

## **Distribution Agreement**

between

**ZOLL Medical UK Ltd**

-hereinafter referred to "ZOLL Medical UK Ltd"  
and

-hereinafter referred to as "Distributor"-

**NOTE – this form of agreement will become binding on the Distributor in the manner described in clause 15**

### **Preamble**

WHEREAS, ZOLL Medical UK Ltd, of 16 SEYMOUR Court, Tudor Road, Manor Park, Runcorn, Cheshire WA7 1SY is entitled to import medical equipment manufactured by ZOLL Medical Corporation Inc, Chelmsford, Ma USA (hereinafter referred to as "ZOLL Medical Corporation")

WHEREAS ZOLL Medical UK Ltd is fully authorised to conclude an Distributor Agreement (hereinafter referred to as "Agreement") with respect to the distribution and sale of ZOLL Medical Corporation's products;

AND, WHEREAS, DISTRIBUTOR is willing to distribute ZOLL Medical Corporation products limited to resuscitation equipment and associated consumables (as defined in Appendix 1 and hereinafter referred to as "Products") to third parties residing in the Territory (see Appendix 3.)

AND, WHEREAS, ZOLL Medical UK Ltd has agreed that, NOW, THEREFORE, in consideration of the terms and conditions set forth hereunder, both parties in their full legal capacities convene and agree to the following, which does not in any way form the basis of any agreement between the Distributor and ZOLL Medical Corporation.

### **1. Appointment of the Distributor**

ZOLL Medical UK Ltd grants to the Distributor non-exclusive sales rights for the Territory with respect only to the Products, as set forth in the Product and Price List (**Appendix 1**). ZOLL Medical UK Ltd will inform the Distributor of any changes to this Product and Price List accordingly.

The Distributor shall buy the Products directly from ZOLL Medical UK Ltd in his own name and on his own account and shall then sell them to third parties residing in the Territory in his own name and on his own account. Nothing in this Agreement shall constitute a right of the Distributor to act as an agent of ZOLL Medical UK Ltd or ZOLL Medical Corporation or to represent ZOLL Medical UK Ltd or ZOLL Medical Corporation in any way whatsoever. The Distributor shall have no right to enter into any obligations on behalf of ZOLL Medical UK Ltd or ZOLL Medical Corporation.

In consideration of the non-exclusive sales rights granted to the Distributor he agrees to use his best endeavours to increase the sales of the Products in the Territory, not to sell or distribute competitive products and not to participate in any form of sales promotion of such competitive products.

In any event and for the avoidance of doubt, the Distributor agrees under no circumstances to export the Products (or to sell the Products to distributors or to any customer who buys them with the intention to export, resell or redistribute them) to ultimate destinations in countries embargoed or boycotted by the laws of the United Kingdom or the European Union.

If the Distributor becomes aware of a sales opportunity outside of the territory he will pass on the details of this sales opportunity to ZOLL Medical UK Ltd.

## **Purchase and Sale**

ZOLL Medical UK Ltd agrees to sell the Products to the Distributor on an FOB basis at prices which are in accordance with the current price list contained in Appendix 1. ZOLL Medical UK Ltd has the right to change the prices at any time. Price changes shall become effective only 30 (thirty) days after the Distributor was notified of them by ZOLL Medical UK Ltd in writing. If the Distributor upon being notified of a price increase orders more goods than usual, ZOLL Medical UK Ltd shall have the right to invoice the Distributor with the increased prices for orders which are in excess of the quantities usually ordered. The Distributor agrees to publish an end-user price list. ZOLL Medical UK Ltd retains the sole discretion to offer to include any future products into this agreement. All purchase orders placed by the Distributor on ZOLL Medical UK Ltd will be unconditional and not contingent on the Distributor selling the products) ordered on to third parties.

All payments shall be made by the Distributor to ZOLL Medical UK Ltd within 30 days of the due date of the invoice. ZOLL Medical UK Ltd reserves the right to extend such credit to the Distributor as ZOLL Medical UK Ltd may, at its sole discretion, deem appropriate. Withdrawal of such credit will at all times be at ZOLL's sole discretion.

Clause 2 ("F.O.B, Delivery and risk of loss"), 3 ("Terms of Payment") and 1 ("Acceptance") of the "General terms and Conditions" of the Products (of Appendix 2) are an integral part of this Agreement. The "General Terms and Conditions" are subject to change by ZOLL Medical UK Ltd, giving written notice to the Distributor.

Both parties agree and understand that the non-exclusive sales rights granted to the Distributor (see clause 1.1 above) relate to the sale of the Products to customers who intend to use them for the purposes for which they are manufactured and fully in accordance with operating instructions and all applicable laws, regulations and guidelines

The Distributor agrees to make all necessary arrangements for an immediate and fast delivery to its customers and to take care that the "Use-Before-Date" on any product packaging is observed and that the Products are distributed in the same sequence in which they were received from ZOLL Medical UK Ltd.

The Distributor may not return Products unless otherwise agreed by ZOLL MEDICAL UK LTD in writing in advance. The costs for return shipments (transportation and insurance) shall be borne in any event by the Distributor.

## **Sales Promotion**

Distributor shall provide Sales Support to his customers in the Territory. Such Sales Support activities shall include in particular advising customers in product matters, handling of complaints and warranty requests and any further support activity reasonably necessary to establish and/or maintain good relations with all current, former or prospective ZOLL Medical UK Ltd customers in the Territory.

In carrying out his responsibilities in respect of this Agreement, the Distributor agrees to always act in an ethical manner and fully to comply with all current regulations, codes of practice and guidelines and all ZOLL policies and procedures which relate to interactions in the market as may from time to time be in force.

All Sales Promotion activities as contemplated under this section 4 shall be the obligation of the Distributor, without any further compensation payments due, and any material originated by the Distributor will be submitted for approval to ZOLL prior to distribution in the market.

## **Warranty**

ZOLL Medical UK Ltd does not warrant the Products supplied to the Distributor. For those Products which are warranted by ZOLL Medical Corporation in its capacity as the manufacturer, the only warranty is the one ZOLL Medical Corporation gives for the individual product. The Distributor must not stipulate any warranty terms for ZOLL Medical Corporation products other than ZOLL Medical Corporation`s warranty which applies to the respective product.

In relation to his customers, the Distributor is responsible for the administration of warranty settlements in accordance with the applicable ZOLL Medical Corporation warranty terms. He must return the device for which a warranty claim is made together with the required paperwork to ZOLL Medical UK Ltd which, if necessary will forward both to ZOLL Medical Corporation for evaluation of the warranty claim. The cost for return shipments to ZOLL Medical UK Ltd (transportation and insurance) shall be borne in any event by the Distributor. The cost of return shipment will be at ZOLL Medical UK Ltd's expense.

Only ZOLL Medical authorised service personnel may carry out any technical repair or modifications to any ZOLL device. Distributors may not carry out any form of repair or modification to equipment they have purchased and or sold on to their customers unless they have undergone the required training carried out by ZOLL technical service engineers. Failure to comply will result in the warranty of the device becoming null and void and will result in the device being condemned for clinical use.

Only the manufacturer ZOLL Medical Corporation shall comment on problems encountered with its products

## **Information Requirements**

The Distributor agrees to furnish ZOLL Medical UK Ltd with a report by the Friday of the week immediately following the end of each quarter detailing the sales of the preceding quarter which state the respective unit sales and revenue amounts. In addition, the Distributor agrees to supply ZOLL Medical UK Ltd with a forecast for the forthcoming quarter by the last Friday in the preceding quarter.

## **Confidentiality**

The Distributor agrees to observe good business practices and safeguard ZOLL Medical UK Ltd's and ZOLL Medical Corporation's interests. He agrees not to disclose ZOLL Medical UK Ltd's or ZOLL Medical Corporation's trade secrets or any other information related to their products or business affairs. In return, ZOLL Medical UK Ltd agrees to not to disclose the Distributor's trade secrets or any other information relating to its business affairs. The Distributor also agrees not to enter into agreements with third parties which might affect his obligations under this clause

The Distributor agrees to secure the prior written consent of ZOLL Medical UK Ltd or ZOLL Medical Corporation if he intends to make information available to the public which contains the name or trademarks of ZOLL Medical Corporation. This applies particularly to advertisements in magazines as well as to press releases, written presentations in exhibitions booths, hand-out information and letters to customers containing other information about ZOLL Medical Corporation's products than is published by ZOLL Medical Corporation in its product literature.

## **Traceability**

The Distributor agrees to maintain Traceability of the Products by keeping in a product tracking file as a minimum the following information:

- a. Product type and serial number
- b. Date of receipt from ZOLL Medical UK Ltd
- c. Name and address of customer to which product was sold or loaned
- d. Date sold or loaned to customer
- e. Service history

The Distributor agrees also to maintain a complaint file related to the utilization of the Products in compliance with the procedure established by ZOLL Medical Corporation.

On request the Distributor shall within one week supply ZOLL Medical UK Ltd with a copy of the product tracking file and the complaint file.

### **Force Majeure**

Neither party shall be liable for non-performance of any of its obligations under this Agreement due to causes beyond its control.

In the event of such non-performance of material obligations under this Agreement due to causes beyond one party's control continuing for 6 (six) months or more, either party may terminate this Agreement without notice.

### **Duration and Termination**

This Agreement shall commence on **XXXXXXXXXXXX** and shall, subject to any rights of prior termination contained herein, continue until terminated at any time by either party giving to the other party thirty (30) days written notice.

Clause shall not affect the right of either party to terminate this Agreement without notice on the occurrence of a material breach of any obligation hereunder or under any of the provisions for termination.

### **Disclosure**

ZOLL operates within the requirements of the applicable codes of conduct and other regulations including those listed in Appendix 5

If any person connected with the Distributor, whether as shareholder, director, employee, consultant or otherwise, is a member, officer or servant of any public body (which for the avoidance of doubt includes any UK or Irish government department, NHS trust or Irish healthcare institution) the Distributor will procure that such person will promptly make full and proper declaration and/or disclosure of his/her interest in this contract in accordance with all applicable codes of conduct and other regulations.

### **Ethical Standards**

ZOLL is committed to conducting its business, including specifically interactions by ZOLL, its employees and its Distributors with healthcare professionals, according to the best ethical business practices and socially responsible industry conduct. As part of this policy ZOLL is committed to complying with regulations governing businesses that interact with healthcare professionals.

The Distributor shall observe, and procure that all its personnel observe, all "Relevant Codes", namely all laws, regulations and generally adopted codes of conduct (whether or not having the force of law) concerning ethical business practices and the prevention of corruption. The Distributor must identify all Relevant Codes and shall promptly notify ZOLL of these in writing. At the date of this Agreement the Relevant Codes for the Territory include

those listed in Appendix 5, the U.S. Foreign Corrupt Practices Act (FCPA) and the AdvaMed Code referred to in the following paragraph.

In respect of all territories ZOLL supports the Code of Ethics on Interactions with Healthcare Professionals, as adopted by the Advanced Medical Technology Association (AdvaMed) from time to time. ZOLL's approach to the policy is to implement the standards promulgated in the AdvaMed Code, the most recent version of which is contained in Appendix 4. Any interpretation of the provisions of this policy, as well as interactions with healthcare professionals not specifically addressed in this policy, should be made in light of the principle that the Distributor and its personnel will encourage ethical business practices and socially responsible industry conduct; and shall not engage in any unlawful inducement. Without reservation, ZOLL Medical strongly endorses both the letter and spirit of the AdvaMed Code of Ethics.

The Distributor agrees that it will adopt and comply in full with the provisions of the AdvaMed Code of Ethics when conducting business relating in any way to ZOLL's products and if requested to do so that it will sign acknowledgements from time to time that it understands and is in compliance with the provisions of this Code of Ethics. More information is found in Appendix 4 of this document and at <http://www.advamed.org>.

Failure by the Distributor to comply with any Relevant Code will be a material breach of this Agreement entitling ZOLL, without prejudice to any other remedy, to terminate this Agreement without notice.

### **Export Compliance**

ZOLL Medical UK Ltd is a wholly owned subsidiary of the ZOLL Medical Corporation, a U.S. company, and is subject to the various U.S. Export regulations that apply to the sale of its products.

At the date of this Agreement, licenses are required from the Office of Foreign Assets Control (OFAC) of the U.S. Department of the Treasury for the shipment of medical devices to Cuba, Iran, Syria, and Sudan.

ZOLL is also prohibited from dealing with certain listed foreign nationals and persons, who commit, threaten to commit or support terrorism.

The sanctioned countries and degrees of restrictions and the lists of Specially Designated Nationals and Terrorist Groups subject to sanctions are constantly changing. The Distributor must regularly refer to information on Sanctions Programs and Country Summaries at [www.ustreas.gov/ofac](http://www.ustreas.gov/ofac).

The Distributor undertakes to ascertain the ultimate destination of products the Distributor is purchasing from ZOLL, and to comply with the US Export regulations referred to above, and to notify ZOLL immediately if the Distributor becomes aware of attempted export to a sanctioned country or restricted individual or group.

### **ZOLL Trademark**

Distributor acknowledges that ZOLL is the owner of and holds the right, title and interest in and to the mark "ZOLL" and all other Product marks associated with the "ZOLL" mark, including the "ZOLL" name in any website domain name.

Distributor agrees that it will not use the "ZOLL" name in any website domain name without the expressed written consent of ZOLL (and if any such consent is given it shall last only while this Agreement remains in force). Subject to this the Distributor is hereby licensed while this Agreement remains in force to use the mark "ZOLL" and all other Product marks

associated with the "ZOLL" mark for the promotion and sale of Products within the Territory but not further or otherwise.

### Miscellaneous

This Agreement together with the Appendices attached hereto constitutes the entire agreement between the parties and supersedes all previous agreements between the parties relating to the sale of ZOLL Medical Corporation products. No additional verbal arrangements have been made. Any modification or amendment to this Agreement, including this written form clause, shall only be effective if made in writing.

Should any provision of this Agreement be or become invalid or unenforceable, this shall not affect the remaining provisions. The Parties will then agree on a substituting provision which comes closest to the invalid or unenforceable one.

This Agreement shall be governed by and construed in accordance with English law.

### Acceptance by conduct

This form of agreement, once signed on behalf of Zoll Medical UK Ltd and delivered to the Distributor, constitutes an offer to appoint the Distributor as distributor of ZOLL Medical Corporate products on the terms set out herein. Such offer will be conclusively deemed to be accepted if the form of agreement is signed by or on behalf of the Distributor (in which case the date of the Agreement shall be the date on which it is so signed) or by the Distributor placing an order for any ZOLL Medical Corporation product after receipt of the form of agreement signed on behalf of Zoll Medical UK Ltd (in which case the date of the Agreement shall be the date on which the Distributor places such order).

AS WITNESS the signatures of duly authorised representatives of the parties or (if this Agreement comes into effect by "acceptance by conduct" as described above) the signature of the duly authorised representative of ZOLL Medical UK Ltd and the conduct of the Distributor.

Date: \_\_\_\_\_

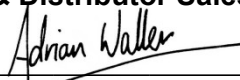
Date: \_\_\_\_\_

Name: Adrian Waller

Name: \_\_\_\_\_

Office held: **PAD & Distributor Sales Manager**

Office held: \_\_\_\_\_

Signature:  \_\_\_\_\_  
for and on behalf of the ZOLL Medical UK Ltd




Signature: \_\_\_\_\_  
for Distributor

# APPENDIX 1

## Distribution Agreement Between ZOLL Medical LTD and

### Product and Price List (Purchasing prices)

#### PRICE LIST 2012/2013

Product Code	Description	ZOLL UK Suggested List Price (£)	Distributor Purchase Price (£)
<b>AED Devices</b>			
2010000102011050 	<b>ZOLL AED Plus® defibrillator - Lay Rescuer</b> Supplied with a graphical user interface with 8 illuminated picture prompts, an LCD screen showing voice prompts, device advisory messages, elapsed time, shock count and chest compression graph display. Configurable to display ECG. Supplied with passive airway support lid, soft case, batteries, CPR-D electrode with First Responder Kit, operator's guide and a 7 year warranty. Instructional training DVD also included.	£1295	£900
2010000302011050 	<b>ZOLL AED Plus® defibrillator - First Responder with professional interface</b> Supplied with minimal front panel graphics, a clear LCD screen with optional ECG, voice and text prompts, elapsed time, shock count and chest compression graph display. Supplied with a passive airway support lid, a soft case, batteries, CPR-D electrode, operator's guide and a 7 year warranty.	£1295	£900
90210200499991050 	<b>ZOLL AED Pro® defibrillator</b> The AED Pro® semi-automatic with manual override is supplied with; 3-lead ECG cable, a disposable lithium ion battery and a carry case. Comes with a 5 year warranty as standard. Please note: <b>THIS DEVICE IS NOT SUPPLIED WITH ANY TYPE OF ELECTRODE</b> - please order separately from the section below.	£2650	£1650
8008-0050-05	<b>ZOLL AED Plus Trainer II® - Training Device</b>	£379	£311
<b>AED Plus &amp; Pro Electrodes</b>			
8900-0800-01	CPR-D padz® and First Responder Kit (5 year shelf life) - single	£81	£61
8900-0402	CPR stat-padz® (2 year shelf life) - single	£46	£35
8900-0400	CPR stat-padz® (2 year shelf life) - box of 8	£330	£248
8900-0801-01	stat-padz II® - single	£21	£16
8900-0802-01	stat-padz II® - box of 12	£215	£161
8900-0810-01	pedi-padz II® (paediatric) - single	£55	£40
<b>AED Plus Trainer</b>			
8900-0804-01	CPR-D training padz® with reusable puck and replacement pads	£81	£61
8900-0803-01	Replacement gel pads for CPR-D training padz® - set of 5	£30	£23
<b>Mountings</b>			
8000-0809-01	Wall mounting bracket	£136	£102
8000-0855	Wall cabinet (surface mount)	£271	£203
<b>Miscellaneous</b>			
8000-0819-01	AED Plus® simulator	£320	£240
8000-0807-01	AED Plus® batteries (pack of 10)	£76	£57
8000-0860-01	AED Pro® disposable lithium ion battery	£125	£91
8000-0839	3-lead ECG cable	£97	£72.25
<b>Training &amp; Demonstration</b>			
8000-0834-01	AED Plus® demonstration kit including: large padded carry bag, manikin, velcro straps, CPR-D demo-padz® with Y cable and connector for simulator	£320	£240
8900-5007	CPR-D demonstration and training electrode with velcro strap and Y connection cable, with Real CPR help® (for use with live device and simulator)	£143	£107
<b>Software</b>			
	ZOLL Data Review® - event review software, downloadable from <a href="http://www.zoll.com">www.zoll.com</a>	FREE	FREE

ZOLL Medical UK Ltd's list price is shown for information only. It is not in any way intended to influence or determine the distributor's list or selling price.  
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## **APPENDIX 2**

### **Distribution Agreement**

**between**

**ZOLL Medical UK Ltd**

**and**

#### **GENERAL TERMS AND CONDITIONS**

1. **ACCEPTANCE:** This quotation constitutes an offer by ZOLL Medical UK to sell to the Customer the equipment (including a license to use certain software) listed in this Quotation and described in the specifications either attached to, or referred to in this Quotation (hereinafter referred to as Equipment). Any acceptance of such offer is expressly limited to the terms of this Quotation, including these General Terms and Conditions. Acceptance shall be so limited to this Quotation notwithstanding (i) any conflicting written or oral representations made by ZOLL Medical UK or any agent or employee of ZOLL Medical UK, or (ii) receipt or acknowledgement by ZOLL Medical UK of any purchase order, specification, or other document issued by the Customer. Any such document shall be wholly inapplicable to any sale made pursuant to this Quotation, and shall not be binding in any way on ZOLL Medical UK.

Acceptance of this quotation by the customer shall create an agreement between ZOLL Medical UK and the Customer (hereinafter referred to as the "Contract"). The terms and conditions of which are expressly limited to the provisions of this Quotation, including these Terms and Conditions. No waiver, change or modification of any of the provisions of this Quotation, or the Contract, shall be binding on ZOLL Medical UK unless made in writing, expressly stating that it is a waiver, change or modification of this Quotation or the Contract and is signed by an authorised representative of ZOLL Medical UK.

2. **F.O.B, DELIVERY AND RISK OF LOSS:** All products FOB Chelmsford, Boston USA

3. **TERMS OF PAYMENT:** Unless otherwise stated in this Quotation, terms of payment are NET thirty (30) days after the date of appearing on ZOLL Medical UK's invoice.

4. **CREDIT APPROVAL:** All shipments and deliveries shall at all times be subject to the approval of credit by ZOLL Medical UK. ZOLL Medical UK may at any time decline to make any shipment or delivery except upon receipt of payment or security, or upon terms regarding credit or security satisfactory to ZOLL Medical UK..

5. **WARRANTY:** (a) ZOLL Medical UK warrants to the Customer that from the date of the installation, or thirty (30) days after the date of shipment from ZOLL Medical UK's facility, whichever first occurs, the equipment (other than accessories and electrodes) will be free from defects in material and workmanship under normal use and service for the period noted on the reverse side. Accessories and electrodes shall be warranted for 90 days from date of shipment. During such period ZOLL Medical UK will, at no charge to the Customer, either repair or replace (at ZOLL Medical UK's sole option) any part of the equipment found by ZOLL Medical UK to be defective in material or workmanship. If ZOLL Medical UK's inspection detects no defects in material or workmanship, ZOLL Medical UK's regular service charges shall apply. (b) ZOLL Medical UK shall not be responsible for any equipment defect, the failure of the equipment to perform any specified function, or any other non-conformance of the equipment, caused by or attributable to, (i) any modification of the equipment by the Customer, unless such modification is made with the prior written approval of ZOLL Medical UK; (ii) the use of the equipment with any associated or complementary equipment, accessory or software not supplied by ZOLL Medical UK; (iii) any misuse of abuse of the equipment; (iv) exposure of the equipment to conditions beyond the environmental, power or operation constraints specified by ZOLL Medical UK, or (v) installation or wiring of the equipment other than in accordance with ZOLL Medical UK's instructions. (c) This warranty does not cover items subject to normal wear and tear and burnout during use, including but not limited to lamps, fuses, batteries, cables and accessories. (d) The foregoing warranty does not apply to software included as part of the equipment (including software embodied in read-only memory, known as "firmware"). (e) The foregoing warranty constitutes the exclusive remedy of the Customer and the exclusive liability of ZOLL Medical UK for any breach of any warranty related to the equipment supplied herein. **THE WARRANTY SET FORTH HEREIN IS EXCLUSIVE AND ZOLL MEDICAL UK EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES WHETHER WRITTEN, ORAL, IMPLIED OR STATUTORY, INCLUDING BUT NOT LIMITED TO ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.**

6. **SOFTWARE LICENCES:** (a) All software (the "Software" which term shall include firmware) included as part of the equipment is licensed to Customer Pursuant to a nonexclusive limited license on the terms hereinafter set forth. (b) Customer may not copy, distribute, modify, translate or adapt the Software, and may not disassemble or reverse compile the software, or seek in any manner to discover, disclose or use any proprietary algorithms, techniques or other confidential information contained therein. (c) All rights in the Software remain the product of ZOLL Medical UK and the Customer shall have no right or interest therein except as expressly provided herein. (d) Customer's right to use the Software may be terminated by ZOLL Medical UK in the event of any failure to comply with the terms of this agreement. (e) Customer may transfer the license conferred hereby only in connection with a transfer of the equipment and may not retain any copies of the Software following such a transfer. (f) ZOLL Medical UK warrants that the read-only memory or other media on which the Software is recorded will be free from defects in materials and workmanship for the period and on the terms set forth in section 6. (g) Customer understands that the Software is a complex and sophisticated software product, and no assurance can be given that operation of the Software will be uninterrupted or error-free, or that the Software will meet Customer's requirements. Except as set forth in section 7(i), **ZOLL MEDICAL UK MAKES NO REPRESENTATIONS OR WARRANTIES WITH RESPECT TO THE SOFTWARE AND IN PARTICULAR DISCLAIMS ANY IMPLIED WARRANTIES OR MERCHANTABILITY OR FITNESS OF A PARTICULAR PURPOSE WITH RESPECT THERETO.** Customer's exclusive remedy for any breach of warranty or defect relating to the Software shall be the repair or replacement of any defective read-only memory or other media so that it correctly reproduces the Software.

7. **DELAYS IN DELIVERY:** ZOLL Medical UK shall not be liable for any delay in the delivery of any part of the equipment if such delay is due to any cause beyond the control of ZOLL Medical UK, including but not limited to acts of God, fires, epidemics, floods, riots, wars, sabotage, labour disputes, government actions inability to obtain materials, components, manufacturing facilities or transportation, or any other cause beyond the control of ZOLL Medical UK. In addition, ZOLL Medical UK shall not be liable for any delays in delivery caused by failure of the Customer to provide any necessary information in a timely manner. In the event of any such delay, the date of shipment or performance herein shall be extended to the period equal to the time lost by reason of such delay. In the event of such delay, ZOLL Medical UK may allocate available equipment among its Customers on any reasonable and equitable basis. The delivery dates set forth in the Quotation are approximate only, and ZOLL Medical UK shall not be liable for, nor shall the Contract be breached by any delivery by ZOLL Medical UK within a reasonable time after such a date.

8. **LIMITATION OF LIABILITY:** In No Event Shall ZOLL Medical UK Be Liable For Indirect, Special, Or Consequential Damages Resulting From ZOLL Medical Corporation's Performance Or Failure To Perform, Pursuant To This Quotation Or The Contract, Or The Furnishing, Performance, Or Use Of Any Equipment Or Software Sold Hereto, Whether Due To A Breach Of Contract, Breach Of Warranty, The Negligence Of ZOLL Medical UK, Or Otherwise.

9. **PATENT INDEMNITY:** ZOLL Medical UK shall, at its own expense defend any suit that may be instituted against the Customer for alleged infringement of any patents or copyrights related to the parts of the equipment or the Software manufactured by ZOLL Medical UK, provided that (i) such alleged infringement consists only in the use of such equipment or the Software by itself and not as a part of or in combination with any other devices or parts (ii) the Customer gives ZOLL Medical UK immediate notice in writing of any such suit and permits ZOLL Medical UK, through counsel of its own choice, to answer the charge of infringement and defend such suit, and (iii) the Customer gives ZOLL Medical UK all requested information, assistance and authority, at ZOLL Medical UK's expense, to enable ZOLL Medical UK to defend such a suit. In the case of a final award of damages for infringement in any such suit, ZOLL Medical UK will pay such award, but shall not be responsible for any settlement made without its written consent.

Section 9 states ZOLL Medical UK's total responsibility and liability, and the Customer's sole remedy for any actual or alleged infringement of any patent by the equipment or the Software, or any part thereof provided herein. In no event shall ZOLL Medical UK be liable for any indirect, special or consequential damages resulting from any such infringement.

10. **CLAIMS FOR SHORTAGE:** Each shipment of equipment shall be promptly examined by the Customer upon receipt thereof. The Customer shall inform ZOLL Medical UK of any shortage in any shipment within ten (10) days of receipt of equipment, if no such shortage is reported within the ten (10) day period, the shipment shall be conclusively deemed to have been complete.

11. **ASSIGNMENT:** This Quotation, and the Contract, may not be assigned by the Customer without the prior written consent of ZOLL Medical UK and any assignment without such consent shall be null and void.

12. **VALIDITY OF QUOTATION:** This Quotation shall be valid and subject to acceptance by the Customer in accordance with the terms of Section 1 hereof for the period set forth on the face hereof. After such a period, the acceptance of this Quotation shall not be binding upon ZOLL Medical UK and shall not create a contract unless such acceptance is acknowledged and accepted by ZOLL Medical UK by a writing signed by an authorised representative of ZOLL Medical UK.

13. **Carriage Charge:** All orders shall be subject to a carriage charge of £9.95 per box within the UK. Deliveries to the Republic of Ireland & Europe are subject to the relevant delivery charges plus export packaging and handling..

14. **Electrode Life :** All electrodes are guaranteed to have a minimum of nine months shelf life from the date of dispatch with the exception of Biphasic electrodes and Paediatric MFE's which are guaranteed to have a minimum of six months shelf life from the date of dispatch.

15. **Ultimate: End User -** The products shown in this quotation must not be exported to any country or destination embargoed, boycotted or subject to any export restrictions by the EU, the UK or USA .

16. Any lease costs shown are for indicative purposes only, and are subject to formal credit and residual investment approval, and any fluctuation in interest rates and are subject to documentation.

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**APPENDIX 3**  
**Distribution Agreement**

between  
ZOLL MEDICAL UK LTD  
And

**Territory**

The United Kingdom

## Appendix 4



### CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

ADOPTED BY THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION

#### I. Preamble: Goal and Scope of AdvaMed Code

The Advanced Medical Technology Association (“AdvaMed”) represents companies that develop, produce, manufacture, and market medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities (“Medical Technologies”) in order to enable patients to live longer and healthier lives (collectively “Companies,” and individually “Company”). AdvaMed is dedicated to the advancement of medical science, the improvement of patient care, and, in particular, the contributions that high quality, innovative Medical Technologies make toward achieving these goals. AdvaMed recognizes the obligation to facilitate ethical interactions between Companies and those individuals or entities involved in the provision of health care services and/or items to patients, which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies’ Medical Technologies in the United States (“Health Care Professionals”).

#### *Medical Technologies*

Medical Technologies are often highly dependent upon “hands on” Health Care Professional interaction from beginning to end—unlike drugs and biologics, which act on the human body by pharmacological, immunological or metabolic means. For example, implantable Medical Technologies are often placed in the human body to replace or strengthen a body part. Surgical Medical Technologies often serve as extensions of a physician’s hands. In other circumstances, Medical Technologies are noninvasive reagents, instrumentation and/or software to aid in the diagnosis, monitoring and treatment decisions made by Health Care Professionals. Some Medical Technologies work synergistically with other technologies, or are paired with other products that deploy devices in the safest and most effective manner. Many Medical Technologies require technical support during and after deployment.

#### *Interactions with Health Care Professionals*

The scope of beneficial interactions between Health Care Professionals and Companies is broad and includes interactions intended to:

- *Promote the Advancement of Medical Technologies.* Developing and improving cutting edge Medical Technologies are collaborative processes between Companies and Health

Care Professionals. Innovation and creativity are essential to the development and evolution of Medical Technologies, which often occur outside a Company's laboratory.

- *Enhance the Safe and Effective Use of Medical Technologies.* The safe and effective use of sophisticated electronic, *in vitro* diagnostic, surgical, or other Medical Technologies often requires Companies to provide Health Care Professionals appropriate instruction, education, training, service and technical support. Regulators often require this type of training as a condition of product approval.
- *Encourage Research and Education.* Companies' support of *bona fide* medical research, education, and enhancement of professional skills improves patient safety and increases access to Medical Technologies.
- *Foster Charitable Donations and Giving.* Companies make monetary and Medical Technology donations for charitable purposes, such as supporting indigent care, as well as patient and public education. This increases access to—as well as the quality of—care and treatment in patient populations that may not otherwise be reached.

### ***The Purpose of the Code of Ethics***

AdvaMed recognizes that Health Care Professionals' first duty is to act in the best interests of patients. Companies can serve the interests of patients through beneficial collaborations with Health Care Professionals. To ensure that these collaborative relationships meet high ethical standards, they must be conducted with appropriate transparency and in compliance with applicable laws, regulations and government guidance. AdvaMed recognizes the obligation to facilitate ethical interactions between Companies and Health Care Professionals in order to ensure that medical decisions are based on the best interests of the patient. The ethical principles that govern these interactions are the subject of this Code of Ethics.<sup>1</sup> To that end, AdvaMed restates and amends its Code of Ethics and Frequently Asked Questions (collectively "Code of Ethics" or "Code"), effective July 1, 2009.

## **II. Code of Ethics Compliance**

All Companies are strongly encouraged to adopt this Code and to implement an effective compliance program – one which includes policies and procedures that foster compliance with the Code with respect to their interactions with Health Care Professionals related to Medical Technologies. A Company that adopts the Code is strongly encouraged to submit to AdvaMed an annual certification that the Company has adopted the Code and has implemented an effective compliance program. This certification must be signed by the Company's Chief Executive Officer and Chief Compliance Officer or individuals with equivalent responsibilities within the certifying Company. AdvaMed will publish on its website a list of those Companies that have submitted the annual certification.

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<sup>1</sup> The principles of the Code are derived from a variety of authorities, including the federal Anti-kickback Statute. Throughout the Code, we refer to the concept of an "unlawful inducement" to reflect Anti-kickback Statute prohibitions.

Companies that are AdvaMed members shall, and Companies that are non-members may, supply contact information for the Company's Compliance Department or an anonymous hotline to facilitate reporting of possible violations of the Code. AdvaMed will publish on its website the contact information supplied by each such Company.

Companies are strongly encouraged to follow the seven elements of an effective compliance program, appropriately tailored for each Company, namely: (1) implementing written policies and procedures; (2) designating a compliance officer and compliance committee; (3) conducting effective training and education; (4) developing effective lines of communication (including an anonymous reporting function); (5) conducting internal monitoring and auditing; (6) enforcing standards through well-publicized disciplinary guidelines; and (7) responding promptly to detected problems and undertaking corrective action.

*Note:* This Amended and Restated Code supersedes and replaces all previous AdvaMed Codes of Ethics. Companies adopting this Code shall communicate the principles of this Code to their employees, agents, dealers and distributors with the expectation that they will adhere to this Code. All Companies have an independent obligation to ensure that their interactions with Health Care Professionals comply with all applicable laws and regulations. The information provided by the Department of Health and Human Services, Office of Inspector General ("OIG"), as well as applicable laws or regulations, may provide more specificity than this Code, and Companies should address any additional questions to their own attorneys. This Code of Ethics is intended to facilitate ethical behavior, and is not intended to be, nor should it be, construed as legal advice. The Code is not intended to define or create legal rights, standards or obligations. Any interpretation of the provisions of this Code, as well as Companies' interactions with Health Care Professionals not specifically addressed in this Code, should be made in light of the following principle: Companies shall encourage ethical business practices and socially responsible industry conduct and shall not engage in any unlawful inducement.

### **III. Company-Conducted Product Training and Education**

Companies have a responsibility to make training and education on their products and Medical Technologies available to Health Care Professionals. Companies may also provide education to Health Care Professionals. "Training" means training on the safe and effective use of Medical Technologies. "Education" means communicating information directly concerning or associated with the use of Companies' Medical Technologies, *e.g.*, information about disease states and the benefits of Medical Technologies to certain patient populations. Training and Education programs include, but are not limited to, "hands on" training sessions, cadaver workshops, lectures and presentations, and grand rounds. In fact, the U.S. Food and Drug Administration mandates training and education to facilitate the safe and effective use of certain Medical Technologies. Companies should adhere to the following principles when conducting training and education programs concerning Medical Technologies for Health Care Professionals:

- Programs and events should be conducted in settings that are conducive to the effective transmission of information. These may include clinical, educational, conference, or other settings, such as hotels or other commercially available meeting facilities. In some cases, it may be appropriate for a Company representative to provide training and education at the Health Care Professional's location.
- Programs providing "hands on" training on Medical Technologies should be held at training facilities, medical institutions, laboratories, or other appropriate facilities. The training staff used by the Company should have the proper qualifications and expertise to conduct such training. Training staff may include qualified field sales employees who have the technical expertise necessary to perform the training.
- Companies may provide Health Care Professional attendees with modest meals and refreshments in connection with these programs. Any such meals and refreshments should be modest in value and subordinate in time and focus to the training and/or educational purpose of the meeting.
- Where there are objective reasons to support the need for out-of-town travel to efficiently deliver Training and Education on Medical Technologies, Companies may pay for reasonable travel and modest lodging costs of the attending Health Care Professionals. It is not appropriate for Companies to pay for the meals, refreshments, travel, or other expenses for guests of Health Care Professionals or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

#### **IV. Supporting Third-Party Educational Conferences**

*Bona fide* independent, educational, scientific, and policymaking conferences promote scientific knowledge, medical advancement and the delivery of effective health care. These typically include conferences sponsored by national, regional, or specialty medical associations and conferences sponsored by accredited continuing medical education providers. Companies may support these conferences in various ways:

- *Conference Grants.* Companies may provide a grant to the conference sponsor to reduce conference costs. They may also provide grants to a training institution or the conference sponsor to allow attendance by medical students, residents, fellows, and others who are Health Care Professionals in training. Companies may provide grants when: (1) the gathering is primarily dedicated to promoting objective scientific and educational activities and discourse; and (2) the training institution or the conference sponsor selects the attending Health Care Professionals who are in training. Such grants should be paid only to organizations with a genuine educational function and may be used to reimburse only the legitimate expenses for *bona fide* educational activities. Such grants also should be consistent with applicable standards established by the conference sponsor and any body accrediting the educational activity. The conference sponsor should independently control and be responsible for the selection of program content, faculty, educational methods, and materials.

- *Conference Meals and Refreshments.* Companies may provide funding to the conference sponsor to support the provision of meals and refreshments to conference attendees. Also, Companies themselves may provide meals and refreshments for Health Care Professional attendees if such meals and refreshments are provided: (1) to all Health Care Professional attendees (with the limited exception noted below), and (2) in a manner that is consistent with applicable standards established by the conference sponsor and the body accrediting the educational activity. Meals and refreshments may be provided to fewer than all Health Care Professional attendees if the Company providing such meals and refreshments satisfies all other principles related to meals set forth in Section VIII. Any meals and refreshments should be modest in value, subordinate in time and focus to the purpose of the conference, and clearly separate from the continuing medical education portion of the conference.
- *Faculty Expenses.* Companies may make grants to conference sponsors for reasonable honoraria, travel, lodging, and modest meals for Health Care Professionals who are *bona fide* conference faculty members.
- *Advertisements and Demonstration.* Companies may purchase advertisements and lease booth space for Company displays at conferences.

#### **V. Sales, Promotional, and Other Business Meetings**

Companies may conduct sales, promotional, and other business meetings with Health Care Professionals to discuss, for example, Medical Technology features, sales terms, or contracts. Often, these meetings occur close to the Health Care Professional's place of business. It is appropriate to pay for reasonable travel costs of attendees when necessary (*e.g.*, for plant tours or demonstrations of non-portable equipment) and/or to provide occasional modest meals and refreshments in connection with such meetings. However, it is not appropriate to pay for meals, refreshments, travel, or lodging of guests of Health Care Professionals or any other person who does not have a *bona fide* professional interest in the information being shared at the meeting. See Section VIII for additional principles related to the provision of meals associated with Health Care Professional business interactions.

#### **VI. Consulting Arrangements with Health Care Professionals**

Companies engage Health Care Professionals to provide a wide-range of valuable, *bona fide* consulting services through various types of arrangements, such as contracts for research, product development, development and/or transfer of intellectual property, marketing, participation on advisory boards, presentations at Company-sponsored training and other services. Companies may pay consultants fair market value compensation for performing these types of services, provided that they are intended to fulfill a legitimate business need and do not constitute an unlawful inducement. Companies should comply with the following standards in connection with consulting arrangements with Health Care Professionals:

- Consulting agreements should be written and describe all services to be provided. When a Company contracts with a consultant to conduct clinical research services, there should also be a written research protocol.

- Consulting arrangements should be entered into only where a legitimate need for the services is identified in advance and documented.
- Selection of a consultant should be made on the basis of the consultant's qualifications and expertise to meet the defined need.
- Compensation paid to a consultant should be consistent with fair market value in an arm's length transaction for the services provided and should not be based on the volume or value of the consultant's past, present or anticipated business.
- A Company may pay for documented, reasonable and actual expenses incurred by a consultant that are necessary to carry out the consulting arrangement, such as costs for travel, modest meals, and lodging.
- The venue and circumstances for Company meetings with consultants should be appropriate to the subject matter of the consultation. These meetings should be conducted in clinical, educational, conference, or other settings, including hotel or other commercially available meeting facilities, conducive to the effective exchange of information.
- Company-sponsored meals and refreshments provided in conjunction with a consultant meeting should be modest in value and should be subordinate in time and focus to the primary purpose of the meeting. Companies should not provide recreation or entertainment in conjunction with these meetings.
- A Company's sales personnel may provide input about the suitability of a proposed consultant, but sales personnel should not control or unduly influence the decision to engage a particular Health Care Professional as a consultant. Companies should consider implementing appropriate procedures to monitor compliance with this section.

***Provisions on Payment of Royalties.*** Arrangements involving the payment of royalties to a Health Care Professional should meet the contractual standards set forth above. Health Care Professionals, acting individually or as part of a group in which they are an active participant, often make valuable contributions that improve products or Medical Technologies. They may develop intellectual property, for example, patents, trade secrets, or know-how, under a product or technology development or intellectual property licensing agreement. A Company should enter into a royalty arrangement with a Health Care Professional only where the Health Care Professional is expected to make or has made a novel, significant, or innovative contribution to, for example, the development of a product, technology, process, or method. A significant contribution by an individual or group, if it is the basis for compensation, should be appropriately documented.

The calculation of royalties payable to a Health Care Professional in exchange for Intellectual Property should be based on factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence. For example, royalties paid in exchange for Intellectual Property should not be conditioned on: (1) a requirement that the Health Care Professional purchase, order or recommend any product or medical technology of the

Company or any product or technology produced as a result of the development project; or (2) a requirement to market the product or medical technology upon commercialization. (Companies may, however, elect to enter into separate consulting agreements with Health Care Professionals for marketing services if such services meet the requirements set forth in this Section VI above.) Companies are strongly encouraged to consider whether it is appropriate and practicable to exclude from the calculation of royalties the number of units purchased, used, or ordered by the Health Care Professional and/or members of the Health Care Professional's practice.

## **VII. Prohibition on Entertainment and Recreation**

Company interactions with Health Care Professionals should be professional in nature and should facilitate the exchange of medical or scientific information that will benefit patient care. To ensure the appropriate focus on an educational and/or informational exchange and to avoid the appearance of impropriety, a Company should not provide or pay for any entertainment or recreational event or activity for any non-employee Health Care Professional. Such activities include, for example, theater, sporting events, golf, skiing, hunting, sporting equipment, and leisure or vacation trips. Such entertainment or recreational events, activities, or items should not be provided, regardless of: (1) their value; (2) whether the Company engages the Health Care Professional as a speaker or consultant; or (3) whether the entertainment or recreation is secondary to an educational purpose.

## **VIII. Modest Meals Associated with Health Care Professional Business Interactions**

A Company's business interactions with Health Care Professionals may involve the presentation of scientific, educational, or business information and include, but are not limited to, the different types of interactions described in Sections III through VI of this Code of Ethics. Such exchanges may be productive and efficient when conducted in conjunction with meals. Accordingly, modest meals may be provided as an occasional business courtesy consistent with the limitations in this section.

**Purpose.** The meal should be incidental to the *bona fide* presentation of scientific, educational, or business information and provided in a manner conducive to the presentation of such information. The meal should not be part of an entertainment or recreational event.

**Setting and Location.** Meals should be in a setting that is conducive to *bona fide* scientific, educational, or business discussions. Meals may occur at the Health Care Professional's place of business. However, in some cases the place of business may be a patient care setting that is not available for, or conducive to, such scientific, educational, or business discussions. In other cases, it may be impractical or inappropriate to provide meals at the Health Care Professional's place of business, for example, (1) where the Medical Technology cannot easily be transported to the Health Care Professional's location, (2) when it is necessary to discuss confidential product development or improvement information, or (3) where a private space cannot be obtained on-site.

**Participants.** A Company may provide a meal only to Health Care Professionals who actually attend the meeting. A Company may not provide a meal for an entire office staff where



everyone does not attend the meeting. A Company also may not provide a meal where its representative is not present (such as a “dine & dash” program). A Company may not pay for meals for guests of Health Care Professionals or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

**Other principles.** Depending on the type of business interaction or meeting, additional principles may apply, as described in other sections of this Code of Ethics. Specifically:

- Section III: Company-Conducted Product Training and Education.
- Section IV: Supporting Third-Party Educational Conferences.
- Section V: Sales, Promotional, and Other Business Meetings.
- Section VI: Consulting Arrangements with Health Care Professionals.

#### **IX. Educational Items; Prohibition on Gifts**

A Company occasionally may provide items to Health Care Professionals that benefit patients or serve a genuine educational function for Health Care Professionals. Other than medical textbooks or anatomical models used for educational purposes, any such item should have a fair market value of less than \$100. A Company may not provide items that are capable of use by the Health Care Professional (or his or her family members, office staff or friends) for non-educational or non-patient-related purposes, for example, a DVD player or MP3 player/I-Pod.

A Company may not give Health Care Professionals any type of non-educational branded promotional items, even if the item is of minimal value and related to the Health Care Professional’s work or for the benefit of patients. Examples of non-educational branded promotional items include pens, notepads, mugs, and other items that have a Company’s name, logo, or the name or logo of one of its Medical Technologies. Companies also may not provide Health Care Professionals with gifts such as cookies, wine, flowers, chocolates, gift baskets, holiday gifts or cash or cash equivalents.

This section is not intended to address the legitimate practice of providing products for evaluation and demonstration purposes, which is addressed in Section XII.

#### **X. Provision of Coverage, Reimbursement and Health Economics Information**

As Medical Technologies have become increasingly complex, so have payor coverage and reimbursement policies. Patient access to necessary Medical Technology may be dependent on Health Care Professionals and/or patients having timely and complete coverage, reimbursement, and health economic information. Consequently, a Company may provide such information regarding its Medical Technologies if it is accurate and objective. A Company also may collaborate with Health Care Professionals, patients and organizations representing their interests, to achieve government and commercial payor coverage decisions, guidelines, policies, and adequate reimbursement levels that allow patients to access its Medical Technologies.

Permissible activities involving the provision of coverage, reimbursement and health economic information may include, but are not limited to:

- Identifying the clinical value of the Company's Medical Technologies and the services and procedures in which they are used when providing coverage, reimbursement and health economics information and materials to Health Care Professionals, professional organizations, patient organizations, and payors.
- Collaborating with Health Care Professionals, their professional organizations, and patient groups to conduct joint advocacy on coverage, reimbursement and health economics issues; supporting Health Care Professionals and their professional organizations in developing materials and otherwise providing direct or indirect input into payor coverage and reimbursement policies.
- Promoting accurate Medicare and other payor claims by providing accurate and objective information and materials to Health Care Professionals regarding the Company's Medical Technologies, including identifying coverage, codes and billing options that may apply to those Medical Technologies or the services and procedures in which they are used.
- Providing accurate and objective information about the economically efficient use of the Company's Medical Technologies, including where and how they can be used within the continuum of care.
- Providing information related to the Company's Medical Technologies regarding available reimbursement revenues and associated costs.
- Providing information relating to changes in coverage or reimbursement amounts, methodologies and policies and the effects of such changes in order to facilitate a Health Care Professional's decision to buy or use the Company's Medical Technologies.
- Providing accurate and objective information designed to offer technical or other support intended to aid in the appropriate and efficient use or installation of the Company's Medical Technologies.
- Facilitating patient access to the Company's Medical Technologies by providing Health Care Professionals with assistance in obtaining patient coverage decisions from payors. This assistance may include providing information and/or training on payor policies and procedures for obtaining prior authorization, and providing sample letters and information on medical necessity and appeals of denied claims. In addition, at the request of a Health Care Professional to facilitate patient access to the Company's Medical Technology, and subject to appropriate privacy safeguards, the Company may assist the patient by facilitating the preparation and submission of requests for coverage determinations, prior authorizations, pre-certifications and appeals of denied claims, relating to a Company's own Medical Technology; however such assistance should not be provided as an unlawful inducement.

A Company may not interfere with a Health Care Professional's independent clinical decision-

making or provide coverage, reimbursement and health economics support as an unlawful inducement. For example, a Company should not provide free services that eliminate an overhead or other expense that a Health Care Professional would otherwise of business prudence or necessity have incurred as part of its business operations if doing so would amount to an unlawful inducement. Further, a Company should not suggest mechanisms for billing for services that are not medically necessary, or for engaging in fraudulent practices to achieve inappropriate payment.

## **XI. Research and Educational Grants and Charitable Donations**

A Company may provide research and educational grants and charitable donations. However, a Company may not provide such grants or donations as an unlawful inducement. Therefore, a Company should: (a) adopt objective criteria for providing such grants and donations that do not take into account the volume or value of purchases made by, or anticipated from, the recipient; (b) implement appropriate procedures to ensure that such grants and donations are not used as an unlawful inducement; and (c) ensure that all such grants and donations are appropriately documented. A Company's sales personnel may provide input about the suitability of a proposed grant or charitable donation recipient or program, but sales personnel should not control or unduly influence the decision of whether a particular Health Care Professional or institution will receive a grant or donation or the amount of such grant or donation. Companies should consider implementing procedures to monitor compliance with this section.

### **a. Research Grants**

Research provides valuable scientific and clinical information, improves clinical care, leads to promising new treatments, promotes improved delivery of health care, and otherwise benefits patients. In furtherance of these objectives, a Company may provide research grants to support independent medical research with scientific merit. Such activities should have well-defined objectives and milestones and may not be linked directly or indirectly to the purchase of Medical Technologies.

Company-initiated or directed research involving a Company's Medical Technologies (such as clinical study agreements) is addressed separately in Section VI.

### **b. Educational Grants**

Educational grants may be provided for legitimate purposes, including, but not limited to, the examples below. As noted in Section IV, a Company may make educational grants to conference sponsors or training institutions. A Company may not make educational grants to individual Health Care Professionals.

- *Advancement of Medical Education.* A Company may make grants to support the genuine medical education of medical students, residents, and fellows participating in fellowship programs that are charitable or have an academic affiliation, or other medical personnel. (For additional considerations regarding educational grants, see Section IV.)
- *Public Education.* A Company may make grants for the purpose of supporting education

of patients or the public about important health care topics.

### c. Charitable Donations

A Company may make monetary or Medical Technology donations for charitable purposes, such as supporting indigent care, patient education, public education, or the sponsorship of events where the proceeds are intended for charitable purposes. Donations should be motivated by *bona fide* charitable purposes and should be made only to *bona fide* charitable organizations or, in rare instances, to individuals engaged in genuine charitable activities for the support of a *bona fide* charitable mission. Companies should exercise diligence to ensure the *bona fide* nature of the charitable organization or charitable mission.

## XII. Evaluation and Demonstration Products

Providing products to Health Care Professionals at no charge for evaluation or demonstration purposes can benefit patients in many ways. These benefits include improving patient care, facilitating the safe and effective use of products, improving patient awareness, and educating Health Care Professionals regarding the use of products. Under certain circumstances described below, a Company may provide reasonable quantities of products to Health Care Professionals at no charge for evaluation and demonstration purposes.

This section is limited to providing evaluation and demonstration products only and is not intended to address any other arrangement.

Company products that may be provided to Health Care Professionals for evaluation include single use (e.g., consumable or disposable products) and multiple use products (sometimes referred to as “capital equipment”). These products may be provided at no charge to allow Health Care Professionals to assess the appropriate use and functionality of the product and determine whether and when to use, order, purchase, or recommend the product in the future. Company products provided for evaluation are typically expected to be used in patient care.

**Single Use/Consumables/Disposables.** The number of single use products provided at no charge should not exceed the amount reasonably necessary for the adequate evaluation of the products under the circumstances.

**Multiple Use/Capital.** Multiple use products provided without transfer of title for evaluation purposes should be furnished only for a period of time that is reasonable under the circumstances to allow an adequate evaluation. The terms of an evaluation of such multiple use products should be set in advance in writing. Companies should retain title to such multiple use products during the evaluation period and should have a process in place for promptly removing such multiple use products from the Health Care Professional’s location at the conclusion of the evaluation period unless the Health Care Professional purchases or leases the products.

**Demonstration.** Company demonstration products are typically unsterilized single use products or mock-ups of such products that are used for Health Care Professional and patient awareness, education, and training. For example, a Health Care Professional may use a demonstration product to show a patient the type of device that will be implanted in the patient. Demonstration

products typically are not intended to be used in patient care. Demonstration products also are typically identified as not intended for patient use by use of such designations as “Sample,” “Not for Human Use,” or other suitable designation on the product, the product packaging, and/or documentation that accompanies the product.

A Company should provide Health Care Professionals with documentation and disclosure regarding the no-charge status of evaluation and demonstration products.

## **Appendix 5**

Non-exclusive list of Relevant Codes specific to the Territory  
(Note – these are additional to the other provisions referred to in clause 11)

Public Bodies Corrupt Practices Act 1889;  
the Prevention of Corruption Act 1906;  
the Prevention of Corruption Act 1916;  
the Bribery Act 2010;  
the Standards of Business Conduct for NHS Staff dated January 1993 and published  
by the NHS Management Executive as HSG(93)5  
'The Commercial Sponsorship – Ethical Standards for the NHS' (dated November  
2000)