

# Data Processing Agreement Provisions on the disclosure and processing of patient data

## Status January 2025

#### **Preamble**

The Client uses a system provided by or acquired from LAP (the "Contractor") in the field of radiotherapy ("System"). The System also records health data of the patients treated by the Client ("Patient Data"). The Patient Data remains in the Client's IT infrastructure. The System does not transmit Patient Data to the Contractor, nor does the Contractor have access to this data during normal operation of the System.

In the case of maintenance and support, however, it is possible that the Contractor may gain access to the Patient Data or that Patient Data may be transferred to the Contractor.

All obligations described in this Agreement apply to all activities in which employees of the Contractor or third parties commissioned by the Contractor come or may come into contact with Patient Data or other personal data (hereinafter collectively referred to as "personal data") of the Client.

#### § 1. Subject Matter

1. The Contractor shall provide the following services in particular:

Purpose of data processing	Type of data	Circle of those affected
Support and mainte- nance of the System manufactured and provided by LAP and used by the Client Error analysis	Patient data  Name, gender, age, nationality, health insurance company, patient number, insurance number, examination results, therapy measures, course of illness, treatments carried out, medical image data, any previous illnesses	Patients of the client

This Agreement applies to the processing of all personal data of the client, irrespective of the country from which the client or the patients concerned originate.

#### § 2. Responsibilities

- The Client is the "controller" within the meaning of data protection and is
  responsible for ensuring that (i) it has collected and may process the personal
  data in accordance with the applicable statutory provisions and (ii) it protects
  the personal data in its infrastructure through appropriate technical and
  organizational measures. The Client is also responsible for the secure and data
  protection-compliant transfer of personal data to the Contractor for the purpose
  of processing on behalf.
- 2. The Client shall only make available to the Contractor or enable the Contractor to obtain knowledge of the personal data that is absolutely necessary for the provision of the Contractor's services. If anonymized data can be used for the provision of services, the Client is obliged to anonymize the personal data before making it available in accordance with the applicable data protection regulations.
- The Contractor is the processor. The processing of the personal data on behalf of the Client by the Contractor shall be carried out in accordance with the applicable statutory provisions and the provisions set out in this Agreement.
- 4. Client and Contractor must ensure that its personnel authorized to process the personal data (i) are familiar with the provisions of data protection law and (ii) have undertaken to maintain confidentiality or are subject to an appropriate statutory duty of confidentiality. Each party is responsible for its own personnel.

#### $\S$ 3. Authority of the client to issue instructions

- The data shall be processed exclusively within the framework of the agreements made and in accordance with the documented instructions of the Client. The responsibility for the instructions issued by the Client lies with the Client.
- The Client's instructions are initially given in the underlying service order. Any further instructions must be issued by the Client in writing (at least in text form). The Client shall confirm verbal instructions immediately in writing or by e-mail (in text form).
- The Contractor shall notify the Client immediately if, in its opinion, an instruction issued by the Client violates statutory provisions. The Contractor shall be entitled to suspend the execution of the relevant instruction until it is confirmed or amended by the Client.

#### § 4. Place of performance

The Contractor shall provide the contractual services on-site at the Client's premises, remotely or at its registered office.

#### § 5. Obligations of the Contractor

- The Contractor may only process personal data within the scope of the order and the Client's instructions. Processing by the Contractor for its own purposes is prohibited.
- 2. The Contractor shall design the internal organization in its area of responsibility in such a way that it meets the special requirements of data protection. It shall take appropriate technical and organizational measures to adequately secure the Client's personal data against misuse and loss in accordance with the requirements of the relevant data protection regulations. The Contractor's technical and organizational measures are available under the following link www.lap-laser. com/en/data-processing. The Parties agree that these describe an appropriate level of protection. If a need for adjustment arises in the course of the main order (e.g. due to new legal requirements), this must be implemented by mutual agreement.
- The technical and organizational measures are subject to technical progress and further development. In this respect, the Contractor is permitted to implement alternative, adequate measures. In doing so, it must be ensured that the contractually agreed level of protection is not undercut. Significant changes must be documented.
- 4. The Contractor shall comply with the applicable data protection documentation obligations and shall provide the Client with the information that the Client requires to fulfill its statutory data protection documentation obligations to the best of its ability. The Contractor shall also provide information available to it to assist with any data protection impact assessment that may be required.
- The Contractor shall be obliged to treat as confidential all knowledge of the Client's business secrets and data security measures obtained in the course of the contractual relationship. Furthermore, all persons of the Contractor shall be obligated with regard to the obligations to maintain the Client's business and trade secrets.
- 6. The person responsible for data protection at the Contractor can be contacted at datenschutz@lap-laser.com .
- 7. The Contractor shall inform the Client without delay of any breaches by the Contractor or the persons employed by the Contractor against data protection regulations or the stipulations made in this Agreement if personal data from the sphere of the Client is or can be affected. The Contractor shall take the necessary measures to secure the data and to minimize possible adverse consequences for the data subjects and shall consult with the Client immediately in this regard. The Contractor shall support the Client in fulfilling the information obligations vis-à-vis the competent supervisory authority or those affected by a personal data breach.
- If a data subject contacts the Contractor directly to correct or delete their data, the Contractor will forward this request to the Client without delay.
- If the Client is obliged under applicable data protection laws to provide a data subject with information on the processing of that person's data, the Contractor shall support the Client in providing this information.
- The Contractor shall inform the Client immediately of any controls and measures carried out by the supervisory authorities or if a supervisory authority investigates the Contractor if the Client's personal data is or could be affected.
- 11. Should the Client's personal data be jeopardized by seizure or confiscation, by insolvency or composition proceedings or by other events or measures of third parties, the Contractor shall inform the Client thereof without delay. The Contractor shall immediately inform all persons responsible in this context that the sovereignty and ownership of the data lies exclusively with the Client as the responsible person.
- 12. If the Contractor is obliged by the law applicable to it to process the personal data in another way, the Contractor shall notify the Client of these legal requirements prior to processing. The notification shall not be made if the relevant national law prohibits such notification due to an important public interest.

#### § 6. Professional secrecy (where applicable)

 Within the scope of an order, patient data may be processed that is subject to statutory professional secrecy, e.g. within the meaning of Section 203 of the German Criminal Code ("Professional Secret").





- 2. The Client undertakes to provide the Contractor with knowledge of Professional Secrets only to the extent that this is absolutely necessary for the execution of the order. The Client shall take appropriate measures to prevent the Contractor from gaining knowledge of Professional Secrets that go beyond this. The Contractor undertakes to maintain confidentiality regarding Professional Secrets and to obtain knowledge of such data only to the extent that this is necessary for the fulfilment of the tasks assigned to it.
- 3. The Contractor shall ensure that all employees involved in the processing of the Client's data subject to professional secrecy and other persons working for the Contractor who are involved in this have undertaken in text form to maintain confidentiality about the Professional Secrets that become known to them in the course of or on the occasion of their work (even beyond the duration of their employment) and that they have been instructed about the possible criminal liability. The Client shall point out to the Contractor that a collaborating person can be liable to if they make use of another collaborating person who, for their part, discloses without authorization a Professional Secret that has become known to them in the course of or on the occasion of their work and has not ensured that they have been obliged to maintain confidentiality.
- 4. Should the Contractor receive requests including in the case of interrogations and questioning by courts, public prosecutors' offices, police stations or other authorities to disclose, pass on or otherwise use Professional Secrets, the Client must be informed of this immediately and its consent obtained in advance. Only the Client is entitled to release the Contractor from the obligation of confidentiality or to authorize the release of the data. In the event of confiscation, the Contractor shall object to this and inform the Client immediately.

#### § 7. Special provisions for Patient Data

- Access to Patient Data stored on the Client's system shall only take place as part
  of support and/or maintenance work on the system and only with the consent
  of the Client. In the event of remote access, the Parties shall agree in advance
  on the software to be used and other security measures. The Client is entitled to
  inspect testing and maintenance work before, during and after it is carried out.
- Remote access shall be documented and logged. The Client is authorized and instructed - as far as technically possible - to track remote access at any time. The client also has the option of cancelling or preventing remote access at any time.
- 3. The Client shall only grant the Contractor the access rights required for the execution of the order (also for a limited period of time) and shall ensure that the Contractor does not obtain any knowledge of data that is not absolutely necessary for the execution of the order. The Contractor shall only make use of the access rights granted to it to the system to the extent also in terms of time that is necessary for the proper execution of the commissioned maintenance, service or support.
- Activities for error analysis that require data transfer to the Contractor are always carried out in consultation with the client.
- 5. Data transfer shall preferably take place via a data upload as further agreed between the Parties. If Patient Data is transferred via external data carriers of the Client, the Client shall be responsible for the protection of the data carriers provided (e.g. by encryption / password protection). The data carriers must be stored carefully by the Contractor so that they are not accessible to third parties. Patient data from the sphere of the Client shall not be transmitted to the Contractor by e-mail.
- 6. If the Client sends back the System to the Contractor for maintenance, service, replacement, exchange or return, the Client must delete the Patient Data on it in advance, otherwise the Contractor shall delete it immediately. The only exception is if the Patient data is required for troubleshooting. The Client must ensure that the Patient Data is properly stored or archived elsewhere and that deletion of the patient data by the Contractor on the System made available to it does not lead to the final deletion of the Patient Data. The Contractor shall not be responsible for the availability of the Patient Data.

#### § 8. § 8 Obligations of the Client

- The Client is solely responsible for assessing the permissibility of the data
  processing and for safeguarding the rights of the data subjects. The client shall
  ensure in its area of responsibility that the legally required conditions for data
  collection and data processing (e.g. by obtaining declarations of consent for the
  processing of the data) are fulfilled so that the Contractor can provide the agreed
  services without infringing the law.
- The Client must inform the Contractor immediately and if it discovers errors or irregularities in the data processing by the Contractor.
- The Client is obliged to inform (i) the supervisory authority if the client's personal data is affected and (ii) the data subjects affected by a personal data breach.
- The Client shall stipulate the measures for the return of the data carriers
  provided and/or the deletion of the stored data after completion of the order by
  contract or by instruction.
- The Client is obliged to treat all knowledge of the Contractor's trade secrets and data security measures obtained in the course of the contractual relationship as confidential.

- The Client shall ensure that it also takes appropriate technical and organizational measures to protect the data and that it complies with these measures. This applies in particular if Client provides remote access to its databases for Contractor
- If the Client issues individual instructions that go beyond the contractually
  agreed scope of services, the resulting costs shall be borne by the Client. If the
  agreed scope of services is exceeded, a separate written agreement must be
  made in advance.

#### § 9. Control rights of the client

- The Client is entitled, after timely notification during normal business hours and without disrupting operations, to inspect the Contractor's compliance with the agreed regulations in person or through a competent third party who may not be in a competitive relationship with the Contractor.
- If the Contractor or the persons employed by the Contractor violate data processing regulations, the Client's instructions or the provisions of this Agreement, a related inspection may also be carried out without timely notification.
- The Contractor shall support the Client in carrying out the aforementioned inspection and shall provide it with all information required to carry out an inspection within a reasonable period of time upon written request.

#### § 10. Deletion of data and data carriers

- Once the processing services have been completed, the Contractor shall delete
  all personal data in accordance with data protection regulations; the return of
  the data to the Client must be agreed in advance. Exceptions exist if the Contractor is legally obliged to store the personal data. In this case, the provisions of this
  contract for the protection of personal data shall continue to apply until the final
  deletion / handover.
- 2. Confirmations / proof of the deletion of the Client's personal data in compliance with data protection regulations will be made available to the Client on request.
- The Contractor's obligation to delete shall also apply to personal data stored on external storage media by the Contractor. If it is necessary to transport the storage medium, the Contractor shall take appropriate measures to protect it, in particular against unauthorized reading, copying or modification.
- The Contractor is not obliged to store the Client's personal data. The Contractor only receives Patient Data for support and service purposes and will delete Patient Data afterwards. Availability of Patient Data is always the sole responsibility of Client.

### § 11. Subcontractors

- If LAP GmbH Laser Applikationen is the Contractor, no orders involving the
  processing of patient data shall be passed on to subcontractors. In exceptional
  cases, subcontractors may be involved if this is necessary for the provision of
  services (e.g. error analysis, correction).
- If another LAP entity is the Contractor, it can pass on orders to the following subcontractor: LAP GmbH Laser Applikationen.
- The Contractor shall ensure that the subcontractor complies with the provisions set out in this Agreement and has an adequate level of protection to protect the Client's personal data. The Contractor shall also ensure that the legal requirements for the transfer of personal data to the subcontractor are met.

#### § 12. Right of retention

The defense of the right of retention, regardless of the legal grounds, to the contractual data and any existing data carriers is excluded.

#### § 13. Liability

- The Client and the Contractor are jointly liable to the data subject for any damage caused by processing of its personal data due to non-compliance with the applicable data protection regulations.
- If a party has paid full compensation to an affected person, it shall be entitled to recover from the other party that part of the compensation which corresponds to its share of responsibility for the damage.
- The Contractor shall be liable in the internal relationship exclusively for damage resulting from processing carried out by it in which
  - it has not complied with the obligations arising from the data protection laws applicable to it and specifically imposed on processors, or
  - (b) it acted in disregard of the lawfully issued instructions of the Client or
  - (c) it has acted contrary to the lawful instructions of the Client.
    Further liability claims under the applicable laws remain unaffected.







#### § 14. Inclusion and amendments

This Agreement shall apply to all orders that involve the processing of personal data from the sphere of the Client by the Contractor. Any amendments and supplements require a written agreement and an express reference to the fact that these provisions are being amended or supplemented (electronic signature is sufficient).

#### § 15. Severability clause

- Should individual provisions of this Agreement prove to be invalid or unenforceable in whole or in part or become invalid or unenforceable as a result of changes in legislation after conclusion of the Agreement, this shall not affect the remaining provisions of the Agreement and the validity of the Agreement as a whole
- The invalid or unenforceable provision shall be replaced by a valid and enforceable provision that comes as close as possible to the meaning and purpose of the invalid provision.
- If the Agreement proves to be incomplete, the provisions that correspond to the meaning and purpose of the contract and would have been agreed in the event of consideration shall be deemed to have been agreed.
- If there are several effective and enforceable provisions that can replace the ineffective provision referred to in Section 11 (1), the provision that best guarantees the protection of personal data within the meaning of this contract must be selected.

#### $\S$ 16. Choice of law, place of jurisdiction

- Place of jurisdiction for any disputes arising from and in connection with this
  agreement shall be Contractor's place of business. The law of the place of
  business of Contractor shall apply to the exclusion of the conflict of laws rules.
- If a different law / place of jurisdiction is mandatory under local law (e.g. in the case of claims by data subjects), the law and place of jurisdiction prescribed by law shall apply.

Lüneburg, January 2025

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Local court of Lüneburg HRB 206423