

## SALUDA MEDICAL – PRICING ACKNOWLEDGEMENT TERMS AND CONDITIONS

1. **Definitions:** In these Conditions, the following definitions apply:

**Business Hours:** the period from 9am to 5pm (Central Time time) on any business day;

**Commencement Date:** the earliest date on which both the Customer and Saluda have signed the Order;

**Conditions:** the terms and conditions set out in this document as amended from time to time;

**Confidential Information:** any and all know-how, documentation and information, whether commercial, financial, technical, operational or otherwise, relating to the business, affairs, customers, suppliers, employees, affiliates, products and/or methods of Saluda and disclosed to or otherwise obtained by the Customer in connection with the Contract;

**Contract:** the contract between Saluda and the Customer for the supply of Products and/or Services which incorporates these Conditions and the Order;

**Customer:** the person identified as "the Customer" in the Order;

**Evoke System Products:** the Evoke® System products set out in the Order;

**Force Majeure Event:** has the meaning given in Condition 16;

**Insolvency Event:** has the meaning given in Condition 14.1;

**Intellectual Property Rights:** patents, rights to inventions, copyright and related rights, moral rights, trademarks, business names and domain names, rights in get-up, goodwill and the right to sue for passing off, rights in designs, database rights, rights to use and protect the confidentiality of, confidential information (including know-how and trade secrets) and all other intellectual property rights, in each case whether registered or unregistered and including all applications and rights to apply for and be granted renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world;

**Order:** the Customer's order for the supply of the Products and/or Services;

**Patient:** any person in whom any of the Evoke System Products are implanted by the Customer;

**Price:** the price payable by the Customer for the supply of the Products and the Services in accordance with Condition 10;

**Products:** the Evoke System Products, each a **Product** and together the **Products**;

**Services:** the services, including support services, to be provided by Saluda under the Contract;

**Standard Delivery:** delivery by any reasonable means within forty-eight (48) hours of receipt of an Order by Saluda;

**Support Period:** the period during which any Product is implanted within and used by any Patient;

**Warranty Period:** in the case of an Evoke System Product, the period for which Saluda provides a warranty for such Evoke System Product as set out in the Appendix to this document.

2. **Products**

2.1 Saluda reserves the right to amend the Product specifications if required by any regulatory requirements.

3. **Delivery of the Products**

3.1 Saluda shall ensure that each delivery of the Products is accompanied by a delivery slip which shows the

date of the Order, all relevant Customer and Saluda reference numbers, and the type and quantity of the Products (including the code number of the Products, where applicable).

- 3.2 Saluda shall deliver the Products to the location set out in the Order or such other location as the parties may agree (**Delivery Location**) at a time agreed between the parties acting reasonably.
- 3.3 Delivery of the Products shall be completed on the arrival of the Products at the Delivery Location. The Customer shall ensure that any delivery of Products is signed for by an authorized representative of Customer.
- 3.4 Time of delivery is not of the essence. Saluda shall not be liable for any delay in delivery of or failure to deliver the Products that is caused by a Force Majeure Event, or the Customer's failure to provide Saluda with adequate delivery instructions or any other instructions that are relevant to the delivery of the Products.
- 3.5 If the Customer refuses or fails to accept delivery of the Products then, except where such failure or delay is caused by a Force Majeure Event or Saluda's failure to comply with its obligations under the Contract:
- (a) delivery of the Products shall be deemed to have been completed;
  - (b) Saluda shall store the Products for thirty (30) days from and including the date on which the Customer refused or failed to accept delivery (the **Availability Period**); and
  - (c) Saluda shall make reasonable efforts to effect delivery of the Products to the Customer during the Availability Period.
- 3.6 Saluda must provide notice to the Customer prior to offering for sale any new product in the product category covered by the Contract. The Company may substitute a comparable device with equal price upon receipt of FDA approval for such device without notice to the Customer. During this period, the Company and the Customer may add new products with new pricing to the Contract by amending it to add such new product at a mutually-agreed price.

#### 4. **Quality of the Products**

4.1 Saluda provides the warranties in respect of the Evoke System Products as set out in the Appendix.

4.2 If:

- (a) the Customer gives notice in writing to Saluda (i) during the Warranty Period and (ii) within a reasonable time of discovery, that there is a breach of warranty in relation to an Evoke System Product;
- (b) the Customer (if asked to do so by Saluda) makes such Evoke System Product available for collection (which shall include if reasonably required by Saluda the removal by the Customer of the Evoke System Product from a Patient, (where relevant)) by Saluda within seven (7) days after removal (where relevant) or within seven (7) days of failure (in all other cases) at which point it shall become the property of Saluda; and
- (c) the Customer gives Saluda a reasonable opportunity to examine the Evoke System Product in order to confirm whether or not there is a breach of warranty,

then Saluda shall collect and replace any such Evoke System Product which does not comply with the applicable warranty with a functionally comparable replacement (a "**Replacement**").

#### 5. **Exclusions from warranties**

5.1 Saluda shall not be liable for the failure of any Evoke System Products to comply with the warranty set out in Condition 4.1 if:

- (a) any further use (which does not include continued use by an existing Patient) is made of such Evoke System Products after giving notice to Saluda in accordance with Condition 4.2(a);
- (b) the defect arises because of a failure by any person other than Saluda to follow Saluda's instructions (whether written or oral) as to the storage, use and/or maintenance of the Evoke System Products or (if there are none) good practice regarding the same;

- (c) any person other than Saluda alters or repairs such Evoke System Products without the written consent of Saluda;
- (d) any components or equipment are attached to the Evoke System Products, which are not supplied or permitted by Saluda; or
- (e) the defect arises as a result of accident, damage, negligence, or abnormal storage or working conditions after delivery of such Evoke System Products.

5.2 The warranties are subject to any additional exclusions, limitations and conditions contained in the Appendix.

5.3 Except as provided in this Condition 5 Saluda shall have no liability to the Customer in respect of the Products' failure to comply with the warranties set out in Conditions 5.1 and 5.2.

5.4 **SALUDA WARRANTS THAT THE PRODUCT TO BE SUPPLIED UNDER THIS CONTRACT IS FIT FOR THE PURPOSE INTENDED WHEN USED AS INTENDED AND AS DIRECTED IN THE PRODUCT INSTRUCTIONS FOR USE. SALUDA DOES NOT WARRANT OR GUARANTEE ANY OUTCOME. EXCEPT AS OTHERWISE SPECIFICALLY SET FORTH IN THESE CONDITIONS AND THE APPENDIX ATTACHED HERETO, NO OTHER EXPRESS OR IMPLIED WARRANTIES ARE GIVEN TO CUSTOMER, INCLUDING, BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.**

5.5 This Condition 5 shall apply to any replacement Products supplied by Saluda, save as otherwise provided for in the Appendix.

## 6. Title and risk

Upon receipt of a purchase order, prices are for goods delivered F.O.B. point of origin to customer's specified destination, freight prepaid and added to invoice. Customer shall inspect each product upon delivery and reject products which have been damaged upon delivery. Customer shall notify Saluda's customer service department immediately upon receipt of damaged product by calling Saluda's customer service department and Saluda shall repair or replace such products at Saluda's option. Notwithstanding the foregoing, if customer does not reject a shipment of product within fifteen (15) days of delivery, such shipment shall be deemed to have been accepted.

## 7. Performance of the Services

7.1 Subject to the Customer's performance of its obligations under Condition 8.1 (Customer Obligations), Saluda shall make reasonable efforts to provide the Services to the Customer in accordance with the Contract.

7.2 Saluda warrants that it shall provide the Services with reasonable care and skill.

7.3 The Customer's exclusive remedy for a breach of Condition 7.2 shall be for Saluda to repeat the Services within a reasonable period of time of being notified of such breach.

## 8. Customer obligations

8.1 The Customer shall:

- (a) ensure that the terms of the Order are complete and accurate;
- (b) cooperate with Saluda in all matters relating to the Services;
- (c) make all reasonable arrangements required by Saluda in order for the Customer to receive the Services, including, providing Saluda with access to the Customer's premises, office accommodation and other facilities;
- (d) provide such information to Saluda as Saluda may reasonably request for the purpose of providing the Services and ensure that such information is accurate in all material respects; and
- (e) comply with all applicable laws with respect to its activities under the Contract and the use of the Products.

- 8.2 If Saluda's performance of any of its obligations under the Contract is prevented or delayed by any act or omission of the Customer or failure by the Customer to perform any relevant obligation (**Customer Default**):
- (a) Saluda shall have the right to suspend provision of the Products and/or performance of the Services until the Customer remedies the Customer Default;
  - (b) Saluda shall not be liable for any losses sustained or incurred by the Customer arising directly or indirectly from Saluda's failure or delay to perform any of its obligations under this Contract; and
  - (c) the Customer shall reimburse Saluda on demand for any losses sustained or incurred by Saluda arising directly or indirectly from the Customer Default.

## 9. **Evoke System Product Recall**

- 9.1 If the Customer becomes aware of or is the subject of a request, court order or other directive of a governmental or regulatory authority, including the U.S. Food and Drug Administration (**FDA**), to withdraw any Evoke System Products from the market (**Recall Notice**) it must immediately notify Saluda in writing and attach a copy of the Recall Notice. Saluda may issue a notice to recall or withdraw the Evoke System Products from the market on any reasonable ground in its discretion (**Voluntary Recall Notice**).

- 9.2 The Customer shall:

- (a) comply with any Recall Notice or Voluntary Recall Notice; and
- (b) give such assistance as Saluda reasonably requires to recall or withdraw, as a matter of urgency, the Evoke System Products from the market, and comply with Saluda's reasonable instructions about the process of implementing that recall or withdrawal.

- 9.3 The Customer undertakes to maintain appropriate, up-to-date and accurate records to enable the immediate recall of any Evoke System Products or batches of Evoke System Products from the market. These records shall include details of the location of the Evoke System Products and records of the Patients.

## 10. **Price and payment**

- 10.1 The Price for the Products shall be the price set out in the Order, or, if no price is quoted, the price set out in Saluda's standard price list in force on the date of delivery of Products. The Price is inclusive of the Services, and Standard Delivery of the same, but exclusive of:

- (a) any additional or alternative delivery requirements that the Customer may specify; and
- (b) all sales and use taxes, if any, due pursuant to the laws of any state or local government authority, or the federal government of the United States, in connection with the purchase and sale of the Products (**Sales and Use Tax**).

- 10.2 Saluda shall invoice the Customer for the Products (plus Sales and Use Tax) on or at any time after the completion of delivery of the Products.

- 10.3 The Customer shall pay each invoice in full and in cleared funds within thirty (30) days of the date of the invoice. Payment shall be made to the bank account nominated in writing by Saluda.

- 10.4 The Customer shall pay all amounts due under the Contract in full without any set-off, counterclaim, deduction or withholding (except for any deduction or withholding that may be required by law).

## 11. **Intellectual Property Rights**

- 11.1 The Customer acknowledges that all Intellectual Property Rights used by or subsisting in the Products, or arising in the performance of the Services are and shall remain the sole property of Saluda or (as the case may be) the third-party rights owner.

- 11.2 Saluda may inform third parties that it provides or has provided the Products to the Customer. The Customer licenses Saluda to use its name and logo(s) for this sole purpose.

## 12. **Liability**

- 12.1 Saluda agrees to indemnify, defend and hold Customer harmless from any liability, loss, expense, cost, claim

or judgment arising out of any claim for property damage, or personal injury or death to the extent the Product is alleged to have caused or contributed to the damage, injury or death, provided that this indemnification does not extend to injuries, damages or death to the extent caused by the negligence, reckless disregard or intentional acts of Customer or any third party.

- 12.2 NOTWITHSTANDING ANYTHING IN THIS CONTRACT TO THE CONTRARY, SALUDA SHALL NOT BE LIABLE TO CUSTOMER FOR SPECIAL, INDIRECT, CONSEQUENTIAL, PUNITIVE OR EXEMPLARY DAMAGES SUFFERED BY CUSTOMER RESULTING FROM OR ARISING OUT OF THE CONTRACT OR THE BREACH THEREOF, OR UNDER ANY OTHER THEORY OF LIABILITY, WHETHER TORT, NEGLIGENCE, STRICT LIABILITY, BREACH OF CONTRACT, WARRANTY, INDEMNITY OR OTHERWISE.
- 12.3 CUSTOMER'S SOLE AND EXCLUSIVE REMEDY FOR A BREACH OF WARRANTY HEREUNDER IS TO HAVE SALUDA PROMPTLY REPAIR, REPLACE OR MODIFY ANY PRODUCT. CUSTOMER SHALL HAVE NO OTHER REMEDIES UNDER THIS CONTRACT.

### 13. Confidentiality

- 13.1 All information provided to Customer hereunder, and information specific to this Contract and relating to pricing of the Products shall be deemed "Confidential Information." Subject to its disclosure obligations described herein of this Contract, Customer agrees not to disclose such Confidential Information to any third party, or to use such information for any other purpose. Confidential Information shall not be deemed confidential if: (i) it is or becomes public knowledge through no fault of Customer, or (ii) it is required to be disclosed by law, if Customer shall give maximum practical notice of same and request such confidential treatment of such disclosure from the recipient as may be afforded by law.
- 13.2 Saluda represents that it is not a Business Associate as defined in the Health Insurance Portability and Accountability Act ("HIPAA"). The functions Saluda is required to perform hereunder shall involve the disclosure of Protected Health Information ("PHI") to Saluda for treatment purposes performed by Saluda on behalf of the patient as permitted by 45 C.F.R. § 164.506(c) such as to allow Saluda to provide guidance on the safe use of products and to enable the full functionality of such products. It is thus expressly agreed by Customer that Saluda may access, view and maintain PHI on the basis of a treatment disclosure by Customer to Saluda for (i) purposes of providing support and guidance regarding the appropriate use, implantation, calibration or adjustment of a medical device for a particular patient or (ii) to provide consultation, advice or assistance, where the Customer in their professional judgment believes this will assist with a particular patient's treatment. Saluda shall be authorized to use information so disclosed by Customer for any purposes as are permitted by applicable law.
- 13.3 This Condition 13 shall survive termination of the Contract.

### 14. Termination

- 14.1 Without limiting its other rights or remedies, either party may terminate the Contract with immediate effect by giving written notice to the other party if the other party:
- (a) commits a material breach of any term of the Contract and (if such a breach is remediable) fails to remedy such breach within thirty (30) days of being notified of such breach in writing;
  - (b) files for protection under bankruptcy laws, makes an assignment for the benefit of creditors, files a petition under any bankruptcy or insolvency act or has any such petition filed against it which is not discharged within sixty (60) days of the filing thereof (an **Insolvency Event**); or
  - (c) suspends, or threatens to suspend, or ceases or threatens to cease to carry on all or a substantial part of its business.
- 14.2 Without limiting its other rights or remedies, Saluda may:
- (a) terminate the Contract with immediate effect by giving written notice to the Customer if the Customer fails to pay any amount due under the Contract on the due date for payment and fails to pay all outstanding amounts within thirty (30) days after being given written notice to do so; or
  - (b) suspend provision of the Products and/or Services under the Contract or any other contract between Saluda and the Customer if the Customer becomes subject to an Insolvency Event, or if the Customer fails to pay any amount due under the Contract on the due date for payment.

14.3 On termination of the Contract for any reason:

- (a) the Customer shall immediately pay to Saluda all outstanding unpaid invoices owed to Saluda and, in respect of Services supplied but for which no invoice has been submitted, Saluda shall submit an invoice, which the Customer shall pay immediately upon receipt;
- (b) the Customer shall return all of the Products which have not been fully paid for and which are not in current use for the treatment of a Patient and, if the Customer fails to do so, Saluda may enter the Customer's premises and take possession of them. Until the Products have been returned, the Customer shall be solely responsible for their safe keeping and will not use them for any purpose other than receiving and using the Services;
- (c) the Parties' rights and remedies that have accrued as at termination shall be unaffected; and
- (d) Conditions 1, 5.1, 5.3 to 5.5 (inclusive), 11, 12, 13, 14.3 and 17 shall continue in full force and effect.

15. **Compliance with laws**

Each party represents and warrants that it shall comply with all applicable federal and state laws and regulations, including, without limitation, the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, any applicable "exceptions" or "safe harbors" under the Federal Anti-Kickback Statute with respect to the Contract, and any state laws comparable to the Federal Anti-Kickback Statute. Both Parties expressly acknowledge that the Federal Anti-Kickback Statute, prohibits "illegal remuneration" as defined therein, in connection with the provision of goods or services for which payment is made in whole or in part under Medicare. It is the intention of the parties hereto that the Contract shall in all respects comply with the Discount Safe Harbor, 42 C.F.R. § 1001.952(h) or the Statutory Discount Exception, 42 U.S.C. § 1320a-7b(b)(3)(A). Customer agrees that, if Customer is required to report its costs on a cost report, then (i) any discounts, rebates or other price reductions provided must be based on purchases of the same good bought within a fiscal year; (ii) Customer must claim the benefit in the fiscal year in which the discount is earned or in the following year; and (iii) Customer must fully and accurately report any discounts in applicable cost reports. Furthermore, Customer represents and warrants that it has independently determined that the Product is in the best interest of Customer's patients.

16. **Force majeure**

Neither party shall be liable for any failure or delay in performing its obligations under the Contract to the extent that such failure or delay is caused by a Force Majeure Event. A **Force Majeure Event** means any event which hinders, delays or prevents performance of a party's obligations and which is either beyond that party's reasonable control, which by its nature could not have been foreseen, or, if it could have been foreseen, was unavoidable, including but not limited to strikes, lock-outs or other industrial disputes (whether involving its own workforce or a third party's), failure or interruption of energy sources, other utility service or transport network, acts of God, war, threat of or preparation for war, armed conflict, terrorism, riot, sanctions, embargo, export or import restriction, malicious damage, breakdown of plant or machinery, nuclear, chemical or biological contamination, explosion, loss at sea, epidemic, pandemic or similar events, natural disasters or extreme adverse weather conditions, or default of Saluda's subcontractors.

17. **General**

- 17.1 **Entire agreement** The Contract (incorporating these Conditions) constitutes the entire agreement between the parties relating to its subject matter.
- 17.2 **Waiver** No failure or delay by a Party to exercise any right or remedy provided under the Contract or by law shall constitute a waiver of that or any other right or remedy.
- 17.3 **Severance** If any provision of the Contract is or becomes invalid, illegal or unenforceable, it shall be deemed modified to the minimum extent necessary to make it valid, legal and enforceable.
- 17.4 **Notices** Any notice given to a party under or in connection with the Contract shall be in writing.
- 17.5 **Governing law** The Contract and any dispute or claim arising out of or in connection with it or its subject matter or formation shall be governed by the laws of the State of Minnesota.
- 17.6 **Jurisdiction** The Customer irrevocably agrees that the courts of the State of Minnesota shall have exclusive jurisdiction to settle any dispute or claim arising out of or in connection with the Contract or its subject matter or formation. Nothing in this Condition shall limit Saluda's right to take proceedings against the Customer in any other court of competent jurisdiction.

## Appendix to Saluda Terms and Conditions

### 1. Saluda Medical Evoke® System Limited Warranty

The Evoke® System includes a Closed Loop Stimulator (the "CLS"), temporary and permanent leads, external accessories and single-use accessories (the "Components").

#### 1.1 Closed Loop Stimulator

- (a) **Saluda** warrants that the CLS will function within normal tolerances and be free from defects in materials or workmanship for a period of five (5) years from the date of implantation of the CLS.
- (b) The warranty contained in paragraph (a) does not apply to the Leads (defined in paragraph 1.2(a)), or surgical accessories used with the CLS.
- (c) **The warranty for any Replacement CLS provided by Saluda pursuant to Condition 5.3 of the Terms and Conditions will last for five (5) years from the date of implantation of the original CLS.**
- (d) **CLS battery depletion will occur over time and is not therefore a defect in materials or workmanship. Depletion of the battery will depend on the settings used to meet the patient's requirements for neurostimulation.** Therefore, Saluda gives no warranty in respect of the duration of the CLS battery.

#### 1.2 Leads

- (a) **Saluda** warrants that the Evoke® lead (the "Lead") **will be free from defects in materials or workmanship within a period of one (1) year, starting from** its date of implantation.
- (b) The warranty contained in paragraph (a) does not apply to the **surgical accessories used with the** Lead.
- (c) The warranty for any Replacement Lead provided by Saluda **pursuant to Condition 4.3 of the Terms and Conditions will last** for one (1) year from the date of implantation of the original Lead.

#### 1.3 Externals

- (a) **Saluda** warrants that the Evoke® Pocket Console (the "EPC") and the Evoke® Charger (**the "Charger"**) **will function within normal tolerances and be free from defects in materials or workmanship within a period of one (1) year from the date of purchase.**
- (b) The warranty for any Replacement EPC provided by Saluda **pursuant to Condition 4.3 of the Terms and Conditions will last for one (1) year from the date of purchase of the original EPC.**
- (c) **The warranty for any Replacement Charger pursuant to Condition 4.3 of the Terms and Conditions will last** for one (1) year from the date of purchase of the original Charger.

#### 1.4 Claims

The warranties set out above shall not apply in relation to the CLS unless:

1. The CLS is implanted prior to its "use by" date and the Customer provides documented proof of such.

2. The explanted or dysfunctional CLS must be returned to Saluda Medical as instructed by Saluda Medical and shall be the property of Saluda Medical.
3. Component failure must be confirmed by Saluda Medical.
4. For the rechargeable CLS and as described in the relevant surgical and patient manuals, the battery in the CLS must not be over discharged or exposed to contraindicated procedures described in the relevant manuals.
5. This limited warranty does not include failures caused by:
  - a. A failure by any person other than Saluda to follow Saluda's instructions (whether written or oral) as to the storage, use and/or maintenance of the Evoke System Products.
  - b. Attaching components or equipment to the Saluda Medical Evoke® System, which are not supplied or permitted by Saluda Medical.
  - c. Accident, damage, misuse, abuse, negligence or the Patient's failure to operate the Evoke® System according to the labelling and instructions for use provided.
  - d. Unapproved attempts to repair, maintain or modify the Evoke® System by the Patient or any unauthorized third party.

#### 1.5 Limitations

This warranty is limited to its stated terms. Specifically:

1. The warranty relating to the CLS shall apply only in relation to use in the Patient in whom the CLS was first implanted and no other person or entity.
2. Saluda shall not be liable for the failure of Components that are reused, reprocessed or re-sterilized.