Leids Universitair Medisch Centrum

Standard Service Agreement (SSO)

"Version 4.1 (ENG 07-2021)"

between

Leiden University Medical Center

hereinafter referred to as the Client

and

[Supplier]

hereinafter referred to as the Supplier

Reference: L-EU-25-17
Date: : concept

Standard Service Agreement

Agreement regarding service and maintenance

Academic Hospitals Instrumentation Management Working Group (WIBAZ; *Werkgroep Instrumentatie Beheer Academische Ziekenhuizen*)

Nevi Care

FHI, Federation of Technology Industries
Dutch Trade Association for Medical Technology
Dutch Trade Association for Laboratory Technology

Version 4.1
July 2021

Supplier and Client agree as follows:

1. Client commissions service and maintenance from Supplier, and Supplier performs service and maintenance on the Equipment.

2. In principle, this Standard Service Agreement also applies to further and other service agreements which may be concluded between the parties.

In consultation, the parties involved may agree to make preferred or necessary adjustments to service modules or to exclude certain articles in this Agreement.

Such adjustments or exclusions must be set out in the Service Agreement Template, which constitutes as an integral part of this Standard Service Agreement. The agreements set out in the Service Agreement Template, henceforth the Template, will prevail in the event of conflicts between articles.

Article 1. SUBJECT AND PURPOSE OF THE AGREEMENT

1.1 With due observance of the provisions of this Agreement and its appendices, Supplier will perform work on Client's equipment as specified in the Template, hereinafter referred to as the Equipment (with a capital 'E').

1.2 The Template (with a capital 'T') contains a description of the Equipment, including the serial numbers or system numbers of the various components when available, and the location of the Equipment.

A system is an assembly of Equipment that together forms a functional unit. Equipment lists must be provided by Supplier and will include the assembly of the Equipment.

1.3 Supplier (with a capital 'S') is any natural or legal person, partnership, limited partnership or any other entity by whom or on behalf of whom this Standard Service Agreement is declared applicable, as well as its representative(s), agent(s) and legal successor(s).

1.4 Client (with a capital 'C') is any natural or legal person, partnership, limited partnership or any other entity who enters into or has entered into a Standard Service Agreement with Supplier.

1.5 The Template also lists per device the content as well as the effective date of the agreement. Article 2 provides an overview of the service modules that can be added to the agreement after mutual consultation.

The Template also indicates which additional appendices apply to this agreement. The appendices must be dated and signed by both parties.

Supplier and Client may agree to jointly perform the work on the relevant Equipment, as well as the conditions under which this work must be performed. In such cases both parties will establish per device which work will be performed by Supplier, which by Client and which jointly. Please refer to the modules defined in Article 2 regarding the nature and extent of the work to be performed.
Any further agreements made by the parties as part of **possible mutual cooperation** must be specified in the Template.

Article 2. DESCRIPTION OF AVAILABLE SERVICE MODULES

The content of this Agreement is specified per device in the Template. After mutual consultation, the Agreement may include one or more of the modules referred to in this Article. The total price depends on the choice and interdependence of the selected modules.

Supplier will perform the work within the framework of this Agreement in accordance with the laws and regulations that apply to the Equipment, including the relevant standards, instructions and implementation decisions in so far as they have been specifically agreed.

2.1 Safety Inspection

Safety inspection entails the testing of the safety aspects of the Equipment in line with factory specifications. The Equipment´s proper functioning is also tested.

The operating procedure and measurement methods used in performing the safety inspection are set out in a safety check list. This safety check list must be made available to Client beforehand. Any additions or modifications to the safety measurements prescribed by the manufacturer must be agreed upon separately and specified in the Template.

Unless otherwise agreed, the safety inspection report will be made available to Client within four weeks. A work report must be drawn up and presented to Client immediately on completion of the work.

Any unsafe situation must be reported to Client immediately. The unsafe situation must also be confirmed in writing by Supplier.

2.2 Quality Measurement

Quality measurement is the periodic measuring of a number of previously agreed parameters which are considered relevant for the objective evaluation of the quality of the Equipment concerned. The set of parameters established at the acceptance or purchase of the relevant Equipment forms the base reference.

The work and measurement methods to be used during the performance of the quality measurement are described in a quality check list. The quality check list will be made available to Client beforehand. Any additions or modifications to the standard manufacturers quality measurement must be agreed upon separately and specified in the Template.

A work report must be drawn up and presented to Client immediately on completion of the work. Unless otherwise agreed, the quality measurement report will be made available to Client within four weeks of completion of the work.

Any non-compliance with the requirements must be reported to Client immediately. The non-compliance must also be confirmed in writing by Supplier.

2.3 Periodic Maintenance

Periodic maintenance comprises the checking, adjusting and technical cleaning of the Equipment, the lubrication of mechanical parts, if necessary, as well as the replacement of prescribed parts. The Equipment´s proper performance is also tested. Periodic maintenance includes any repairs that proved necessary during the maintenance check that can be implemented within the planned time period. If Article 2.8 does not form part of the agreement, the parts will be replaced based on actual costs.

Periodic maintenance must take place in line with the manufacturers instructions using clearly described procedures, check lists, guidelines and specifications, which must be made available to Client on request. Any additions or modifications to these must be agreed upon separately by the parties involved and specified in the Template.

A work report must be drawn up and presented to Client immediately on completion of the work. Unless otherwise agreed, the periodic maintenance report will be made available to Client within four weeks of completion of the work.
Any unsafe situation must be reported to Client immediately. The unsafe situation must also be confirmed in writing by Supplier.

The written report will also inform and advise Client about any follow-up actions deemed necessary or desirable by Supplier based on its findings.

2.4 Corrective Maintenance

Corrective Maintenance includes the detection and resolution of reported faults in the Equipment, as well as repairs that prove to be necessary during the performance of periodic maintenance or a safety inspection or quality measurement. Performance of the work takes place on location or using remote service, always in accordance with the articles in this agreement.

A work report must be drawn up and presented to Client immediately on completion of the work.

If there is a limited amount of corrective maintenance work by the Supplier, this must be specified in the Template.

2.5 Calibration

Calibration is a process described by the manufacturer which compares the functioning of a device or measuring device, or parts thereof, to the relevant specification or standard.
The result of every calibration is recorded in a document issued to Client on delivery of the Equipment.

This document must contain at least the following: date of calibration, device identification, identification of measuring device(s) used and calibration status and traceability, description of the measuring conditions, description of the calibration method(s), calibration results, statement of the measurement uncertainty, name of the person who performed the calibration and, if relevant, a Netherlands Calibration Organization (NKO) accreditation number.

If adjustment forms part of the calibration, the calibration results both before and after the adjustment must be included in the calibration document.

2.6 Validation

Validation is a specified process for carrying out measurements and the collection and assessment of measurement data in order to determine whether a certain method or process consistently produces the intended results. Legal guidelines may apply to specific devices or applications.

The validation results are recorded in a validation report. Such a report must at least contain: date of validation, identification of device or process, identification of measuring device(s) used and calibration status, description of the validation method used, validation results, name of the person who performed the validation, name of the person who assessed the validation, date of assessment, description and reference to the legal validation guidelines used. If there are no legal guidelines for the relevant Equipment or process, Supplier and Client must agree on the guidelines to be applied, to be included as an appendix to this Agreement.

A work report must be drawn up and presented to Client immediately on completion of the work.
The validation report must be sent to Client within 2 weeks of the validation.

Validation will be interrupted if the relevant device does not perform in line with the technical specifications, and the person performing the validation will immediately report this to Client.

2.7 First-line work

First-line work includes the localization and, if possible, repairing of simple faults in the Equipment by Client and may also include certain maintenance work. The scope of the work to be performed by Client depends on the number of technical staff on the side of Client and their qualifications. A trained technician of Client will be the first to perform analytical and repair work. A more detailed description of the work to be carried out by Client must be included in the Template. The time within which Client must involve the Supplier (response term) is 2 hours by default. Any other response term agreed between Client and Supplier must be specified in the Template.

Client's technicians will report on the work carried out by them in the maintenance administration documents of the relevant Equipment.
Client will inform Supplier periodically of this work and any faults.

If applicable, Supplier will pay Client a previously agreed fee for work to be performed by Client and any necessary material. The level of this fee must be specified in the Template.

Client's technicians will be trained and instructed by Supplier, if necessary, in order to perform the agreed work in a responsible manner. Specific system courses will be provided by Supplier at the agreed fee.

The first-line work module is in principle only possible in combination with the corrective maintenance or periodic maintenance modules.

2.8 Spare parts

Those parts of the Equipment that require replacement under this Agreement will be provided by Supplier. Any excluded parts must be specified in the Template. Spare parts do not include nondurables and accessories. Parties may agree in advance on a guaranteed delivery time for spare parts, which must be specified in the Template.

2.9 Phone Support

Phone support refers to the possibility for Client's technicians to consult a technician with relevant expertise at Supplier's in the event of faults with the Equipment. This consultation must take place via a coordinator at Supplier's unless otherwise agreed. The maximum response time for Supplier is specified in the Template by both parties. Phone support is provided during regular office hours on normal working days, unless otherwise specified by the parties in the Template.

2.10 Status Report

A status report is a regular written report on the condition of the Equipment covered by the Agreement provided by Supplier to Client.

Supplier gives a value judgement on the performance quality of the Equipment, together with advice and a prognosis for the future, depending on the modules covered by the Agreement and listed in the Appendix. This judgement may be substantiated with data such as:

- the number of corrective actions performed by Supplier during the reporting period
- a summary of the work performed during periodic maintenance and, if applicable, including any anomalies observed and necessary follow-up actions (if any);
- overview of the relevant safety inspections and the results of any checks carried out as a result.

2.11 Loan Equipment/Module

If Supplier cannot resolve a reported fault within the agreed repair time, Supplier will provide loan equipment or a loan module for the duration of the repair. The expected repair times and the agreed availability percentage for this loan equipment or module are specified in the Template. This loan equipment or loan module must have at least the same functionality and usability as the equipment or module it replaces. If the Template does not specify an availability percentage, a percentage of 100% is assumed for the loan equipment/loan module. Parties may agree on a guaranteed delivery time for the loan equipment/ loan module in advance, which will be specified in the Template. Supplier will also provide a user and service guide for the loan device or loan module.

2.12 Update

An update comprises manufacturer recommended adaptations to the software or hardware to increase operational reliability or safety. Such updates do not extend functionality. All updates developed for the Equipment must be made available by Supplier and implemented in the Equipment after permission from Client. If, in the opinion of Supplier, service support cannot be properly provided for the outdated version, Supplier can install new updates after obtaining permission from Client. Implementation may be performed by Supplier or Client.

Prior to the update, Supplier must provide written information on the nature and content of the update and any changes to the use and maintenance of the Equipment that implementing the update may cause. Client may not refuse safety updates to the Equipment.

The Software Conditions Appendix contains additional provisions with regard to this service module.

2.13 Upgrade

An upgrade is new software or hardware or the extension of the existing software or hardware of the Equipment on the existing hardware platform with new functionality or extension of the existing functionality of the licences purchased.

All upgrades developed for the Equipment must be made available to Client by Supplier.
Prior to the upgrade, Supplier must provide written information on the nature and content of the upgrade and any changes to the use and maintenance of the Equipment that implementing the upgrade may cause. Upgrades may only be implemented with the consent of Client.

The Software Conditions Appendix contains additional provisions with regard to this service module.

2.14 Remote Service

Remote service comprises the identification of system errors, diagnosis, real-time monitoring or time interval monitoring, software updates and problem resolution over a VPN connection.
The External Connections Appendix contains additional provisions with regard to this service module.

2.15 Uptime

In combination with Articles 2.3, 2.4, 2.8 and 2.12, and provided that all software updates deemed necessary by Supplier have been implemented, Supplier will ensure that an agreed uptime, i.e. availability, per system is achieved. The agreed uptime per year, quarter or other unit of time must be specified in the Template. The implementation of upgrades may be a precondition for an uptime guarantee. If such a situation arises, Supplier will report this immediately to Client in writing.

Definition of Uptime

$$\text{Uptime} = \frac{\text{Normal production time} - \text{downtime during normal production time}}{\text{normal production time}}$$

Normal production time

Normal production time must match the coverage hours in the Agreement, unless otherwise specified in the Template.

Downtime

Downtime starts at the moment the fault is reported to Supplier and lasts until the moment the fault is resolved. It is measured during normal production time, unless otherwise agreed.

Downtime does not include the time spent detecting and resolving faults as a consequence of:
- non-expert repairs or work by Client, its staff or third parties;
- improper use of the installation or use that is not in accordance with the user and service guide provided by Supplier;
- outside causes affecting the installation for which Supplier cannot be held responsible;
- the time needed to perform periodic maintenance, quality measurements, safety inspections and overhauls, and to implement updates and upgrades;
- the time when the system is not available to Supplier to start repairs;
- the intrusion of elements alien to the program such as, but not limited to, viruses, worms and Trojan horses.

Faults

A fault is non-compliance with the technical specifications provided by Supplier, caused by damage or a system defect, as a consequence of which responsible use of the system is not possible. Client decides whether the system is 'unsafe to use'.

Warranty

If necessary and effective, work will continue beyond normal working hours if attainment of the agreed uptime is at risk. Any additional costs will be borne by Supplier.
Client is entitled to compensation if the agreed uptime percentage per year/quarter/other time unit is not achieved. The level of this compensation must be agreed upon by the parties and specified in the Template.

2.16 Application Training

Client is entitled to a fixed number of application training days or sessions for the term of the Agreement, depending on the system purchased. Client and Supplier will agree on the content and scope of the application training in advance and will specify this in the Template.

2.17 Technical training

Client is entitled to a fixed number of Technical training days or sessions for the term of the Agreement, depending on the system purchased. Client and Supplier will agree on the content and scope of the Technical training in advance and will specify this in the Template or in an appendix to the Template.

Article 3. FEE, INVOICING AND PAYMENT

3.1 The fee payable by Client for the work to be performed or parts to be delivered under this Agreement must be specified by Supplier for each device/system. This fee must include all costs associated with the implementation of the Agreement, with the exception of the costs that will be borne by Supplier under this Agreement. All fees referred to in this Agreement are exclusive of VAT.
The costs of corrective maintenance and the replacement of defective parts during the warranty period are included in the purchase price, with due observance of the agreed warranty regulations. The fee or additional fee payable for the present Agreement must be specified in the Template.

3.2 Invoicing takes places in advance annually, unless otherwise agreed. Supplier must state the hospital purchase order number on the invoice as well as a description of the amounts invoiced.

3.3 Supplier may adjust the agreed fees each calendar year, with due observance of the relevant legal price regulations. The index applicable to this Agreement must be specified in the Template.

With regard to fee increases, Client has the right to terminate the maintenance agreement in writing within two months of publication of the increase as of the date on which the increase will take effect. Any changes in the taxes and other government charges to which the fees are subject can be passed on at any time without the right of termination.
Parties may also agree on a fixed maintenance fee for a longer period of time, in which case this will be specified in the Template.

3.4 The costs of faults and repairs occurring within two weeks of the performance of periodic maintenance, in so far as they are not covered by this Agreement, will be borne by Supplier if they are due to the periodic maintenance performed by Supplier. In all other cases the costs will be for Client, whereby Supplier may, if necessary, reasonably prove the absence of a causal link with the periodic maintenance performed by Supplier. Supplier will provide a three-month guarantee for work performed and parts supplied, if they are not already covered by this Agreement or have been otherwise agreed on in this Agreement. Client and Supplier may agree on another guarantee period if desired. Any diverging guarantee periods must be specified in the Template.

If the resolution of a fault report reveals that the fault was caused by inexpert use, outside influences or insufficient compliance or non-compliance with the instructions (see 7.1), Supplier will invoice call-out charges, working hours and any parts supplied.

3.5 Client undertakes to pay invoices within 30 days of receipt. Supplier may suspend implementation of the Agreement in the event of late payment, including non-compliance with the corporate action for cash payment in advance or upon delivery, and terminate the Agreement wholly or in part in the event of partial payment after a written reminder. In the event of late payment, Client must pay statutory interest on the unpaid part, without notice and without affecting its right of compensation.

3.6 To ensure timely processing, agreement must be reached with Client about which information to include on the invoice. This information must be specified in the Template.

Article 4. WORK TO BE PERFORMED AND SCHEDULE

4.1 The work will be performed by Supplier on normal business days between 8.30 a.m. and 5 p.m., unless the parties have agreed otherwise.

Planned work will be performed by Supplier on dates and times to be agreed on with Client.
The implementation period will also be agreed and specified in the Template at the time of entering into the agreement.

4.2 Client and Supplier will agree on a detailed planning for periodic work, taking into account the previously agreed implementation term referred to in 4.1.
After consultation, it is possible for Supplier to continue working outside business hours if Client's business operations require this. Supplier is entitled to charge an additional fee in such cases, unless otherwise agreed by the parties.
The level of this fee must be agreed annually and specified in the Template.

4.3 Client will issue notice of default to Supplier if Supplier exceeds the agreed planning. If Supplier does not fulfil the obligation within 4 weeks, Client will be entitled to a reimbursement equal to an agreed percentage of the invoice as specified in the Template for the relevant equipment. If Client is entitled to a reimbursement of the agreed fee, Supplier will provide the relevant credit note within 30 days at the request of Client.

4.4 If Supplier wishes to commence activities in accordance with the schedule and agreement, but Client does not have the Equipment available at the agreed time for the work to be performed, Supplier will be entitled to charge Client for the costs arising from the waiting time.

Article 5. FAULT REPORTING

5.1 Users will report faults to the Clients contact person or responsible staff member, as agreed with Client and specified in the Template.

Faults may only be reported to Supplier by this contact person or responsible staff member. Supplier will write down the name and department of the person giving the order. Client must be able to request this name from Supplier.

Article 6. RESPONSE TIMES

6.1 Initial response time is the time that passes between the moment that the fault is reported to Supplier and the moment that a technician from Supplier contacts Client by phone.

6.2 On-site response time is the time that passes between the moment that the fault is reported to Supplier and the moment that a technician from Supplier starts the work on site.

6.3 Remote response time is the time that passes between the moment that the fault is reported to Supplier and the moment that a technician from Supplier starts the work remotely.

6.4 Any response times agreed by parties must be specified in the Template.

6.5 The parties may agree on and record in the Template a maximum response time for Supplier to handle faults. If the agreed response time is exceeded, Client will be entitled to a discount for each event of an agreed percentage, as set out in the Template. If Client is entitled to a reimbursement of the agreed fee, Supplier will provide the relevant credit note within 30 days at the request of Client. Supplier is not liable for any compensation if it can plausibly demonstrate that the breach was due to force majeure.

Article 7. OBLIGATIONS OF CLIENT AND SUPPLIER

7.1 Client will treat, use and maintain the Equipment according to the instructions provided by the Supplier of the Equipment and ensure the temporary or permanent storage of test data if relevant. Client will bear full responsibility for this.

7.2 In consultation with Supplier, Client will offer the necessary cooperation and facilities for the implementation of the work set out in this Agreement. Client will provide support to Supplier's staff in the form of a suitable working area which is clean, free of infection risk and readily accessible. Client will also provide Supplier's staff access to all premises that need to be accessed in connection with the work.

7.3 Upon transfer of the equipment, Client and Supplier will comply with the WIP guidelines for 'Microbiological safety during the maintenance of medical and laboratory equipment', dated December 2010, as well as any additional guidelines from Client or Supplier. The manufacturer's guidelines prevail over the WIP guidelines in the event of conflicting instructions.

7.4 Client and Supplier must cancel appointments at least 3 working days in advance.

7.5 Client must ensure that any mounted Equipment or connected parts comply with the relevant factory specifications for those parts and with the reasonable requirements of usability and soundness and that they will be removed if they hinder the work.

7.6 In accordance with the relevant directives and any additional instructions by Client, Supplier and its employees are obliged to take prudent care of patient data and treat them confidentially at all times. If data processing is involved, parties will also enter into a processing agreement. This processing agreement will be attached as an appendix to the Template

7.7. Supplier guarantees that all employees who are involved in the implementation of the agreed work are and will remain properly qualified. This also applies to third parties or their staff engaged by Supplier within the framework of this Agreement. At the request of Client, Supplier will disclose the qualification requirements as well as demonstrate that the staff mentioned above meet and will continue to meet these requirements.
Suppliers possessing a quality certification for maintenance in the healthcare sector (*Gecertificeerd Onderhoud Zorgsector, or GOZ*) can demonstrate compliance with the requirements referred to here by means of the certification and the associated personal badges.

7.8 After completion of the work, the Equipment will be transferred from Supplier to Client, whereby Client will have the opportunity to assess the correct performance of the Equipment if desired. The Equipment is subsequently released and becomes the responsibility of Client. After release, the Equipment will be put to clinical use again and thus accepted.

After the performance of a periodic activity, the Equipment will be fitted with a date sticker stating the date of the next round of maintenance and calibration. This obligation relates to Articles 2.1, 2.2, 2.3, 2.5 and 2.6. The date stickers will be provided by the Client's contact person. If these stickers are unavailable, Supplier must use its own date sticker

Article 8. TRANSFER OF RIGHTS AND OBLIGATIONS

Parties may not transfer, either fully or partially, the obligations arising from this agreement to third parties without the prior written consent of the other party. This consent may be conditional. Neither party will unreasonably refuse a transfer.

Article 9. CONFIDENTIALITY

Both parties will observe confidentiality in respect of all business information, in the broadest sense of the word, that the parties obtain in the implementation of this Agreement, and the parties are unconditionally bound to take all reasonable measures to ensure the confidentiality of all data.
The above does not apply if one party has a legal reporting obligation or if one party is involved in a conflict where keeping this information confidential would hinder its own defense, in which case this party will restrict itself to reporting the necessary information for the case.

Article 10. LIABILITY

10.1 Supplier is responsible for the quality of the work it performs. Any damage suffered by Client for which Supplier can be held liable by law and through these terms and conditions will only be reimbursed to Client under observance of the following provisions: Any work performed by or for Client under its own responsibility is at Client's own risk, and Supplier will not accept any liability.

10.2 Damage for which Supplier is liable as part of this Agreement may not exceed EUR 1,200,000 per incident or, by way of derogation, the amount agreed upon by the parties involved, as specified in the Template to this Agreement.

Supplier must be adequately insured against the liability referred to in Article 10.1. In this context, Supplier will compensate for personal injury or damage to equipment and property of Client if the injury or damage was caused by the performance of work within the framework of the Agreement and by persons appointed by the Supplier to perform the work. In addition, damage to the Equipment covered by the Agreement will be fully repaired in those cases, up to the agreed maximum amount indicated above. If a system replacement is necessary, this will be paid for by Client bearing in mind the normal depreciation rates.

Consequential damage does not qualify for compensation. Consequential damage includes, but doesn't exclude: damage due to loss of profit, loss of revenue, loss of production, stagnation or delay in the production or business processes, loss of information including the cost of reconstruction, missed savings, missed agreements, labor costs incurred in vain, an increase in operational costs, additional costs due to purchasing elsewhere and discounts or fines payable to third parties.

Underused availability and the exceeding of response times are excluded within the framework of this Article.

10.3 The right to compensation will lapse if it is not invoked in writing within a reasonable time of discovery of the damage.
Damage discovered more than twelve months after delivery of the good or after the message that a service has been provided does not qualify for compensation, unless the exceeding of this term cannot reasonably be blamed on Client.

10.4 Third parties involved in the implementation of an agreement and who are part of the same concern as Supplier will always be able to invoke the same defense against any claim from Client as Supplier can on the grounds of these terms and conditions. Damages obtained from Supplier and third parties together may not exceed the maximum damages from Supplier alone.

10.5 Supplier accepts no liability for the suitability and soundness of designs, drawings, guidelines, materials etcetera which have been prescribed and provided by or on behalf of Client.

10.6 Supplier accepts no liability whatsoever for damage, incorrect operation or safety risks directly or indirectly resulting from the use of components not provided by Supplier.

Article 11. DURATION OF THE AGREEMENT

11.1 This Agreement is concluded for an indefinite period with the possibility of including a termination date in the Template.

11.2 After the production stop for the relevant Equipment, Supplier will offer Client the opportunity to conclude an agreement for a period specified in the Template. After the expiry of this period, Supplier may conclude an agreement under conditions to be agreed on.

11.3 The parties involved will consult in the event of temporary or final decommissioning of the Equipment by Client during the term of the Agreement The parties involved will consult about any compensation payable by Supplier or Client if the Equipment is prematurely decommissioned during the term of the Agreement. The way in which this amount is decided is specified in the Template. Compensation will typically take place on a pro rata basis in accordance with the agreements made.

Article 12. EARLY TERMINATION

12.1 Client and Supplier may terminate the agreement in writing at the end of a calendar year, with due observance of the minimum term in accordance with the Template and a notice period of two months, if not provided otherwise in the Template.

12.2 The Agreement may be terminated with immediate effect if a party fails to meet its obligations under the Agreement for reasons beyond its control and if the non-compliance is permanent. If the non-compliance is not permanent, termination may only take place after a period of seventy-five consecutive calendar days of non-compliance.

A non-culpable failure to meet an obligation is when this failure is not the fault of the party involved, is not covered by its accountability under law, legal act or generally accepted opinion, or is a case of force majeure. Such circumstances always include war or fire.

12.3 The Agreement can also be wholly or partially terminated with immediate effect by both parties:
- if the other party is in a state of bankruptcy or has been granted suspension of payments;
- if a third party seizes part or all of the assets of the other party;
- if the other party is a legal entity, if the liquidation of the other party has commenced, or a claim for the dissolution of the other party has been filed or a dissolution decision is being or has been made.

12.4 Each party has the right to fully or partially terminate the Agreement after written notice of default, but without the intervention of the Court, if the other party does not meet its obligations under this agreement for a period of at least thirty days.

12.5 Client and Supplier will inform each other about the use of non-original parts. Supplier will have the option of terminating the Agreement in whole or in part if Client is using, or has used, parts that were not provided by Supplier.

12.6 Termination of the Agreement will take place by sending a registered letter to the other party.

Article 13. AMENDMENTS

Any amendments or additions to this Agreement will be valid only if they have been agreed between Supplier and Client in writing.

Article 14. APPLICABLE LAW AND DISPUTES

14.1 This Agreement and all subsequent agreements are governed by Dutch law only.

14.2 All disputes arising between parties resulting from this Agreement or ensuing agreements will be referred

to the competent court in the jurisdiction where the Client has its registered office or principal place of business.

14.3 Parties may agree to subject a dispute as referred to in Article 14.2 to arbitration, in accordance with an arbitration agreement, to be drawn up or to request a binding opinion on the matter. There is a dispute when one of the parties claims there is.

Article 15. OTHER CONDITIONS

15.1 Client is entitled to ask staff involved by the Supplier in the implementation of the agreement to identify themselves.

15.2 Prior to implementation of the agreement, Supplier and its staff will familiarize themselves with the substance of the requirements and regulations regarding, *inter alia*, safety, health and the environment on Client's premises and in Client's buildings and will behave accordingly.
Client will make these requirements and regulations available for inspection to Supplier at its request well in advance.

15.3 All rights are reserved, including intellectual and industrial property rights, regarding information provided to the other party in order to realize the Agreement, for example in the form of drawings, diagrams, designs or software. The information may only be used as part of the realization and implementation of this Agreement. The perpetrator will be liable for damages as a result of a breach of these rights.

15.4 The Standard Software Conditions Appendix applies, as well as Articles 2.12 and 2.13. Any deviations from the Standard Software Conditions agreed between Supplier and Client must be specified in the Template. In the event of a conflict between one or more provisions in the Agreement and those of the standard software conditions, as well as any agreed-upon subsequent changes to these conditions, the latter will prevail.

15.5 Revision work is work resulting from the wear or ageing of parts of the Equipment that cannot be prevented or remedied by regular periodic or corrective maintenance and which are necessary to keep the Equipment in a normal state of usability in the longer term. Revision work is not covered by this Agreement and is offered by Supplier on a commercial basis.

15.6 Documents provided to Client by Supplier as part of the implementation of work specified in the Template should preferably be in PDF/A format.

15.7 Supplier is bound by the Code of Conduct for Medical Aids, which has been effective since 1 January 2012. For further information see: www.gmh.nu. Institutions will abide by the Code of Conduct in so far as it is applicable to them and will ensure that their employees or care professionals working under their responsibility comply with the Code of Conduct for Medical Aids.

15.8 The composition of the agreement and the execution of the work must take into account the need to meet the requirements of the MDR (Medical Device Regulation) and the covenant on the safe application of medical technology in hospitals (*Veilige toepassing van medische technologie in het ziekenhuis*). For additional details, see: http://www.keurmerkgoz.nl/regelgeving

AS AGREED AND SIGNED IN DUPLICATE /// AS AGREED AND DIGITALLY SIGNED WITH VALIDSIGN:

Client (LUMC)	**Supplier**
Name: ……..	Name: ……..
Title: ……..	Title: ……..
Signature:	Signature:
{{esl:signer1:Signature:size(150,40)}}	{{esl:signer2:Signature:size(150,40)}}

Appendix A: Software Terms and Conditions

This Appendix is applicable in combination with Article 2.12: Updates and/or Article 2.13: Upgrades.

Supplier guarantees that the software update or software upgrade will function in accordance with the specifications defined in the accompanying documentation and is suitable for its intended use in conjunction with the Equipment and the systems or application software to be used by Client.

Client will not alter the software in any way without the prior written consent of Supplier, unless legal provisions require this. The source code of the software will not be made available to Client. The guarantee for the proper functioning of the software becomes void if the software has been altered by Client or under its responsibility, unless Client can demonstrate that this alteration is not related to the deficiency.

Client undertakes to use the software in accordance with the guidelines or manuals provided by Supplier.

A shortcoming in the software is defined as a substantial deviation from the program specification listed in the accompanying documentation for which Supplier is responsible, provided that such a deviation is reproducible and occurs in the latest version of the supplier-installed software.

Client will immediately report to Supplier any shortcomings identified after a software upgrade/update. Supplier undertakes to remedy these shortcomings as soon as possible. Supplier will immediately upon Client s request uninstall the update or upgrade and restore the old situation if the situation is not acceptable in the opinion of Client, whereby proper, unimpaired functioning will be guaranteed as before. The ensuing costs are borne by Supplier.

Supplier will remedy any shortcomings in the software at its own cost for a period of twelve months after delivery or twelve months after acceptance if an acceptance test was agreed. In consultation with and with the consent of Client, Supplier is allowed to provide a temporary solution to a shortcoming which as far as possible retains the functionality of the software.

In the event of shortcomings in third-party software, only the third-party terms and conditions will apply. Supplier is obliged to provide information on the new software versions of third parties upon request. The user rights for these software versions are available at the usual fees. Supplier will communicate the third-party conditions to Client during the conclusion of a Standard Service Agreement. These software conditions are also included in the Standard Service Agreement as an Appendix. New software modifications are only made available to the extent that Supplier has them. Supplier and Client undertake to put maximum effort into remedying any shortcomings identified as soon as possible.

Supplier will assume full responsibility for the proper functioning of the software of a medical device, regardless of whether or not this software was provided by a third party.

Client has the right to make a copy of the software for security purposes. Client is required not to provide or grant use of the software to third parties.

Supplier will indemnify Client against any claims by third parties for infringement or alleged infringement of intellectual property rights.

Client undertakes to provide adequate measures against the penetration of viruses, worms etcetera, where applicable. Client is responsible for ensuring overall network security by means of adequate organizational and technological measures.
Supplier is not obliged to remedy shortcomings as a result of inadequate measures in these areas. If Client instructs Supplier to remedy such problems, Supplier will be entitled to charge for the costs incurred.

Supplier guarantees that software updates or upgrades do not contain inappropriate elements such as viruses, worms etcetera.

Supplier will take all necessary steps to prevent a virus infection of Client’s systems during the work performed at Client s premises or online on Client’s systems. For the purpose of this Article, the term ‘virus’

also includes logic bombs, worms, phishing or other elements alien to usage for which the computer and software industry has generally used terms.

Supplier will be responsible for any damage resulting from any lack of or insufficient compliance with the necessary steps referred to here.

To ensure safety and proper functioning, Client will not install software which does not come from Supplier on stand-alone systems unless Supplier has given its express consent. Supplier accepts no liability for damage, malfunctions of Equipment or additional work that arise from conflicts with software or viruses which were not supplied or installed by Supplier.

Supplier does not guarantee that the Equipment or software to be maintained will remain free of viruses. Client will ensure proper security of the Equipment, the software and the relevant data against internal and external abuse and will be responsible for keeping the environment virus-free.

Appendix B: Agreement on External Connections

This Appendix is applicable in combination with Article 2.14: Remote Service.

Considering that:

In the event of incidents and calamities or for the purpose of regular maintenance work and support, Supplier needs access to Client's IT infrastructure in general, and the Equipment in particular;

For the purpose of the support and maintenance work, a 'Remote Service' VPN connection will be established between Supplier's Service Center and Client's IT infrastructure;

Supplier has or can gain access to Client's IT infrastructure and the Equipment through this VPN connection, without the intervention of Client;

Access is to be understood as either access from or through Supplier's Customer Center using the VPN connection, or direct access on site;

Supplier acknowledges that Client's business operations generate confidential information that is subject to Client's duty of confidentiality;

Supplier acknowledges that Client and/or third parties (including patients) could potentially suffer considerable damage if such confidential information were to become known to third parties or if the confidentiality, availability and integrity of the information and/or the Equipment were to be harmed;

Supplier realizes that the confidentiality, availability and integrity of the data in the Equipment, as well as the correct operation of Client's Equipment must remain guaranteed or warranted;

Supplier and Client agree as follows:

1. Supplier will maintain strict confidentiality regarding the existence, form, content and purport of all confidential and other information to which it will be exposed through its access.

2. Supplier will observe all existing legal and other guidelines, including the Personal Data Protection Act (Dutch: WBP) and the applicable NEN7510 norm for Information Security in Care.

3. Supplier will ensure and guarantee the confidentiality, availability and integrity of the Equipment of Client to which it has or will gain access, including the data stored therein.

4. Supplier will make the access facilities covered by this contract available to its permanent staff only.

5. Supplier will ensure that its employees using the access facilities have taken note of, and comply with, the conditions outlined in this statement, the Supplier Access Code *(Gedragscode toegang Leveranciers)* and the Description of External Supplier Access *(Beschrijving externe toegang Leveranciers)*.

6. Supplier will ensure that the employees involved have signed the Supplier Employee Overview *(Overzicht medewerkers Leverancier)*.

7. At Client's request, Supplier will immediately provide the current Supplier Employee Overview to those employees who have been granted access to facilities by Supplier.

8. Supplier will be responsible for logging all work performed by its staff on the Client's Equipment through the VPN connection.

9. Supplier will provide an overview of the above log at Client's request and for the period designated by Client.

10. Connections may only be made to Equipment to which access has been explicitly granted.

11. The Encryption level is minimal.

12. At the request of Client, Supplier will cooperate with audits of the structure, existence and operation of Supplier's Information Security system.

13. Supplier accepts that the Code of Conduct may be adapted by Client from time to time.

14. Supplier will be responsible for the consequences and any damage resulting from non-compliance or insufficient compliance with the Code of Conduct by its staff or its subcontracted staff.

Appendix C: Code of Conduct

1. Supplier's staff will take the utmost care in performing their duties for Client and in accessing the Client's IT infrastructure and Equipment.

2. Supplier is required to do everything in its power to prevent unauthorized use of the remote connection. This may, among other things, include protecting this connection and access to the network, applications or Equipment against unauthorized use by third parties, for example by keeping passwords etcetera confidential.

3. Supplier's staff will do everything that may reasonably be expected of them to safeguard the confidentiality, integrity and availability of the Equipment that is accessible to them and of the data on that Equipment.

4. Supplier's staff will only use the opportunity to gain access to the Client's Equipment at the request of or in consultation with Client.

5. Supplier's staff will only use the opportunity to gain access to perform work which is directly related to the use and proper functioning of Client's Equipment.

6. Supplier's staff will not make any changes to the Equipment that may affect its proper functioning.

7. Supplier's staff will only make changes to the Equipment after consultation with and the consent of Client.

8. If Supplier's staff make any changes to the Equipment after consultation with and the agreement of Client, they will file a written report or an email report on the exact nature of the changes and the reason(s) for making them.

9. Supplier's staff will immediately report any alleged or real security incidents known to them to their superior within the Supplier's organization as well as to the Service Desk of Client.

10. Supplier's staff will make use of the authorizations obtained only insofar as necessary for the performance of work. The use of these authorizations must be work related and the authorizations cannot be used for other purposes.

11. Supplier's staff have received specific authorizations, which cannot be used by or transferred to others.

12. Supplementary to Articles 1 to 11 of this appendix, the Code of Conduct for Medical Devices (*Gedragscode Medische Hulpmiddelen*; www.gmh.nu) applies.

Appendix D.1: Service Agreement Template

1. General

a. The Standard Service Agreement (SSO) applies (version 4.1, July 2021 - ENG).

b. To the extent that the agreements stated in this Service Agreement Template conflict with the standard WIBAZ terms and conditions of the SSO, the agreements in this Service Agreement Template are decisive.

c. With the conclusion of this Agreement, any other Agreement between Supplier and Client relating to the Equipment mentioned in the Equipment list in Annex D.2 lapses.

d. During the term of this Agreement, Client is entitled to make (free of charge) interim changes, including the insertion and removal of Equipment, by means of a written response to the Supplier, if:
- Maintenance with a similar service level is required for newly purchased Equipment and the Supplier agrees to the addition of this Equipment;
- Client decides and/or is obliged to replace Equipment (earlier) and maintenance is no longer necessary;
- Client decides to organize certain maintenance activities differently.

During the term of this Agreement, Client is entitled to make (free of charge) changes per contract year, including the change of service levels, by means of a written response to the Supplier, if:
- Client needs a service level other than what has been agreed at that time or earlier.

2. Total amount of the Agreement

The total amount of this Agreement at the time of conclusion is: € [amount] per year (excl. VAT).
Price level: [year]. This amount [can/cannot] be indexed annually according to the average NZa standard with a maximum of 2%.

The average NZa consists of 50% personnel and 50% material index. Indexation should be applied in a weighted manner (at instrument level). The NZa indexation of that applicable year is applied for the following year.

3. Contact details

Agreement

Starting date	: [?]
End date	: [?]
Contract duration	: [?]
Renewal option	: [?]
Notice period*	: Three (3) months

Client

Name	: LUMC
Contact	: Backoffice
Department	: Medische Technologie
Phone number	: 071 – 52 63288
E-mail	: backoffice_medtech@lumc.nl

Supplier

Name firm	: [?]
Contact person	: [?]
Phone number	: [?]
E-mail	: [?]

Working hours Supplier

Monday	: [normal workday hours]
Tuesday	: [normal workday hours]
Wednesday	: [normal workday hours]
Thursday	: [normal workday hours]
Friday	: [normal workday hours]
Saturday	: [normal workday hours]
Sunday	: [normal workday hours]

** Any termination of this Agreement must be made in writing. If the Agreement has not been terminated in writing in the stipulated notice period, the Agreement will be tacitly extended by one year each time.*

4. Periodic maintenance (preventive)

The frequency of the maintenance is [number] times a year.

5. Corrective maintenance

Corrective maintenance [is / is not] part of the Agreement and therefore the Supplier [will / will not] charge extra in case this is necessary.

Hourly rates Supplier (excl. VAT)

During working hours	: € [?]
Outside working hours	: € [?]
Outside working hours or Saturdays	: € [?]
Outside working hours or Sundays and holidays	: € [?]
Standard call-out charges	: € [?]

6. Applicable modules of the SSO

All modules of the SSO apply, unless otherwise described here. See the tables below for any changes or additional agreements.

Module (of the SSO)	**Applicable?**	**Additional agreements/ provisions on the standard agreements**
2.1 Safety Inspection	[Yes / No]	[Text box for entering agreed additions or changes]
2.2 Quality Measurement	[Yes / No]	[Text box for entering agreed additions or changes]
2.3 Periodic Maintenance	[Yes / No]	[Text box for entering agreed additions or changes]
2.4 Corrective Maintenance	[Yes / No]	[Text box for entering agreed additions or changes]
2.5 Calibration	[Yes / No]	[Text box for entering agreed additions or changes]
2.6 Validation	[Yes / No]	[Text box for entering agreed additions or changes]
2.7 First-line work	[Yes / No]	[Text box for entering agreed additions or changes] Reimbursement to Client for this work: € [amount] Any abnormal response time for the involvement of Supplier: [response time]
2.8 Components	[Yes / No]	[Text box for entering agreed additions or changes] Guaranteed delivery time for parts [text box] Description of supplies and accessories not covered by this module: [text box]
2.9 Phone Support	[Yes / No]	[Text box for entering agreed additions or changes]
2.10 Status Report	Yes	Supplier must annually (in January) provide a Status Report in Excel format, free of charge, to backoffice_medtech@lumc.nl.
2.11 Loan Equipment/Module	[Yes / No]	[Text box for entering agreed additions or changes] Expected repair time: [number of] [working hours / regular hours]. Availability percentage of loan equipment/module: [percentage] %. Guaranteed delivery time of loan equipment/module: [delivery time].

2.12 Update	[Yes / No]	[Text box for entering agreed additions or changes] Updates, to software or hardware, may only be installed with the Client's permission.
2.13 Upgrade	[Yes / No]	[Text box for entering agreed additions or changes] Upgrades, to software or hardware, may only be installed with the Client's permission.
2.14 Remote Service	[Yes / No]	[Text box for entering agreed additions or changes]
2.15 Uptime	[Yes / No]	[Text box for entering agreed additions or changes] Availability: [percentage] % per year. Agreed compensation for not meeting uptime requirements: € [amount]
2.16 Application Training	[Yes / No]	[Text box for entering agreed additions or changes]
2.17 Technical Training	[Yes / No]	[Text box for the description of the scope and content of Technical training]

Module (of the SSO)	**Additional agreements / provisions on the standard agreements**
3.1 Fee, Invoicing and Payment	Reduced compensation during the warranty period: € [amount]
3.2 Agreement on different invoicing method	Annually afterwards.
3.3 Fixed maintenance fee for the longer term	Price : € [?] Period : [?]
3.4 Agreement on different guarantee period	[Guarantee period]
3.6 Billing Information	Invoices must be submitted in pdf-format to the Client's Accounts Payable Administration via the email address crediteuren@lumc.nl. Invoices must include (1) Job number, (2) Instrument number and (3) Serial number. *In the future, electronic invoicing by means of an XML file may be required. In that case, the LUMC will inform you of this in writing in advance and, if necessary, a term will be set within which this must be met.*
4.1 Implementation period for planned work	In consultation with the department.
4.3 Reimbursement Rate	Agreed reimbursement rate in the event of delayed implementation of planned work 20% of invoice price for the relevant device.
6.4 Response Times	On-site : [?] working hours (present in the LUMC) Remote : [?] working hours (remote acquisition) Initial : [?] working hours (telephone support by technician)

6.5 Reimbursement Rate	Agreed reimbursement rate for exceeding the maximum response times in the event of faults 20% of invoice price for the relevant device.
7.6 Processing agreement	Agreed: [Yes / No]. *If Yes, attach processing agreement as an appendix to the Template.*
10.2 Liability	Maximum amount in cases of liability: EURO 1.200.000,- per event.
11.2 Minimum Service Period after a Production Stop	Minimumperiod: [number] year Notification of end of service after production stop: three (3) years before the end. Supplier must send EOL/EOS notifications by e-mail to backoffice_medtech@lumc.nl.
11.3 Compensation for premature decommissioning	If a device covered by this agreement is taken out of use, the Client can cancel the agreement for the relevant instrument free of charge and a credit will be made for the remaining months. Client shall inform Supplier of this in writing at least one month in advance in order to be able to cancel any already planned orders in time.

7. Accessibility

For questions regarding the activities in this Agreement please contact our Medical Technology (MedTech) department by e-mail: medischetechnologie@lumc.nl and / or by telephone: 071 – 52 63288.

8. Houserules LUMC

For planned maintenance (on a contract basis, generally), the following rules apply:

- Maintenance is done on appointment only, which appointment is made by a staff member of Medical Technology dpt. (a technician or the Servicedesk MedTech).
- Preceding maintenance, the employee of Supplier must report to the Servicedesk of Medical Technology (Servicedesk MedTech)** or to the technician involved at C-01-076 or C-01-080. Outside office hours, the employee is to report to Security. Proceeding to the department where the maintenance is to be carried out is not allowed, unless reported to the Servicedesk MedTech, the technician involved or Security first.
- The employee of Supplier then receives maintenance stickers and the work list from the technician or the Service Office.
- The employee of Supplier then carries out the maintenance and affixes the LUMC maintenance sticker to a visible part of the equipment.
- The employee of Supplier then writes the firm report number in the 2nd column of the work list and fills in any particulars in the last column.
- The employee of Supplier checks out with the Servicedesk MedTech or the technician. Upon checking out, the work list is to be handed in together with the signed Service Report(s).
- After 4.30 p.m., the work list and signed Service Reports are to be handed in to LUMC Security (in the main hall). IA will contact the firm in question the following workday to conclude any - Costs other than those stipulated in the contract must be specified on the job receipt.
- Parking costs may not be charged; after handing in the work list and Service Report.
- Within 5 workdays, and preferably by e-mail to medischetechnologie@lumc.nl. Supplier will deliver one Service Report/calibration report per job or order in pdf-format, using the job number as the file name. In addition, the total costs are to be given on the job receipt. For validation reports, different terms apply.

For unplanned, incidental maintenance (mostly corrective maintenance and repairs), the following rules apply:

- Maintenance is only carried out after an order number (job number) has been issued to Supplier by the LUMC. By way of exception, this rule may be deviated from, but this should always be confirmed by an authorized LUMC staff member.
- Preceding maintenance, the employee of Supplier reports to the Servicedesk MedTech or to the technician involved at C-01-076 or C-01-080. Outside office hours the employee should report to Security. Proceeding to the department where the maintenance is to be carried out is not allowed, unless reported to the Servicedesk MedTech, the technician involved or Security first.
- The employee of Supplier checks out with the Servicedesk MedTech or the technician. When checking out, the signed Service Report(s) are to be handed in.

- Outside office hours, the Service Reports are to be handed in to LUMC Security (in the main hall); the firm involved will be contacted the following workday.
- Within 5 workdays, and preferably by e-mail to medischetechnologie@lumc.nl. Supplier will deliver one Service Report/calibration report per job or order in pdf format, using the job number as the file name. In addition, the total costs are to be given on the job receipt. For validation reports, different terms apply.

For certain LUMC departments, i.e. the Pharmacy, additional rules apply.

9. Additional agreements

The following additional agreements have been made:

- Supplier's personnel must be properly trained.
- [?]

Appendix D.2: Equipment list

The Equipment/devices covered by this Agreement are shown in the table below.

No.	Equipment description	Model	Serial Number	System number Supplier	Maintenance costs	Service level	Inventory number LUMC
1	[?]	[?]	[?]	[?]	[?]	[?]	[?]
2							
3							

Appendix D.3: Service and maintenance documentation

Here the Supplier must provide information about the periodic maintenance:

- Which activities will be carried out?
- Which parts will be replaced?

When purchasing a device and with periodic maintenance, the provision of service and maintenance documentation is mandatory. (refer to) External attachment (s) is allowed.

Appendix D.4: Offer Supplier

See separately enclosed offer with reference [reference quote] dated [date].