[Certain portions of this exhibit have been omitted based on a request for  
confidential treatment. An unredacted copy of this exhibit has been filed with  
the Securities and Exchange Commission.]  
  
  
 PORTAL MANUFACTURING AGREEMENT  
  
 By and between  
  
 DIAMETRICS MEDICAL, INC.  
  
 0000 XXXXXX XXXX  
  
 XX. XXXX, XX 00000, XXX  
  
 (hereinafter referred to as "DIAMETRICS")  
  
 and  
  
 PHILIPS MEDICAL SYSTEMS  
  
 (hereinafter referred to as "PHILIPS")  
  
 on the supply of Portal cartridge reader M3561A (M3561-60001);  
 exchange repair unit M3561-68000  
 plus accessories edge connector cleaning kit M3672A (DMI 450000);  
 temp card M3565A (DMI 467900); edge connector M3561-66403  
 (DMI 516300); and DeviceSet with DeviceCom on a CD M3564A (DMI464218)  
  
  
  
  
  
  
 PORTAL MANUFACTURING AGREEMENT  
  
 THIS PORTAL MANUFACTURING AGREEMENT (the "Manufacturing Agreement"),  
made as of this 10th day of April, 2003 (the "Effective Date"), by and among  
Diametrics Medical Incorporated, a Minnesota corporation having its principal  
place of business at 0000 Xxxxxx Xxxx, Xx. Xxxx, Xxxxxxxxx 00000 ("Diametrics")  
and Philips Medical Systems North America Company, a division of Philips  
Electronics North America Corporation, a Delaware corporation with offices at  
0000 Xxxxxxxxx Xxxx, Xxxxxxx, Xxxxxxxxxxxxx ("Philips"). Diametrics and Philips  
shall each be a "Party."  
  
 RECITALS  
  
 A. Philips and Diametrics previously entered into a distribution  
agreement dated June 6, 1999 (the "Distribution Agreement") the term of which  
expired on October 31, 2002, and the parties are entering into an amendment to  
the Distribution Agreement, dated as of the date of this Manufacturing Agreement  
(the "Amendment") in order to clarify some of the surviving rights and  
obligations under the Distribution Agreement. All capitalized terms shall have  
the meanings set forth in this Manufacturing Agreement.  
  
 B. Whereas as governed by the Distribution Agreement, Philips and  
Diametrics have jointly developed the M3650A Blood Analysis Portal System  
consisting of the M3561A Portal Reader and the M3562A Interface Module.  
  
 C. Under the terms of the Distribution Agreement, Philips has surviving  
rights to distribute the Portal Measurement Module as a part of the Portal  
Product in a specific field of use until October 31, 2004, and Diametrics will  
manufacture the Portal Measurement Products in accordance with the Amendment and  
this Manufacturing Agreement and provide Portal Measurement Products to Philips  
to allow for the completing of the postponement step by Philips of the Portal  
Products.  
  
 C. The Parties desire to enter into this Manufacturing Agreement for  
the purposes of Diametrics' manufacture of the Portal Measurement Products  
solely for Philips on the terms of this Manufacturing Agreement.  
  
 NOW THEREFORE, in consideration of the foregoing premises and of the  
mutual covenants and subject to the terms and conditions set forth herein below,  
Philips and Diametrics agree as follows:  
  
1. Definitions  
  
 1.1 DeviceSet/DeviceCom Software. Means DeviceSet software with DeviceCom  
 software on a CD M3564A (DMI 464218), as more particularly described  
 in the Specifications.  
  
 1.2 Portal Measurement Accessories. Means the following (a) accessories  
 edge connector cleaning kit M3672A (DMI 450000); (b) temp card M3565A  
 (DMI 467900); (c) edge connector M3561-66403 (DMI 516300), and (d)  
 M3561-40003  
  
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 edge connector cover (DMI 466400), as more particularly described in  
 the Specifications.  
  
 1.3 Portal Measurement Module. Means the Portal cartridge reader M3561A  
 (M3561-60001), as more particularly described in the Specifications.  
  
 1.4 Portal Measurement Products. Means the Portal Measurement Module, the  
 exchange repair unit M3561-68000, Portal Measurement Accessories and  
 DeviceSet/DeviceCom Software, collectively.  
  
 1.5 Portal Products. Has the meaning set forth in Section 1.14 of the  
 Amendment.  
  
 1.6 Required Quality Data. Means the data and information described on  
 Schedule 1.  
  
 1.7 Specifications. Means the specifications set forth in Schedule 2.  
  
 1.8 Term. Means the period from the Effective Date through October 31,  
 2004.  
  
 1.9 Schedule References. All Schedule references shall mean the Schedules  
 to this Amendment.  
  
2. EFFECT OF AGREEMENT  
  
 2.1 Portal Manufacturing Agreement. This Manufacturing Agreement  
 stipulates the additional terms and conditions for the supply of  
 Portal Measurement Products to Philips by Diametrics, including any  
 Portal Measurement Products supplied by Diametrics prior to or during  
 the Term hereof. The Portal Measurement Products will be manufactured  
 and supported by Diametrics as provided herein and the Amendment.  
  
 2.2 Supplementary Agreement. The Parties are executing this Manufacturing  
 Agreement as a supplement to the Amendment in order to provide for  
 certain additional terms and conditions relating to the manufacture of  
 the Portal Measurement Products. This Manufacturing Agreement does not  
 supercede the Amendment, and the terms of the Amendment shall apply to  
 the Portal Measurement Products, except as expressly set forth herein.  
  
3. EXAMINATION AND DELIVERY OF THE DIAMETRICS PRODUCTION UNITS PRIOR TO  
 SHIPMENT TO PHILIPS.  
  
 3.1 Supplier Evaluation. Diametrics shall manufacture the Portal  
 Measurement Products with material purchased directly by Diametrics. A  
 list of suppliers and contacts have been provided by Philips to  
 Diametrics. Philips agrees to provide initially the "Supplier  
 Evaluation". Diametrics' and Philips' engineering contacts (listed on  
 Schedule 5) will jointly agree as to which supplied components of the  
 Portal Measurement Module are required to be periodically audited by  
 the Diametrics quality personnel.  
  
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 3.2 Certificate of Compliance. Each serialized Portal Measurement Module  
 will be provided with a completed Diametrics "Certificate of  
 Compliance" certifying that said product was inspected and tested per  
 controlled manufacturing procedures.  
  
 3.3 Production Units. Diametrics shall produce units of Portal Measurement  
 Modules and other Portal Measurement Products in accordance with the  
 terms and provisions hereof. The scope of delivery and supply shall be  
 as set forth in this Manufacturing Agreement and the Amendment.  
  
 3.4 Audit by Philips. Philips may periodically audit via a functional test  
 a sample of the delivered Portal Measurement Module. Should Philips  
 detect deviations from the Specifications or defects during the course  
 of the functional check of the full production Portal Measurement  
 Modules, Philips shall inform Diametrics thereof forthwith in writing  
 via an SAR ( Supplier Action Request) per the Supplier Action Request  
 Process Q2920-00224. In this event, Diametrics shall provide Philips  
 with repaired or newly manufactured units of Portal Measurement  
 Modules which are free of the defect(s) in question and shall provide  
 a written corrective action plan within a reasonable period of time to  
 be defined and agreed to by the Parties. Diametrics shall ensure that  
 defects are remedied and rectified by certified employees. Subject to  
 mutual agreement between the Parties, such rectification of defects  
 may be carried out by Philips.  
  
 3.5 Functional Checks after Delivery. Following delivery of the repaired /  
 newly manufactured units, Philips shall conduct another functional  
 check in accordance with Section 3.4 above. If deviations from the  
 Specifications or defects are still detected in the repaired/newly  
 manufactured Portal Measurement Modules and these are not remedied and  
 rectified within mutually agreed upon date negotiated within the SAR  
 process, subject to mutual agreement of the Parties, such  
 rectification of defects may be carried out by Philips or a third  
 party named by Diametrics and agreed by Philips prior to the  
 implementation at Diametrics expense.  
  
 3.6 Ship to Stock. The quality of the Portal Measurement Modules will  
 allow ship-to-stock, without need of incoming inspection/test. Philips  
 may periodically audit via a functional test a sample of the delivered  
 Portal Measurement Module with a goal of acceptable failure rate of 1  
 per 100 units.  
  
4. SCOPE OF DELIVERY.  
  
 4.1 Forecasting and Ordering. Philips shall issue to Diametrics a monthly  
 written, rolling, non-binding six (6) month forecast of its purchase  
 of Portal Measurement Products. Such forecasts shall be updated  
 monthly. Philips shall issue binding written purchase orders for  
 Portal Measurement Products at least sixty (60) days prior to the  
 proposed shipping date for such items. All purchase orders in excess  
 of Philips' forecast shall be subject to written acceptance by  
 Diametrics. Diametrics will use reasonable efforts to supply such  
 items in a timely fashion,  
  
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 subject to Diametrics' reasonable production capabilities and provided  
 that such purchase orders are consistent with Philips' forecasts.  
  
 4.2 Fluctuations in Orders. The parties shall address purchasing of  
 components and materials as provided in Section 4.1(c) of the  
 Amendment. In addition, Diametrics will diligently monitor its supply  
 chain and its production processes and will promptly inform Philips of  
 any anticipated interruption or inability to supply Portal Measurement  
 Products to Philips to meet its forecasts or its firm, binding  
 purchase orders, in order to permit Philips to assess the  
 manufacturing situation, to inform its sales and planning personnel to  
 attempt to adjust for such shortfall, and to advise and assist  
 Diametrics, at Diametrics' expense in its efforts to minimize or avert  
 such interruption in or inability to supply Portal Measurement  
 Products.  
  
5. DELIVERY.  
  
 5.1 Purchase Orders for Portal Measurement Products. Philips shall be  
 entitled to use its then current standard purchase order for its  
 purchases hereunder. In the event of a conflict between the terms of  
 any such purchase order and the terms of this Manufacturing Agreement,  
 the terms of this Manufacturing Agreement shall take precedence.  
 Additional terms included in the purchase order that are not terms of  
 this Manufacturing Agreement will be subject to prior mutual written  
 agreement.  
  
 5.2 Terms for Delivery. All deliveries of Portal Measurement Products and  
 Consumables shall be made by Diametrics F.O.B. Diametrics U.S. or  
 European facility. Title and risk of loss shall pass to Philips at the  
 time of tender at Diametrics' facility to the carrier designated by  
 Philips. Upon delivery to Philips' designated carrier, Philips will  
 assume title and risk of loss, and will be responsible for  
 transportation, and, if applicable, export of such products from the  
 country of manufacture and shall be entitled to any duty drawback for  
 which the products qualify. Diametrics shall provide Philips, upon  
 Philips' reasonable request and at Philips' expense, reasonable  
 substantiation and assistance with respect to such duty drawbacks. The  
 pricing for products excludes, and Philips shall pay, all shipping,  
 handling and insurance costs for and other costs of transporting such  
 products after delivery to the F.O.B. point.  
  
 5.3 Diametrics Supply Obligation. Diametrics shall manufacture the Portal  
 Measurement Products in accordance with the applicable specifications  
 and in accordance with the FDA, EU and all applicable regulations.  
  
6. PRICES.  
  
 6.1 Prices. Portal Measurement Products shall be supplied at the prices  
 set forth in Schedule 4. All prices are F.O.B. Diametrics  
 manufacturing facility.  
  
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 6.2 Price Changes. Prices may be changed upon ninety (90) days written  
 notice by Diametrics. Any changes will not impact orders received  
 prior to the date of such change.  
  
 6.3 Terms of Payment. All payments for Portal Measurement Products shall  
 be due and payable within thirty-five (35) days of the date of the  
 applicable invoice. Philips shall make all payments in immediately  
 available funds to the location and in the manner reasonably  
 designated by Diametrics from time to time. A late fee shall be paid  
 by Philips on any amount not received by Diametrics when due at a rate  
 of 1.5% per month on all unpaid amounts, or the maximum rate permitted  
 by law, whichever is less. As between the Parties, Philips shall be  
 responsible for all taxes relating to the Portal Measurement Products  
 so purchased (except for taxes on Diametrics' net income).  
  
7. INVOICE ADDRESS.  
  
 All of Diametrics' invoices are the addressed to:  
  
 Philips Medizin Systeme Boeblingen Gmbh  
 Financial Service Center  
 Xxxxxxxx 0000  
 00000 Xxxxxxxxxx/ Xxxxxxx  
  
8. CONTACT PERSONS. Diametrics and Philips shall each designate a Contact  
 Person who will meet (by phone or in person) as required to discuss and  
 monitor any manufacturing and manufacturing capacity issues for the Portal  
 Measurement Products. Both Parties shall appoint additional contact persons  
 in Schedule 5 to facilitate communication regarding specific aspects of the  
 manufacture and supply of the Portal Measurement Products hereunder.  
  
9. TERM AND TERMINATION OF THIS MANUFACTURING AGREEMENT.  
  
 9.1 Term. This Manufacturing Agreement shall become effective on the  
 Effective Date and shall terminate on October 31, 2004, unless  
 terminated as provided herein.  
  
 9.2 Termination for Material Breach. Either party may terminate this  
 Manufacturing Agreement if the other party materially breaches this  
 Manufacturing Agreement and fails to remedy such breach within ninety  
 (90) days written notice from the non-breaching party. Material  
 breaches shall include failure by Diametrics to meet the agreed  
 quality standards for the Portal Measurement Products as set forth in  
 Schedule 2.  
  
 9.3 Effect of Termination. No termination or expiration of this  
 Manufacturing Agreement shall affect or discharge any obligations,  
 rights, disclaimers, conditions or limitations of either Party which  
 arose prior to the effective date of  
  
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 such termination. In addition, Articles 15 (Confidentiality) and 21  
 (Miscellaneous) and any Sections necessary to give effect to this  
 Article 9 shall survive any termination or expiration of this  
 Manufacturing Agreement.  
  
10. TECHNICAL ALTERATION. Diametrics agrees and undertakes to effect technical  
 alterations (i.e., any required technical changes due to third party  
 supplier changes, such as part obsolescence, revision changes and the like)  
 to the Portal Measurement Modules only after written consent of Philips.  
  
11. Product Change Notification. No process changes, design changes,  
 geographical relocation of manufacturing processes, or process step  
 discontinuances affecting the electrical performance (whether specified or  
 not), the mechanical form or fit, the environmental compatibility or  
 material chemical characteristics, or the life reliability of Portal  
 Measurement Products, but excluding any changes that do not affect the fit,  
 form or function of the Portal Measurement Products (hereinafter  
 collectively called "Changes") shall be made or incorporated in Portal  
 Measurement Products without following the change notification process  
 established herein. Diametrics shall give Philips written notice of any  
 proposed change via the established Philips/Diametrics change order process  
 and provide evaluation samples and other appropriate information as  
 specified by Philips. For planned/scheduled changes that require  
 re-qualification by Philips, Diametrics notice must be received by Philips  
 at least three (3) months prior to the first proposed shipment of any such  
 Products. For changes not requiring re-qualification by Philips, Diametrics  
 notice must be received by Philips at least one (1) month prior to the  
 first proposed shipment unless mutually agreed by the Parties. The Supplier  
 Change Notification Agreement process Q2920-00094 will be followed. All  
 product changes will be reflected in the 10 digit serial number by an  
 appropriate change of the year (digit 3) and/or week of the change (digit  
 4-5) as appropriate.  
  
12. REPLACEMENT REQUIREMENTS/EXCHANGE PRODUCTS. Diametrics guarantees to  
 Philips that replacement and or exchange Portal Measurement Modules will be  
 supplied for a further seven (7) years following delivery of the last  
 series/batch. After expiration of this seven (7) year period, Diametrics  
 shall make available replacements (backward compatible or equivalent) in  
 accordance with the respective technical possibilities or give Philips the  
 possibility of placing a final order of a reasonable quantity, thus  
 guaranteeing Philips a supply up until the end of the service period. The  
 prices, terms and conditions as well as the technical feasibility of these  
 two cases will form the subject of a separate agreement at the time of  
 delivery of the last series/batch.  
  
13. REPAIRED / EXCHANGED PRODUCTS.  
  
 Diametrics will provide a test and repair service for Portal Measurement  
 Modules returned from the customers (internal or external) as faulty  
 whether still in warranty or out of warranty. Philips will provide  
 Diametrics' field failure information. Philips will pay Diametrics the  
 exchange repair cost per Schedule 4. Diametrics shall perform root cause  
 analysis (sub-assembly level) on any failed unit in order to determine  
 failure mode.  
  
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 Diametrics will provide a pareto trend analysis of failure data for all  
 failed units to Philips on a monthly basis.  
  
14. DOCUMENTATION  
  
 14.1 Rights of Access. Philips shall have the right to access and use  
 Diametrics' manufacturing documentation for the Portal Measurement  
 Products to comply with regulatory requirements.  
  
 14.2 Record Retention. Diametrics shall retain records of any safety,  
 quality and reliability related data relating to the Portal  
 Measurement Products as well as any data necessary for "Current Good  
 Manufacturing Practices" (CGMP, as required by FDA), the "In Vitro  
 Diagnostics Directive" (the IVDD, as required by the European Union)  
 and the "Medical Device Directive" (MDD, as required by the European  
 Union), to the extent provided under Schedule 1, Required Quality  
 Data.  
  
 14.3 Access to Filings. Diametrics assures the access of DHR (Device  
 History Record), DHT (Device History Traveler), and DMR (Device Master  
 Record) in support of Philip's timely answering of Portal Measurement  
 Product questions from the FDA. Diametrics shall cooperate with  
 Philips in connection with its regulatory obligations to provide to  
 Philips, on a timely basis, the necessary reports relating to  
 complaints and product performance issues regarding the Portal  
 Measurement Products. Upon reasonable request, Diametrics shall  
 promptly make such reports (on behalf of Philips) directly to the  
 appropriate regulatory authorities.  
  
15. CONFIDENTIALITY.  
  
 15.1 Non-Use and Non-Disclosure. Each Party acknowledges and agrees that  
 all the other Party's Confidential Information is confidential to the  
 disclosing Party. Each Party shall take the same reasonable measures  
 as it uses to protect its own confidential information from the  
 unauthorized disclosure or misuse to protect the other Party's  
 Confidential Information from unauthorized disclosure or misuse,  
 including without limitation, any disclosure by its employees, agents,  
 contractors, permitted sublicensees, or consultants of the other  
 Party's Confidential Information. As used herein, the term reasonable  
 measures shall mean at least those measures a Party applies to the  
 protection of its own Confidential Information and the term misuse  
 shall mean use for any purpose other than as permitted or required  
 hereunder.  
  
 15.2 Marking. To be entitled to protection as Confidential Information, all  
 Diametrics or Philips documents containing that Party's Confidential  
 Information shall be appropriately and clearly marked as  
 "Proprietary," "Secret," "Confidential," or other words to similar  
 effect. If a disclosure of Confidential Information is made orally, as  
 in a meeting, the disclosing Party shall indicate the nature of that  
  
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 information at the time of its disclosure and shall confirm such  
 designation in writing within ten (10) days of the date of such  
 disclosure to the receiving Party.  
  
 15.3 Exclusions. Information shall not be considered Confidential  
 Information hereunder if it:  
  
 (a) was already in the possession of the receiving Party prior to its  
 receipt from the disclosing Party;  
  
 (b) is, or becomes, part of the public knowledge or literature  
 through no fault, act or omission of the receiving Party,  
 provided, Confidential Information shall not be deemed to have  
 entered the public domain by reason of its having been filed with  
 any regulatory authority; provided the disclosing Party has taken  
 advantage of any procedures available to protect confidentiality,  
 including FOIA marking and protective orders;  
  
 (c) is, or becomes, available to the receiving Party from a source  
 other than the disclosing Party, which source has rightfully  
 obtained the same information and has no obligation of  
 confidentiality to the disclosing Party with respect to it;  
  
 (d) is made available on an unrestricted basis by the disclosing  
 Party to a third party unaffiliated with the disclosing Party; or  
  
 (e) is required to be revealed pursuant to law or requirements of any  
 securities exchange on which a Party's shares are listed and  
 traded, provided, however, the receiving Party which is under any  
 such requirement of law shall give reasonable notice to the  
 disclosing Party of such requirement and shall cooperate with the  
 disclosing Party, at the disclosing Party's expense in reasonable  
 legal efforts to limit or mitigate any such revelation so as to  
 preserve the proprietary nature of any Confidential Information  
 contained therein.  
  
 15.4 Duration; Surviving Obligation. This Article 15 shall be deemed to  
 cover and include any non-public information disclosed by a Party to  
 the other during the course of their negotiations of this  
 Manufacturing Agreement, whether or not marked or indicated as  
 provided in Section 15.2. Each Party's obligations of non-use and  
 non-disclosure of the other Party's Confidential Information shall  
 apply during the term of this Manufacturing Agreement and shall also  
 survive for a period of three (3) years after its termination for any  
 reason.  
  
 15.5 Confidentiality of this Agreement. The terms of this Manufacturing  
 Agreement itself and the Schedules hereto shall be deemed to be  
 Confidential Information hereunder. In the event that a Party is  
 required to disclose the content of this Manufacturing Agreement  
 pursuant SEC requirements or requirements of any securities exchange  
 on which a Party's share are listed and traded, such Party  
  
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 shall use its reasonable efforts to obtain confidential treatment of  
 at least the terms of Schedules 1, 2, 4, 6 and 7.  
  
16. WARRANTY.  
  
 16.1 Warranty Terms. Diametrics warrants to Philips that the Portal  
 Measurement Products at the time of their delivery by Diametrics to  
 Philips (a) shall meet the Specifications as set forth on Schedule 2;  
 (b) shall have been manufactured in accordance with all laws and  
 regulations applicable to their manufacture in those jurisdictions in  
 which Philips is distributing the Portal Measurement Products  
 (provided that Philips gives Diametrics at least ninety (90) days  
 written notice of any jurisdictions in addition to those in effect as  
 of the Effective Date of this Amendment); (c) shall be new or newly  
 manufactured; and (d) shall be of good and merchantable title, free of  
 liens and encumbrances. Diametrics shall, promptly, at Diametrics'  
 sole option, replace, repair or make a purchase price (in the amount  
 paid by Philips to Diametrics) refund for any of such Portal  
 Measurement Products proved to be non-conforming, provided that  
 written notice and reasonable documented evidence of each warranty  
 claim and the fact that the failure occurred during the warranty  
 period is received by Diametrics within thirty (30) days after the  
 expiration thereof. Diametrics shall have the sole right to verify  
 such non-conformance. Such replacement, repair or refund shall be  
 Philips' sole remedy hereunder. Unless otherwise agreed by the  
 Parties, the warranty period under this Section 16.1 for (1) the  
 Portal Measurement Modules shall be eighteen (18) months from the date  
 of shipment to Philips; (2) any DeviceSet/DeviceCom Software shall be  
 forty-five (45) days from the date of delivery of such software to  
 Philips' customer; and (3) any Portal Measurement Accessory shall be  
 ninety (90) days from the date of shipment to Philips. If requested by  
 Diametrics, Philips shall return the non-conforming Portal Measurement  
 Products to Diametrics at the time of submission of the warranty claim  
 therefore. Philips agrees to provide Diametrics sufficient notice of  
 additional countries in which it intends to distribute the Portal  
 Measurement Products to permit Diametrics to meet its obligations  
 under subsection (b) of this Section 16.1.  
  
 16.2 Exclusions. This warranty does not apply to Portal Measurement Modules  
 or Portal Measurement Accessories that have been repaired, modified or  
 tampered with by anyone other than Diametrics qualified technical  
 personnel, nor to Portal Measurement Modules or Portal Measurement  
 Accessories that have been exposed (by customer negligence) to adverse  
 conditions through improper installation, application or maintenance.  
  
 16.3 NFF Procedures. Any Portal Measurement Modules returned to Diametrics  
 with no fault found (NFF) shall undergo twenty four (24) hour  
 "burn-in" (i.e. 4 cycles of Treadmill test) upon no fault  
 determination. Following completion of burn-in, the Portal Measurement  
 Modules shall be subjected to a full functional test. Provided no  
 fault is found, the Portal Measurement Modules shall be labeled (i.e.  
  
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 DHR annotated) prior to return to Philips in order to identify the  
 Portal Measurement Modules, should they every be returned again. If  
 the same Portal Measurement Modules should be returned to Diametrics'  
 facility for a second time, and NFF, the Portal Measurement Modules  
 shall be analyzed and replaced. For Portal Measurement Module's second  
 NFF, the pc boards will be replaced and product fully tested before  
 returned to Philips. If same Portal Measurement Module is returned a  
 third time and NFF, the entire Portal Measurement Module will be  
 removed from use and replaced at Diametrics' expense. The foregoing  
 obligations apply only if the Portal Measurement Module is under  
 warranty.  
  
 16.4 Warranty Disclaimer. EXCEPT AS EXPRESSLY PROVIDED IN THIS ARTICLE 16  
 OF THIS AGREEMENT, DIAMETRICS MAKES NO REPRESENTATIONS OR WARRANTIES,  
 EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF  
 MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.  
  
 16.5 Customer Warranties. Philips shall be entitled to warrant the Portal  
 Measurement Products to its customers on terms it deems appropriate;  
 provided that Philips shall bear any expenses it may incur with  
 respect to such warranties, to the extent that such warranties exceed  
 the scope or term of the express warranties made by Diametrics  
 hereunder.  
  
 16.6 Customer Complaints, Warranty and Out-of Warranty Repair. Philips will  
 be responsible for handling customer complaints regarding the Portal  
 Measurement Products. Diametrics will provide reasonable assistance to  
 Philips in resolving such customer complaints. Diametrics will accept  
 the return of any Portal Measurement Products that do not conform to  
 the warranties set forth in Section 16.1, and will repair or replace  
 any such defective Portal Measurement Product (or refund Philips'  
 purchase price) as provided in Section 16.1. Philips agrees to  
 maintain an inventory of Portal Measurement Products to meet its  
 on-going repair obligations; provided that Diametrics agrees to  
 maintain a reasonable inventory of Portal Measurement Products to  
 support significant Product warranty issues. As between Diametrics and  
 Philips, Philips will be responsible for providing its customers with  
 such replacement Portal Measurement Products for use while such  
 defective Products are being repaired or replaced. Diametrics will  
 also provide out-of-warranty repair service on the Portal Measurement  
 Modules, on the terms set forth on Schedule 4 for a period of not less  
 than seven (7) years after last production run of the Portal  
 Measurement Module (or such longer period as may be required by local  
 laws).  
  
 16.7 Return Procedures. Reasonable attempts by Philips 1st Level  
 Application Support (Response Centers) to determine failure mode(s) of  
 the Portal Measurement Products is assumed. This information will be  
 transferred to Diametrics prior to any Portal Measurement Products  
 being returned from the field. This will provide initial information  
 to assist in the investigation of the failed Portal Measurement  
 Product. Upon receipt of a failed Portal Measurement  
  
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 Module, the unit will go through the standard repair process, which  
 includes the known repair (if applicable) and then 1 cycle of  
 Treadmill testing (roughly equivalent to 6 hour "burn-in"), and the  
 subsequent quality tests. If the failure mechanism cannot be  
 identified the unit will undergo the quality (diagnostic) tests, the  
 repair pursued and then a full retest of the Portal Measurement Module  
 (including Treadmill and the quality tests). If the fault cannot be  
 re-created internally, and it passes all testing requirements the unit  
 will be sent back out as acceptable (and documented as no fault found  
 ("NFF") on the DHR). Diametrics will follow the Supplier Corrective  
 Action Report ("SCAR") process or Distributor Action Request ("DAR")  
 process to notify Philips if there is are multiple failures of any one  
 component of any of the Philips engineered components. Diametrics,  
 likewise will also pursue a Corrective Action Report ("CAR") if there  
 are multiple failures of any one component of any Diametrics  
 engineered components. Philips will be notified at the time of the CAR  
 initiation.  
  
 16.8 Repair Period. Diametrics agrees to use commercially reasonable  
 efforts to repair or replace the non-conforming Portal Measurement  
 Products and return conforming Portal Measurement Products to Philips  
 within four (4) weeks of receipt of Diametrics. Failed units returned  
 from the field that are out-of-warranty will be repaired within 10  
 working days for customer units and within 30 days for Service  
 Logistics International ("SLI") exchange units.  
  
17. QUALITY PERFORMANCE. If the failure rate of the Portal Measurement Module  
 exceeds specified limits, (e.g. as per Section 3.5) and/or the Philips  
 field failure rate is higher than the expectation (i.e. for Portal  
 Measurement Module less than 4% the first year with a decrease to 1% the  
 second year), Diametrics commits to initiate an SCAR, DAR or CAR driven  
 corrective action project for quality / reliability improvements on Portal  
 Measurement Modules (material, processes, subassemblies) effective per the  
 SCAR or CAR.  
  
 The goal for the Portal Measurement Module is not to exceed an annual  
 failure rate (AFR) of 4% the first year with a decrease to 1% the second  
 year for the Portal Measurement Module within a one year rolling period  
 starting when the contract becomes effective:  
  
 AFR = # units failed/ #units shipped by Philips (annualized)  
  
 Diametrics and Philips will do a monthly failure clearance on a common  
 basis before entering the numbers into the calculation.  
  
18. PRODUCT RECALL.  
  
 18.1 If either Party believes that a recall of any Portal Measurement  
 Product manufactured under this Manufacturing Agreement is desirable  
 or required by law, it shall promptly notify the other Party. The  
 Parties shall then discuss reasonably and in good faith whether such  
 recall is appropriate or required and the  
  
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 manner in which any mutually agreed recall shall be handled. This  
 Section 18 shall not limit the obligations of either Party under law  
 with respect to recall of Portal Measurement Products required by law  
 or properly mandated by governmental authority. Voluntary recalls  
 shall be conducted by mutual agreement (with such agreement not to be  
 unreasonably withheld) provided that if mutual agreement is not  
 reached, either Party may individually conduct the voluntary recall in  
 question in a manner consistent with its own regulatory guidelines and  
 criteria. The "Recalling Party" shall bear all costs and expenses of  
 any voluntary recall of any Portal Measurement Products and shall  
 reimburse the "Other Party" for the reasonable, out-of-pocket costs  
 incurred by the Other Party as a result of such recall, including the  
 replacement cost of any Portal Measurement Products affected thereby,  
 unless (i) such recall is unjustified and neither requested nor  
 classified as a recall by a governmental agency or delegee or (ii) the  
 cause or basis of such recall is attributable to a condition, fact or  
 action that constitutes (A) a breach by the Other Party of any of its  
 obligations hereunder or (B) negligence or willful misconduct of the  
 Other Party in which case the Other Party will be liable for the costs  
 and expenses of such recall, and shall reimburse the Recalling Party  
 for the reasonable, out-of-pocket costs incurred by Recalling Party as  
 a result of such recall, including the replacement cost of any Product  
 affected thereby. The Parties shall cooperate fully with each other in  
 effecting any recall of the Products pursuant to this Section 18,  
 including communications with any customers or to the public.  
  
 18.2 If any governmental agency having jurisdiction (including without  
 limitation the FDA) shall request or order any corrective action with  
 respect to Portal Measurement Products supplied hereunder, including  
 any Portal Measurement Product recall, customer notice, restriction,  
 corrective action or market action or any Product change, Diametrics  
 shall bear the costs and expenses of such corrective action and shall  
 reimburse Philips for the reasonable, out-of-pocket costs incurred by  
 Philips as a result of such corrective action, including the  
 replacement cost of any Products affected thereby, to the extent that  
 the cause or basis of such corrective action is attributable to a  
 condition, fact or action that constitutes (A) a breach by Diametrics  
 of any of its obligations hereunder or (B) negligence or willful  
 misconduct of Diametrics. Philips shall bear all other costs and  
 expenses of such corrective action, and shall reimburse Diametrics for  
 the reasonable out-of-pocket costs incurred by Diametrics as a result  
 of such action, including the replacement cost of any Portal  
 Measurement Product affected thereby.  
  
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19. ENVIRONMENTAL CONSIDERATIONS.  
  
 Diametrics agrees to provide commercially reasonable support to Philips, at  
 Philips' written request and at Philip's expense, as required to meet  
 United States and international environmental laws, regulations and  
 standards applicable to the manufacture of the Portal Measurement Products.  
  
20. PRODUCT DISCONTINUANCES. Diametrics acknowledges its obligation to  
 manufacture the Portal Measurement Products during the term of this  
 Manufacturing Agreement; however, if the Portal Measurement Products will  
 not be available from Diametrics prior to the conclusion of the term,  
 Diametrics shall give written notice to Philips. Diametrics notice shall be  
 given immediately upon Diametrics knowing about the unavailability, but in  
 any event no less than six (6) months in advance of the last order date of  
 the Products. In any event of termination of this Manufacturing Agreement  
 and subject to Diametrics' manufacturing capacity, and in addition to any  
 other remedies that Philips may have at law or in equity, Philips shall be  
 entitled to determine its lifetime-buy quantities and to purchase such  
 quantities in accordance with this Manufacturing Agreement for purchase and  
 shipment by the end of the Term.  
  
21. MISCELLANEOUS PROVISIONS  
  
 21.1 Entire Agreement. This Manufacturing Agreement, together with any  
 Schedules or other Attachments hereto and the Amendment, constitutes  
 the entire agreement between the parties in relation to this subject  
 matter and as such, supersedes all prior and contemporaneous  
 negotiations, agreements, representations, understandings and  
 commitments with respect thereto and shall take precedence over all  
 terms, conditions and provisions on any purchase order form, or order  
 acknowledgment, or order release purporting to address the same  
 subject matter.  
  
 21.2 Modification. This Manufacturing Agreement shall not be released,  
 discharged, changed or modified in any manner except by a writing  
 signed by the duly authorized officers or agents of each Party hereto,  
 which writing shall make specific reference to this Manufacturing  
 Agreement and shall express the plan or intention to modify same.  
  
 21.3 Severability. If any provision or provisions of this Manufacturing  
 Agreement shall be determined to be unenforceable, then the Parties  
 shall in good faith negotiate for a substitute provision addressing  
 the same subject matter as the unenforceable provision(s) as may then  
 be considered to be enforceable, provided, however, if no substitute  
 provision can be formulated which shall be accepted by the Parties as  
 enforceable, this Manufacturing Agreement shall nonetheless continue  
 in full force and effect with the unenforceable provision(s) stricken  
 here from. In such case the applicable law shall apply with regard to  
 unenforceable and / or void provisions.  
  
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 21.4 Governing Law. This Manufacturing Agreement shall be governed by and  
 construed in accordance with the laws of the United States and the  
 State of Delaware, excluding its choice of law rules. The Parties  
 consent to the jurisdiction of the state and federal courts of  
 Delaware.  
  
22. SCHEDULES. Should conflicts occur between this Manufacturing Agreement and  
 any part of the following Schedules, the requirements of this Manufacturing  
 Agreement shall govern. The following Schedules form an integral part of  
 this Manufacturing Agreement:  
  
 Schedule 1: Required Quality Data  
 Schedule 2: Portal Measurement Products and Specifications  
 Schedule 3: Philips Terms of Delivery  
 Schedule 4: Prices/Quantities  
 Schedule 5: Contact Persons  
 Schedule 6: Cosmetic Defect Guideline  
 Schedule 7: Cosmetic Inspection Guideline  
  
  
DIAMETRICS MEDICAL, INC. PHILIPS MEDICAL SYSTEMS NORTH AMERICA  
 COMPANY, A DIVISION OF PHILIPS  
 ELECTRONICS NORTH AMERICA CORPORATION  
  
  
By: By:  
 --------------------------------- -------------------------------------  
 Xxxxx Xxxxxx, Chairman of the Xxx Xxxxxxxx  
 Board and Chief Executive Officer Vice-President & General  
 Manager - POCD  
  
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 SCHEDULE 1  
  
 REQUIRED QUALITY DATA  
  
Diametrics assures 5 years of record retention of all the following quality and  
reliability related data:  
  
Starting on the Effective Date, Diametrics shall provide the following data to  
Philips Procurement once every quarter:  
  
1. Outgoing data (Also known as F2 data) on each Portal Measurement Module:  
 100% outgoing inspection means  
 N = total (100%) each products tested.  
  
2. YIELD (overall - from incoming through outgoing -  
 Philips expects a yield > 92%, per test station  
 @ manufacturing, 1st cycle)  
  
 2.1) and a pareto analysis of all materials failures,1st cycle.  
  
 2.2) and a pareto analysis of all process failures, 1st cycle.  
  
3. A pareto analysis of all root cause failures (sub-assembly level) for  
 returned products.  
  
  
  
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 SCHEDULE 2  
  
 PORTAL MEASUREMENT PRODUCTS & SPECIFICATIONS  
  
Item Part Number Respective Date of  
 Description Specification Specification  
  
1. M3561A Portal Reader B-M3561-60000-1\* 09/12/03  
 (M3561-6001)  
  
2. M3561-68001 B-M3561-60000-1 09/12/03  
 Exchange repair Portal  
  
3. M3565A temp card B-M3561-60000-1 09/12/03  
 (DMI 467900)  
  
4. M3561-66403 edge connector  
 (DMI 516300) B-M3561-60000-1 09/12/03  
  
5. M3564A DeviceSet w/DeviceCom  
 (DMI 464218) B-M3561-60000-1 09/12/03  
  
6. M3672A edge connector  
 Cleaning kit (DMI 450000) N/A N/A  
  
7. Cosmetic Defect Guideline see schedule 6  
  
8. Cosmetic inspection see schedule 7  
  
\*B-M3561-60000-1 is the M3561A Portal Product Specification. Rev. A of such  
specification applied prior to 9/12/03. To the extent of any conflict between  
Rev. A or B of the M3561A Portal Product Specification and Diametrics'  
manufacturing process document MP46000 Rev. X., MP46000 shall apply.  
  
  
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 SCHEDULE 3  
  
 TERMS OF DELIVERY  
  
- Delivery and Packaging Standard of Philips HP Dwg. A-5961-3658-1, Xxx. X  
  
- XXX - capabilities for order receiving and acknowledgment  
  
- Shipping date as specified on Philips-Purchase Order  
  
- Date of dispatch: Philips Delivery Date minus 7 days  
  
- Mode of transport: Airfreight  
  
- Each shipment must indicate the exact address of the addressee on the  
 outside of the packaging.  
  
- Products are shipped F.O.B. point of origin.  
  
 FOR SHIPPING AND PRODUCTION AND FAILURE ANALYSIS:  
  
 PHILIPS MEDIZIN SYSTEME BOEBLINGEN GMBH  
 HEWLETT XXXXXXX XXX. 0  
 00000 XXXXXXXXXX /GERMANY  
 POCD PRODUCTION ENGINEER  
 XXXXXXXX 0/ XXXXX 0 0 X00  
  
- Xxx minimum order and ship quantity is 10 pieces.  
- Dangerous goods must be packed and labeled in accordance with the relevant  
 regulations (Postal regulations, Regulation on the transport of dangerous  
 goods, etc.).  
  
- Each shipment must contain a delivery voucher indicating the Philips order  
 number and the Philips part number.  
  
- The total number of Portal Measurement Modules shipped shall be exactly as  
 specified on the Philips purchase order.  
  
  
  
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 SCHEDULE 4  
  
 DIAMETRICS/PHILIPS TRANSFER PRICES  
  
1. M3561A Portal Reader \*  
 (M3561-60001)  
  
2. M3561-68000 Exchange repair Portal  
  
The first two rates assume the unit is part of the exchange program, whereas the  
third rate assumes the unit is not part of the exchange program.  
  
  
   
- Combined repair/recondition rate (if outside warranty): \*  
 (assumes part of exchange program, and covers  
 reconditioning and functional repairs while  
 outside of the standard warranty period)  
  
- Recondition only rate (would apply if within warranty): \*  
 (assumes part of exchange program, and covers  
 reconditioning and functional repairs while within  
 the standard warranty period, e.g., reconditioning  
 is not covered by warranty)  
  
- Repair only rate (no recondition occurs): \*  
 (assumes not part of exchange program)  
  
3. M3565A temp card \*  
 (DMI 467900)  
  
4. M3561-66403 edge connector \*  
 (DMI 516300)  
  
5. M3564A DeviceSet w/DeviceCom \*  
 (DMI 464218)  
  
6. M3672A edge connector \*  
 Cleaning kit (DMI 450000)  
  
7. M3561-40003 edge connector cover \*  
 (DMI 466400)  
  
  
  
\* Confidential treatment requested  
  
  
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 SCHEDULE 5  
  
 CONTACT PERSONS  
  
FOR PHILIPS:  
  
MANUFACTURING E-MAIL: XXXXX.XXXXXXXXX@XXXXXXX.XXX  
 TELEPHONE:x00 (00000) 000-0000  
 FAX:x00(0000)000-0000  
  
PURCHASING DEPT. E-MAIL: XXXXXXXX.XXXXXXXXX@XXXXXXX.XXX  
 TELEPHONE:x00(00000)000-0000  
 FAX:x00 (00000)000-0000  
  
MATERIALS ENGINEERING E-MAIL: XXXXXX.XXXXXXXX@XXXXXXX.XXX  
 TELEPHONE:x00(00000)000-0000  
 FAX:x00(0000)000-0000  
  
ORDER PROCESSING E-MAIL:XXXXXXXX.XXXXXXXXX@XXXXXXX.XXX  
 TELEPHONE:x00(00000)000-0000  
 FAX:x00(00000)000-0000  
  
--------------------------------------------------------------------------------  
  
  
FOR DIAMETRICS:  
  
OPERATIONS E-MAIL:xxxxxxx@xxxxxxxxxx.xxx  
Xxxxx Xxxxxx TELEPHONE: 000-000-0000  
 FAX: 000-000-0000  
  
PURCHASING DEPT. E-MAIL: xxxxxxxxx@xxxxxxxxxx.xxx  
Xxxx Xxxxxxxx TELEPHONE: 000-000-0000  
 FAX: 000-000-0000  
  
MATERIALS ENGINEERING/MANUFACTURING E-MAIL: xxxxxxxxxx@xxxxxxxxxx.xxx  
Xxx Xxxxxxxxx TELEPHONE: 000-000-0000  
 FAX: 000-000-0000  
  
ORDER PROCESSING E-MAIL: xxxxxxxxx@xxxxxxxxxx.xxx  
Xxx Xxxxxxxx TELEPHONE: 000-000-0000  
 FAX: 000-000-0000  
  
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 SCHEDULE 6  
 COSMETIC DEFECT GUIDELINE  
  
 Exchange Portal Cosmetic Defect Guideline  
  
PURPOSE  
  
This document provides guidelines for inspecting used (also called exchange)  
Portal Measurement Modules during the repair process. The overall purpose of  
this guideline is to ensure that exchange products which are shipped to  
customers are in a condition which will lead to consistent customer  
satisfaction.  
  
SCOPE  
  
This document does not cover cosmetic specifications for individual recovered  
parts of assemblies, nor cosmetic specifications for new whole units. This  
guideline only applies to the Portal Measurement Module and its related exchange  
parts.  
  
Because this guide applies to refurbished product only, inspectors should be  
examining the product for end-user and shipping induced damage, or wear, not  
defects caused during manufacturing. Only cosmetic defects that could be caused  
by end-user or shipment can fail the product since any manufacturing-induced  
defects have already passed manufacturing inspection. For that reason,  
manufacturing-caused cosmetic defects such as blush, flash, flow marks, haze,  
sinks, and weld lines should not be considered as defects when examining  
refurbished units.  
  
GENERAL GUIDELINES  
  
Cosmetics, in this context refer to superficial, visual appearance of the  
product and as such do not affect the functioning of the product. Any defect  
that interferes with the normal operation of the product, should be considered a  
non-cosmetic defect. In the strictest sense, missing parts are not considered a  
cosmetic defect, even if they are not needed for the operation of the product  
(example: missing label). Note, however, that a missing part would be considered  
a defect, and would necessitate some form of repair or action. Also, it is very  
important to realize that cosmetics are largely subjective, so inspectors should  
apply their best judgment in all cases.  
  
The guiding principal when applying this judgment should be that this product is  
not a new product and should not be considered as such. A balance needs to take  
place between attempting to achieve near perfect cosmetic appearances which  
would result in a large financial liability to the company versus the  
possibility of having a high customer dissatisfaction rate if we were to ship  
exchange product which looks shabby.  
  
EVALUATION CRITERIA  
  
Cosmetic defects will be evaluated using a weighted criteria basis based on the  
location of the defect and the severity of the defect. Guidance is provided in  
Table 1.  
  
  
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CUSTOMER ADDED LABELS  
  
Any labels or marking put on a system by customers must be removed . This  
includes such items as inventory tags and safety stickers. All glues used to  
attach these labels must also be removed.  
  
  
  
  
 (a) Type of Cosmetic Defect  
 SURFACE  
 AREA --------------------------------------------------------------------------------------  
 LOCATION PAINT HEAT SMALL DEEP  
----------------- DISCOLOR- ABRASION DISCOLOR- PITS, SCRATCHES SCRATCHES  
 ATION OR ATION NICKS (MINIMAL- (VERY  
 OR WEAR GOUGES- LY VISIBLE) VISIBLE  
 (NOTE 2 NOTE 2)  
 ------------- --------------- ------------ ------------ -------------- ---------------  
  
   
PRODUCT Minor OK- Minor OK- Minor OK- Minor OK Minor OK OK  
SERIAL # LABEL  
  
 Note 1 Note 1 Note 1 Note 1 Note 1 Note 1  
  
  
LOGO "PORTAL" Very minor; Very minor; Very minor; None Very minor; None  
(TOP)  
 Still Still clearly Still Still  
 clearly read name clearly clearly read  
 read name read name name  
  
DISPLAY SCREEN  
(GLASS AREA) N/A None N/A None None None  
  
CASE TOP Minor OK Minor OK Minor OK None Minor OK None  
  
CASE BOTTOM Minor OK Minor OK Minor OK Minor OK Minor OK Minor OK  
----------------- ------------- --------------- ------------ ------------ -------------- ---------------  
  
  
NOTE 1: Damage to the label that makes the reading of the serial number, product  
number, impossible or difficult to read are not acceptable.  
NOTE 2: Judgment needed here. A scratch, xxxxx, or xxxx, could be deep but small  
in size (width and length). If this defect is small in size it may be acceptable  
if in a location where seldom seen).  
  
  
  
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 SCHEDULE 7  
  
 COSMETIC INSPECTION GUIDELINE  
  
  
  
  
ACCEPTANCE CRITERIA  
  
   
Checking Contents Packaging / box labeling  
 Portal  
 Edge connector cleaning kit  
 Certification sheet  
  
Checking Portal Confirm Correct Label, Placement & Affixment for the Unit  
 Ensure that there are 4 Rubber Feet and no abnormal  
 scuffing or damage, other than normal production scuffs  
 Check for 4 torque screws on the bottom of Portal  
 Check for serial port cover and 2 torque screws  
 Check for light pipe  
 No scratches or fingerprints on screen  
 No dust between the touchscreen and display  
 No residues on portal  
 Sensor/IR probe flush or less  
 Discoloration, Flow marks, and Haze: Two per surface; max dimension;  
 0.5 mm (.02")  
 Weld Line Exceptions: Weld lines of up to 9.5mm (.375") long shall be  
 allowed next to the IR Probe hole and the Light Pipe hole in the M3561-  
 40000 Top Housing  
 Pits and Specks: Two per surface; max dimension; 0.5 mm (.02)  
 Scratches: Two per surface; max dimension: 0.3 mm x 0.8 mm (.01" x  
 .03")  
 Sinks: Two per surface; max dimension: 0.8mm (.03")  
 Weld Lines per surface: Two; max dimension: 3 mm (.125")  
 No visual gasket btw. Touchscreen and top housing  
  
Checking portal box Edge connector cleaning kit in Box  
 Certificate of Conformance  
 No crumb or dirt in the box  
 No bent connector pins  
 Confirm Correct Label, Placement & Affixment / for the XXX  
  
  
  
  
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