



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY
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October 23, 2006

DEPARTMENT CIRCULAR

No.2006- 0407

TO: ALL UNDERSECRETARIES, ASSISTANT SECRETARIES; DIRECTORS OF BUREAUS, CENTERS FOR HEALTH DEVELOPMENT, SERVICES AND SPECIALTY HOSPITALS; CHIEFS OF MEDICAL CENTERS & HOSPITALS AND ALL OTHER CONCERNED

SUBJECT: Department of Health-Bureau of Health Devices and Technology Alert No. 161 s. 2006.

The Bureau of Health Devices and Technology is monitoring medical device product recalls and safety alerts posted on the website of the different medical device regulatory agencies of the United States of America, Australia, Canada, Japan, Singapore and the European Union.

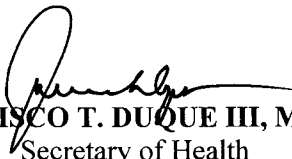
Posted on the Health Canada website is the product recall for ABL800 Series Blood Gas Analyzer equipped with Software Version 5.21 manufactured by Radiometer Medical Aps, Bronshoj, Denmark. The reason for recall of ABL800 Series Blood Gas Analyzer is that "ABL800 Series Blood Gas Analyzer became inoperable when the restore default setup button was touched".

The Department of Health was informed by Micro-Biological Laboratory, Inc., the local distributor of ABL800 Series Blood Gas Analyzer, that "[Micro-Biological Laboratory, Inc.] still do not have installation of this ABL-800 in the market".

This device alert is being issued to warn those people who might have purchased this brand/model of Blood Gas Analyzer from overseas sources or may have received these units through foreign donations.

Posting of press releases and other notices of recalls and market withdrawals is a way of providing services to the consumers, the media and other interested parties. The **BHDT DOES NOT** endorse either the product or the company.

For further information, call Director Agnette P. Peralta, Bureau of Health Devices and Technology (711-6016).


FRANCISCO T. DUQUE III, MD, M.Sc.
Secretary of Health



MICROLAB Since 1960
"We Provide and Prolong Quality Life"

Our ref: SALES/06/10/M-081

October 3, 2006

Bureau of Health Devices and Technology
Department of Health
San Lazaro Compound, Rizal Avenue,
Sta. Cruz, Manila

Attention : Ms. Agnette P. Peralta
Director IV – CESO III

Subject : Product Recall for ABL 800

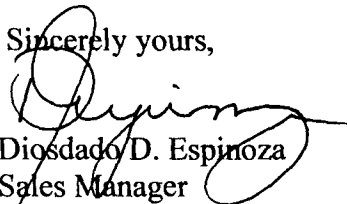
Dear Ms. Peralta,

This is with reference to your letter dated September 18, 2006 regarding the product recall for ABL 800 Series Blood Gas Analyzer that was being posted in the U.S. FDA website.

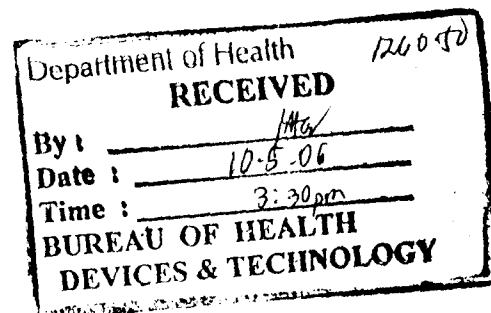
We communicated this matter with our principal, Radiometer International A/S, Copenhagen, Denmark and attached is the action done and monitoring report on the ABL 800Series. Although "we still do not have installation of this ABL-800 in the market," we will make sure that the first unit to be sold would be the upgraded one.

Should you have any further inquiries, please do not hesitate to contact us.

Sincerely yours,


Diosdado D. Espinoza
Sales Manager

/mmd



Micro-Biological Laboratory, Inc.:

INDENTOR & IMPORTER OF HOSPITAL MEDICAL
EQUIPMENT & ANALYTICAL INSTRUMENTS
MANUFACTURED & EXPORTER OF PREPARED
MICROSCOPE SLIDES for:
General Biology, Zoology, Histology,
Embryology, Parasitology & Bacteriology

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Management Cover

for Field Action Notes (FAN)

RADIOMETER
COPENHAGEN 

Attention: Agnette P. Peralta M.Sc.
Director IV – CESO III
Bureau of Health Devices and Technology
Department of Health

915-225

Product: ABL800 Software

October 3, 2006

Subject: Mandatory Software Update

Background: It has been found that ABL800 with software version V5.21 will lose the communication between the PC Module and the Analyzer Control PC in case "Restore default setup" is used. This causes the analyzer to become inoperative.

Implementation: The above has been corrected in ABL800 software version V5.23.

Action: Upgrade all ABL800 analyzers presently running with software version V5.21 to the new version V5.23.

Tools: CD-ROMs with the revised analyzer software are available from stock as follows:

914-720 - ABL800 Analyzer software V5.23

Recommendation: With reference to FAN 915-215 we recommend to stop upgrading ABL800 to V4.141 and instead upgrade to V5.23 (or higher). Further, we recommend that ABL800 analyzers, which have already been upgraded to V4.141, must be upgraded to V5.23 (or higher).

Prepared by: Mogens Thomasen
Manager
Technical Documentation