<Insert Date>

<Address>

Re: URGENT FIELD SAFETY NOTICE for MACROLYTE® Premie Dispersive Electrode, Catalogue/Reference Number 440-2400 lots manufactured between April 27, 2012 to January 7, 2014

Type of Action: REMOVAL

Dear <Insert Contact>,

This Field Safety Notice is to notify you regarding a product issue with the MACROLYTE® Premie Dispersive Electrode, Catalogue/Reference Number 440-2400. The device is manufactured by ConMed Corporation. ConMed has received complaints regarding sparking, no output and burning at the cord set connection. The complaints have been confirmed by ConMed. ConMed has decided to recall the MACROLYTE® Premie Dispersive Electrode products to the user level. Therefore, please stop the use of this device immediately. Baylis has distributed the following affected lots:

1210225
1309105

Baylis Medical is contacting you on behalf of ConMed as we are a distributor of this device for ConMed. Our records show that you have received this product from us. Please examine your inventory for any of the lot numbers in your possession from lot numbers 1210225 and 1309105.

In order to confirm that you have received this field safety notice, please complete the attached acknowledgment form and return it to Baylis Medical at 1-905-602-5671 within 2 business days of receipt. If you have any of the lot numbers within the date range identified below, please indicate the quantity in the acknowledgement form and indicate if you are requesting credit or replacement of the device. **Please do not return used units.**

Our records show that you have received this product from Baylis Medical Company. Please see the instructions below.

Affected Products	MACROLYTE® Premie Dispersive Electrode, Catalogue/Reference Number 440-2400 Identification of Affected Devices: Reference/Catalogue Number: 440-2400 Description: MACROLYTE® Premie Dispersive Electrode

	Baylis has distributed the following affected lots: 1210225 1309105
Safety Instructions	1. Immediately segregate all affected product in your inventory in a manner that ensures it will not be used. 2. Complete the attached acknowledgement form and include with it a list of customers impacted by this field safety notice and fax it back to ATTN: Quality Department (905) 602-5671. 3. A Baylis Medical Representative will contact you once your acknowledgment form has been received and will provide you with a RMA # for return of product. 4. Return all product clearly labeled with the RMA# to: Attn: Quality Department RMA# 2645 Matheson Blvd. East Mississauga, ON L4W 5S4
Product Correction	For every MACROLYTE® Premie Dispersive Electrode you return, you will be supplied with a MACROLYTE® Premie Dispersive Electrode at no charge when they become available
Contact Information	Ellen Harfield, Quality Team Lead eharfield@baylismedical.com; (905) 602-4875 ext. 264

Please be advised that the applicable National Competent Authorities have been notified of this safety notice. The Authorized European Representative for Baylis Medical is:

Mr A Atchia
Quality First International
Suites 317 & 318 Burford Business Centre
11 Burford Road
London E15 2ST
United Kingdom
Tel: +44 (020) 8221 2361 Fax: +44 (020) 8221 1912
~~20 Eversley Road, Bexhill-on-Sea, East Sussex~~
~~TN40 1HE, United Kingdom~~
~~Tel: +44 (20) 8-522-1937 Fax: +44 (20) 8-522-1937~~

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Please contact us immediately if you have any questions.