EXHIBIT 1

In Support of Petition of: Transtate Equipment Company, Inc. d/b/a Avante Diagnostic Imaging 1040 Derita Rd. Suite A Concord, NC 28027 Robert A. Wheeler, President Telephone: 800-710-9996

Of counsel: Dentons US LLP 233 South Wacker Drive, Suite 5900 Chicago, IL 60606 David R. Metzger Email: <u>david.metzger@dentons.com</u> Telephone: 312-867-2578 Taaj Reaves Email: <u>taaj.reaves@dentons.com</u> Telephone: 312-867-8176

Attorneys for Transtate Equipment Company, Inc. d/b/a Avante Diagnostic Imaging

DECLARATION OF ROBERT A. WHEELER

I, Robert A. Wheeler, am over 21 years old and hereby declare as follows:

 I am the President of the Imaging and Oncology Division at Transtate Equipment Company, Inc. d/b/a Avante Diagnostic Imaging ("Transtate"), a position I have held since 2018. Transtate Equipment Company, Inc. began business during April, 2017. Before 2018, I served as Vice President of Transtate. From 2008 to 2017, I was Vice President of TEC Holdings, Inc., which until April, 2017 was known as Transtate Equipment Company, Inc. In approximately March 2017, TEC Holdings, Inc. sold substantially all of its assets to Transtate.

Background:

- 2) Transtate is a member of the Avante Health Solutions group of companies that provide high quality refurbished medical systems and devices; provide post warranty repair, diagnosis, and maintenance of medical systems and devices; and sell new and used parts, all manufactured by Original Equipment Manufacturers ("OEMs").
- Transtate is an independent service organization ("ISO") that focuses on medical imaging systems, namely catheterization and angioplasty X-ray systems, magnetic resonance imaging ("MRI") systems, and computed tomography ("CT") systems.
- 4) Transtate operates nationwide and services medical equipment on a daily basis, including by responding to service calls each day.

- 5) Transtate's sister companies include Dre Medical, Inc. d/b/a Avante Medical Surgical, Pacific Medical, Inc. d/b/a Avante Patient Monitoring, Global Medical Imaging, Inc. d/b/a Avante Ultrasound, and Oncology Services International, Inc. d/b/a Avante Oncology Services. Avante Medical Surgical focuses on surgical equipment including C-Arm fluoroscopy devices, anesthesia machines, and electrosurgical units. Avante Patient Monitoring focuses on monitoring systems including patient monitors, telemetry systems, gas analyzers, and fetal monitors. Avante Ultrasound focuses on ultrasound machines. Avante Oncology Services focuses on linear accelerators and CT simulators.
- 6) Transtate performs sales and servicing activities for x-ray and diagnostic imaging systems, including catheterization labs, CT systems, and MRI systems (collectively "medical equipment"). I also have experience servicing catherization systems myself.
- Transtate services machines manufactured by OEMs including Siemens, Phillips, GE and Canon (formerly Toshiba).¹

Brief History of Servicing Activities:

- 8) Medical devices and systems used to be composed only of mechanical and electrical parts, i.e., hardware. Over time, some hardware functions were replaced by software. For example, at some point, film used in X-ray systems was replaced by digital image capturing devices rendering them digital devices.
- 9) In the past, the specifications and other information relating to the functions of the devices and systems were provided freely by OEMs in hard copy manuals. These devices and systems could be serviced by technicians with access to the manuals and with the relevant mechanical and electrical knowledge, experience, and tools.
- 10) More recently, hardware components are being and have been replaced by computing processors and software. As computers have developed, computerized functions have become integrated into the medical equipment. As a result, more and more functions are being controlled or performed by computers, and the computers have become integrated into the devices such that the devices, computers and software are inseparable. Now, large sophisticated systems such as MRI and catheterization and angioplasty X-ray systems (often referred to as "cath lab" systems) are completely controlled by computers integrated into the systems and can only be serviced with software integrated into the systems.

¹ GE refers to GE Healthcare, a subsidiary of General Electric Company.

Siemens refers to Siemens Healthineers AG (formerly Siemens Healthcare, Siemens Medical Solutions, Siemens Medical Systems), a subsidiary of Siemens AG.

Philips refers to Koninklijke Philips N.V., including its subsidiaries Philips Electronics and Philips Healthcare.

Cannon refers to Canon Medical Systems Corporation, formerly Toshiba Medical, and a subsidiary of Canon, Inc.

Toshiba refers to Toshiba Medical, now Canon Medical Systems Corporation.

- 11) OEMs are also less likely to provide manuals these days. They are only being provided by certain OEMs some of the time. Even when we do receive manuals, they are often incomplete.
- 12) Manuals are sometimes provided by OEMs electronically, as data files installed on the medical equipment or through DVD/compact discs. As a result, many servicing activities require access to and use of computer programs and electronic manuals.
- 13) Medical device servicing is handled in a variety of ways. Consumers such as hospitals and other medical providers may have one or more in-house departments fully staffed by employees, fully staffed by third party contractors, or a mixture of the two. Other providers might enter into servicing contracts with ISOs. If there is more than one in-house department, they tend to specialize in different types of equipment. The most specialized departments tend to be those which manage medical imaging equipment. While some servicing such as troubleshooting and calibration might be undertaken by the in-house department, much servicing is contracted out given the complexity of the systems involved. Third parties like Sodexo Group are hired to manage some of these functions for medical providers.
- 14) In-house departments will often call in outside service entities such as OEMs or ISOs to repair malfunctions. Among other information, diagnosis, maintenance, and repairs often require access to event logs, error logs, and configuration files.
- 15) OEMs also offer post warranty services and compete with ISOs for the post warranty servicing work. My experience is that ISOs often charge much less than OEMs and are about 30% to 50% less expensive for this work.

Technological Protective Measures ("TPMs") and ISO Servicing Activities:

- 16) OEMs equip modern medical systems and devices with TPMs such as encryption, embedded software, and challenge-response mechanisms², involving access codes, passwords, keys, or digital signatures.
- 17) TPMs hinder and prevent medical equipment owners and their agents from repairing, diagnosing, and maintaining the medical systems and devices they own by restricting or denying access to necessary electronic service materials installed in the medical equipment or otherwise provided via electronic media.
- 18) Servicing medical equipment, particularly large medical systems such as medical imaging devices, often requires access to software that is integrated with the medical equipment because this is the only way to service the machines due to the integration of the hardware and the software.

² Challenge–response mechanisms involve protocols in which one party presents a question (i.e., a "challenge") and another party must provide a valid answer (i.e. a "response" such as a password) to be authenticated.

- 19) Existing medical equipment must be calibrated and configured in order to work properly. Often times when medical equipment is calibrated, access to the software that is integrated with that machine is required.
- 20) In addition to the operating software and servicing programs, OEMs place data files including event logs, error logs, and configuration files behind the same TPMs. As a result of the comingling of the software and the data files, OEMs restrict access to the data files in an attempt to thwart even the most basic servicing, particularly troubleshooting, of medical equipment.

Specific OEMs and Adversity Caused:

- 21) There are several TPMs used by OEMs that restrict, limit, or deny access to medical equipment. Most typically, access to the software requires a keyed-in access code or an access key such as a dongle (e.g., a USB flash drive with a code). For example, Siemens uses 256 bit hexadecimal access codes that must be keyed-in, while GE and Philips use dongles.
- 22) The amount of access technicians such as Transtate's engineers and technicians have to conduct servicing activities on medical equipment varies depending on the manufacturer of the machine.
- 23) Philips is the most egregious OEM that Transtate has encountered in my experience. Philips charges a fee for its dongle keys and requires keys to be renewed every thirty days. Technicians and engineers servicing equipment also have to register for InCenter to access some or all of the information on its website.³
- 24) Siemens requires a technician to either (i) call for a one-time access code each time medical equipment requires servicing, or (ii) pay an exorbitant yearly fee that can cost between \$20,000.00 and \$25,000.00 USD per device.
- 25) GE will provide dongles for a fee.
- 26) Additionally, certain OEMs will also only sell and provide ISOs access to certain limited tiers of information. Often the tier of access provided by certain OEMs is inadequate to fully service the medical equipment.
- 27) Other times, OEMs will only provide access to some of what is necessary to configure, calibrate, or test the machine for a limited time (e.g., the code will not function after a certain number of hours).
- 28) By OEMs refusing appropriate access to ISOs that is required to service a machine, the OEMs are forcing the medical equipment owner and lessees to use the OEMs to service the medical equipment directly. Using an OEM to service medical equipment can increase the cost of each service event by thousands of dollars.

³ InCenter is an eSupport system provided by Philips. According to Philips' website, InCenter provides an enhanced document distribution platform including "a majority of the service information you will need to support your Philips medical systems and devices."

- 29) Additionally, OEMs will often refuse to support older versions of medical equipment because the OEMs deem the medical equipment to have reached the end of its commercial life. OEMs will either not service the machines or not provide renewed access codes and keys either to the consumers or to ISOs, even though with the appropriate access codes and keys, the ISOs would be able to continue to service and repair the medical equipment.
- 30) Despite the fact that older models of medical equipment can still function well and continue to be used, thereby saving healthcare providers and in turn patients significant sums of money, OEMs refuse to provide the requisite support and access needed to service that medical equipment.
- 31) Transtate's engineers, technicians, and professionals have the skill, training and expertise to service medical equipment from a wide variety of OEMs, however, the limited access provided by OEMs hinders our ability to do so.
- 32) In addition to restricting access to necessary software required to service medical equipment, Philips currently refuses to train ISO technicians.
- 33) TPMs hinder our professionals and servicing engineers from accessing diagnostic error codes that provide critical information about what part of the machine is not functioning properly. To properly diagnose faults and errors in the operation of a device, it is often necessary to access error logs to decipher causes of errors, and this requires access to the software.
- 34) OEMs have previously said that these types of event and error logs and programs are their proprietary, copyrightable information. However, this is disputed and the subject of litigation.
- 35) The computer programs and data files have no other use. Although OEMs might sell or make available updates to their software, there is no independent market for the computer programs and data files outside of the purchase of new or used equipment because the software is not of any value outside of use on this equipment. The software is specific to the machine on which it is sold.
- 36) The medical provider consumers are hurt by the TPM practices of OEMs because they cannot take advantage of the lower prices offered by purchasing services from ISOs like Transtate. For example, OEM's typically charge 30% to 50% more for service calls to diagnose and repair medical equipment than ISOs, in my experience. I understand these higher costs must be passed along to patients.
- 37) The TPM practices of OEMs have also contributed to limited competition from and amongst ISOs. At the time of this declaration's execution, I only know of a very small number of ISOs, including Transtate, that provide post-warranty maintenance services for Philips-manufactured systems within the United States.
- 38) The undersigned being warned that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001. The undersigned declares that all statements made of his/her own knowledge are true; and all statements made on information and belief are believed to be true.

12/11/2020

Date:

had When

Robert A. Wheeler

EXHIBIT 2

Your One Source To Maximize Capital Equipment Performance

ISO Certified Services Equipment Choice On-Time Parts & Supplies

Avante Health Solutions is a single source provider of medical, surgical, diagnostic imaging, and radiation oncology equipment, including sales, service, repair, parts, refurbishing, and installation. Avante is making it easier and more affordable for every hospital, clinic, and medical practice to have the very best equipment, supplies and service.

Medical Surgical



One source for operating, critical care, procedure, and exam equipment

Avante Medical Surgical is a premier supplier of surgical equipment for the modern operating room. Surgical facilities of any size or specialty can rely on Avante equipment experts to help them find the perfect combination of factory new and professionally refurbished products for their unique needs.

VIEW MEDICAL SURGICAL HOME

Patient Monitoring



One source for patient monitoring service, parts, and equipment

Avante Patient Monitoring provides hospitals and medical facilities worldwide a reliable source for repair and refurbishment of patient monitoring equipment, as well as OEM compatible accessories and parts.

VIEW PATIENT MONITORING HOME >

Diagnostic Imaging



One source for cath/angio, CT, and MRI equipment solutions

Avante Diagnostic Imaging is a leading provider of high-quality new and refurbished cath/angio, CT and MRI equipment. Our equipment is supported by a wide range of technical support and repair services from experienced engineers.



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MENU



One source for complete ultrasound service, parts, and equipment

Avante Ultrasound provides a reliable choice for customers seeking effective solutions to rising costs in the healthcare marketplace. We provide new and refurbished systems, advanced probe repair, have a large inventory of OEM parts, and support our clients with certified engineers nationwide.

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Oncology Services



One source for linear accelerator service, parts, and equipment solutions

As a partner to hospitals and cancer centers around the world, Avante Oncology Services is focused on delivering extraordinary reliability, improved productivity, simplified procedures and greater economy to cancer care providers so they can provide the same to their patients.

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Rental Services



One source for equipment rentals from the brands you trust

Avante Rental Services is a leading provider of rental medical equipment. We are ready (24 x 7 x 365) to help clients meet the changing demands of their operations. Our team provides short or long term solutions for service shut downs, seasonal changes, and equipment evaluation scenarios.

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Trademark Statement Privacy Policy Terms of Use



Global | English

EXHIBIT 3

In Support of Petition of: Transtate Equipment Company, Inc. d/b/a Avante Diagnostic Imaging 1040 Derita Rd. Suite A Concord, NC 28027 Robert A. Wheeler, President Telephone: 800-710-9996

Of counsel: Dentons US LLP 233 South Wacker Drive, Suite 5900 Chicago, IL 60606 David R. Metzger Email: <u>david.metzger@dentons.com</u> Telephone: 312-867-2578 Taaj Reaves Email: <u>taaj.reaves@dentons.com</u> Telephone: 312-867-8176

Attomeys for Transtate Equipment Company, Inc. d/b/a Avante Diagnostic Imaging

DECLARATION OF MICHAEL SPENCER

I, Michael Spencer, am over 21 years old and hereby declare as follows:

- I am the founder of DRE Medical, Inc. ("DRE Medical"), now d/b/a/ as Avante Medical Surgical ("AMS"), which is a sister company of petitioner and commenter Transtate Equipment Company, Inc. d/b/a Avante Diagnostic Imaging ("Transtate"). I founded DRE Medical in 1984 and sold the company in 2015. I am the President of Corporate Sourcing at Avante Medical Surgical and have held this position since March 2020.
- 2) AMS's business focuses on a mix of surgical equipment including a number of devices that require software to operate and to service them. Devices requiring software to operate and service include C-Arm fluoroscopy devices, anesthesia machines, intravenous pumps, electrosurgical machines, and syringe pumps. Other products we sell and rent include incubators, radiant warmers, ventilators, oxygen stretchers and patient examination rooms, among others.
- A large part of our business, about sixty percent (60%), is the sale of private label machines.
 AMS also sells and rents refurbished machines.
- 4) AMS sells its own private label patient examination monitors, lights, tables, anesthesia machines, electrosurgical units, and ultrasound units. The private label syringe pumps and RT ventilators sold by AMS are for export only. AMS has access codes, where applicable, for all private label units.

- 5) AMS sells refurbished anesthesia machines from Dräger, GE, and Penlon, electrical surgical generators from Covidian, and respiratory ventilators from a number of manufacturers including Puritan Bennett and Pulmonetic.¹ AMS also sells I.V. pumps from a variety of manufacturers.
- 6) Some of the Dräger, GE, and Penlon machines require access codes in the form of passwords to access the software integrated in the machines. It would be difficult to diagnose malfunctions or to maintain these machines without access to the integrated software. For some of the machines, it is not possible to access any configuration files, error logs, or event logs without using an access code.
- Since AMS sells a very limited amount of service contracts, we hire OEM technicians to service some of the OEM branded devices during the refurb process.
- 8) OEMs often make technicians participate in trainings on the machines before the OEMs will provide the required access codes. The cost to send our technicians for training on the machines can range between \$10,000.00 USD to \$20,000.00 USD per student. As a result, we must make a cost-benefit analysis concerning for which medical devices to purchase trainings and which of our technicians will attend.
- 9) In addition to challenges related to the high cost of training, we also struggle with the retention of our technicians following their participation in trainings. This is due to the high market value for technicians that have attended an OEM's medical device training.
- 10) While I am aware that access codes can be obtained via vendors on the Internet, AMS uses service technicians who have their own access codes.
- 11) The undersigned being warned that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001. The undersigned declares that all statements made of his/her own knowledge are true; and all statements made on information and belief are believed to be true.

Date:

20

Michael Spencer

Penion refers to Penion Ltd.

¹ Dräger refers to Draeger Medical Inc. and is a natural segment of Drägerwerk AG & Co. KGaA. GE refers to GE Healthcare, a subsidiary of General Electric Company.

Covidien refers to the subsidiary of Medtronic plc.

Puritan Bennett is a division of Covidien, formerly TYCO Healthcare.

Pulmonetic refers to Pulmonetic Systems Inc., acquired by VIASYS Healthcare Inc. and d/b/a CareFusion.

EXHIBIT 4

Reduce repair restrictions to aid hospitals during COVID-19

COVID-19 has underscored the need for a more cooperative relationship between Original Equipment Manufacturers (OEMS) of medical technology, hospital-based BMETs, and independent medical device service providers.

As the FDA found in 2018, "the continued availability of third party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system," and all three "provide high quality, safe, and effective servicing of medical devices." This is especially true as a pandemic stress tests our medical system. However, hospital-based and third-party technicians often struggle to access the repair information needed to service equipment.

We, the undersigned clinical engineers and health technology managers, support requiring service materials (repair documentation, schematics, parts, tools and diagnostics) be made available immediately. We support the following changes:

- Manufacturers must meet the goals of 2012 NFPA 99 Health Care Facilities Code requirements around providing service information, and post their service materials in a manner that consistently allows hospitals to decide for themselves whom to hire for repair.
- Access to all service materials (all information, software, replacement parts and tools necessary to perform corrective and preventive maintenance actions in accordance with the manufacturers recommendations, such as repair documentation, schematics and diagnostics), available to the device owner even when equipment changes hands, on fair and reasonable terms.
- Product-specific training for repair must be made available online, on fair and reasonable terms, to biomedical engineering technicians, imaging service engineers, and other parties responsible for operation of medical equipment under CMS rules.

Sincerely,

Aaron Telesz, Clinical Engineering, BMET I, Biomedical Engineering Technician Abigail Lane-Savage, Biomedical Engineering Project Manager, Sodexo CTM Abron Mullings, Service Technician/Chamber Cleaner, HSS Inc. Adam Kohl, Sr. Biomedical Imaging Technician, ProHealth Care Alex Gaufman, Service Engineer and Owner, National Instrument Service Corp Alex Peterman, Operations Manager of Clinical Engineering, University of Washington Medical Center Allan Morgan, Clinical Engineering / BMET, Catholic Health Initiatives Allan Prunty, BMET Supervisor, ISS solutions Amber Tucker, Biomed and biomedical tech 3, Spectrum health Lakeland Andrew Dunlap, BIOMED, Senior BMET, CHI Andrew Ibey, Senior Manager, CHEO Andrew Schadegg, Operations Manager, Independent Medical Device Service Provider Andrew Stephen Gagne, Clinical Engineering Biomedical Equipment Technician, ABM Andrew Strong, Clinical Engineer, Yale New Haven Hospital Andy Armenta, VP of Enhanced Biomedical Infection Control Division, ERD LLC Anthony Dutra, Clinical Engineering, Diagnostic Imaging Service, Hospital Based BMET Anthony Masseur, Equipment Specialist, ACT - Paragon Anthony Scavella, Biomedical Electronics Technician, Sinai-Grace Hospital Austin Feagins, Clinical Technology Dept. /Area Service Mgr, Kaiser Permanente Austin Otto, President, OB Healthcare Corporation Averil Calambro, Biomed, Common Spirit Health Barbara Maguire, Vice President, Healthcare Technology Management, ISS Solutions/Geisinger Bashar mahanweh, Biomed, HSS Bassam Tabshouri, Medical Engineering, Director, American University of Beirut Beau Butts, Service - BMET 1, FOBI Medical Benjamin Kuchar, Regional Manager, Third Party Vendor Benjamin Riley, Biomed - Senior Biomedical Technician, Nebraska Methodist Hospital Benny Rodriguez, Biomedical Engineering: Biomedical technician, Brookdale Medical Center Beverly Kupiszewski, Biomed Site Manager, Trimedx Bhaskar Iduri, VP, Healthcare Technology Management & QA, RENOVO SOLUTIONS LLC Bill Barley, HTM Security, Healthcare Technology Management Bill Putz, Clinical Engineering, Common Spirit Health Bill Summers, CEO, Anchor Medical Company Blake Collins, Clinical Engineering, Delaware Hospital Blake Rother, MEM - BMET II, HSS Bob Turk, Clinical Engineering Supervisor, McLaren Northern Michigan Hospital Bobbie DeBord, Clinical Engineering CBET, Michigan Medicine Boyd Campbell, VP, Southeastern Biomedical Associates, Inc Brad Motes, Clinical Engineering Senior Biomedical Technician, UCHealth Greeley Hospital Brandi L. Rosenau, Section Chief, Medical Maintenance, USAF Brandon Howard, CE BMET II, CHI Brendan Gribbons, Regional Engineering Team Manager, Lower Mainland Biomedical Engineering Brenna Sanchez, Cabmet Member, Cabmet Brent Rankin, COO, Rankin Biomedical Corporation Brian Kelly, Clinical Engineering Manager, St. James Healthcare Brian Lefler, Director Biomedical Services, FirstHealth of the Carolinas Brian McLaughlin, Manager, Perioperative Clinical Engineering, Massachusetts General Hospital Bruno Piccin, Biomedical Engineering Tech II, The Ottawa Hospital Bryan Rhoades, FSS III, CHI-CE / CSH / Centura Health Corp Bryant Chang, Healthcare Technology Management, Biomedical Equipment Technician, ISS Solutions, Inc. Candace England, Director of Quality & Compliance, Modern Biomedical & Imaging

Carlos Villafane, Clinical Engineering/ BMET 3, Baycare Health Carol Garibaldi, CBET, Sr. Lead Biomedical Equipment Technician, Washington Hospital Healthcare System Cass Holland, Clinical Engineering Lead Tech., Biomed Tech.at littleton Adventist Hosp. Catherine Weitenbeck, Clinical Technologies, Clinical Engineer, UCSF Medical Center Charles Connor, Clinical Engineering, Manager, Karmanos Cancer Institute Charles E Cowles Jr, Physician - Anesthesiology, University of Texas Charles Mifsud, Biomed II, Beaumont hospital Chokri Baalouche, Biomed, CBET3, St John Hospital and Medical Center Chris Ellis, Industrial Hygienist, HSS Chris Gutmann, Executive Director, Clinical Engineering, Yale New Haven Health Chris Stanosheck, Biomed Tech ll CBET, Saint Elizabeth's Hospital Christine Pirillo, Analyst II Project Mgr, Diagnostics Christopher DiNapoli, Clinical Engineering BMET Senior, CommonSpirit Christopher Endres, VP, Atlantic Biomedical Company, Inc. Christopher G. Leger, Principal Consultant, CLeger Consulting Christopher Greer, Field Service/ Territory Manager, Prescott's Inc Christopher Ney, Biomedical Engineering- BMET, AAMI Christopher Thomas, Technician, Tyler Bio-Engineering Clinton Anderson, Clinical Technology/Lead Technician, Kaiser Hospital Conroy D. Victorine, Biomedical Engineering / Chief, Department of Defense Corey Andrews, Special Equipment Tech, ISS Solutions Corey Bialkowski, Clinical Engineering Project Manager, University of Michigan Michigan Medicine Corey Robinson, Clinical Eng/ BMET II, Ascension Providence Hospital Courtney Nanney, National Quality Manager, Clinical Engineering, CommonSpirit Health Craig Bakuzonis, Clinical Engineering, Director of Clinical Engineering, UF Health Shands Hospital Craig V. Virzi, Clinical Engineering Dept., Regulatory Compliance Specialist, Henry Ford Health System Curtis R Shaw, Biomed III, ISS Solutions Biomed Curtis Stump, Biomedical Network Engineer, Common Spirit Health Dale Crakes, Clinical Engineering Manager, Dignity Health Dale Mattison, Clinical Engineering, FSS, CHI & CABMET Damion Aiello, Biomed/ PACS Admin, Ultimate Biomedical Solutions Dan Blaisdell, Biomedical Engineering, Supervisor, ProHealth Care Dan Cutshall, Biomed - Field Service Specialist 2, In House CE Dan Dinh, Clinical Engineering /Biomedical Equipment Technician, Try Touch Service Dan Harper, Clinical Engineering, CBET, St. Mary's Hospital and Regional Medical Center Dan Hoffart, Engineering Technician, DHA Daniel Adams, Director of Imaging Service, Renovo Solutions Daniel Elias, Clinical Engineering Dept., CBET, McLaren Flint Daniel Hauer, Clinical Engineering - Senior Biomed, Catholic Health Initiatives

Daniel M Hooper, Asset Manager - Technical Analyst, ISS Solutions Daniel Munson, Clinical Engineering, Imaging Specialist, Trinity Health Daniel Penticoff, Clinical Engineering; Imaging Tech I, CommonSpirit Health Daniel Ritter, CE/ Director Clinical Engineering, System, SCL Health System Daren Kneeland, President, MultiMedical Systems, LLC (MMS) Darren Maas, Clinical Engineering/Biomed Lead Technician, CHI Clinical Engineering Darren Vianueva, SVP, Trinity Health Dave Johnston, Clinical Engineering Mgr, Clinical Engineering Mgr David Banister, Field Service Engineer, HSS, Inc, David Campbell, Clinical Engineering, Biomed Specialist, ISSSolutions David L. Smith, Field Service Engineer, National Jewish Health via HSS, Inc. David McBratney, Healthcare Technology Management BMET III, ISS Solutions David Orozco, BioMedical Technician, Try Touch Service, Inc. David Selig, Anesthesiology, Brigham and Women's Hospital David Simpson, Clinical Engineering Medical Device Security, Catholic Health Initiatives David Singer, Biomedical Equipment Technician, ISS Solutions David Stiles, Director, Biomedical Engineering, Long Beach Medical Center David Thorman, Clinical Engineering/IS Specialist, Common Spirit Health Dean Skillicorn, Certified Biomedical Equipment Technician, Allina Health Dennis Brant, Southern Region, Field Service Engineer, HSS Inc Diana Upton, President, IAMERS Domenique Livingston, NA, Veteran Biomedical Equipment Technician Don McCarty, Clinical Engineering Director, Don Whitebread, GMC-CE / BMET, ISS Solutions Donald McMillion II, Senior BMET, CommonSpirit Donald Savard, Biomedical engineering, technologist, Biomedical engineering technologist Dorothy Hodges, CTBE Clinical Systems Analyst, LPCH Dorothy M Cubrich, Biomed, Sodexo-Biomed Department Doug Carroll CISSP, Information Service CISO, Mount Nittany Health Doug Lafko, Lead BMET, Common Spirit Health Dr.Robert Loeb, Professor, Anesthesiology, University of Florida Dustin Telford, Clinical Engineering Manager, Children's Hospital & Medical Center Omaha Dylan DiJulio, CEO, Prescott's, Inc. Edward Gomez, Biomedical technician, Western Arizona Regional Medical Center Edward Raeke, Director, Materials Management, Massachusetts General Hospital Edward Ravenkamp, President, ISO Eliud Tejada, Biomedical Technician, Try Touch Service Inc. Elizabeth Rickerson, Anesthesia, MD, BWH Elkin Lara-Mejia, Biomedical Engineering, Manager, Zuckerberg San Francisco General Hospital Emmanuel Sherman, Director of Clinical Engineering, Crothall Healthcare Engr. Naveed Ahmed Khan, Sr. Biomedical Engineer, Saudi German Hospital, Riyadh Eric Levac, Biomed Biomed Technologist, TOH

Eric Perez, Biomed and Field service Multi Vendor Biomed Tech, Philips Eric W Armocida, Clinical Engineering / Sr. Service Specialist, Hospital Staff; Medical **Equipment Repair** Ernie Rau, Supervisor of Biomedical Services, NovaMed Corp. Eron Gailey, Clinical Eng. Imaging Tech 3, SCL Health F. Mike Busdicker, System Director, Clinical Engineering, Intermountain Healthcare Felicity Billings, Anesthesiology, M.D., Brigham and Women's Hospital Frank Oltman, Clinical Engineering, BMET III, AAMI, MSCE Frank West, Owner, Equipment Trac (Biomedical Services) Freddy Matamoros, Maintenance Engineering, ACCE Fredrick Fugate, Clinical Engineering BMET Intermediate, ISS Solutions Gary Barkov, Vice President, Healthcare Technology Management, Advocate Aurora Health Gary Nop, Biomedical Clinical Engineer, Try Touch Service, Inc. Georgy Philip, BMET 2, Ascension macomb Oakland hospital Gerald Lay, Biomed, Detroit Medical Center Gerald McNeil, Clinical Engineering/CE Operations Manager, EMMC Gerald R McDaniel, Biomedical Equipment Technician, Trinity Health Giovanni Viscusi, Medical Equipment Technician, Tualatin Valley Fire & Rescue Glenn Havens, Jr. CBET, Healthcare Technology Management Site Coordinator, ISS Solutions Gordon Holder, Clinical Engineering Division Director, CommonSpirit Health Greg Boots, Clinical Engineering - Field Svc. Spec III, CHI Memorial Hospital, Chattanooga, TN Greg Chappel, Biomedical Equipment Technician, Repair technician Greg Czajka, Clinical Engineering, Manager, Advocate Aurora Health Greg Williams, Biomed Imaging Engineer, FirstHealth of the Carolinas NCBA member Gregory Phillips, Manager, HTM, US Military Gregory Zoucha, CBET, Clinical engineering, Imaging service, Common Spirit Health, Immanuel Hospital Omaha Hajarat Rasheed, Engineering, St Clair College Hank Ly, Clinical Technology (Biomed Manager), LASH (Los Angeles Surge Hospital) Harvey Fortune, Biomedical Eng., Biomed Technician, Washington Hospital Helen Cheong, Supervisor, First Health of Carolinas Hezam Alsubari, Biomed Tech, St. John Hospital, Detroit, MI Horace B Hunter, Executive Director, Georgia Biomedical Instrumentation Society (GBIS) Ian Garcia, Clinical Engineer - Department of Biomedical Engineering, Brigham and Women's Hospital Ilir Kullolli, President, American College of Clinical Engineering (ACCE) J Scot Mackeil CBET, Senior Anesthesia Biomed, Mass General Hospital Anesthesia Clinical **Engineering Dept** Jack McAuliffe, Service Manager, Sonodepot, Inc. Jacob Hunter, CE- Field Service Specialist II, CHI Jacob Urben, Field Service Engineer, HSS Jacqueline Boehme, Dept of Anesthesiology - Senior Resident Anesthesiologist, Brigham and Women's Hospital

Jaime Krueger-Gomez, Asset Manager, Nebraska Medicine Jake Smith CBET, Clinical Engineering, Senior BMET, CommonSpirit Health James Ciaramitaro, Sr Service Specialist, McLaren Healthcare Corp. James Fowler, HSS-Biomedical Technician III, Aspen Valley Hospital James H. Philip, Anesthesiology, Anesthesiologist and Clinical and Biomedical Engineer, Brigham & Women's Hospital, Harvard Medical School James Helton, Clinical Engineering, Sr BMET, Catholic Health Initiatives James J Toma, Clinical Engineering, ISS Solutions James Leonard, Lead Technician of CHI's Physical Asset Services-Clinical Engineering, Common Spirit Health St. Anthony Hospital Pendleton, OR James Linton MiM, PmP, Cmbb, AAMIF, Biomedical engineering coordinator/ professor, St. **Clair College** James R Knight, Clinical Engineering Sr. Clinical Systems Engineer, Renown Healthcare Reno NV James Vaughan ,CBET, Biomed. CBET II, CBET James Whitaker, Clinical Engineering, Senior BMET, Catholic Health Initiatives James Z. Rider, Senior Biomedical Equipment Technician, ISS Solutions Jared Wilson, Co-owner and CTO, Insight HTM Jason Chaffin, Clinical Engineering BMET Senior, Common Spirit Jason Dobbs, Biomed / SR BMET., CHI Jason Hoffer, Clinical Engineering / Lead Tech, Common Spirit Health Jason Lucas, Biomedical Services/BMET II, FirstHealth of the Carolinas Jason Warner, BMET III, HSS-US, San Luis Valley Regional Medical Center Jay W. Hall, MS, PE, Owner/Principal, Biomedical Consulting Services Jean roberts, Technical services partnership - BMET III, University of vermont Jean Sydney Humes, Director of Business Development and Board Member, ZRG Medical and California Medical Instrumentation Association Jeff Alvarado, Medical Equipment Management: FS-1, Health Shared Services (HSS) Jeff Gibson, Clinical Engineering / Biomedical Tech, Common Spirit/CHI Clinical Engineering Fargo ND Jeff Hooper, PhD, Director, Biomedical Engineering and Medical Instrumentation, Children's National Health System Jeff Kelly, Biomedical Services Manager, Moberly Regional Medical Center Jeff Ross, Owner, ACT Biomed Jeffery P. Semple, Clinical Engineering CE Program Manager, McLaren Healthcare Jeffrey C Lagrutta, Chief Compliance Officer, MultiMedical Systems, LLC. Jeffrey Feldman, MD, Anesthesiology, Prof of Clinical Anesthesia, Children's Hospital of Philadelphia Jeffrey L. Berry, Clinical Engineering / Senior Biomed, Common Spirit Health Jeffrey Ruiz, Biomedical Engineering/Site Manager, Trimedx/Holland Hospital Jeffrey Shier, BMET, Argo Biomedical Services Jeffrey Smith, Clinical Engineering Senior Service Specialist, McLaren Jeffrey Wicks, Business Manager of Surgical Services, ProHealth Care

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EXHIBIT 5

In Support of Petition of: Transtate Equipment Company, Inc. d/b/a Avante Diagnostic Imaging 1040 Derita Rd. Suite A Concord, NC 28027 Robert A. Wheeler, President Telephone: 800-710-9996

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Attorneys for Transtate Equipment Company, Inc. d/b/a Avante Diagnostic Imaging

DECLARATION OF KEVIN MELVIN

I, Kevin Melvin, am over 18 years old and, based on my personal knowledge, hereby declare as follows:

(1) I am the Clinical Engineering Lead at a large hospital system. I have been with my current employer since May 2006. I have been a Clinical Engineering Lead for the past two (2) years. My previous job title was Biomedical Electronics Technician (BMET). I have experience working as a BMET for an independent service organization (ISO). In my opinion there are no significant differences in job duties between in house BMETs and ISO BMETs and both encounter the same impediments to servicing of medical equipment.

(2) I am an expert in servicing medical equipment such as anesthesia machines, respiratory therapy machines, endoscopy machines, cardiac rehabilitation monitoring machines, and medical laboratory equipment. I previously taught how to service respiratory therapy machines, i.e., ventilators, and was an invited speaker at a national conference on respiratory therapy machines.

(3) In my 22 years of experience, I personally witnessed the evolution of medical equipment and the increase of use of technical protective measures (TPMs) to prevent access to medical equipment software required for servicing of the medical equipment. Today, access to most of the software is prevented by a TPM, especially in connection with machines made by large OEMs. (4) In addition to servicing machines that have experienced a malfunction or anomaly, I and my department also perform preventative maintenance. Preventative maintenance can also require access to the software on a machine. For example, ventilators require annual calibration

(5) Some preventative maintenance measures relate to the machine's mechanical and electrical components which are not protected by software measures. But, it is still essential to review the service manual for this type of preventative maintenance and repair. However, larger OEMs that use TPMs do it to protect the service manual and access to the error logs, which are required to properly diagnose faults and errors in the operation of the medical device. In other words, the TPMs prevent me from being able to repair, diagnose, and maintain the medical devices at my hospital. The OEMs are using TPMs to place data files, including error logs, configuration files, and other protected work behind the same TPMs.

(6) Through these practices, hospitals are forced to rely on the OEMs for all repairs and routine maintenance. Generally, the OEMs charge about \$300 for travel expenses and between \$1,000 to \$,5000 for repair costs. In my estimation, my employer could save about \$1,000 per equipment repair and significantly shorten the medical equipment repair time, if we could bypass the TPMs for our preventative maintenance and repair needs.

(7) The current COVID-19 pandemic has exasperated our servicing problems. During the current COVID-19 pandemic, increases to equipment repair time have become an issue. Prior to the COVID-19 pandemic, the OEMs would take about two (2) weeks to send a technician out to the hospital for machine servicing, and the OEM technicians use about 24 hours to deliver parts to my employer. However, as a result of the current pandemic, service times have increased from an average of two (2) weeks to a month, and part delivery average time has increased from 24 hours to one (1) week. The OEMs have also changed their service model. Now, instead of being able to speak to an operator, servicing and repair calls to the OEM are rerouted to an answering machine. These service and repair calls are placed in a queue to receive a return call from one of the OEM's technicians. My understanding is that a lot of the OEM technicians are working from home, and it takes even the OEMs a few days to reach their own technicians. Additionally, the OEMs seem to have a high turnover for their technicians and they do not readily replace the outgoing technicians. This lack of available technicians is detrimental to our ability to fulfill all of our maintenance and servicing needs, especially during this pandemic. In some cases, OEMs may have one technician that is responsible for servicing machines for three US_Active\115746170\V-2

(3) to six (6) different states, and, as can be appreciated, this means that this hampers their ability to travel quickly and perform service calls. In this uncertain time, it's unclear how long the OEMs' new COVID-19 procedures are going to continue, but this hinders the hospital's ability to provide proper medical care to its patients.

(8) If in house BMETs were able access the service manuals and the software to service and repair medical devices, With planning and parts on the shelf we could repair the medical equipment within 30 minutes to several hours, not the average wait time during the pandemic which has ranged from two weeks to one month.

(9) There are also a few third party manufacturers that are able to send replacement parts, such as batteries, faster than the OEMs. In my opinion, a healthy third party equipment and service/repair market would encourage the OEMs to provide better service packages. OEMs exploit the current regulations to offer fewer services at higher prices. Hospitals have no choice but to accept these inflated service packages out of fear of retaliation and other consequences.

(10) My understanding is my hospital owns or leases the medical equipment, and the OEM controls the software on the medical equipment. The OEMs place a proprietary chip in the computer board and an access code is required to gain access to the TPMs. For example, ventilator machines usually have about 15 modes of mechanical ventilation, including a neonatal mode. All of the different modes are preinstalled in the ventilator machine, and an access code is needed to unlock each mode. If the computer board needs to be replaced, the OEM has to provide new codes or pull the proprietary chip from the old board and insert it into the new board.

(11)Many OEMs implement TPMs, and larger OEMs tend to be far more stringent in what they make accessible . At my hospital, we include access to the service manual in the purchase order, but some of the OEMs still do not provide it when they deliver the medical equipment.

(12) The undersigned being warned that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001. The undersigned declares that all statements made of his/her own knowledge are true; and all statements made on information and belief are believed to be true.

Date: 12/8/2020

Kevin Melvin

Kevin Melvin

EXHIBIT 6

In Support of Petitioner of: Transtate Equipment Company, Inc. d/b/a Avante Diagnostic Imaging 1040 Derita Rd. Suite A Concord, NC 28027 Robert A. Wheeler, President Telephone: 800-710-9996

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Attorneys for Transtate Equipment Company, Inc. d/b/a Avante Diagnostic Imaging

DECLARATION OF JOHN KAHLER

I, John Kahler, am over 21 years old and, based on my personal knowledge, hereby declare as follows:

(1) I am a manager of biomedical imaging for a large urban hospital network, and I have three technicians that report to me. My hospital network spans seven (7) counties, has over 7,000 employees, and has 1,200 hospital beds. I specialize in servicing medical equipment used in the catheterization-angioplasty laboratory, which is commonly referred to as the "cath lab." I am familiar with servicing and repairing various types of medical equipment including vascular C-arm machines, medical imaging radiology machines, ultrasound machines, and all other imaging modalities.

(2) I have been working as a biomedical electronics technician for over 35 years. I started circa 1984 while serving in the United States Air Force where I became trained in this field. After 8 years in the Air Force, then worked for nine (9) years as a technician for two different independent service organizations (ISOs). At ISO Med Imaging, I became the supervisor for the Washington, D.C. territory. I then moved to Premier which was acquired by Aramark, which was later acquired by TriMedx. At Aramark, I was permanently assigned to work onsite at my present hospital network. I eventually became an employee of my hospital network.

(3) In addition to my military training, I received formal training from both independent service organizations (ISOs) and original equipment manufacturers (OEMs).

(4) My understanding is that my hospital network owns its medical equipment. We use in-house technicians, like myself, for some servicing. In-house service technicians provide financial benefits to the hospital network, including reduced service costs and service times as compared to OEMs. We also provide a service benefit by maintaining continuous operation of the medical devices.

(5) Due to the current technical protective measures (TPMs) in many devices, without purchasing access, we are unable to access basic service on the hospital network's newest equipment. More specifically, the TPMs prevent access to all data files, including error logs and configuration files.

(6) Our in-house service group is mainly concerned with being able to diagnose malfunctions and to identify parts that need replacing. However, with the service and error logs, especially on newer equipment, placed behind the TPMs, this is not possible for us with those devices employing the TPMs.

(7) On machines that are about five (5) years old and older, we are able to successfully service the machines and access the service manuals because they typically do not have TPMs. However, even when purchasing keys for machines that are less than five years old, we have trouble servicing machines due, in large part, due to expiring keys and dongles. Further, the OEMs are constantly changing the documentation and even the level of support provided by the OEMs' technical support. With the current TPMs, often times even the technical support staff of the OEMs do not have copies of the support manuals. These tactics ensure that my technicians cannot service the equipment themselves, and we have to rely on the OEMs for much of our servicing needs for these newer devices.

(8) The OEMs that use aggressive TPMs are Philips, Siemens, GE, and Hologic. Cannon and Fuji do not use aggressive TPMs.¹

(9) My hospital network does buy licenses for access keys and service materials out of necessity. The access keys expire annually. I have purchasing power in my role as manager of biomedical imaging, and in my estimation my hospital spends about \$20,000 annually per machine for licensing keys. Without these keys, the in-house technicians

¹ Philips refers to Koninklijke Philips N.V., including its subsidiaries Philips Electronics and Philips Healthcare. Siemens refers to Siemens Healthineers AG (formerly Siemens Healthcare, Siemens Medical Solutions, Siemens Medical Systems), a subsidiary of Siemens AG.

GE refers to GE Healthcare, a subsidiary of General Electric Company.

Hologic refers to Hologic, Inc.

Cannon refers to Canon Medical Systems Corporation, formerly Toshiba Medical, and a subsidiary of Canon, Inc. Fujifilm refers to Fujifilm Healthcare which is a part of Fujifilm Holdings Corporation.

cannot see descriptive error and diagnostic codes in the machines that are necessary to properly diagnose faults and errors in the operation of the medical devices.

(10) I am aware of outside vendors that will make unlicensed keys, and we have had to resort to such a vendor on several occasions to be able to quickly diagnose malfunctions.

(11) I try to leverage my purchasing power to reduce the annual costs of the access codes. However, the OEMs are continuing to increase the prices for their licenses and service contracts.

(12) The OEMs license different levels of access to the machines. GE, for example, has three levels of access, A, B, and C. Level A allows access only to some basic information and does not enable deep troubleshooting. Level C allows access to the most tools and deeper trouble shooting.

(13) The lack of access to data files, error logs cause various health concerns for hospital patients. For example, at my hospital when a CT scanner shuts down in the middle of a patient scan, Technologists often rerun the CT scan hoping that the machine will selfcorrect. Unfortunately, this also means that the patient gets a double exposure to radiation from the scanner. This increased level of radiation exposure is dangerous to the patient. This health risk could be avoided if in house technicians have access to the error codes, so we can quickly repair the device in minutes; and avoid the excessive wait time for diagnosis by the OEM's technician.

(14) Under the current agreements we have with several OEMs, based on the diagnostic access, my hospital network must rely on the OEM technicians for servicing. But, this servicing invariably takes a longer time than if an in-house service technician can service the machines. This increased servicing time can cause actual harm to patients. Again, physicians are double dosing patients with radiation when a faulty CT scan occurs to avoid having to shut down the machine for many hours to wait for an OEM's technician.

(15) Generally, OEMs have limited service technicians, and this means that even their same day servicing contracts are insufficient. One OEM has one service technician that is located about three (3) hours away from my hospital. For another, it can take up eight (8) hours for the service technician to reach the hospital. Due to this delay in service, my hospital has had to turn down and/or reschedule patients for some procedures because we cannot obtain timely servicing from the OEMs. In my experience, the OEMs need an average of four (4) hours to respond to a request for service. In contrast, in house service technicians often respond to service medical equipment within one hour, but only if we have access to the service manuals and error codes.

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(16) Service times and delays have only increased with the current COVID-19 pandemic. During the pandemic, the response times for the OEMs' technicians have increased, which, in turn, increases the times to properly diagnose medical devices. My hospital has attempted to mitigate some of the down time and servicing problems by preordering parts that we suspect are causing the machines to malfunction. The OEMs have an ordering cutoff time, so if we do not order the parts by the cutoff time, the parts will not be delivered in time and the medical device can be inoperable for a whole day. This means that the hospital must reschedule its patients until the problem is resolved. If we order the wrong part, the OEMs charge my hospital restocking fees. Again, these costs are part of the hospital's overhead that gets added to medical bills.

(17) In my opinion, ISOs provide a huge benefit to the field of medical devices. ISOs improve the quality of service because they seem to have more of an interest in satisfying the customer. This in turn seems to cause the OEMs to provide better service packages. Additionally, ISOs do often send better quality replacement parts. I have had experiences in which the OEMs sent repackaged parts, and even broken or inoperable parts. The OEMs are currently operating with minimal competition, so they do not have any motivation to provide quality services.

(18) The undersigned being warned that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001. The undersigned declares that all statements made of his/her own knowledge are true; and all statements made on information and belief are believed to be true.

Date: 12/14/2020

John/Kahler

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EXHIBIT 7

In Support of Petition of: Transtate Equipment Company, Inc. d/b/a Avante Diagnostic Imaging 1040 Derita Rd. Suite A Concord, NC 28027 Robert A. Wheeler, President Telephone: 800-710-9996

Of counsel: Dentons US LLP 233 South Wacker Drive, Suite 5900 Chicago, IL 60606 David R. Metzger Email: <u>david.metzger@dentons.com</u> Telephone: 312-867-2578 Taaj Reaves Email: <u>taaj.reaves@dentons.com</u> Telephone: 312-867-8176

Attorneys for Transtate Equipment Company, Inc. d/b/a Avante Diagnostic Imaging

DECLARATION OF ABIGAIL LANE-SAVAGE

I, Abigail Lane-Savage, am over 21 years old and, based on my personal knowledge, hereby declare as follows:

Background and Information

(1) I am a Director of Imaging for Sodexo, Inc.'s Healthcare Technology Management division. Sodexo has contract to manage the servicing of imaging devices for a large hospital network with facilities in three counties in North Carolina (sometimes "the hospital network" or "my hospital network"). I am the Operations Manager for the hospital networks' Imaging Services.

(2) I have been servicing medical devices for 20 years. I spent the first 18 years of my career as an employee at various hospitals in their technical services departments where I would service Biomedical devices. At one such hospital I also managed the implementation of electronical medical records software. For the last two years I have worked for what now is Sodexo, a Fortune 500 company that offers management services in many areas.

(3) In my current position, I am responsible for managing the daily operation of the imaging services throughout the hospital network. I oversee the purchase of medical imaging devices and service contracts. I manage a team of technicians, who like me, are employed by Sodexo, but who work in my department under contract with the hospital network. My experience is that most hospitals predominantly purchase the imaging

devices of one manufacturer. In the hospital network, we use Philips, GE and Siemens devices, with the Siemens devices predominating.

Servicing Activities and Experience with Technological Protective Measures ("TPMs")

(4) My team manages the extended servicing, including maintenance schedules, of medical imaging devices after the manufacturer's warranty expires. My hospital network utilizes our technical service technicians in lieu of purchasing the Original Equipment Managers' ("OEMs") extended service plans, whenever possible . My hospital network is hesitant to allow the OEM technicians access to the hospital due to legitimate safety and privacy concerns. In addition, our services cost much less than the OEM services, and we can deal with service events in a more timely fashion.

(5) The OEMs use technological protective measures (TPMs) and place data files, including error logs, configuration files, and event logs behind these TPMs. These TPMs hinder my team's ability to properly and quickly diagnose faults and errors in the operation of a device. We need the error logs to decipher the causes of errors.

(6) My hospital network purchased their medical imaging devices with the understanding that hospital employees would be given access keys for regular maintenance. However, the OEMs fail to provide my team with the hospital network's access keys because they see the members of my team as third-party contractors, hence competitors, not hospital network employees.

(7) The OEMs that I am particularly aware of that use TPMs are Philips, Siemens, and GE.¹ While GE used to be particularly aggressive in restricting access to the software and data files needed for servicing its equipment, in recent years, they seem to have relented somewhat and will now provide an access key to those who train on their equipment via the Radiological Services Training Institute. Sodexo will send some technicians for training there, but at a cost.

(8) Siemens and Philips are still very aggressive in their use of TPMs. I am aware that Philips has filed lawsuits against some third parties it believes have accessed the software and data files without a key issued to them by Philips.

¹ Philips refers to Koninklijke Philips N.V., including its subsidiaries Philips Electronics and Philips Healthcare. Siemens refers to Siemens Healthineers AG (formerly Siemens Healthcare, Siemens Medical Solutions, Siemens Medical Systems), a subsidiary of Siemens AG. GE refers to GE Healthcare, a subsidiary of General Electric Company. US_Active\116011030\V-2 US_Active\116011030\V-3

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(9) Siemens will only issue time-limited access codes, and the codes only provide access to restricted levels of software and data files. For example, error logs are available to those who pay for higher level access.

(10) Recently, Siemens updated their software to require stronger access codes. Siemens also changed the access levels and what software and data files are available at a given access level. Now we are not able to view the event logs and error codes. Instead, we have to call Siemens and explain to them why we are asking for access to the information before they will provide us with a code. Siemens then decides whether they will provide an access code or require a Siemens service technician to travel and enter the access code.

(11) When we get access to a Siemens access code, it takes about 24 hours to receive approved access code, and then the access code only good for about 4 days. On multiple occasions, Siemens has denied us access to higher level access keys.

(12) When we cannot get access to the keys, we have to pay the OEMs for tech support. If the OEM has to send a technician on-site, they charge about \$600 to \$800 per hour, including travel time, and OEM parts pricing. For servicing, GE charges \$600/hour and Siemens charges \$800/hour.

(13) The OEMs recently have also increased their service response time from 24 hours to 48 hours unless higher priced overtime is pre-approved via a purchase order issued prior to the service call. This has been detrimental to patient care and public safety as machines requiring the visit of an OEM technician remain unusable for a longer period of time.

(14) The unavailability of a machine is also very expensive to a hospital. Each day that a large machine is unusable, the hospital must cancel services at a cost of lost revenue which I understand to be in the hundreds of thousands of dollars, which also impacts patient care.

(15) The OEMs' field service engineers have the access keys to obtain the error codes. With the access key, they are able to fix common errors within 15 minutes of coming to the hospital, but the OEMs still charge a minimum of two hours for technical support fees along with hourly travel rates. My hospital network could greatly reduce the repair time and medical care delays if we have access to the error codes.

Adversity Caused by TPMs

(16) My hospital network must reschedule patients when a machine is down and waiting for an OEM field service engineer to come on-site and repair the machine. On occasion it can take several days to get the MRI scanner, CT scanner, or Cath Lab device back in service.

(17) This problem has only magnified during the COVID-19 pandemic. My hospital network for many months had one hospital that is solely dedicated to caring for COVID-19 patients. That hospital had dedicated CT machines in the COVID-19 hospital. More recently, given the increase in Covid-19 cases, my hospital network has dedicated floors in four other hospitals to Covid-19 patients.

(19) When these critical machines were down, my hospital network had to transport patients from the COVID-19 designated hospital to another campus. This decision was not taken lightly and potentially compromised my hospital network's ability to minimize the spread of COVID-19.

(20) The FDA acknowledged medical device shortages from the COVID-19 public health emergency (PHE).² The OEM-caused delays add to the demand for medical devices during the PHE. My hospital network leases one such medical device for about \$22,500 a month because we cannot afford to lose critical time for the OEMs to properly repair the machines.

(21) TPMs add cost to the purchase of, among others, the MRI, CT, and Cath-Angio labs by as much as \$125,000 per machine, just for the access keys.

(22) In an effort to quickly restore the machines and minimize the adverse effects, we order parts from third party vendors, under their quickened and technical support, which is also limited due to their own lack of access keys. We try to diagnose faults using our experience and, as needed, the experience of our third party vendors, and then order the parts, hoping that the diagnosis, without access to the error logs and the like is correct.

(23) Patients are understandably frustrated due to unnecessary delays in medical care, and they express this in their negative feedback to the hospital network. This frustration then is reflected in the hospital network's view of the performance of my

² U.S. Food and Drug Administration, *Medical Device Shortages During the COVID-19 Public Health Emergency*, available at https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-shortages-during-covid-19-public-health-emergency#shortage.

U.S. Food and Drug Administration, Statement on concerns with medical device availability due to concertation sterilization facility closures, available at <u>https://www.fda.gov/news-events/press-announcements/statement-concerns-medical-device-availability-due-certain-sterilization-facility-closures</u>.

Thomas Sullivan, FDA CDRH Issues Guidance on Notifications of Medical Device Shortages, Policy & Medicine (May 19, 2020), <u>https://www.policymed.com/2020/05/fda-cdrh-issues-guidance-on-notifications-of-medical-device-shortages.html</u>.

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department. It also impacts Press Gainy Scores, which are customer satisfaction scoresthat impact reimbursements to the hospital by the Centers for Medicare & Medicaid Services ("CMS").

(24) In my opinion, removing the OEMs' aggressive TPM practices will increase my hospital network's ability to provide quality medical care while also decreasing medical bills.

(25) The undersigned being warned that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001. The undersigned declares that all statements made of his/her own knowledge are true; and all statements made on information and belief are believed to be true.

Date: 12/9/2020

<u>Abigail Lane-Savage</u> Abigail Lane-Savage

EXHIBIT 8

In Support of Petition of: Transtate Equipment Company, Inc. d/b/a Avante Diagnostic Imaging 1040 Derita Rd. Suite A Concord, NC 28027 Robert A. Wheeler, President Telephone: 800-710-9996

Of counsel: Dentons US LLP 233 South Wacker Drive, Suite 5900 Chicago, IL 60606 David R. Metzger Email: <u>david metzger@dentons.com</u> Telephone: 312-867-2578 Taaj Reaves Email: <u>taaj.reaves@dentons.com</u> Telephone: 312-867-8176

Attorneys for Transtate Equipment Company, Inc. d/b/a Avante Diagnostic Imaging

DECLARATION OF EUGENE STUART GROGAN

I, Eugene Stuart Grogan, am over 21 years old and hereby declare as follows:

(1) I am the Enterprise Imaging Servicing Manager at a large academic hospital with over 13,000 employees. I have been with my current employer for about 22 years, about 12 years as the Enterprise Imaging Servicing Manager, and about 10 years as a Service Engineer. Prior to my current position, I worked for 11 years as a field service engineer with General Electric Company (GE), an original equipment manufacturer ("OEM"). I and those in my department service various medical devices including computer axial tomography scan ("CT Scan") systems, magnetic resonance imaging ("MRI") systems, and cyclotron machines.

(2) My hospital is a branch of a large academic medical center with approximately850 beds, 4 satellite hospitals of various sizes, and 9 catheterization laboratories.

(3) My hospital uses medical devices from Philips, GE, and Siemens. It also uses Del Medical X-ray equipment, x-ray devices from Canon and Toshiba, Hologic mammography machines, and Fujifilm ultrasound machines.¹

¹ GE refers to GE Healthcare, a subsidiary of General Electric Company.

Siemens refers to Siemens Healthineers AG (formerly Siemens Healthcare, Siemens Medical Solutions, Siemens Medical Systems), a subsidiary of Siemens AG.

Philips refers to Koninklijke Philips N.V., including its subsidiaries Philips Electronics and Philips Healthcare. Del Medical refers to Del Medical, Inc.

(4) With over 30 years of experience in medical device servicing, I have witnessed the evolution of access to software servicing tools used for diagnosing, repairing, and maintaining medical devices. Software has been used for testing GE medical devices nearly all of my career if not my entire career. However, for many modern medical devices the software is embedded in the devices, and access to software and files needed to service these devices is restricted by technological protective measures (TPMs).

(5) In addition, starting about 2015, OEM's began migrating service manuals into digital databases saved in cloud-based systems. Currently, many of those systems require an access key or code to access the electronically stored service manuals. My experience is that medical device owners need to make additional purchases for access keys or passwords just to access to these types of service manuals. The service documentation typically is made accessible at a cost of about \$1,500 to \$25,000 per year, per medical device.

(6) Even error logs needed to properly diagnose faults and errors in the operation of the medical devices have been placed behind TPMs. Without access to these error logs, I cannot decipher causes of malfunctions in the medical devices. This lack of important information prevents me from repairing, diagnosing, and maintaining the medical devices that my hospital uses. In addition to the error logs, data files, configuration files, and other unprotected work have been placed behind the same TPMs.

(7) The TPMs typically are challenge-response systems that require access keys in the form of passwords, encrypted codes that the OEMs generate, or encrypted thumb drives to unlock access to the software. Some OEMs provide access to different levels of software depending on the amount paid to them. The highest priced access keys provide access to the most servicing software. Philips keys provide varying levels of access based on the equipment, but typically Philips provides owners up to three levels of access. GE keys provide three levels of access; and Siemens keys provide seven access levels.

(8) My hospital pays for the highest access key levels available to it, for among other reasons, to also obtain prioritized service calls.

(9) Philips' use of TPMs on some devices, e.g., catheter/angioplasty labs prevents my hospital from connecting our medical devices to our internal network system without requiring a servicing call to a Philips technician. When my hospital obtains such a medical device, it usually has to place an additional \$2,000.00 service call with Philips just

Hologic refers to Hologic, Inc.

Cannon refers to Canon Medical Systems Corporation, formerly Toshiba Medical, and a subsidiary of Canon, Inc. Toshiba refers to Toshiba Medical, now Canon Medical Systems Corporation.

Fujifilm refers to Fujifilm Healthcare which is a part of Fujifilm Holdings Corporation.

to populate an IP address in the medical device. In a multiunit hospital setting, such medical devices are essentially rendered useless unless they are connected to a network to communicate the data they produce.

(10) In my experience, GE and Siemens provide rudimentary service manuals with some parts diagrams, while Philips uses TPMs to protect their replacement parts catalog. Without access to the Philips replacement parts catalog, one cannot determine part numbers, and thus cannot order replacement parts when needed.

(11) The Hologic devices I have encountered are so locked down that owner selfservicing is virtually impossible. Hologic does not provide keys or access codes to bypass the TPMs unless one purchases a service contract.

(12) Del Medical, Cannon, and Toshiba devices currently are relatively unlocked and can be owner self-serviced.

(13) In my experience, typically, smaller device makers who are trying to grow their market share tend to not lock down their machines and provide ready access to owner manuals and the installed servicing software.

(14) Some medical devices also seem configured to thwart owners from troubleshooting the devices themselves in other ways. For example, I have experience the triggering of a cooling fan to work at a noisy, high speed after raising the cover of some GE ultrasound imaging devices. The only remedy I know of is to make a service call to GE to have one of their technicians reset the fan.

(15) I consider the access and use of servicing software embedded in medical devices to be critical to providing fast and efficient patent services.

(16) The use of TPMs to prevent access to servicing software is troublesome to me due to the delays they can cause. With access to the servicing software, the device repair time by my department is between about 1 to 8 hours. Without access to the servicing software, repair time can increase to 24 hours or more because a service call by an OEM technician is required.

(17) My hospital owns most if not all of its medical equipment and has licenses to use the software that is installed on the equipment. Each software license is unique to each machine.

(18) I use independent service organizations ("ISOs") including Transtate
 Equipment Company, Inc., on occasion, but mostly to order parts for some medical devices.
 In my experience, the ISOs typically charge 30% to 50% less than OEMs for service calls.
 However, due to licensing restrictions, ISOs usually are not permitted to access the

software on some of the medical devices, and thus we do not use them for servicing those devices.

(19) As stated above, during my career, OEMs have increased their use of TPMs in medical devices. In that same time period, the service technicians that assist with TPMs are taking longer to respond to service calls. My understanding is this is due to the OEMs decreasing their employee base, and because servicing engineers are not being replaced after retirement.

(20)Under penalty of perjury, I affirm that this Declaration accurately reflects my knowledge.

2020 Date: 12

ene Stuart Gogan

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EXHIBIT 9

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF GEORGIA

I

PHILIPS MEDICAL SYSTEMS NEDERLAND B.V.; PHILIPS NORTH AMERICA LLC; and PHILIPS INDIA LTD.,
Plaintiffs,
v. TEC HOLDINGS, INC., F/K/A TRANSTATE EQUIPMENT COMPANY, INC., TRANSTATE EQUIPMENT COMPANY, INC., F/K/A TRANSTATE HOLDINGS, INC.; and ROBERT A. ("ANDY") WHEELER, individually and in his capacity as executor and personal representative of the Estate of DANIEL WHEELER

Defendants.

Civil Action No. 1:17-cv-02864-LMM

JURY TRIAL DEMANDED

SECOND AMENDED COMPLAINT

Plaintiffs Philips Medical Systems Nederland B.V., Philips North America

LLC, and Philips India Ltd. (collectively, "Philips" or "Plaintiffs"), by and through

their undersigned counsel, hereby bring the following Amended Complaint against

TEC Holdings, Inc., formerly known as Transtate Equipment Company, Inc.

("Transtate I"), Transtate Equipment Company, Inc., formerly known as Transtate

Holdings, Inc. ("Transtate II") (collectively, "Transtate"), and Robert A. ("Andy")

Wheeler, individually and in his capacity as executor and personal representative

of the Estate of Daniel Wheeler ("the Estate") (Andy Wheeler and the Estate are

<u>Count V: Violations of the Digital Millennium</u> <u>Copyright Act (DMCA), 17 U.S.C. § 1201 (Transtate I and II)</u>

193. Philips reasserts, re-alleges, and incorporates by reference the allegations in all other paragraphs of this Amended Complaint as if fully set forth herein under Count V.

194. Philips' medical imaging systems include Philips' copyrighted and proprietary software.

195. Philips' log files on its medical imaging systems are protected by copyright under Title 17.

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196. Philips Internal Software is proprietary software protected by copyright under Title 17.

197. Philips electronic documentation is protected by copyright under Title17.

198. Philips employs numerous technological measures including, but not limited to, its Access Key protection scheme and protocol, in order to protect and control access to and use of its copyrighted proprietary software and/or portions thereof.

199. Transtate I and II intentionally modified Philips' proprietary software to circumvent a technological measure that controls access to Philips' protected software. Specifically, Transtate I and II circumvented the access controls to gain access to the USB drive, then used Transtate's software exploit to modify computer files in order to deactivate a requirement for an Access Key to access Philips' proprietary software. Transtate I and II were thus able to bypass the technological measure and gain unauthorized access to the proprietary software.

200. Philips' technological measures on the Systems also prevent unauthorized access to Philips' copyrighted log files. Transtate I and II intentionally circumvent access controls through use of their software exploit and potentially other methods to gain unauthorized access to and copy Philips' copyrighted log files on the Allura systems.

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201. Philips employs technological measures, including but not limited to, its account authorization and IST Key protection scheme and protocol, in order to protect and control access to and use of its copyright protected Philips Internal Software.

202. Transtate I and II employ the circumvention mechanism in order to bypass or circumvent the requirement for a Philips account and an IST Key to access Philips Internal Software. Transtate I and II were thus able to bypass the technological measure and in each instance gain repeated unauthorized access to the proprietary copyright protected Philips Internal Software by virtue of such bypass or circumvention.

203. Philips employs technological measures, including but not limited to, encryption of its proprietary and copyrighted electronic documentation, in order to protect and control access to and use its copyright protected Philips electronic documentation.

204. Transtate I and II have intentionally modified Philips' encrypted electronic documents by decrypting them in order to make unencrypted copies thereof which Transtate I and II can then distribute. Transtate I and II were thus able to bypass or circumvent the technological measure in order to gain repeated unauthorized access to Philips copyright protected electronic documentation.

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205. Transtate I and II have intentionally and/or knowingly circumvented technological measures that effectively control access to a work or works protected under Title 17, in violation of 17 U.S.C. § 1201(a)(1)(A) of the Digital Millennium Copyright Act.

206. Transtate I and II's unauthorized means of accessing the Systems, including Philips' proprietary software and copyrighted logs, the Philips Internal Software, and Philips electronic documentation has, and does, entail the unauthorized access, copying, and potential alteration of the contents of Philips' copyrighted proprietary software, log files, and electronic documentation.

207. Philips has been and will continue to be damaged in an amount not presently known with certainty, but that will be proven at trial.

208. Philips is entitled to the range of relief provided by 17 U.S.C. § 1203, including but not limited to, injunctive relief, compensatory damages or statutory damages, punitive damages, and Philips' costs and attorneys' fees in amounts to be proven at trial. Transtate I and II's conduct also has caused irreparable and incalculable harm and injuries to Philips, and, unless enjoined, will cause further irreparable and incalculable injury, for which Philips has no adequate remedy at law.

<u>Count VI: Violations of the Digital Millennium</u> <u>Copyright Act (DMCA), 17 U.S.C. § 1202 (Transtate I and II)</u>

209. Philips reasserts, re-alleges, and incorporates by reference the allegations in all other paragraphs of this Amended Complaint as if fully set forth herein under Count VI.

210. Philips' electronic documentation is protected by the copyright laws, and Philips owns the copyright in its electronic documentation.

211. Philips electronic documentation is made available by Philips to authorized users.

212. Philips grants authorization to access Philips InCenter database, and the files therein, to third parties having registered for AIAT level access.

213. Philips distributes a wide range of documents through the InCenter database, and controls access to certain electronic documentation by encrypting such documents. Philips authorized users are authorized to access documentation commensurate with their roles, *i.e.* AIAT level authorization grants access to AIAT level electronic documentation. Access is facilitated by virtue of Philips IST Keys, such that a user's valid IST Key will enable decryption of files that a user is authorized to access.

214. Philips electronic documentation includes metadata that may identify the author of the file and that the file originates from Philips, the copyright holder.

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215. Philips electronic documentation's metadata thus includes copyright management information ("CMI") pursuant to 17 U.S.C. § 1202.

216. Employees of Transtate I and Transtate II download encrypted copies of files that they are not authorized to access, and decrypt those files by making use of Transtate decryption and stripping mechanism.

217. Transtate I and Transtate II's decryption and stripping mechanism first decrypts Philips electronic documentation without authorization, and then removes the metadata, including CMI, from the unauthorized copies of Philips electronic documentation created and distributed by Transtate.

218. Employees of Transtate I and Transtate II then distribute such decrypted files stripped of their metadata.

219. Transtate I and II have intentionally and/or knowingly removed and altered the copyright management information contained in Philips' electronic documentation metadata without the authority of the copyright owner or the law knowing, or having reasonable grounds to know, that such behavior will induce, enable, facilitate, or conceal an infringement of Philips rights under Title 17, in violation of 17 U.S.C. § 1202(b)(1) of the Digital Millennium Copyright Act.

220. Transtate I and II have intentionally and/or knowingly distributed copyright management information knowing that the copyright management information contained in Philips' electronic documentation metadata has been

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removed or altered without the authority of the copyright owner or the law knowing, or having reasonable grounds to know, that such behavior will induce, enable, facilitate, or conceal an infringement of Philips rights under Title 17, in violation of 17 U.S.C. § 1202(b)(2) of the Digital Millennium Copyright Act.

221. Transtate I and II have intentionally and/or knowingly distributed copies of Philips' electronic documentation knowing that the copyright management information contained in Philips' electronic documentation metadata has been removed or altered without the authority of the copyright owner or the law knowing, or having reasonable grounds to know, that such behavior will induce, enable, facilitate, or conceal an infringement of Philips rights under Title 17, in violation of 17 U.S.C. § 1202(b)(3) of the Digital Millennium Copyright Act.

222. Philips has been and will continue to be damaged in an amount not presently known with certainty, but that will be proven at trial.

223. Philips is entitled to the range of relief provided by 17 U.S.C. § 1203, including but not limited to, injunctive relief, compensatory damages or statutory damages, punitive damages, and Philips' costs and attorneys' fees in amounts to be proven at trial. Transtate I and II's conduct also has caused irreparable and incalculable harm and injuries to Philips, and, unless enjoined, will cause further

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EXHIBIT 10

UNITED STATES DISTRICT COURT DISTRICT OF PUERTO RICO

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PHILIPS MEDICAL SYSTEMS PUERTO	CIVIL No. 3:19-cv-01488
RICO, INC., PHILIPS MEDICAL	
SYSTEMS NEDERLAND B.V.; AND	
PHILIPS INDIA LIMITED,	RE: PERMANENT INJUNCTIVE RELIEF
	PURSUANT TO THE COMPUTER FRAUD
Plaintiff,	AND ABUSE ACT, 18 U.S.C. §1030,
	COPYRIGHT ACT, 17 U.S.C. § 1201,
v.	PUERTO RICO'S INDUSTRIAL AND
	TRADE SECRET PROTECTION ACT, 10
ALPHA BIOMEDICAL AND	P.R. LAWS ANN. §§4131-4141; UNFAIR
DIAGNOSTIC CORP., COOPERATIVA	COMPETITION; DIGITAL MILLENNIUM
DE SEGUROS MÚLTIPLES DE	COPYRIGHT ACT, 17 U.S.C. § 1201;
PUERTO RICO,	COPYRIGHT INFRINGEMENT, 17 U.S.C.
	§ 101, et seq. AND DEMAND FOR JURY
Defendant.	TRIAL.

AMENDED COMPLAINT

TO THE HONORABLE COURT:

COMES NOW Philips Medical Systems Puerto Rico, Inc. ("Philips PR"), Philips Medical Systems Nederland B.V. ("Philips Nederland") and Philips India Limited ("Philips India") (collectively, "Philips" or "plaintiffs"), through their undersigned attorneys and, in support of this Complaint ("Complaint"), respectfully aver and pray as follows:

NATURE OF ACTION

1. This is an action for permanent injunctive relief to prevent defendant from causing irreparable harm to plaintiff and for damages to redress injuries suffered by plaintiffs, all because of the wrongful conduct by defendant, in violation of the Computer Fraud and Abuse Act, 18 U.S.C. §1030 ("CFAA"), the Copyright Act, 17 U.S.C. § 1201, Puerto Rico's Industrial and Trade Secret Protection Act, 10 P.R. Laws Ann.

<u>TIHRD CAUSE OF ACTION</u> 17 U.S.C. § 1201, et seq. (DMCA)

121. Plaintiffs repeat and reallege the averments set forth above.

122. Plaintiffs employ numerous technological measures including, but not limited to, a valid UserID and IST account, a "Smart Card Dongle" – an authentication and service authorization device- the "MR Response Generator Tool" – a protection scheme and protocol- all to protect and control access to copyrighted material in the MRI systems it manufactures.

123. Alpha Biomedical has engaged in conduct that circumvents a technological measure that effectively controls access to a copyrighted work, including using and/or creating a deactivated and fake UserID and IST account, and reproducing a copy of a circumvented and/or hacked *MR Response Generator Tool*, among other infringing conduct to gain access to protected information.

124. Defendant intentionally used tools and/or credentials to defeat and circumvent technological measures that control access to Philips's protected software, the *Philips' CSIP* embedded in the MRI systems.

125. Alpha Biomedical has intentionally and/or knowingly circumvented technological measures that effectively control access to a work or works protected under Title 17, in violation of 17 U.S.C. § 1201(a)(1)(A) of the DMCA.

126. Defendant has not obtained the right to use or access Philips CSIP from plaintiffs. All of defendant's acts were and are performed without permission, license or consent of plaintiffs.

127. Upon information and belief, defendant has received substantial benefits, revenues, compensation and/or cost savings as a direct and proximate result of the

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foregoing unfair and wrongful scheme.

128. Plaintiffs are entitled to the remedies provided by 17 U.S.C. § 1203, including but not limited to, injunctive relief, compensatory damages or statutory damages, punitive damages, and costs and attorneys' fees in amounts to be proven at trial.

129. Defendant has willfully infringed, and unless enjoined will continue to unlawfully infringe plaintiffs' copyrighted content, as set forth above, by knowingly circumventing access controls to plaintiffs' copyrighted software in violation of 17 U.S.C. § 1201 *et seq*.

EXHIBIT 11

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF FLORIDA

Case No.

PHILIPS NORTH AMERICA LLC, PHILIPS MEDICAL SYSTEMS NEDERLAND B.V.; PHILIPS INDIA LTD.; PHILIPS MEDICAL SYSTEMS (CLEVELAND), INC; PHILIPS MEDICAL SYSTEM TECHNOLOGIES LTD.; and KONINKLIJKE PHILIPS N.V.,

Plaintiff,

vs.

626 HOLDINGS, INC., and ALEXANDER KALISH,

Defendants.

COMPLAINT

Plaintiffs Philips North America LLC, Philips Medical Systems (Cleveland), Inc., Philips India Ltd., Philips Medical Systems Technologies Ltd., Philips Medical Systems Nederland B.V., and Koninklijke Philips N.V. (collectively "Philips" or "Plaintiff"), by and through its undersigned counsel, hereby brings the following Complaint against 626 Holdings, Inc. ("626 Holdings") and Alex Kalish ("Kalish" or collectively with 626 Holdings, "Defendants"), and pleads as follows:

NATURE OF THE ACTION

1. Philips develops, sells, supports, maintains, and services medical imaging systems, such as computed tomography (CT) systems, X-ray systems, nuclear medicine systems, PET scanners, magnetic resonance (MR) scanners, ultrasound machines, and the like used at hospitals and medical centers, including the proprietary hardware, software, and documentation used to operate, service, and repair such systems.

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Count VI: <u>Violation of the Digital Millennium Copyright Act (DMCA), 17 U.S.C. § 1201</u>

111. Philips reasserts, re-alleges, and incorporates by reference the allegations in all other paragraphs of this Complaint as if fully set forth herein under Count VI.

112. Philips medical imaging systems include Philips copyright protected proprietary works.

113. Philips documents and software obtainable from Philips InCenter service include Philips copyright protected and proprietary works.

114. Philips proprietary works within Philips medical imaging systems and accessible through Philips InCenter service are protected by copyright under Title 17.

115. Philips employs numerous layered technological measures including, but not limited to, Philips access key, username and password combination, access control certificates, and machine specific access controls, to control access to and use of its copyrighted proprietary software and/or portions thereof on Philips medical imaging devices.

116. Philips also employed layers of technological measures, including username and password combinations and access control certificates, in order to protect Philips copyright protected works, including *inter alia* software and documentation, by controlling access to and the duration of such access to Philips protected works available from Philips InCenter system.

117. Defendants have employed software exploit tools to intentionally modify Philips proprietary software to circumvent a technological measure that controls access to Philips' protected software. Specifically, Defendants software exploit tools access Philips medical imaging systems from a USB drive or other external media in order to modify computer files within Philips medical imaging devices to deactivate a requirement for either a Philips generated key code or a Philips issued access key, bearing a current and duly authorized Philips' access control certificate, in order to access Philips proprietary software. Defendants were thus able to bypass technological measures to gain unauthorized access to the proprietary software.

118. Defendants have also employed false, modified, or counterfeit access control certificates to circumvent a technological measure that controls access to Philips' protected software. Specifically, Defendants false, modified, or counterfeit access control certificates enable

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unauthorized users to access Philips medical imaging systems thereby circumventing technological measures to gain unauthorized access to the proprietary software.

119. Defendants have further employed their false, modified, or counterfeit access control certificates in order to decrypt encrypted Philips proprietary documentation and software accessed by Defendants from Philips InCenter database through Defendants fraudulent scheme of impersonating Philips FSE credentialed users. Philips encrypted documents and software from Philips InCenter database are encrypted by Philips specifically to protect such documents and software from unauthorized access by unlicensed third parties and to prevent further distribution of Philips works to others without license to do so.

120. Defendants multiple methods of bypassing or circumventing access controls protecting Philips' works and controlling access to Philips' works also prevent unauthorized access to Philips' copyright protected log files within Philips medical imaging devices. Upon information and belief Defendants intentionally circumvent access controls using their exploit tools and unlawful certificates and potentially other methods to gain unauthorized access to and copy Philips' copyrighted log files on the Philips medical imaging devices.

121. Thus, Defendants have intentionally and/or knowingly circumvented technological measures that effectively control access to a work or works protected under Title 17, in violation of 17 U.S.C. § 1201(a)(1)(A) of the Digital Millennium Copyright Act.

122. Defendants' unauthorized means of accessing the Philips medical imaging systems, including Philips' proprietary software and copyrighted logs, and Philips encrypted documentation and software has, and does, entail the unauthorized access, copying, and potential alteration of the contents of Philips' copyrighted proprietary software, log files, and electronic documentation.

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123. Philips has been and will continue to be damaged in an amount not presently known with certainty, but that will be proven at trial.

124. Philips is entitled to the range of relief provided by 17 U.S.C. § 1203, including but not limited to, injunctive relief, compensatory damages or statutory damages, punitive damages, and Philips' costs and attorneys' fees in amounts to be proven at trial. Defendants' conduct also has caused irreparable and incalculable harm and injuries to Philips, and, unless enjoined, will cause further irreparable and incalculable injury, for which Philips has no adequate remedy at law.

EXHIBIT 12

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS

EASTERN DIVISION

PHILIPS MEDICAL SYSTEMS (CLEVELAND), INC.; PHILIPS INDIA LTD.: PHILIPS MEDICAL SYSTEMS TECHNOLOGIES LTD.; KONINKLIJKE PHILIPS N.V.; and PHILIPS NORTH AMERICA LLC,	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	Civil No: 1:17-CV-03425 Judge Robert M. Dow, Jr.
Plaintiffs, v.	\$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	JURY TRIAL DEMANDED
ZETTA MEDICAL TECHNOLOGIES, LLC; and RONALD J. DUNCAN,	§ § 8	
Defendants.	5 8 8	

AMENDED COMPLAINT

Plaintiffs Philips Medical Systems (Cleveland), Inc., Philips India Ltd., Philips Medical Systems Technologies Ltd., Koninklijke Philips N.V., and Philips North America LLC (collectively, "Philips" or "Plaintiffs"), by and through their undersigned counsel, hereby bring the following Amended Complaint against Zetta Medical Technologies, LLC ("Zetta") and Ronald J. Duncan ("Mr. Duncan") (collectively, "Defendants"), and now plead as follows:

Overview

1. As set forth more fully below: Plaintiffs are collectively, *inter alia*, involved in the business of developing, manufacturing, selling, supporting, maintaining, and servicing medical imaging systems used at hospitals and medical centers, including the proprietary

Count III: Violations of the Digital Millennium Copyright Act (DMCA), 17 U.S.C. § 1201

80. Philips reasserts, re-alleges, and incorporates by reference the allegations in all other paragraphs of this Complaint as if fully set forth herein under Count III.

81. As set forth in Count II, Defendants have improperly accessed works protected under Title 17 (copyright).

82. Philips employs numerous technological measures including, but not limited to, its password and user ID protection scheme and protocol, in order to effectively protect and control access to and use of its copyrighted Philips CSIP and/or portions thereof.

83. Upon information and belief, Defendants manufacture, import, provide, offer to the public, or otherwise traffic in technology, products, services, devices, components, or parts thereof, that are primarily designed or produced for the purpose of circumventing technological measures and/or protection afforded by technological measures that effectively control access to Philips CSIP and/or portions thereof.

84. Upon information and belief, Defendants' technology, products, services, devices, components, or parts thereof have limited or no commercially significant purpose or use other than to circumvent technological measures that effectively control access to Philips' CSIP and/or portions thereof.

85. In the course of doing so, Defendants have intentionally and/or knowingly circumvented technological measures that effectively control access to a work or works protected

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under Title 17, in violation of 17 U.S.C. § 1201(a)(1)(A)—the Digital Millennium Copyright Act.

86. Defendants' unauthorized means of accessing the Systems has, and does, entail the unauthorized access, copying, and potential alteration of the contents of Philips' copyrighted CSIP software.

87. Philips has been and will continue to be damaged in an amount not presently known with certainty, but will be proven at trial.

88. Philips is entitled to the range of relief provided by 17 U.S. C. §§ 1201-12-3, including but not limited to, injunctive relief, compensatory damages or statutory damages, punitive damages, and Philips' costs and attorneys' fees in amounts to be proven at trial. Defendants' conduct also has caused irreparable and incalculable harm and injuries to Defendants, and, unless enjoined, will cause further irreparable and incalculable injury, for which Philips has no adequate remedy at law.

89. By engaging in the conduct set forth in the preceding paragraphs of this Complaint, Defendants have exceeded their authorized levels of access to the Systems and the Philips CSIP, in violation of Philips' copyrights and the Digital Millennium Copyright Act, thereby obtaining valuable diagnostic and proprietary maintenance log files, and access to other valuable tools and information, and thereby causing damages to Philips that include business losses, unfair competition, and intrusion upon trade secrets, and that further include the threat of continuing and ongoing harms relating to the same.

EXHIBIT 13

	Case 8:19-cv-01765 Document 1 Filed	09/16/19 Page 1 of 48 Page ID #:1	
1 2 3 4	Carla M. Wirtschafter (SBN 292142) Email: cwirtschafter@reedsmith.com REED SMITH LLP 1901 Avenue of the Stars, Suite 700 Los Angeles, CA 90067-6078 Telephone: (310) 734-5200 Facsimile: (310) 734-5299		
5 6 7 8 9 10	Kirsten R. Rydstrom (<i>Pro hac vice</i> pending) Email: krydstrom@reedsmith.com Richard A. Graham (<i>Pro hac vice</i> pending) Email: rgraham@reedsmith.com Reed Smith Centre, 225 Fifth Ave Pittsburgh, PA 15222 Telephone: (412) 288-3131 Facsimile: (412) 288-3063 <i>Attorneys for Plaintiffs</i> <i>Philips North America LLC and Koninklijke</i> <i>Philips N.V.</i>		
11	UNITED STATES DISTRICT COURT		
12	CENTRAL DISTRICT OF CALIFORNIA		
13	SOUTHE	ERN DIVISION	
14	PHILIPS NORTH AMERICA LLC, a	Case No.: 8:19-cv-01765	
15	Delaware Company, and KONINKLIJKE PHILIPS N.V., a Company of the Netherlands,	COMPLAINT FOR:	
16	Plaintiffs,	(1) TRADEMARK INFRINGEMENT – 15 U.S.C. § 1125(a), 15 U.S.C. 1114;	
17 18	VS.	(2) FALSE DESIGNATION OF ORIGIN	
18	KPI HEALTHCARE INC., a California	- 15 U.S.C. § 1125(a);	
20	Corporation; KPI HEALTHCARE ECOMMERCE, INC., a California	(3) FALSE ADVERTISING – 15 U.S.C. § 1125(a);	
21	Corporation; and DOES 1-10, inclusive,	(4) CIRCUMVENTING A	
22	Defendants.	TECHNOLOGICAL MEASURE – 17 U.S.C. § 1201;	
23		(5) MODIFYING COPYRIGHT	
24		MANAGEMENT INFORMATION – 17 U.S.C. § 1202; AND	
25		(6) TRADE SECRET	
26		MISAPPROPRIATION – 18 U.S.C. § 1836;	
27		(7) VIOLATIONS OF CALIFORNIA'S UNIFORM TRADE SECRET ACT –	
28		CALIFORNIA CIVIL CODE § 3426,	

REED SMITH LLP A limited liability partnership formed in the State of Delaware

US_ACTIVE-145776994

FOURTH CAUSE OF ACTION

<u>Circumventing a Technological Measure – 17 U.S.C. § 1201</u> (All Plaintiffs Against All Defendants)

109. Philips restates and realleges all of the allegations of all the paragraphs in this complaint as though fully set forth herein this Fourth Cause of Action.

110. Philips medical imaging systems include Philips' copyrighted and proprietary software, which includes Philips' trade secrets.

111. The clinical software and diagnostic and service tools software in Philips' Ultrasound Systems are protected by copyright under Title 17, and include without limitation Philips service tools for updating or modifying the licensed options available on a machine, and for modifying identification numbers associated with a machine.

112. Philips Ultrasound System licensed optional software is also protected by copyright under Title 17.

113. Philips employs numerous access controls in order to protect and control access to and restrict use of its copyrighted proprietary software and/or portions thereof.

114. Philips' access controls include technological measures to protect and control access to and limit use of their copyrighted proprietary software and/or portions thereof.

115. KPI has and continues to intentionally hack one or more of Philips' technological measures to circumvent these access controls to gain unauthorized access to Philips' protected software works, which include Philips trade secrets, and to enable features of these software works which Philips have not licensed or authorized.

Through these unlawful means, KPI unlawfully gains access to unlicensed Philips software and provides unfettered access to all subsequent users of KPI's counterfeit machines.

116. KPI's counterfeit ultrasound systems are created by modifying Philips' access controls in order to provide KPI's customers with unrestricted and constant access to Philips' proprietary software without authorization or an appropriate license. Thus, KPI's business of selling modified ultrasound systems, each of which include modified machine specific access controls is manufacturing, offering to the public, and/or trafficking in a product, device, component, or part thereof, that is primarily designed or produced for the purpose of circumventing Philips' access controls that protect Philips proprietary software and trade secrets.

117. KPI has intentionally and/or knowingly illegally hacked Philips' systems to circumvent the technological measures Philips uses to effectively control access to a work or works protected under Title 17, in violation of 17 U.S.C. § 1201(a)(1) of the Digital Millennium Copyright Act.

118. KPI's counterfeit ultrasound systems are systems that provide KPI's customers with constant access to Philips' proprietary software. Thus, KPI's systems are, or at least include, devices, products, components, or parts thereof that are primarily designed or produced for the purpose of circumventing Philips' access controls that protect Philips software. Thus, KPI's business of creating and selling counterfeit systems, is knowingly marketing, manufacturing, offering to the public, and/or trafficking in a product, device, component, or part thereof, that is primarily designed or produced for the purpose of circumventing Philips' access that protect Philips software.

119. Upon information and belief, Philips alleges that in order to carry out KPI's unlawful circumvention of Philips' access controls, KPI makes use of tools which have no use but to circumvent access controls.

120. KPI has intentionally and/or knowingly manufactured, offered to the

REED SMITH LLP

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public, or otherwise trafficked in technologies, products, services, devices, components, or parts thereof, that are primarily designed or produced for the purpose of circumventing protection afforded by Philips' access controls and/or which have limited commercially significant purpose other than to circumvent Philips' access controls in violation of the DMCA, 17 U.S.C. § 1201(a)(2).

121. Philips has been and will continue to be damaged in an amount not presently known with certainty, but that will be proven at trial.

122. Philips is entitled to the range of relief provided by 17 U.S.C. 1203, including but not limited to, injunctive relief, compensatory damages or statutory damages, punitive damages, and Philips' costs and attorneys' fees in amounts to be proven at trial. KPI's conduct has also caused irreparable and incalculable harm and injuries to Philips, and, unless enjoined, will cause further irreparable and incalculable injury, for which Philips has no adequate remedy at law.

COMPLAINT

EXHIBIT 14

	Case 2:19-cv-01745-JLR Docume	ent 36 Filed 04/20/20 Page 1 of 59		
1 2 3 4 5 6		The Honorable James L. Robart		
7 8	UNITED STATES DISTRICT COURT WESTERN DISTRICT OF WASHINGTON AT SEATTLE			
 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 	PHILIPS NORTH AMERICA LLC, a Delaware Company; KONINKLIJKE PHILIPS N.V., a Company of the Netherlands; and PHILIPS INDIA, LTD., an Indian Company, Plaintiffs, vs. SUMMIT IMAGING INC., a Washington Corporation; LAWRENCE R NGUYEN, an individual; and DOES 1-10, inclusive, Defendants.	 NO. 2:19-cv-01745-JLR SECOND AMENDED COMPLAINT FOR: CIRCUMVENTING A TECHNOLOGICAL MEASURE – 17 U.S.C. § 1201; MODIFYING COPYRIGHT MANAGEMENT INFORMATION – 17 U.S.C. § 1202; TRADE SECRET MISAPPROPRIATION – 18 U.S.C. § 1836 TRADE SECRET MISAPPROPRIATION – RCW 19.108, <i>ET. SEQ</i> FALSE ADVERTISING – 15 U.S.C. § 1125(a); UNFAIR COMPETITION – RCW 19.86.020 COPYRIGHT INFRINGEMENT - 17 U.S.C. §§ 101, 501 <i>ET. SEQ</i>. 		
25 26 27	SECOND AMENDED COMPLAINT - 1 No. 2:19-cv-01745-JLR	SAVITT BRUCE & WILLEY LLP 1425 Fourth Avenue Suite 800 Seattle, Washington 98101-2272 (206) 749-0500		

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11			
12	FIRST CAUSE OF ACTION		
13	<u>Circumventing a Technological Measure – 17 U.S.C. § 1201</u>		
14	(All Plaintiffs Against All Defendants)		
15	77. Philips restates and re-alleges all of the allegations of all the paragraphs in		
16	this complaint as though fully set forth herein this First Cause of Action.		
17	78. Philips medical imaging systems include Philips' copyrighted and proprietary		
18 19	software, which also include Philips' trade secrets.		
20	79. The clinical software and diagnostic and service tools software in Philips'		
21	Ultrasound Systems are protected by copyright under Title 17, and include without limitation		
22	Philips service tools for updating or modifying the licensed options available on a machine, and		
23	for modifying identification numbers associated with a machine.		
24	80. The log file output and user displays of Philips Ultrasound Systems are also		
25	respectively protected by copyright under Title 17 as non-literal elements of Philips software		
26	installed on and executing on Philips Ultrasound Systems.		
27	SECOND AMENDED COMPLAINT - 21 No. 2:19-cv-01745-JLR SAVITT BRUCE & WILLEY LLP 1425 Fourth Avenue Suite 800 Seattle, Washington 98101-2272 (206) 749-0500		

81. Philips Ultrasound System licensed optional software is also protected by copyright under Title 17.

82. Philips employs numerous access controls in order to protect and control access to and restrict use of its copyrighted proprietary software and/or portions thereof.

83. Philips' access controls include technological measures to protect and control access to and limit use of their copyrighted proprietary software and/or portions thereof.

84. Summit knowingly and intentionally circumvents Philips' access controls, using either Summit's Adepto hacking tool, or other unlawful means, or other unlawfully obtained means, or a combination of the Adepto hacking tool with such other means. Summit hacks Philips' access controls in order to gain access to Philips' medical imaging system onboard tools for updating, modifying, or adding Philips software options—tools that only Philips authorized personnel are able to access using either Philips generated key codes or Philips authorized access control dongles in order to comply with Philips access controls.

85. Summit has hacked and continues to intentionally hack one or more of Philips' technological measures to knowingly and intentionally circumvent these access controls to gain unauthorized access to Philips' protected software works, which include Philips trade secrets, and to enable features of these software works which Philips has not licensed or authorized Summit, or its customers, to make use of. Through these unlawful means, Summit unlawfully gains access to unlicensed Philips software and provides unauthorized access to all subsequent users of Philips' machines hacked by Summit.

86. Summit, furthermore, has hacked and continues to knowingly and intentionally hack one or more of Philips' technological measures to circumvent these access controls to gain unauthorized access to a variety of copyrighted works. Summit does this to

SECOND AMENDED COMPLAINT - 22 No. 2:19-cv-01745-JLR SAVITT BRUCE & WILLEY LLP 1425 Fourth Avenue Suite 800 Seattle, Washington 98101-2272 (206) 749-0500

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circumvent Philips controls that limit access to Philips' copyright protected software works in order to enable optional features of these software works which Philips has not licensed or authorized Summit, or its customers, to make use of. Philips has the right to employ technological measures to protect, and control access to, Philips copyright protected works within Philips Ultrasound Systems, the operating system within which Philips copyright protected works are executed, and the files stored within the operating systems' file structure.

87. Upon information and belief, Summit knowingly and intentionally employs these hacked machines providing unlicensed access to Philips copyright protected software and files to Summit's employees in order to provide a parts repair business, and Summit hacks the Philips machines of Summit's customers in furtherance of both its parts repair business and its service contract business.

88. Summit further provides training to Summit's customers that include instructions about how to circumvent Philips' access controls with Summit's hacking tools and techniques.

89. Summit's intentional and knowing circumvention of the technological measures Philips uses to effectively control access to a work or works protected under Title 17, in violation of 17 U.S.C. § 1201(a)(1) of the Digital Millennium Copyright Act.

90. Summit's techniques, including its Adepto hacking tool, are, or at least include, devices, products, components, or parts thereof that are primarily designed or produced for the purpose of circumventing Philips' access controls that protect Philips software to provide Summit and Summit's customers constant access to Philips' proprietary software. Thus, Summit is in the business of knowingly marketing, manufacturing, offering to the public, and/or trafficking in a product, device, component, or part thereof, that is primarily designed or SAVITT BRUCE & WILLEY LLP SECOND AMENDED COMPLAINT - 23 1425 Fourth Avenue Suite 800 No. 2:19-cv-01745-JLR

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produced for the purpose of circumventing Philips' access controls that protect and control access to Philips software.

91. Upon information and belief, in order to carry out Summit's unlawful circumvention of Philips' access controls, Summit makes use of tools which have no use but to circumvent access controls.

92. Summit has intentionally and/or knowingly manufactured, offered to the public, or otherwise trafficked in technologies, products, services, devices, components, or parts thereof, that are primarily designed or produced for the purpose of circumventing protection afforded by Philips' access controls and/or which have limited commercially significant purpose other than to circumvent Philips' access controls in violation of the DMCA, 17 U.S.C. § 1201(a)(2). Upon information and belief obtained from publicly available sources, Nguyen is a principal owner, Governor, Chief Executive Officer (CEO), and Chief Technology Officer (CTO) of Summit.

93. In his role, Nguyen oversees and has the right and ability to supervise Summit's actions addressed in this complaint, including Summit's use of the Adepto hacking tool, and upon information and belief one or more other hacking tools, in order to circumvent Philips access controls that are technological measures that effectively control access to works protected under Title 17, including Philips proprietary software and logs on at least Philips medical imaging systems, including Philips Ultrasound Systems.

94. Nguyen publicly, personally, promotes use of Summit's hacking tools in Summit's marketing material.

95. Nguyen personally controls and oversees the process of selecting to whom Summit employees distribute the Adepto hacking tool.

SECOND AMENDED COMPLAINT - 24 No. 2:19-cv-01745-JLR SAVITT BRUCE & WILLEY LLP 1425 Fourth Avenue Suite 800 Seattle, Washington 98101-2272 (206) 749-0500 96. Upon information and belief, Nguyen personally advertises its Adepto hacking tool as available for distribution to Summit's customers, but Summit only distributes its Adepto hacking tool to contracted customers after such customers have been personally interviewed by Nguyen himself.

97. Upon information and belief obtained from publicly available sources,Nguyen designed and created Summit's Adepto hacking tool and participated in or directed its development.

98. As a principal owner, Governor, CEO and CTO, Nguyen has, has had, and continues to have an obvious and direct financial interest in Summit's circumvention technology.

99. Nguyen has, has had, and continues to have the right and ability to supervise the work of Summit's employees.

100. Because Nguyen had the right and ability to supervise the circumvention actions of Summit, and because Nguyen benefitted financially from Summit's circumvention actions, Nguyen is vicariously liable for Summit's violations of 17 U.S.C. §§ 1201 and 1202 as set forth in this Complaint.

101. In addition, or in the alternative, as an officer of Summit who personally participated in the Summit's tortious activities, Nguyen is liable for Summit's torts.

102. Specifically, as both the CEO and CTO, Nguyen oversaw and directly participated in Summit's acts of circumvention of access controls to gain access to copyrighted material that includes Philips' trade secrets.

 103.
 Nguyen was aware of, participated in the use of, created and/or directly

 developed, Summit's Adepto hacking tool, and oversees, directs, participates, promotes, and

 SECOND AMENDED COMPLAINT - 25

 No. 2:19-cv-01745-JLR

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participates in the use and distribution of Summit's Adepto hacking tool in order to allow Summit to circumvent Philips' technological measures protecting Philips copyright and thereby enable unlicensed software within Philips Ultrasound Systems and access and create copies of Philips copyright protected log files, and in order to allow Summit's customers to do the same.

104. Nguyen has also personally trained Summit's employees and Summit's customers in how to make use of the Adepto hacking tool in order to disable or otherwise circumvent Philips access controls and create copies of Philips copyrighted software and log files.

105. Philips has been and will continue to be damaged by the conduct of Summit and Nguyen conduct in an amount not presently known with certainty, but that will be proven at trial.

106. Philips is entitled to the range of relief provided by 17 U.S.C. § 1203, including but not limited to, injunctive relief, compensatory damages or statutory damages, and Philips' costs and attorneys' fees in amounts to be proven at trial. Defendants' conduct has also caused irreparable and incalculable harm and injuries to Philips, and, unless enjoined, will cause further irreparable and incalculable injury, for which Philips has no adequate remedy at law.

SECOND AMENDED COMPLAINT - 26 No. 2:19-cv-01745-JLR SAVITT BRUCE & WILLEY LLP 1425 Fourth Avenue Suite 800 Seattle, Washington 98101-2272 (206) 749-0500

EXHIBIT 15

In Support of Petition of: Transtate Equipment Company, Inc. d/b/a Avante Diagnostic Imaging 1040 Derita Rd. Suite A Concord, NC 28027 Robert A. Wheeler, President Telephone: 800-710-9996

Of counsel: Dentons US LLP 233 South Wacker Drive, Suite 5900 Chicago, IL 60606 David R. Metzger Email: <u>david.metzger@dentons.com</u> Telephone: 312-867-2578 Taaj Reaves Email: <u>taaj.reaves@dentons.com</u> Telephone: 312-867-8176

Attorneys for Transtate Equipment Company, Inc. d/b/a Avante Diagnostic Imaging

DECLARATION OF STERLING PELOSO

I, Sterling Peloso, am over 21 years old and hereby declare as follows:

- I am the President of Pacific Medical, Inc. d/b/a Avante Patient Monitoring and Ultra Solutions, Inc. d/b/a/ Avante Ultrasound, each of which is a sister company of petitioner and commenter Transtate Equipment Company, Inc. d/b/a Avante Diagnostic Imaging ("Transtate"). I have held this position since September 16, 2013.
- I have serviced or overseen servicing of medical equipment from several OEMs at Avante Ultrasound and Avante Patient Monitoring including Siemens, Phillips, GE, Stryker, and Canon (formerly Toshiba).¹

Stryker refers to Stryker Corporation.

Nihon Koden refers to Nihon Koden Corporation.

¹ Alaris refers to ALARIS Medical Systems, Inc.

Samsung refers to Samsung Ultrasound Systems.

Edward Lifesciences refers to Edward Lifesciences Corporation.

Hospira refers to Hospira Inc., a spin-off of Abbott Laboratories.

Welch Alynn refers to Welch Allyn Inc.

Spacelabs refers to Spacelabs Healthcare, a subsidiary of OSI Systems, Inc.

GE refers to GE Healthcare, a subsidiary of General Electric Company.

Siemens refers to Siemens Healthineers AG (formerly Siemens Healthcare, Siemens Medical Solutions, Siemens Medical Systems), a subsidiary of Siemens AG.

Philips refers to Koninklijke Philips N.V., including its subsidiaries Philips Electronics and Philips Healthcare.

Toshiba refers to Toshiba Medical, now Canon Medical Systems Corporation.

Ultrasound Equipment

- 3) Several ultrasound devices from various OEMs, including GE, Philips, Siemens, Toshiba, and Samsung, restrict or limit access to software and data files with the use of technological protective measures (TPMs). Examples of the ultrasound devices that use TPMs to restrict or limit access to software and data files include the Logiq E9, Vivid E9, Vivid E95, Logiq E10, Vivid IQ, Loqiq E, Logiq I, Vivid I, Vivid E, Voluson I, Voluson E, Voluson S Series, Voluson E6/8, and Voluson E10 Series from GE; the Epiq, Affiniti, CX50, iU22, iE33, HD- Series, and Volcano IVUS models from Philips; all of the S – Series models, the SC2000, and New Sequoia models from Siemens, and the Aplio300/500 and i800 models from Toshiba.
- All models of ultrasound medical devices from Samsung include TPMs that restrict or limit access to software and data files necessary to service the equipment.
- 5) The types of software and data files that OEMs restrict or limit access to through the use of TPMs include service logs, comprehensive diagnostic tests, error codes to identify specific hardware failure, DICOM servers/IP addresses, remote diagnostics, Windows access, touch panel calibration, backup system settings with licensing, and software updates for compatible hardware.
- 6) The TPMs that are used by OEMs on ultrasound medical devices include service dongles, passwords that change on a daily and/or yearly basis, key generated passwords, and software modules that lock out third party transducer repair.
- 7) GE service dongles at one time were a purchasable option when we bought some from a distributor. However, the newer service dongles are not available to third parties.
- 8) There are known workarounds to bypass the TPMs, including reverse engineered key generators, hardware dongles borrowed or purchased from clients, and hardware dongles and/or access codes sold by foreign citizens. Some current and former OEM employees also sell or loan their access dongles. There are also some medical devices models that have built-in pass/fail tests that, if performed correctly, provide sufficient information to enable a technician, using system behavior, to narrow down a problem to a module level, e.g., a power supply, a front-end module, a back-end module, or a display module.
- 9) In addition, for some customers, we have provided a package of parts that we call a Hero Kit, that are sent to customer so that they can repair their ultrasound systems. The Hero Kit includes parts that typically malfunction on that particular system. The customer will "trial and error" those parts based on the their own experience diagnostics until the system is repaired.
- 10) Our technicians and engineers have experienced a number of adverse effects resulting from the inability to access software and data files on ultrasound medical devices. Our IT personnel have been unable to change Picture Archiving and Communication System ("PACS") Servers, Digital Imaging and Communication ("DICOM") and IP addresses on medical devices, resulting in the unavailability of electronic medical records ("EMR")that then resulted in delayed patient care. The inability to access software and data files for replacement parts that our technicians needed in

order to operate in a compatible system have also caused delays in patient care due to the inoperability of the machines.

- 11) Delays in patient care have further resulted from our technicians' inability to access software on medical devices when reloading lawful software on the devices, where as a result the technicians are not able to load the software licenses for the systems to operate normally. Patient safety concerns also occur where technicians cannot access on-board diagnostics when an end user has a complaint concerning imaging anomalies.
- 12) The ability to access software and data files on medical devices directly impacts our ability to provide critical servicing activities to our customers. Once, when a customer's Report Printer failed and needed to be replaced, our technicians required access to Windows to simply add a new Report Printer. Use of a Hardware Service Dongle was used to access Windows and replace the Report Printer.
- 13) In another instance our technicians accessed ultrasound equipment diagnostics and discovered that the power supply was not generating the correct power to run the devices. We replaced the power supply and returned the system back to the end user for further patient care.
- 14) When we are allowed access to the software and data files required to repair and diagnose medical devices, we are able to properly service our clients' systems as well as reduce delay and safety risks associated with patient care.

Patient Monitoring Equipment

- 15) Service documentation for patient monitoring equipment including for display monitors, tourniquets, scales, and compression units is impossible to get from certain OEMs such as Stryker and Edward Life Science. As a result, with the service manual requirement in place, even simple repairs on medical equipment where a manual or service documentation is not actually needed to complete the repair cannot be performed.
- 16) OEMs such as GE, Philips, Nihon Koden, Spacelabs, and Welch Alynn do not provide software access, service documentation, or training for monitors and modules to third parties, i.e., parties who are not employees of customers.
- 17) Philips does not make the MX40 telemetry support tool available to us, which results in higher repair costs for medical centers, longer turnaround times, and equipment that is unavailable for use in situations such as disasters and pandemics like COVID-19.
- 18) Alaris and Hospira do not make various software updates for Plum A+ pumps available to third parties. This causes delays in getting the Plum A+ pump devices to the hospital. For example, at the onset of COVID-19, we could either not supply Plum A+ pumps to New York hospitals in a timely matter or not supply Plum A+ pumps at all.
- 19) COVID-19 has worsened the impact of OEM-related delays. At one critical time during the pandemic, an order that took four weeks to complete would have only taken four to five days to

complete if we would have otherwise had the proper software access from the OEMs to service the medical equipment.

20) The undersigned being warned that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001. The undersigned declares that all statements made of his/her own knowledge are true; and all statements made on information and belief are believed to be true.

12/10/2020 Date:

Sterling Peloso

EXHIBIT 16

how	to c	lone	ac	ong	le

All Regions

Any Time

How to clone sentinel dongle USB key - YouTube

www.youtube.com/watch?v=DoEbzA6iFQ8

VIP **DONGLE**. • 22 тыс. просмотров 3 года назад. **How to** recover data from a hard drive (stuck heads: buzzing, clicking, etc). **HOW TO** DUPLICATE A USB FLASH DRIVE, **Clone a** usb kodi flash drive.

(PDF) How to clone a USB key and make a back up of a Dongle?

A www.academia.edu/39403989/How_to_clone_a_USB_key_and_make_a_back_up_o How to clone a USB license key with additional software Before starting the process to copy the **Dongle**, you must verify that all the basic requirements necessary to make the copy correctly are met, for this you must confirm the following points: • A computer with a valid operating system for the...

How to Clone Dongle and Emulation - Request Software Cracking

cracking4you.com/emulator/62-how-to-clone-dongle-request-software-cracking.html How to Clone Dongle and Emulation - Request Software Cracking How to Copy and Backup Software Dongle - Support window 10 x64 MultiKey Win10 x64 Support, HASP Sentinel Gemalto HL SRM HardLock SuperPro/UltraPro Dinkey Rockey Guardant Wibu CodeMeter Marx Matrix...

How to clone a Sentinel dongle to work with software and... - Quora

Q www.quora.com/How-can-I-clone-a-Sentinel-dongle-to-work-with-software-and-withou But cloning an USB **dongle** would likely be considered a copyright violation. By telling you **how to** do so, I would potentially violate a few laws. Even if you find software tools to make a hardware **clone** of **a dongle**, it might still also contain malware and potentially add the malware to the **clone**.

How to copy a dongle USB key|Why copy a dongle key | Medium

M medium.com/@ViviannSanders/how-to-copy-a-dongle-usb-key-e4811eec7bb

Q: **How** does a **dongle** work? **A**: The security key contains a circuit board that includes a microcontroller, memory and additional components. These items are enclosed in a hard plastic case. Logic is programmed into the **dongle** that enables it to generate blocks of data that can be transmitted...

Clone a USB Dongle? | Overclock.net

www.overclock.net/threads/clone-a-usb-dongle.933115/

Clone a USB **Dongle**? Jump to Latest Follow. Theres a reason you need that **dongle** plugged in and thats to authenticate you as a legitimate user. If there was a way to **clone** the usb drive then there goes there copy protection, along with the iso on TPB will be the iso of the usb drive with instructions on...

How to share a USB license key. Dongle sharing guide.

www.donglify.net/how-to-share-usb-dongle/

Find out **how to** share a USB **dongle** and get access to your security key from any remote location across the Internet. Donglify is a software application that is extremely useful when faced with the challenge of **how to** share a **dongle** USB key with multiple remote computers.

how to clone dongle | Forum

www.finetopix.com/showthread.php/4979-how-to-clone-dongle

Cloning is what u try to make a duplicate copy of that **dongle** ! And Kaka is right, NEMO uses sent Emulation, not HASP Emul ! sir,please tell me **how** emulation of the **dongle** can be done.can it be done for **dongle** of tems & **how** it can be done.i am new in this field .please help me...

how to clone a dongle - Bing

www.windowssearch-exp.com/search?q=how+to+clone+a+dongle&FORM=QSRE8

How to clone a Sentinel **dongle to** work with ... 23.08.2014 · WiFi **Dongle** What is the best USB **Dongle to** buy so I can use WiFi on my computer and if I have a **Dongle** running, can I still use my ordinary keyboard and mouse or do I have to buy WiFi ones please> Regards, RonBin79: Hardware...

Duplicate (Hardware copy) of Hasp or Hasp4 or HaspHL or other...

ongleduplicate.nsys.by

Dongle is a device to plug in to the LPT (or other) port. It is used to store some information and to communicate with protected software. If software can't find required **dongle**, it will not run properly. It's main purpose copy protection. HASP (R) is a trademark name of **dongles** manufactured by Alladin.

2 Best USB Clone Tools Help to Clone USB Drive Without Data Loss

www.minitool.com/backup-tips/usb-clone-tool.html

Do you know **how to clone** USB drive or **how to clone** USB hard disk without losing any your personal data? **How** can you **clone** USB drives or **clone** an external hard drive that

connects via USB with ease and would not bring any damage to the original data?

How to share USB dongle over Network - Sharing dongle 2020 guide

www.flexihub.com/share-usb-dongle.html

Step-by-step for USB **dongle** sharing over the network. **How to** share USB **dongle** 2020 tutorial - TOP tips for **dongle** sharing without hardware and settings. You can **clone a** USB **dongle** and use it as though it was attached to your machine directly. The free Donglify version allows you to send invites...

[SOLVED] How to clone a USB Dongle or security key? - Discussion...

onehack.us/t/solved-how-to-clone-a-usb-dongle-or-security-key/55275

Please, Give a tutorial on cloning of USB **Dongle** or security key. Dunno the possible ways to **clone a dongle** key, but there are other tricks to share access over network...

[SOLVED but not for free] How to clone Sentinel... - Linus Tech Tips

inustechtips.com/topic/1115902-solved-but-not-for-free-how-to-clone-sentinel-hasp-h

Is there any way I could **clone** the USB **dongle** myself? Without significant cost and without involving a third party? Thank you very much in advance for your help and advice. It's quite pricey since it's a monthly subscription. **How** is this product different from other options previously mentioned? Tx.

Xprog 5.3 how to clone dongle? - MHH AUTO - Page 1

mhhauto.com/Thread-Xprog-5-3-how-to-clone-dongle

Does someone have any solution **how to clone** this **dongle** or **how to** read CY mcu? I think that similar **dongle** will be in carprog 4.74. When I connect this **dongle to** USB i have HID interface. hello, the v5.3 is same with others version v5.0, just different software, not the hardware.

Other - how to clone a hardlock usb key | The FreeBSD Forums

forums.freebsd.org/threads/how-to-clone-a-hardlock-usb-key.70880/

Exactly the **dongle** is just part of the license management scheme. All this tied online now to the software company. In the past even companies cheated on Vince, I tried to **clone a dongle** for employees. The task was to complete the project in a short period, I had to use a third-party program.

How to clone sentinel dongle USB key

clip-share.net/video/DoEbzA6iFQ8/how-to-clone-sentinel-dongle-usb-key.html

Am 20 Nov 2018 veröffentlicht. **How to clone** sentinel **dongle** USB key Dowload Link for Video: www.mediafire.com/folder/1x3jbe6et8cbe/. Hi, did you ever get a **clone** of the **dongle**?. Alberto Carmona Vor 7 Monate. Error: can't Init API Error: Initializing Sentinel SuperPro API.

Dongle Backup - Emulator Softwares - Vip Dongle Team

vipdongle.com/mp/dongle-backup/

Dongle Backup - Emulator Softwares - Hardware **Clone** - Software usb key Tested With Hasp, Sentinel, Hardlock, Wibu, Codemeter, Vip **Dongle** Team. We know **how to** Backup and Virtualize **Dongles** Connected to HASP, Sentinel, Hardlock, Eutron Smartkey, Dinkey, Marx, Deskey, Wibu...

Clone Dongle | AudioSEX - Professional Audio Forum

Q. audiosex.pro/threads/clone-dongle.28932/

Is there any way to **clone a dongle**? Can I buy a usb **dongle** and copy the one from my friend to use it myself? It would also be a backup copy if you lose or break. Thanks in advance

A Comprehensive Guide: How to Clone USB Drive

www.ultfone.com/data-recovery/clone-usb.html

Someone may think it very easy to **clone** USB - you just copy the content of the USB to another or to a hard drive. However this works only if there is no boot or special files in the USB, or you cannot As a result, we are often suggested by technicians to **clone a** USB drive with professional USB **clone** tools.

How To Clone Usb Dongle

O trvid.com/w/how+to+clone+usb+dongle

How to clone sentinel dongle USB key Dowload Link for Video: www.mediafire.com/folder/1x3jbe6et8cbe/. How to Create a Clone Image of Your USB flash Drive or micro SD Flash Card . This video guide is for people who need to fully or ...

Eutron Dongle Backup Service - Dongle Emulator - Dongle Clone...

salda.ws/video.php?id=ySn0_J3YBng

Contact us: donglesolutions@gmail.com Eutron Eutron Smartkey Eutron SmartKey 3 **Dongle** copy service **Dongle clone** service **Dongle** emulation service.

Скачать how to clone sentinel dongle - смотреть онлайн

v-s.mobi/how-to-clone-sentinel-dongle-07:57

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How to clone sentinel dongle - YouTube

funer.ru/video/qX_KW9KvQes

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How To Clone A Dongle License

thclips.com/rev/how+to+clone+a+dongle+license/

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Software Dongle Cloning

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How to clone sentinel dongle USB key Dowload Link for Video: www.mediafire.com/folder/1x3jbe6et8cbe/. How to clone sentinel dongle - cara kloning & menjalankan virtual dongle Sentinel Download link

How to clone sentinel dongle

trclips.com/video/qX_KW9KvQes/how-to-clone-sentinel-dongle.html

How can I clone computer ID when installing softaware which require cloud registration key (eg. flexistarter 11 cloud edition). please answer it. JR 2 yıl önce +1. I need to clone a sentinel c plus b dongle. If any body reading this knows how to do it, I am willing to buy a solution at reasonable price...

How to clone sentinel dongle - Видео онлайн

v4k.life/video/qX_KW9KvQes

HASP Sentinel Gemalto SuperPro **Dongle Clone** and Emulator. **How to** make USBTrace log for protection **dongles**. Quy Vlog 2 год. **HOW TO** DUPLICATE A USB FLASH DRIVE, **Clone a** u... Добавлено: 4 год. bloggerdaddy 4 год. Use a bunch of USB Flash drives in a RAID arr...

Next

Feedback

EXHIBIT 17

The fastest way to get Service Password for CT Scanner, MRI Scanner and others

-- You may receive password in ONE hour! *

[Manufacturers | CT Scanner | MRI Scanner | Other Scanners | Success Stories | FAQ | Contacts] (Ask Online) 🖂

Select Language

Powered by Google Translate

Angiography | Magnetic Resonance | Computed Tomography | Cardiology |

Mammography | Radiography | Surgery | Ultrasound | Urology

What is Service Password and Service Key?

Service Password (or Service Key, or even Service Code) is a special password that used by service engineers and service technicians to get access into Service Menu (or Service Mode). Service Menu contains service functions used for reconfiguration and fixing problems of MRI scanners like MAGNETOM Impact Expert, MAGNETOM Vision Plus, MAGNETOM Verio, MAGNETOM Espree, and CT scanners like SOMATOM Esprit+ (SOMATOM Esprit Plus), SOMATOM Spirit Power, SOMATOM Plus, SOMATOM Spirit, and others. Also Service Menu is used for scanner maintenance or installation, and supporting scanners under service contracts.

To access "Service Menu" engineer must have a site-specific variable Service Password that usually acquired from scanner's manufacturer (Siemens, Philips, GE and Toshiba provides these passwords for special price). If support contract is not expired yet, this variable password is written in scanner's manual or other documents. In other cases service company needs to buy new service password or service key to continue support system. This process takes a long time usually. In particular, if you have no direct business ties and contacts in manufacturer's company. Our experience and business contacts in this area allow us to significantly reduce delivery time and *significantly reduce the cost of the service. We do this work instead of you and we do this work for you! Make your service contract more profitable!*



* All orders for Service Passwords and Codes are proceeded through e-mail. Please specify what is interested and required for you, and we will contact you in 24 hours.



These passwords (keys) have a different access levels: low level passwords allow only software diagnostics, scanner tests and view logs; high level password allows to open calibration menues and do all available actions. Also passwords have an expiration date (time period when they are active): one week, one month or one year.

How to request FREE trial Service Password.

Buy Service Password or Service Key

SIEMENS CT/MRI Scanner Service Password



medical

Order Service Password for SIEMENS SOMATOM Definition, SOMATOM Huan Yue Duo, MAGNETOM Open, and other scanners

Select Siemens Scanner: – Not found here? Just contact us! – Buy SIEMENS Service Password PHILIPS CT/MRI Scanner Service Code



Order Service Code for PHILIPS CT and MRI scanner GE (General Electric) CT/MRI Scanner Service Password and Options



GE Healthcare

Order License Options and Service Password for GE (General Electric) CT, MRI and Ultrasound scanners

Select General Electric Scanner: – Not found here? Just contact us! – ✓ Buy License Options for GE Scanner TOSHIBA CT/MRI Scanner Service Password and Service Key

TOSHIBA

Order Service Password for TOSHIBA CT and MRI scanner

Request FREE trial Service Password or Service Key

You can easy request a **FREE trial Service Password**. It will be sent to you immediately after required information about scanner system will be received by us. This password will have an expiration date (it will expire in one day or one week - depending on scanner type), and this service key will be restricted to lowest level access, because it is a FREE trial, and it purpose is to show password service quality only.

To <u>request trial service password</u>, please contact us by mail (click on link), and provide following information about scanner and system: scanner manufacturer (vendor) and scanner type (name). All other details will be asked depending on provided information. You can write all details that you know about your scanner, including previously used variable service password or service key (if you know it).

Order trial Service Key.

NOTE: Currently free trial Service Passwords and demo Service Keys available for most of the SIEMENS scanners only.

ULTRASONIX Ultrasound Scanner Service Password and Options



Order Service Password and Options for ULTRASONIX SonixTOUCH, SonixOP, SonixMDP and other scanners * Actual for most of the SIEMENS Service Password and some of GE License Options. Service Keys and Service Passwords for scanners of other manufacturers may be provided in longer time. Delivery time is depend on some parameters that explained before order processing.

Copyright © 1996-2019, Service Password Ltd. All rights reserved.

EXHIBIT 18

Medical Equipment Maintenance Market

** marketsandmarkets.com/Market-Reports/medical-equipment-maintenance-market-69695102.html

[202 Pages Report] MarketsandMarkets forecasts the medical equipment maintenance market to grow from USD 28.97 billion in 2018 to USD 47.49 billion by 2023, at a Compound Annual Growth Rate (CAGR) of 10.4% during the forecast period. The major factors that are expected to be driving the medical equipment repair market are rising focus on preventive medical equipment maintenance, growth in associated equipment markets, adoption of innovative funding mechanisms, and the increasing purchase of refurbished medical equipment. The objective of the report is to define, describe, and forecast the medical equipment repair market size based on device type (imaging equipment, Electromedical Equipment, Endoscopic Devices, Surgical Instruments, and Other Medical Equipment), service type, service provider, end user, and region.



Attractive Opportunities in the Medical Equipment Repair Market

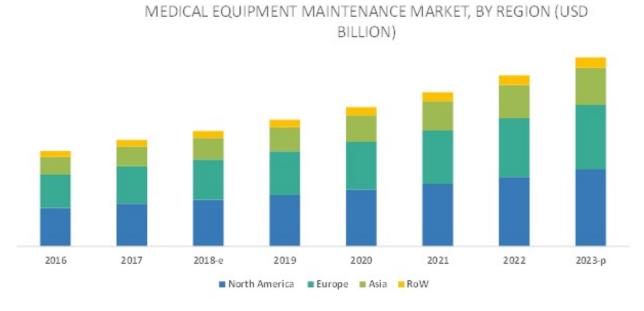
Source: Investor Presentation, Secondary Literature, Expert Interviews, and MarketsandMarkets Analysis

By device type, the imaging equipment segment to witness the highest growth during the forecast period (2018–2023).

Based on device type, the medical equipment repair market is further segmented into imaging equipment, endoscopic devices, surgical instruments, electromedical equipment, and other medical equipment. The imaging equipment segment is expected to grow at the highest CAGR during the forecast period. The high growth of this market segment is attributed to the high demand for maintenance services for imaging equipment, due to high replacement costs and the need for ensuring maximum equipment uptime.

By service provider, the original equipment manufacturers (OEMs) segment to dominate during the forecast period>

The original equipment manufacturers (OEMs) segment is expected to dominate the market. The large share of the OEMs segment can primarily be attributed to the wide geographic presence and strong technical expertise of OEMs.



Source: Investor Presentation, Secondary Literature, Expert Interviews, and MarketsandMarkets Analysis

North America to account for the largest market size during the forecast period.

North America is expected to hold the largest market size in medical equipment repair market during the forecast period, followed by the European region. Factors such as the growing aging population and rising incidence of lifestyle-related diseases, access to quality healthcare, well-established healthcare infrastructure, high adoption of advanced technology, and the presence of prominent players are driving the North American medical devices industry in this region. This will significantly boost the growth of the market for associated maintenance services in the region. Additionally, the availability of funding to purchase advanced medical technologies—through investments and similar initiatives—for hospitals and healthcare providers is also expected to aid market growth.

Asia is the third-largest market for medical equipment repair market and is slated to register the highest CAGR of during the forecast period. Factors contributing to this growth include increasing patient population, rising awareness on the benefits of early disease

diagnosis, increasing public and private funding for the development of healthcare facilities, government initiatives for the modernization of healthcare infrastructure & provision of quality care, and the growing medical tourism in Asian countries.

Market Dynamics

Driver: Rising focus on preventive medical equipment maintenance

The focus on preventive maintenance of medical equipment has grown in recent years, as healthcare institutions seek to enhance patient safety and care quality. This involves a carefully designed program where maintenance tasks are performed in a scheduled manner to avoid larger and costly repairs down the line. It also helps in reducing equipment downtime, which enhances day-to-day operations and improves device reliability.

The preventive maintenance approach is gaining prominence as planned inspections and medical device maintenance help avoid adverse incidents and medical device-related accidents. Regular maintenance services ensure safe, efficient, and long-lasting use of medical devices. The growing focus on implementing preventive maintenance strategies among healthcare organizations is expected to offer growth opportunities for service providers in the coming years.

Restraint: High initial cost and significant maintenance expenditure

Maintenance programs for medical devices enable healthcare providers to track and monitor their condition, and thereby ensure efficient utilization and maximum uptime. This is also essential, given the current focus on preventive maintenance and cost pressures, to control total expenditure against a background of austerity measures. Such programs include the deployment of asset management solutions which use advanced technologies.

However, the deployment of these solutions incurs high initial installation costs and significant maintenance expenditure, while the installation of advanced medical equipment incurs a service contract cost (~12% of the cost of medical equipment) to be paid per year. The service cost thus paid during the lifespan of the equipment is usually more than the cost of the equipment. The high cost associated with the purchase and maintenance of advanced medical equipment is restraining end users from adopting them. This stifles the demand for associated maintenance services and thereby restrains market growth.

Opportunity: Emergence of ISOs

The medical equipment maintenance and services sector was initially dominated by OEMs. However, OEMs typically charge more than third-party vendors, and often take longer for maintenance, resulting in higher associated costs as well as downtime. This situation, especially given the backdrop of continuing austerity measures and the need for costcurtailment in global healthcare systems, has led to the emergence of ISOs dedicated to solely providing maintenance services.

With a strong team of experts, these organizations can cater to customers in situations where OEMs fail to offer satisfactory and time-efficient solutions. Moreover, ISOs offer services for multiple brands of medical devices, providing end users with a central, independent management platform for uniform service delivery across all asset groups, while reducing maintenance costs. This also helps reduce operating expenses and capital spending. According to hospitals and patient advocacy groups, ISOs typically charge 30–50% less than OEMs for maintaining and repairing equipment. Competition among third-party service companies and insurance brokers has also driven down response times and the cost of services. Additionally, ISO contracts have become highly flexible, with negotiable or varied stipulations for parameters, such as response times and spare part costs (for example, whether they are included in a fixed price or charged separately). Considering their advantages as compared to OEMs, the preference for ISOs has increased among end users. The opportunities presented in the ISOs market is expected to draw a number of companies in this sector in the coming years.

Challenge: Interoperability Issues Survival of players in a highly fragmented and competitive market

The medical equipment maintenance market is highly fragmented and competitive and comprises a broad range of players, including multinational companies and small local players. With a number of service providers offering similar services, the cost is a major factor that influences end users selecting a vendor. However, it is usually a challenge for service providers to offer the best-in-class services to customers at a lower cost. Also, the emergence of ISOs is increasing the pressure on OEMs to reduce the price of their service contracts. In this situation, it becomes difficult for players to remain competitive in the market; as a result, a number of larger companies look for consolidation. However, smaller companies do not have the same option, which affects their long-term survival in the medical equipment maintenance market.

Scope of the Report

Report Metric	Details

Market size available for years	2017–2023
Base year considered	2017
Forecast period	2018–2023
Forecast units	Billion (USD)
Segments covered	Device Type (Imaging Equipment, Electromedical Equipment, Endoscopic Devices, Surgical Instruments, and Other Medical Equipment), Service Type (Preventive Maintenance, Corrective Maintenance, Operational Maintenance), Service Provider (Original Equipment Manufacturers, Independent Service Organizations, and In- House Maintenance), End User (Public Organizations, and Private Organizations), and Region
Geographies covered	North America, Europe, Asia, and Rest of the World
Companies covered	<u>GE Healthcare</u> (US), <u>Koninklijke Philips N.V</u> . (Netherlands), <u>Siemens</u> <u>Healthineers</u> (Germany), <u>Toshiba Medical Systems Europe</u> (Germany), and <u>Drägerwerk AG & Co. KGaA</u> (Germany), <u>Aramark</u> (US), <u>BC</u> <u>Technical, Inc.</u> (US), <u>Alliance Medical Group</u> (UK), and <u>Althea Group</u> (Italy).

The research report categorizes the medical equipment repair market to forecast the revenues and analyze the trends in each of the following sub-segments:

		HOSPITAL EMR MARKET	
Component	Mode ofDelivery	Туре	RE GION
☐ Har¢ware ☐ Software ☐ Services	□ Cloud-based □ On-premise	☐ General EMRs ☐ Specialty EMRs	• Noith a merica • US • Canada • Europe • Asia Pacific • RoW

- Imaging Equipment
- Advanced Modalities
 - CT
 - MRI
 - Other Advanced Medical Imaging Modalities (PET-CT, SPECT-CT, PET, Gamma Cameras, and Angiography Systems)
- Primary Modalities
 - Digital X-ray
 - Ultrasound
 - Others Primary Medical Imaging Modalities (General X-ray Systems, Mammography Systems, and Bone Densitometers)
- Endoscopic Devices
- Surgical Instruments
- Electromedical Equipment
- Other Medical Equipment

On the basis of Service Type, the medical equipment maintenance market has been segmented as follows:

- Preventive Maintenance
- Corrective Maintenance
- Operational Maintenance

On the basis of Service Provider, the medical equipment maintenance market has been segmented as follows:

- Original Equipment Manufacturers (OEMs)
 - Multi-vendor OEMs
 - Single-vendor OEMs
- Independent Service Organizations (ISOs)
- In-house Maintenance

On the basis of End User, the medical equipment maintenance market has been segmented as follows:

- Public-sector Organizations
- Private-sector Organizations

On the basis of Region, the medical equipment maintenance market has been segmented as follows:

- North America
- Europe
- Asia
- RoW

Key Market Players

The global medical equipment maintenance market is highly competitive with the presence of both OEMs and ISOs. GE Healthcare (US), Koninklijke Philips N.V. (Netherlands), Siemens Healthineers (Germany), Toshiba Medical Systems Europe (Germany), and Drägerwerk AG & Co. KGaA (Germany) are some of the leading OEMs in this market. Aramark (US), BC Technical, Inc. (US), Alliance Medical Group (UK), and Althea Group (Italy) are some of the leading ISOs operating in the global medical equipment maintenance market.

Siemens Healthineers (Germany) held the second-largest market share in 2017, due to its trend-setting role in the medical imaging, laboratory diagnostics, medical information technology, and hearing aid sectors. The company focuses on putting maximum efforts into its selected growth fields and prioritizes business for resource allocation. Siemens Healthineers also focuses on strengthening its business through partnerships and agreements.

Recent Developments

• In 2018, Koninklijke Philips N.V. (Netherlands) signed a partnership agreement with Kliniken der Stadt Köln (Germany) to provide continuous modernization and maintenance of imaging systems

- In 2018, Koninklijke Philips N.V. (Netherlands) signed a partnership agreement with Städtische Klinikum München (Germany) to provide medical imaging solutions which include healthcare consultancy services
- In 2016, Biomedical Srl sugned an agreement with ASST Orobica (Spain) for provision of integrated services for the management and maintenance of healthcare devices and equipment

Critical questions the report answers:

- Where will all these developments take the industry in the long term?
- What are the upcoming trends for the medical equipment repair market?
- Which segment provides the most opportunity for growth?
- Who are the leading vendors operating in this market?
- What are the opportunities for new market entrants?

Available customizations

With the given market data, MarketsandMarkets offers customizations as per the company's specific needs. The following customization options are available for the report:

To speak to our analyst for a discussion on the above findings, click Speak to Analyst