



Edwards

HemoSphere 360 Service Agreement

This Service Agreement (with its attachments, the "Agreement"), is entered into as of the Effective Date between Edwards Lifesciences LLC ("Edwards") and a customer who issues a purchase order ("Customer") for the service of equipment purchased by Customer (the "Equipment") as referenced in an Edwards quote for service ("Quote").

In consideration for payment of the Service Fee (defined in Section 8), Edwards' obligations under this Agreement shall be to provide service and updates and upgrades to the Equipment software during the Service Period (defined in Section 2(a)) in accordance with the following terms, scope, conditions, limitations, exceptions, and definitions set forth in this Agreement.

1. Definitions.

- (a) "**Covered Equipment**" means the Equipment listed on Appendix A found to be defective under normal use and service (i.e., not fit for use for the purposes and indications described in the labeling when used in accordance with the directions for use). Covered Equipment does *not* include any Equipment that (1) has been disassembled, opened, repaired or altered by persons other than Edwards or its authorized representatives, (2) has been used beyond its "Useful Life" dates as indicated, where applicable, on the Equipment's labeling; (3) has had its labeling or serial number removed; (4) had pre-existing damage or reported or unreported failures prior to execution of this Agreement; or (5) has not been properly maintained by Customer per the operator's manual or IFU.
- (b) "**Effective Date**" means the earlier to occur of (1) the date when the parties execute this Agreement for the Initial Term of the Agreement, subject to provision of payment or (2) Edwards receives a purchase order for payment for the Initial Term of the Agreement.
- (c) "**Monitor**" means the unit including the panel screen of the Covered Equipment but not including the cables, modules, and accessories.
- (d) "**Peripheral Equipment**" –Power Cable, Pressure Out Cable, Swan Ganz Connector Cable, and Roll Stand.
- (e) "**Replacement Equipment**" means new or refurbished equipment or parts provided at Edwards sole discretion, to Customer: (i) on a temporary loaner basis; or (ii) in exchange for Covered Equipment, if Edwards determines the Covered Equipment is not repairable. Replacement Equipment will be provided to Customer if repairs exceed fifteen (15) days or upon request and availability. Although refurbished to factory functional standards, the Replacement Equipment may not be equivalent in appearance to the Covered Equipment returned to Edwards for repair, service, or exchange. Customer shall have full responsibility for the care of the Replacement Equipment in good and efficient working order and condition until its return or conversion to Covered Equipment.

2. Term

- (a) Term – The term for this Agreement shall be for the duration of the term purchased as set forth on the Quote (the "Initial Term"), unless terminated earlier as provided herein. This Agreement may renew upon mutual written agreement unless Edwards gives notice to Customer that such Covered Equipment becomes discontinued, obsolete, or out of service. The Initial Term and any subsequent Renewal Term shall be referred to as the "Service Period."
- (b) Termination by Edwards – Edwards may terminate this Agreement upon five (5) days written notice to Customer for any material breach of this Agreement by Customer. The parties acknowledge and agree that material breaches include, but are not limited to, (1) fraud, (2) material misrepresentation, (3) failure to allow Edwards to provide software Updates to Equipment (as further described in Section 3(l) herein), (4) failure to return Equipment as described in Section 3(c-e) herein, and/or (5) failure to pay applicable fees under this Agreement. Upon Edwards' termination as described in this section, Customer will not receive a refund of any Service Fees already paid.

3. Scope of Services Included: Edwards will repair or replace any Covered Equipment returned to Edwards in accordance with the terms of this Agreement. The decision of whether to repair or replace Covered Equipment (or a part thereof) or to use a new or refurbished part will be made by Edwards, in its sole discretion.

- (a) This Agreement covers the costs of parts, labor and return shipping costs (from Edwards to Customer), to repair or replace Covered Equipment at an Edwards authorized service center per the terms of this Agreement. Damage may include physical and/or liquid damage.
- (b) ClearSight Preventative Maintenance as listed below in Section 11, if applicable.
- (c) Edwards may, at its option, satisfy its service responsibility by providing Customer with Replacement Equipment: if the service or repair of Covered Equipment exceeds fifteen (15) days: (i) on a temporary loaner basis; or (ii) Replacement Equipment in exchange for the Covered Equipment. Replacement Equipment may be provided to Customer on a permanent basis or on a temporary basis during the time required to repair Covered Equipment. Customer assumes full liability for any Replacement Equipment that is missing, damaged, or destroyed resulting from any cause whatsoever, including but not limited to breakage, theft, damage, or other occurrences. Edwards shall retain title to all Replacement Equipment provided hereunder unless it is determined by Edwards that Covered Equipment cannot be repaired.
- (d) When Replacement Equipment is accepted by Customer as a permanent replacement to the original Covered Equipment, Customer no longer owns the Covered Equipment and is responsible for returning the Covered Equipment to Edwards within ten (10) business days from the delivery of the Replacement Equipment. Upon acceptance by Customer, this Agreement will transfer to the Replacement Equipment for the duration of the Service Period. If Customer's original make and model is no longer available, the Customer will receive comparable Replacement Equipment. If Customer does not return the Covered Equipment to Edwards' designated return location within ten (10) business days from delivery of the Replacement Equipment, Customer agrees to be billed for the current List Price of the Replacement Equipment provided.



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- (e) When Replacement Equipment is delivered to Customer on a temporary basis, Customer is responsible for returning the Replacement Equipment to Edwards within ten (10) business days from the return of the original Covered Equipment. If Customer does not return the Replacement Equipment to Edwards' designated return location within ten (10) business days from delivery of the original Covered Equipment, Customer agrees to be billed for the current List Price of the Replacement Equipment provided.
- (f) Materials used by Edwards in the repair or replacement of Covered Equipment will be on an exchange basis and all removed materials will become Edwards' property.
- (g) All repairs shall be performed only by an Edwards authorized Service Center by qualified service technician or other authorized representative using new or factory refurbished parts. Edwards will not reimburse Customer for services that are performed by any party other than an Edwards authorized Service Center. If a party other than an Edwards authorized Service Center disassembles, opens, repairs, alters Equipment or breaks the internal warranty seals of Equipment ("Unauthorized Repair"), Edwards may, in its sole discretion, immediately void the Equipment's warranty and terminate this Agreement or coverage for the particular Equipment with Unauthorized Repair upon written notice to Customer. Third party healthcare technology management entities are not authorized by Edwards to contract for or provide repair services for any of the Covered Equipment.
- (h) Edwards does not authorize any person or entity to create for it any other obligations of liability in connection with this Agreement.
- (i) Edwards' technical support is available twenty-four (24) hours a day, seven (7) days a week and can be contacted at 1-800-822-9837.
- (j) Edwards cannot guarantee next business day replacement on weekends, company holidays, after 2:00 pm Pacific Time each workday or for circumstances beyond Edwards's control (such as carrier strikes, delivery service interruptions, regional holidays, severe weather, etc.). Edwards also cannot guarantee next business day replacement to locations for which FedEx service is not available.
- (k) Any external identification (such as, for example, Customer labels and stickers) sent with the Covered Equipment by Customer to Edwards for repair (or preventive maintenance, if applicable to this Agreement) will not be returned to Customer.
- (l) During the Service Period, software updates may become available from time to time. Software updates means a revision, patches, bug fixes, performance optimization, correction, modification, work-around or derivative to the software that is made generally available by Edwards as part of this Agreement and shall enable it to perform in accordance with the documentation. Customer agrees that Edwards has the right to access the Equipment upon reasonable prior notice to install any and all such updates. If Customer does not permit Edwards to update the Equipment in a timely fashion, Edwards may void the Equipment's warranty.
- (m) During the Service Period, software technology expansion upgrades to the Equipment's software may become available from time to time. Upon Customer request, Edwards may upgrade the Covered Equipment to install any and all such upgrades. Upgrades in this instance shall mean new software versions improvements, modifications, upgrades, and additions to the software that Edwards commercially releases to its end users generally during the term of this Agreement to correct deficiencies or enhance the capabilities of the software, together with update of the documentation to reflect such new versions, improvements, modifications, upgrades or additions; provided, however, that the foregoing shall not include new, separate product offerings, new modules, re-platformed software or new functionality or expansion upgrades including but not limited to Edwards' connectivity services.
- (n) Upon Customer request, Edwards will upgrade the Covered Equipment's operating system to the current operating system in use by Edwards, if necessary for use of the Covered Equipment.

4. **Requirements for Service Eligibility.** To be entitled to receive Service the Customer must do the following:

- (a) **Troubleshoot with Edwards.** Customer is required to reasonably troubleshoot with Edwards' Technical Support personnel to verify the nature of the problem before returns for repairs are authorized by Edwards. Service may be refused if Customer is unwilling to provide detailed information about the failure or isolate defective components or Equipment from hospital inventory.
- (b) **Maintenance.** Customer is required to conduct regular maintenance on the Equipment as prescribed in the operator's manual or Instructions For Use ("IFU").
- (c) **Customer Responsibility for Shipping.** Customer must return the Equipment at Customer's expense, via freight shipping on an Edwards issued Returned Goods Authorization ("RGA") to the location indicated by Edwards. Information regarding the specific nature of each failure and detailed description of logged messages is required prior to the issuance of an RGA from Edwards' Technical Support.
- (d) **Disposable Products.** Customer agrees to use only Edwards' disposable products with Equipment. Edwards can make no guarantee to the accuracy and validity of the parameters displayed by a Monitor when used with the disposables other than genuine Edwards' disposable products. Use of non-approved sensors will have the effect of immediately terminating this Agreement.

5. **Exceptions.**

- (a) Non-serialized cables, accessories (i.e., carts, mounting adapters, patient cables, and CO-Set Probes), disposable products are specifically excluded from coverage under this Agreement; and Edwards is not responsible for returning such accessories or products that are sent to Edwards. Only serialized cables that are listed by serial number in Appendix A are included under this Agreement.
- (b) Also excluded from coverage is any Equipment where the claim, in Edwards' sole opinion, arises out of:
 - i. theft, misuse, abuse or neglect;
 - ii. use of the Equipment outside of normal operating conditions, specifications, or environment or in a manner not authorized by Edwards;
 - iii. lack of routine care or maintenance as indicated in any Edwards operating or maintenance instructions;



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- iv. failure to use or take any proper precautions under the circumstances;
 - v. user modification of any Equipment;
 - vi. computer viruses and other changes to the operating system or environment which adversely affect the applicable Equipment;
 - vii. defects, problems, or failures created by third party products (except those comprising parts or components of Edwards' products) or their interface with Edwards' products;
 - viii. Force Majeure Events;
 - ix. latent defects discovered after the expiration of the Service Period;
 - x. any disassembled, open, repaired, or altered Equipment or Equipment with broken internal warranty seals;
 - xi. any attempts to copy, disassemble, decompile, reverse engineer, or otherwise attempt to derive any code or other trade secrets of or pertaining to the Equipment or software; and
 - xii. any attempts by third party service entity to disassemble, open, repair, or alter Equipment.
6. **Specific Limitation on Equipment Replacement.** Replacement of Equipment under this Agreement shall be determined by Edwards in its sole opinion, after review of a service request or inspection of Equipment.
 - a. **Monitor Replacement:** For each Monitor, service under this Agreement is limited to a maximum of one (1) replacement for each Monitor covered within any twelve (12) month period beginning from the date of the first replacement. The first Monitor replacement will be replaced free of charge, and the second replacement requested within the twelve (12) month duration or any subsequent Monitor requests will be subject to a fee \$2,000.00.
 - b. **Battery Replacement:** For each Battery, service under this Agreement is limited to a maximum of one (1) replacement for each Battery covered within any twelve (12) month period beginning from the date of the first replacement. The first Battery replacement will be replaced at no charge, and the second replacement requested within the twelve (12) month duration or any subsequent battery replacement requests will be subject to a fee \$515.00.
 - c. **Peripheral Equipment:** For Peripheral Equipment, service under this Agreement is limited to liquid or physical damage and failures. Damaged Peripheral Equipment must be sent back to an authorized Edwards service center prior to fulfillment of a replacement request.
 - d. **Heart Reference Sensor Replacement:** For each heart reference sensor covered under this Agreement, service is limited annually to a maximum of one (1) replacement for either (i) a damaged heart reference sensor; or (ii) an expired heart reference sensor. The second or subsequent replacements will be subject to list price.
 - e. **Oximetry Cable Replacement:** For each oximetry cable covered under this Agreement, service is limited annually to a maximum of one (1) replacement for either (i) a damaged oximetry cable; or (ii) an expired oximetry cable. The second or subsequent replacements will be subject to list price.
7. **Charges for Excluded Labor and Parts.** Edwards is obligated to provide service only within the terms stated in this Agreement. Any labor, parts or expense to provide service and/or repairs beyond these terms shall be pre-approved in writing by Customer and paid to Edwards net 30 days from receipt of invoice.
8. **Service Fee.** The fee for the services provided under this Agreement shall be as indicated on Edwards' Quote to which Customer issues a corresponding purchase order (the "Service Fee"). The Service Fee is due and payable at the beginning of the Initial Term and at the beginning of any Renewal Term. Customer shall issue purchase orders for Service Fees upon execution of this Agreement and at least ninety days prior to the renewal of the Service Fees. Edwards shall invoice Customer in advance in accordance with each order. If any issuance of a purchase order or amount due and owing by Customer hereunder is thirty (30) or more days overdue, Edwards may, without limiting its other rights and remedies, suspend all Services to Customer until such amounts are paid in full. Edwards shall give Customer at least ten (10) days' prior notice that its account is overdue before suspending such Services. The Service Fee is non-refundable.
9. **Limited Warranty.** Edwards shall perform its services hereunder in a workmanlike manner. Edwards' obligation to repair any defects in the Equipment shall be limited to the terms of this Agreement. EDWARDS MAKES AND THE CUSTOMER RECEIVES NO WARRANTIES, EXPRESS, IMPLIED, STATUTORY, OR IN ANY OTHER PROVISION OF THIS AGREEMENT OR ANY OTHER COMMUNICATION; AND EDWARDS SPECIFICALLY DISCLAIMS ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.
10. **Limitation of Liability; Exclusion of Consequential Damages for Service.** IN NO EVENT SHALL EDWARDS' AGGREGATE LIABILITY ARISING OUT OF OR RELATED TO THIS AGREEMENT, WHETHER IN CONTRACT, TORT OR UNDER ANY OTHER THEORY OF LIABILITY, EXCEED THE TOTAL AMOUNT PAID BY CUSTOMER HEREUNDER IN THE 12 MONTHS PRECEDING THE INCIDENT GIVING RISE TO SUCH CLAIM, NOT TO EXCEED THE MANUFACTURER'S RETAIL PRICE FOR THE APPLICABLE EQUIPMENT. IN NO EVENT SHALL EDWARDS BE LIABLE FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL, INCIDENTAL OR EXEMPLARY DAMAGES OF ANY NATURE IN CONNECTION WITH THIS AGREEMENT AND THE SERVICES OR SOFTWARE PROVIDED HEREUNDER, INCLUDING, WITHOUT LIMITATION, DAMAGES FOR: LOST PROFITS, BUSINESS INTERRUPTION, LOSS OF BUSINESS INFORMATION OR DATA STORAGE, LOSS OF GOODWILL, COMPUTER FAILURE OR MALFUNCTION, OR ANY AND ALL OTHER COMMERCIAL DAMAGES OR LOSSES, ARISING OUT OF THE USE OR INABILITY TO USE THE SOFTWARE, EVEN IF EDWARDS HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.
11. **Preventive Maintenance for ClearSight (If Applicable)**
 - (a) **PM for ClearSight.** If the purchased service package includes Preventative Maintenance ("PM") for ClearSight, one (1) PM will be provided to the Customer at no charge during the Service Period. PMs are recommended every two (2) years on the ClearSight pump unit (Model HEMCSM10). PM services are not offered or recommended on any other piece of equipment provided by Edwards, including, but not limited to, HEM1, PC2K, EVHRS, HEMPSC100, HEMDPT1000. Edwards agrees to provide PM on an exchange or repair basis, as determined by Edwards, in its sole discretion.



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- (b) **Obtaining PM Service.** Customer is required to contact Edwards' Product Technical Support team (1.800.822.9837) to request PM. At that time of request, the Customer must provide the serial numbers of the devices that need the PM. Customer will be issued a Returned Goods Authorization ("RGA") to send the ClearSight pump unit (Model HEMCSM10) back to Edwards for an exchange. Customer will be shipped, via ground transportation, a fully refurbished, maintained, and current ClearSight pump unit (Model HEMCSM10).
 - (c) **PM Inclusions.** ClearSight pump units returned to the Customer will be returned with the same or compatible software to their existing equipment. The primary system (HEM1) must also be at compatible revisions for the ClearSight pumps and Pressure Controllers to function. Detailed instructions and assistance are available through Product Technical Support.
 - (d) **Returning Equipment.** Customer is encouraged to package the Equipment in the packaging material provided by Edwards with the replacement product to protect it from damage. Customer is responsible for the damage caused to the Equipment if returned Equipment is not sufficiently packaged to protect the Equipment from damage while in transit. All other services provided by this Agreement will be suspended until payment is received by Edwards for damaged Equipment.
 - (e) **Exclusions.** An annual pressure check is recommended on the ClearSight components (the Model HEMCSM10 pump and PC2K wrist unit). The pressure check is not included in the PM and will not be performed by Edwards. Customer will be provided detailed instructions for the annual pressure check at Customer's request and is expected to perform this routine pressure check using readily available equipment on site.
12. **Assignment.** This Agreement is assignable by Customer to a successor owner, as long as the Covered Equipment remains the property of the successor owner, coverage will continue. Edwards may assign this Agreement to any successor of all or substantially all of the business to which this Agreement relates without the prior consent of Customer.
13. **Survival.** The parties agree that the obligations under Sections 10 and 13-24 shall survive termination or expiration of this Agreement.
14. **Force Majeure.** The obligations of either party to perform under this Agreement shall be excused during each period of delay caused by matters (not including lack of funds or other financial causes) such as strikes, utility interruptions, shortages of raw materials, government orders acts of God, epidemics, pandemics, or other circumstances that are reasonably beyond the control of the party obligated to perform (each a "Force Majeure Event"). Each party shall nonetheless use commercially reasonable efforts to recommence performance as soon as reasonably practicable.
15. **Notices.** All notices or other communications required to be given hereunder shall be in writing and shall be delivered by personal delivery, mail, or courier of the other party set forth on this Agreement. Notice shall be deemed given based on any one of the following notification methods: upon personal delivery; upon the courier's confirmed delivery if sent by courier; and if sent by mail with proper postage prepaid, five (5) days after the date of mailing. A party may change its address for notice by delivering to the other party written notice.
16. **Applicable Law; Jurisdiction.** This Agreement shall be construed according to the laws of California without regard to its choice of law principles. For purposes of all claims brought under this Agreement, each of the parties hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts located in Orange County, California.
17. **Attorneys' Fees.** The prevailing party in any action to enforce this Agreement shall be entitled to recover costs and expenses, including attorneys' fees.
18. **Entire Agreement; Modification and Waiver.** This is the entire agreement between Edwards and the Customer relating to the subject matter hereof and supersedes any prior understandings, agreements, or representations by or between the Parties, written or oral, which may have related to the subject matter hereof in any way. This Agreement may be amended only by a writing executed by the Customer and Edwards. The failure of either party at any time to require performance by the other party of any provision hereof shall not affect in any way the right to require such performance anytime thereafter. Nor shall the waiver by either party of a breach of any provision hereof be taken or held to be a waiver of any subsequent breach of the same provision or any other provision.
19. **Purchase Order Terms.** The terms stated in this Agreement and those contained in the Edwards' Quote for the applicable Equipment are the exclusive terms regarding the Customer's rights and obligations with respect to the services provided hereunder. Any inconsistent or conflicting terms or conditions stated in any purchase order, acknowledgement or invoice shall be of no force and effect, and no course of dealing, usage of trade, or course of performance shall be relevant to explain or modify any term expressed in the Agreement. The issuance of a purchase order and/or payment of an invoice by the Customer shall constitute full and unconditional acceptance and acknowledgement of this Agreement and its terms by the Customer.
20. **Severability.** If any of the provisions of this Agreement shall be held to be invalid or unenforceable for any reason, the remaining provisions shall nevertheless be effective, the intent being to fully effectuate this Agreement possible.
21. **No Third-Party Beneficiaries.** This Agreement is intended solely for the mutual benefit of the parties hereto and there is no intention, expressed or otherwise, to create any rights or interests for any other party or person other than the parties.
22. **Counterparts.** This Agreement may be executed in several counterparts, each of which, when so executed, shall be deemed to be an original, and such counterparts shall, together, constitute and be one and the same instrument.
23. **Language.** The official version of this Agreement is in the English language and this Agreement will be construed in accordance with this version. Translations of this agreement into any other language are for the purpose of accommodation only and shall be of no legal effect.