i) usability and user acceptance testing with semi-structured interviews and surveys; (ii) determination of changes in cognitive load resulting from the addition of multispectral data to the visual stream using validated quantitative instruments; and (iii) surgeon performance on the simulated task with and without the enhanced vision of multispectral imaging. We will enroll surgical trainees in a prospective study of these techniques, using animal tissue dissection in the laboratory to assess utility of multispectral imaging under the ARRIscope.

Mixed-Reality Environment

Our team at Stanford has developed a simulation environment (CardinalSim) that allows surgeons to explore virtual representations of patient-specific anatomy derived from pre-operative clinical imaging studies (cardinalsim.stanford.edu). The workstation has been validated to provide insights into surgical expectations for complex skull base procedures. It has become clear that the ultimate advantage of such an instrument would be realized if the virtual models and dissections from rehearsal could be brought into the operating room to facilitate actual surgery. The ARRIscope provides an ideal platform for this next step. With the ARRIscope, we anticipate the projection of virtual models derived from CardinalSim into the surgical field as a roadmap to help navigation in complex anatomic environments.

We will first develop a method to construct 3D representations of anatomy based on the stereoscopic images derived from the ARRIscope. This will assist in the co-registration of the actual anatomy with the virtual models built from imaging studies. Co-registration can be assisted by the surgeon providing updated location of fiducials or anatomic landmarks to correctly align virtual structures. We will then evaluate optimal methods of injecting or overlaying the rendered virtual models onto the surgeon's view in the ARRIscope. Human-machine interface elements will be tested to provide optimal benefit while minimally distracting from the operative procedure. Testing of this approach on cadaver temporal bone specimens will be undertaken to assess benefits of the mixed-reality platform.

Location of Research

The development of the technology and the validation studies described above will take place in the Perkins Microsurgical Laboratory in the Department of Otolaryngology, Stanford University. This will provide space and resources needed for this phase of the research.

Depending on the findings and success of the work described above, we may elect to transfer the ARRIscope to the Lane Surgery Center where it can be used to provide intraoperative image acquisition for additional validation. Such a move would require approval by both the Stanford IRB as well as clinical engineering. A version of the ARRIscope (EVO2) is approved for clinical use in Europe, and is currently under review for FDA approval. We anticipate that such approval may occur in 2019, and would facilitate a transition into the operating room.

Roles of Stanford and ARRI Medical

The Stanford research team has established a working relationship with the managerial and engineering teams at ARRI Medical. We anticipate an ongoing close collaborative relationship as we proceed with these projects. The team at Stanford will be responsible for all validation studies, data collection, result analysis, and IRB approval. ARRI Medical will provide assistance in ~~any~~ hardware modifications, and provide application programming interfaces (API's) that are necessary to allow access to the internal software of the ARRIscope. Software updates, hardware maintenance, and system calibration will also be provided by ARRI Medical as required. Both parties will jointly plan and conclude demands concerning resources, hardware, service requests and milestones.

For the Multispectral Imaging project, we anticipate ARRI Medical will work with the Stanford team to modify lighting and filters to optimize spectral bandwidths to be used for image

acquisition. ARRI Medical will share image processing software resources that will facilitate image manipulation and optimization. For the Mixed-Reality project, ARRI Medical will assist the Stanford team in accessing and modifying the stereoscopic video stream, and provide algorithms to help with depth mapping and volumetric reconstruction as possible.

We plan a continued open sharing of information between Stanford and ARRI Medical as projects progress. Each will share advances, innovations, and knowledge of limitations with the other through regularly-scheduled research meetings.

The Stanford team will be responsible for the timing, content, and venue for academic presentations and publications. ARRI Medical will be provided the ability to review all such content to ensure both accuracy and that it is in keeping with product detail disclosure concerns. Members of ARRI Medical will be invited to be active participants in the preparation of manuscripts and presentations, and will share in authorship as appropriate given the subject material and degree of contribution.