

**Comments by Philips North America, LLC In Response To  
Petitions To Renew DMCA Exemption Relating To Medical Devices**

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**I. INTRODUCTION**

Legal and factual developments since the 2024 rulemaking cycle establish that the prior rulemaking record does not provide a valid or reliable basis to support recommending renewal of the medical device exemption, currently codified at 37 C.F.R. § 401.40(b)(17): “Computer programs that are contained in and control the functioning of a lawfully acquired medical device or system, and related data files, when circumvention is a necessary step to allow the diagnosis, maintenance, or repair of such a device or system.” At a minimum, the legal and factual developments evidence that the current exemption is overbroad to the extent it could be construed as exempting liability for circumventions of technological protection measures (“TPMs”) to access and use diagnostic, maintenance, or repair tools on a medical device or system.

In particular, the record developed in *Medical Imaging & Technology Alliance, et al. v. Library of Congress, et al.*, D.C. Cir. No. 25-5328, established the disputed scope of the exemption and that, under proponents’ construction, it would be read to encompass circumvention to access not only *clinical operational software* on medical devices, but also separately protected *service software* on the medical devices. The opinion focused on clinical operational software, finding that the exemption satisfied the APA with that focus. However, the arguments developed on appeal and crystalized at oral argument highlighted the night-and-day difference between the fair use analysis for clinical operational software on the one hand and service software on the other. Even if bypassing TPMs to access and use clinical operational software could be considered transformative and fair use, bypassing separate TPMs to make commercial use of a manufacturer’s proprietary service software for its intended purpose is not at all transformative and replaces the market for the service software. It plainly is not fair use.

The declaration submitted with these comments provides factual evidence demonstrating material differences between clinical operational software and service software on medical devices. Under the fair use framework of *Andy Warhol Foundation for the Visual Arts v.*

*Goldsmith*, 598 U.S. 508 (2023), an independent servicer’s unlicensed use of a manufacturer’s service software for its intended service purpose manifestly compels a finding of no fair use.

When considered in this context, the renewal petitions themselves provide compelling evidence that the prior rulemaking record *does not* provide a reliable basis for renewal.<sup>1</sup> A careful review of the renewal petitions demonstrates a consistent pattern: petitioners describing the copyrighted works they want to access as repair-specific materials, not the clinical operational software that controls the functioning of a medical device or system. And that makes sense. Because hospitals can give servicers access to the clinical operational software, they have no need to bypass TPMs to access it. The servicers want to bypass separate TPMs to access manufacturers’ proprietary service and repair materials. But servicers using those service and repair materials for their intended purpose is commercial use, and not for any transformative use.

These legal and factual developments show that the administrative record underlying the medical device exemption is a fundamentally unreliable basis for renewal because the Register never distinguished between the materially different categories of software that reside on medical devices. The Register’s fair use analysis, which formed the backbone of the prior exemption recommendation, was built on the premise that the software being accessed is the operational clinical software. But that analysis does not apply to repair software. If the software at issue is software specifically created and marketed for the purpose of repair, then using it for repair is not transformative.

Because the prior rulemaking record never distinguished between operational clinical software and dedicated repair and diagnostic software, the fair use analysis that underpins the current exemption rests on a flawed factual foundation. The analysis that supports the exemption addressed only operational software, but for repair software, every relevant fair use factor points decisively in the opposite direction. The Register should not renew the exemption through the streamlined process in reliance on a record that is, on this critical question, deficient. At minimum, the Copyright Office should require the proponents in this rulemaking cycle to develop a record that disaggregates these distinct classes of works and provides the particularized fair use analysis that each demands and allow a full record to be developed.

## **II. PHILIPS MEDICAL IMAGING SYSTEMS INCLUDE SEPARATE CLINICAL OPERATIONAL SOFTWARE AND SERVICE SOFTWARE PROTECTED BY SEPARATE TPMS**

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<sup>1</sup> Philips responds to the renewal petitions from Brown’s Medical Imaging (COLC-2026-0100-0029), Caylor Equipment Services (COLC-2026-0100-0005), Crothall Facilities Management (COLC-2026-0100-0010), ECMS (COLC-2026-0100-0043), iFixit (COLC-2026-0100-0037), Marshall R. Shannon (COLC-2026-0100-0006), TriMedx Holdings (COLC-2026-0100-0044), and ImageOne Medical Group (COLC-2026-0100-0009). Philips notes that while the ImageOne Medical Group comments indicated they were directed to renewal of the exemption for “computer programs that control devices designed primarily for use by consumers for diagnosis, maintenance, or repair of the device or system,” the substance of its explanation for renewal appears directed to the medical device exemption.

Philips is a well-known leader in the business of developing, manufacturing, selling, supporting, maintaining, and servicing medical imaging systems. Philips medical imaging systems include clinical operational software, which is software used to operate the device and use it in a clinical environment.<sup>2</sup> They separately include system servicing and diagnostic software, which is proprietary software developed by Philips to perform various service tasks on the system.<sup>3</sup> Distinct TPMs control access to the clinical operational software and the servicing and diagnostic software.<sup>4</sup> One set of TPMs restricts access to the clinical operational software to allow device owners to ensure that only hospital-authorized individuals can access a system's medical features and/or patient data.<sup>5</sup> Another distinct set of TPMs restricts access to servicing and diagnostic software to protect Philips' proprietary software, patient and servicer safety, the performance and cybersecurity of the device, and license management.<sup>6</sup>

Philips' TPMs restrict access to servicing and diagnostic software based on tiered levels.<sup>7</sup> Philips provides Level 0 access upon request to any person and Level 1 to hospital biomedics under license agreements and subject to specific license terms (requiring, among other things, license fees, training, and nondisclosure).<sup>8</sup> Philips reserves Level 2 tools for its own trained engineers, and Level 3 tools for more highly trained Philips specialists.<sup>9</sup> After user-specific authentication, the TPMs cause a medical imaging system to present a user with only the service tools the user is entitled to use based on the user's authorization level.<sup>10</sup>

Medical device owners may obtain repair or other services from whomever they chose, including Philips, in-house biomedical engineering personnel, independent service organizations ("ISOs"), or service groups from other manufacturers.<sup>11</sup> Philips licenses Level 1 works to hospital biomedics as part of cooperative service agreements and Philips' service engineers use Level 2 and 3 works to support its own service activities.<sup>12</sup> When ISOs bypass TPMs to gain unlicensed use of Philips' service and diagnostic software, they undermine the license market for Philips' diagnostic and support software and the value of such software supporting Philips' competing service offerings.<sup>13</sup>

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<sup>2</sup> Exhibit A, Declaration of Jacqueline Dickson ("Dickson Decl."), at ¶ 5. Exhibit A is a copy of the declaration Ms. Dickson was provided to the Advanced Medical Technology Association (AdvaMed) in support of its comments.

<sup>3</sup> *Id.* at ¶ 6.

<sup>4</sup> *Id.*, at ¶¶ 7-11.

<sup>5</sup> *Id.*, at ¶¶ 8-9.

<sup>6</sup> *Id.*, at ¶¶ 7, 10-11.

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*, at ¶¶ 12-15.

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

### III. THE EXEMPTION SHOULD NOT BE RENEWED

#### A. Legal Standards

The Digital Millennium Copyright Act provides that “No person shall circumvent a technological measure that effectively controls access to a work protected under this rule.”<sup>14</sup> It also provides authority for the Library of Congress, upon the recommendation of the Register of Copyrights, to enact exemptions from liability for such circumventions for a particular class of works if persons who are users of the class of works are, or are likely to be in the succeeding 3-year period “adversely affected by virtue of such prohibition in their ability to make noninfringing uses of that particular class of works under this title.”<sup>15</sup>

“The tenth triennial proceeding will use the streamlined process to facilitate the renewal of previously adopted exemptions where no meaningful opposition is offered.”<sup>16</sup> “The petitioner must provide a brief explanation summarizing the basis for claiming a continuing need and justification for the exemption.”<sup>17</sup> Any interested party may then submit comments in response. “The purpose of these comments is to identify whether the prior rulemaking record remains a reliable basis for renewal. ... The Office will not recommend renewal of a current exemption under the streamlined procedure if it receives comments showing ‘meaningful opposition.’ Meaningful opposition may be satisfied with ‘evidence that the prior rulemaking record is no longer a valid basis to support recommending renewal of an exemption. Specifically, evidence should consist of new legal or factual developments that address ‘the reliability of the previously-analyzed administrative record.’”<sup>18</sup> “The Office may also consider whether opposition evidence casts doubt only as to renewal of a part of a current exemption.”<sup>19</sup>

#### B. New Legal and Factual Developments Show that the Prior Rulemaking Record does Not Provide a Valid or Reliable Basis to Renew the Exemption

The prior rulemaking record does not provide a reliable basis for renewal of the medical device exemption because the fair use analysis underlying the exemption was never applied to the copyrighted works that ISOs actually circumvent TPMs to access. And when it is, the analysis compels a finding of infringement, not fair use.

The exemption’s fair use reasoning rests on a transformative-use theory: ISOs access clinical operational software for the different purpose of repair, and that repurposing is transformative. Under *Warhol*, that analysis is at least plausible, because the original purpose of the clinical software is clinical operation, not repair.<sup>20</sup>

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<sup>14</sup> 17 U.S.C. § 1201(a)(1)(A).

<sup>15</sup> 17 U.S.C. § 1201(a)(1)(B).

<sup>16</sup> 91 FR 34795 at 34797.

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*, at 34797-98.

<sup>19</sup> *Id.*, at 34798.

<sup>20</sup> Philips disagrees with that finding. ISO’s use of clinical software while repairing a medical imaging system is still using the software for its intended purpose, namely attempting to run the

But the renewal petitions reveal that ISOs are not seeking to circumvent TPMs to access clinical operational software. They are bypassing TPMs to access service and diagnostic software. When the *Warhol* factors are applied to these works, *every factor* shifts decisively against fair use. Under factor one, using repair software for commercial repair is the work's original intended purpose—the epitome of non-transformative, substitutive use. Under factor four, unlicensed use of repair tools directly displaces the OEMs' licensed service market.

The record developed in the *Medical Imaging & Technology Alliance, et al. v. Library of Congress, et al.*, D.C. Cir. No. 25-5328, exposed this gap. On May 15, 2026, the United States Court of Appeals for the District of Columbia Circuit heard oral arguments.<sup>21</sup> As the argument progressed, the judges expressed disagreement over whether the current exemption encompasses both clinical operational software and repair software on the one hand, or just clinical operational software on the other.<sup>22</sup> Judge Pan called attention to the core analytical difficulty with that appeal: “If we view all of the software at issue or computer programs at issue to be one mass of computer programs, and it’s a mix of repair materials and operating clinical stuff, how do we do the fair use analysis if it’s a mix of the two?”<sup>23</sup> She elaborated on this asymmetry: “If you do the fair use factors and think about repair software, it’s one analysis. And if you do the fair use factors and you think about operating factors, it’s kind of a different answer.”<sup>24</sup> Judge Pan recognized that if the fair use analysis were to target the repair software, it would favor the manufacturers:

And it seemed to me that the exemption that was actually adopted focused on the operating clinical software, both in terms of the analysis and its reasoning, it focused on the operating clinical software. And I think depending on which type of software you’re looking at, the whole fair use analysis just falls into line because if you’re looking at operating use software, repair is transformative repair. And, and the-- it-- repair doesn’t interrupt the market for the operating clinical software, and the exemption is fine. But if you define the software we’re talking about as the repair software, then the fair use factors favor your clients, which make repair software. You’re using it for repair. That’s not transformative. You are interrupting our market for repair.<sup>25</sup>

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system to diagnose and repair the system. That is not repurposing of the copyrighted work. Further, FDA regulations prevent transformative uses of the copyrighted works. However, for purposes of evaluating the renewal petitions in the streamlined renewal process the Copyright Office does not need to reach those issues, because, as discussed, the factual and legal developments show that ISOs' separate use of service and diagnostic works for their intended purpose is not fair use.

<sup>21</sup> Available at: <https://media.cadc.uscourts.gov/recordings/docs/2026/05/25-5328.mp3>

<sup>22</sup> Recorded argument at 42:47, Judge Pan stated “And the “control the functioning” sounds to me, the plain meaning of that is the operation clinical software. Like, you don’t need repair software to control the functioning of a device.” Another judge responded, “Yeah, you do.”

<sup>23</sup> Recorded argument at 56:25.

<sup>24</sup> Recorded argument at 58:20

<sup>25</sup> Recorded argument at 31:28.

The Court’s opinion followed on September 1 and focused its fair use analysis on clinical operation software.<sup>26</sup> Accordingly, it concluded that “the Librarian’s conclusion that the ISOs’ use of *clinical operational software* is fundamentally transformative in nature and weighs in favor of fair use did not violate the APA.”<sup>27</sup> By focusing on clinical operational software the Court also concluded that “the ISOs’ use does not replace or substitute for the original work,” therefore it agreed “with the district court that the Librarian did not err in finding that the fourth factor favors fair use.”<sup>28</sup> Both the record developed through the oral argument and the decision that followed present material changes in the legal circumstances warranting denial of renewal.

### **C. The Renewal Petitions Fail to Satisfy the Streamlined Renewal Standard**

The renewal petitions were required to provide “a brief explanation summarizing the basis for claiming a continuing need and justification for the exemption.”<sup>29</sup> To satisfy this standard, petitioners must demonstrate at minimum that the prior record supporting the exemption remains reliable. But the renewal petitions ignore the fundamental legal issue highlighted before the court of appeals: whether the exemption covers service works and, if so, whether ISOs’ unlicensed commercial use of service works constitutes fair use.

Every one of the renewal petitions recites a professed need for access to diagnostic and service works.<sup>30</sup> None of the petitions addresses the distinction between clinical operational software and service works. None attempts to argue that accessing service works, as distinct

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<sup>26</sup> *Med. Imaging & Tech. All. v. Libr. of Cong.*, No. 25-5328, 2026 U.S. App. LEXIS 26759 (D.C. Cir. Sept. 1, 2026).

<sup>27</sup> *Id.* at \*20-21 (emphasis added).

<sup>28</sup> *Id.* at \*28.

<sup>29</sup> 91 FR 34795 at 34797.

<sup>30</sup> Renewal Pet. of Caylor Equip. Servs. LLC at Item C (Apr. 14, 2026) (stating that “[a]ccess to software-generated error logs and diagnostic data is often critical to accurately diagnosing equipment failures and completing necessary maintenance and repairs”); Renewal Pet. of Browns Med. Imaging at Item C (Aug. 21, 2026) (same); Renewal Pet. of Image One Med. Grp. LLC at Item C (Jan. 19, 2026) (describing “[p]assword-protected diagnostic software and restricted access to error logs and service data files” as routinely interfering with “timely diagnosis and repair”); Renewal Pet. of E. Coast Med. Sys., Inc. at Item C (Aug. 24, 2026) (asserting a need for “[a]ccess to software functions, diagnostic information, system logs, error logs, and other related data files” to “identify the cause of equipment failures and to perform appropriate maintenance and repairs”); Renewal Pet. of Crothall Facilities Mgmt., Inc. at Item C (Aug. 19, 2026) (identifying “[a]ccess to software error logs” as “a critical function in the optimal diagnosis, maintenance, and repair of devices”); Renewal Pet. of iFixit at Item C (Aug. 24, 2026) (describing restrictions through “[s]ervice credentials, restricted diagnostic software, firmware authentication, component pairing, and manufacturer-controlled authorization”); Renewal Pet. of TriMedx Holdings, LLC at Item C (Aug. 24, 2026) (describing “software and computer programs, service manuals, diagnostic software, patches, and service keys” as necessary for “required maintenance and repair”); Pet. of Marshall R. Shannon at § IV (July 2026) (seeking access to “embedded software, service modes, configuration files, logs, certificates, credentials, and diagnostic utilities”).

from clinical operational software, would constitute fair use. None argues that they will need to circumvent TPMs to access and use clinical operational software in the succeeding 3-year period. The renewal petitions, by describing a need for service works as opposed to clinical operational software, seek to renew an exemption that was never intended to cover the precise works they wish to access.

**D. Petitions Seeking Expansion of the Exemption are not Properly Before the Office in the Streamlined Renewal Process**

Only “petitions requesting renewal of current exemptions as currently written in the *Code of Federal Regulations*, without modification, may be considered under the streamlined renewal procedure.”<sup>31</sup> A petitioner accordingly “may not use a renewal petition to request *new* language or exempted activities for a current exemption,” and “[t]o the extent a renewal petition includes such requests, it shall be considered solely as a renewal petition.”<sup>32</sup> A party that wishes to broaden a current exemption must instead “submit both a petition to renew the existing exemption and a separate petition for a new exemption that focuses on facts relevant to the proposed expansion.”<sup>33</sup>

The Shannon petition seeks expansion and cannot be evaluated on the prior record. It seeks “clarification or a modified exemption” and the proposed class of works is far broader than the current exemption.<sup>34</sup> His request cannot be assessed against a record that was developed to address a materially narrower class. It cannot be addressed through the streamlined process. Consistent with the Notice of Inquiry, the Shannon submission should be treated “solely as a renewal petition” for purposes of this phase, and the expansion requests should be set aside for the new and expanded exemption process, where “[e]vidence must then be submitted during the public comment phase to develop the substantive record.”<sup>35</sup>

The TriMedx petition similarly seeks expansion. It asks the Office to “continue and renew the exemption ... for the purpose of diagnosis, maintenance, repair, *and regulatory compliance of such devices*.”<sup>36</sup> “Regulatory compliance” is not currently included in § 201.40(b)(17). TriMedx’s supporting narrative confirms that it seeks broader access to OEM works, including not only works on medical devices but also service manuals and other works.<sup>37</sup> It even professes that it needs access to “service keys,” which are parts of TPMs themselves and not classes of works subject to the exemption process.<sup>38</sup> These new requests must be treated as requests for a new exemption and also considered outside of the streamlined process.

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<sup>31</sup> 91 FR 34795 at 34797.

<sup>32</sup> *Id.* (emphasis in original).

<sup>33</sup> *Id.*

<sup>34</sup> Pet. of Marshall R. Shannon at §§ II, III.

<sup>35</sup> 91 FR 34795 at 34797.

<sup>36</sup> Renewal Pet. of TriMedx Holdings, LLC at Item C (emphasis added).

<sup>37</sup> *Id.*

<sup>38</sup> *Id.*

The streamlined renewal proceeding “is not a forum to litigate other concerns,” and the Office has instructed that opposition comments in this phase are directed to whether “the prior rulemaking record remains a reliable basis for renewal.”<sup>39</sup> Philips accordingly confines its comments in this phase to that question, and for the reasons stated above, the prior record is not a reliable basis for renewal.

If the Office elects to consider the Shannon or TriMedx requests as petitions for new or expanded exemptions, Philips will respond fully during the comment period established for new and expanded exemptions. Philips respectfully requests that the Office confirm in the notice of proposed rulemaking which portions of these submissions, if any, it intends to carry forward as new or expanded exemption proposals, so that interested parties receive adequate notice and a meaningful opportunity to develop the record on each proposed change.

#### IV. CONCLUSION

The Register should not renew the exemption through the streamlined process. The D.C. Circuit’s decision in *Medical Imaging & Technology Alliance v. Library of Congress* reveals that the fair use analysis supporting the exemption was built on the premise that the copyrighted works being accessed are clinical operational software—software whose original purpose is clinical operation, not repair. That analysis does not extend to the service and diagnostic software that the renewal petitioners expressly seek to access—software whose intended purpose is repair itself. Under the *Warhol* framework, using repair software for its intended repair purpose is not transformative, and unlicensed use of that software directly displaces the market the manufacturer created for it. The renewal petitions confirm this gap: every petitioner describes a need for access to repair-specific materials, not clinical operational software. Because the prior rulemaking record never distinguished between these materially different categories of software, and because the fair use analysis that underpins the exemption addressed only clinical operational software, the record is fundamentally unreliable as a basis for renewal. At a minimum, the Copyright Office should decline to renew the exemption under the streamlined procedure and require proponents to develop a disaggregated record in a full rulemaking that provides particularized fair use analysis for each distinct category of copyrighted work residing on medical devices.

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<sup>39</sup> 91 FR 34795 at 34797-98.

# Exhibit A

Declaration submitted in support of Comments from:

**Advanced Medical Technology Association (AdvaMed)**

1301 Pennsylvania Ave NW, Ste 400

Washington, DC 20004

**DECLARATION OF JACQUELINE DICKSON**

I, Jacqueline Dickson, declare as follows based on my personal knowledge:

**I. DECLARANT AND COMPANY BACKGROUND**

1. I am the CSIP Services Operations Director of Philips North America LLC (“Philips”). I have held this position since 2024. My responsibilities include oversight and support relating to service governance, access management, investigations, compliance activities, and cross-functional escalation management. These responsibilities require regular interaction with personnel from service, cybersecurity, privacy, legal, regulatory, and business organizations, and provide me with direct knowledge of the policies, procedures, and operational controls relevant to the matters discussed in this declaration.

2. I have 22 years of experience in service operations related to medical devices, with a focus on governance and administration of service documentation and service applications. In my role, I am familiar with Philips’ medical devices, clinical operation software, system servicing and diagnostic software, Maintenance-Related Documentation, access controls, licensing practices, and service offerings described below.

3. Philips develops, manufactures, sells, and/or leases a comprehensive portfolio of medical systems including medical imaging systems (e.g., magnetic resonance imaging (MRI), computed tomography (CT), ultrasound systems, diagnostic x-ray (radiography and fluoroscopy), and image-guided therapy systems for angiography).

**II. RELEVANT SOFTWARE AND MATERIALS**

4. As used in this declaration:

- (a) “Clinical Operation Software” means software that health care professionals use to operate a medical device and to perform patient care activities;
- (b) “System Servicing/Diagnostic Software” includes software applications, diagnostic tools, calibration programs, configuration utilities, service interfaces, and related digital resources used to install, inspect, calibrate, test, maintain, diagnose, troubleshoot, update, or repair a medical device to its intended performance and safety specifications; and

(c) “Maintenance-Related Documentation” is non-software, digital work used for servicing, such as digital service manuals or repair procedure documentation.

5. Philips uses Clinical Operation Software on its medical imaging systems to enable clinicians to operate the device’s medical features and to access patient information in the course of patient care. Devices typically have two or more types of accounts for the Clinical Operation Software, including a login for technologists to access the clinical interface and patient information, and an information technology or hospital administration account used to configure clinical user accounts.

6. Philips uses System Servicing/Diagnostic Software for those devices. That software is proprietary to Philips and is used to perform various service tasks on the devices, including but not limited to system diagnostics, system installation, and system configuration. Some of that software may be used to check systems for errors, access system diagnostic information and service logs, perform system calibration or troubleshooting, verify device operation, modify device configurations (e.g., radiation dose), and customize devices. These service software tools are divided into categories that Philips calls “Levels.” Access to the tools in each Level is protected by TPMs and is governed by different terms and conditions, as described below.

### **III. TECHNOLOGICAL PROTECTION MEASURES (TPMs) & DIFFERENTIAL ACCESS**

7. Philips uses several TPMs to control access to its System Servicing/Diagnostic Software. The principal measure is Philips’ proprietary Integrated Security Tool (“IST”), which controls both authentication and entitlement. Through IST, Philips applies encrypted certificates together with multifactor authentication to the device. The user must present a physical smartcard, which uses a proprietary program, in order to present the medical device with an encrypted, time-limited, user-specific certificate, and the user must enter the matching password for that specific user account. Upon successful login, the system presents only the service software tools that the user is entitled to use, based on the user’s IST entitlements.

8. These TPMs are separate and apart from the protections or controls governing access to the Clinical Operation Software. The Clinical Operation Software is managed separately. Its logins are username and password based, more like a Windows-type login, and they do not involve the IST smartcard, the encrypted user-specific certificate, or the entitlement system that determines which service software tools a user may access.

9. Access to the Clinical Operation Software is controlled by the technologist and information technology or hospital administration accounts described above, which are administered by the health care facility that owns or leases the device and its information technology personnel. Those logins are not in place to protect copyrighted material; they

are in place to allow device owners to ensure that only hospital-authorized clinical staff or other individuals can access a system's medical features and/or patient data. By contrast, access to the System Servicing/Diagnostic Software is controlled by the IST smartcard, the encrypted user-specific certificate, the matching account password, and the user's IST entitlements, each of which is issued and administered by Philips.

10. A person who has authorized access to the Clinical Operation Software does not thereby receive authorized access to the System Servicing/Diagnostic Software. A system owner is not authorized to access the protected System Servicing/Diagnostic Software, so it has no authority to authorize others to access or use such proprietary Philips software. To obtain such access, the person or organization must satisfy the conditions that apply to the Level of the tool sought. Level 0 tools are available to any person, including independent service organizations ("ISOs") or hospital biomedes, on request. Level 1 tools are available to hospital biomedes under a license granted as part of certain cooperative service agreements that include license fees, and subject to specific terms and conditions, including completion of Philips service training for that product and execution of a non-disclosure agreement. Level 2 tools are not available for licensing and are reserved for trained Philips engineers. Level 3 tools present an even greater risk if used with insufficient training and are likewise not available for licensing and are restricted to a small number of more highly trained and experienced service specialists.

11. These access controls serve purposes including protecting proprietary Philips software, patient and servicer safety, the performance and cybersecurity of the device, and license management. All Levels contain proprietary software developed by Philips and should only be used by sufficiently trained individuals given the safety-critical nature of medical device servicing. Level 2 and Level 3 in particular contain tools that are highly proprietary, pose a greater risk to patient or servicer safety, or that can alter or impact the performance or cybersecurity of the device. The strict restrictions Philips places on these tools are in line with FDA guidelines for remanufacturing and cybersecurity for medical devices.

#### **IV. LICENSING, SERVICE OFFERINGS, AND DISTINCT MARKET**

12. Philips licenses access to its System Servicing/Diagnostic Software separately from the sale or lease of the device, on terms that correspond to the Level of the tool. Philips provides Level 0 access to ISOs, hospital biomedes, and others on request. Philips licenses Level 1 access to hospital biomedes under certain cooperative service agreements, subject to requirements for system-specific service training and non-disclosure agreements. Level 2 and Level 3 access is not available for license and is retained for Philips.

13. Access is offered both through separate service agreements and through licensing. The consideration charged for Level 1 access takes the form of license fees included in

certain cooperative service agreements. The access provided includes the licensed service software tools themselves, the IST credentials and encrypted certificate required to authenticate to them, the IST entitlements that determine which tools the licensee may use, and access to the Maintenance-Related Documentation described below at the corresponding Level.

14. The market for these works and services includes hospital biomedical engineering departments that license the Level 1 works as part of certain cooperative service agreements, and Philips' own engineers and service specialists, for whom the Level 2 and Level 3 works are reserved and whose tools support Philips' own service activities. Philips competes in servicing and repairing these devices with ISOs, other OEMs, and in-house biomedes. In the FDA's 2018 report, "FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices," the FDA estimated that over 16,000 firms perform medical device service in the United States.

15. Customers may obtain maintenance or repair services from whomever they chose, including Philips, their own in-house biomedical engineering personnel, ISOs, or other OEMs. If additional authorized System Servicing/Diagnostic Software access or expertise would assist with a service, the customer or servicer may request Level 0 tools, or, in the case of hospital biomedes, may obtain a license to Level 1 tools as part of a cooperative service agreement upon completion of Philips service training for that product and execution of a non-disclosure agreement. Use of Level 2 or Level 3 tools for servicing is reserved for Philips.

## **V. MAINTENANCE-RELATED DOCUMENTATION**

16. Philips provides Maintenance-Related Documentation, which is likewise organized by Level. Basic maintenance manuals are available at Level 0 on request. More advanced documentation is available at Level 1 under license, subject to training and confidentiality requirements. Level 2 documentation poses additional safety, cybersecurity, or remanufacturing risks and is limited to Philips only.

17. This documentation is nearly exclusively stored on a cloud server and is not stored on the medical device. It is therefore maintained separately from both the Clinical Operation Software and the System Servicing/Diagnostic Software that reside on the device, and it is accessed through a Philips-hosted cloud server (InCenter) rather than through the device's clinical interface.

18. The documentation may be used by those performing service, including ISOs, hospital biomedes, and Philips personnel, with access on demand, based on a user's entitlements, at the time of need.

19. Access to this documentation is controlled by TPMs. Philips uses the proprietary IST to protect the login for service documentation, and multifactor authentication is required: the user must log in to the IST application on their computer to activate the encrypted certificate, and must use the IST account to log in to the cloud server (InCenter). The certificate is valid only on that user's computer; a user cannot log in from a different computer without re-registering with IST. Once logged in, the server presents only the materials that match the user's entitlements. To open protected Level 1 or higher materials, which are encrypted, the IST application must be active and logged in on the computer, and the tool then decrypts the documentation for viewing. These protection measures prevent the protected documents from being downloaded, saved, or printed. Level 0 documentation requires a login using IST credentials but is not encrypted, and select documents, such as Instructions for Use for the medical devices, are available with a "guest" login and are not subject to these additional protections. These measures are wholly separate and apart from the logins used for the Clinical Operation Software, because IST credentials, certificates, and entitlements are issued and controlled by Philips, whereas the Clinical Operation Software logins are username and password accounts administered by the health care facility and its information technology personnel.

20. Philips offers access to this documentation separately from the sale or lease of the device, on terms that correspond to the Level of the material: Level 0 maintenance manuals are available to any person, including ISOs and hospital biomedics, on request; more advanced Level 1 documentation is available under license, subject to completion of Philips service training for the product and execution of a non-disclosure agreement; and Level 2 documentation is not offered for license and is limited to Philips.

## **VI. UNAUTHORIZED ACCESS AND PRACTICAL EFFECTS**

21. Philips enforces against unauthorized use of, and infringement relating to, its System Servicing/Diagnostic Software, service keys, and Maintenance-Related Documentation. Philips enforces both through more informal means, such as cease-and-desist letters, and through more formal means, up to and including litigation. Philips has obtained judgments in multiple litigations, including against Transtate/Avante, KPI Ultrasound, and Image Technology.

22. Unauthorized circumvention of the TPMs described above would permit persons who have not completed Philips service training for the product, and who are not subject to the license terms and non-disclosure agreements under which Philips grants access, to obtain access to the System Servicing/Diagnostic Software and the Maintenance-Related Documentation. That includes the Level 2 and Level 3 tools and the Level 2 documentation that Philips does not license to anyone, which are highly proprietary, pose

a greater risk to patient or servicer safety, or can alter or impact the performance or cybersecurity of the device.

23. Based on my responsibilities and experience, authorized access to Philips' service software and Maintenance-Related Documentation is available through IST and, in the case of documentation, through the InCenter cloud server, subject to the conditions that apply to each Level: Level 0 tools and documentation are provided on request, and Level 1 tools and documentation are licensed to hospital biomedes as part of certain cooperative service agreements that include license fees, completion of Philips service training for that product, and execution of a non-disclosure agreement.

## VII. CONCLUSION

24. The Clinical Operation Software, System Servicing/Diagnostic Software, and Maintenance-Related Documentation described above are distinct in function and are subject to distinct access controls. The Clinical Operation Software is protected by username and password accounts administered by the health care facility and its information technology personnel, and those accounts exist to control who may access the device's medical features and patient data. The System Servicing/Diagnostic Software and Maintenance-Related Documentation are protected by Philips' proprietary Integrated Security Tool, which requires a physical smartcard, an encrypted user-specific certificate, and the matching account password, and which presents only those tools and materials that match the user's Philips-issued entitlements.

25. The System Servicing/Diagnostic Software and Maintenance-Related Documentation are monetized through the license fees charged for Level 1 access as part of certain cooperative service agreements with hospital biomedical engineering departments, subject to service training and non-disclosure requirements, and they participate in a market that includes ISOs, other OEMs, and in-house biomedes — a market in which the FDA estimated in 2018 that over 16,000 firms perform medical device service in the United States.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed on September 28, 2026 in Highland Heights, Ohio.

DocuSigned by:

*Jacqueline M Dickson*

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Jacqueline Dickson

CSIP Services Operations Director  
Philips North America LLC