Patient Safety Alert

Veterans Health Administration Warning System
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Item: **Philips IntelliVue G1/G5 Anesthesia Gas Modules:**
Model Numbers M1013A and M1019A and
Dräger Apollo Anesthesia Machines and Multigas Monitor:
Model SCIO

Specific Incident: Two VAMCs experienced multiple occurrences of data inaccuracies with their Philips Anesthesia Gas Modules. The CO_2 concentration values were erratic during the cases, were not consistent with the values from their blood gas analyzers and the readings failed to return to zero at the conclusion of the cases. The erroneous data or the presence of an Inoperative (INOP) status condition can result in the inability to monitor the patient and inappropriate patient management. In one case, the site exchanged their units and the problem was resolved. In the other location, problems persisted even after the modules were replaced. The problem has been identified as a cracked pneumatic circuit pump component and a Field Change Order (FCO) was issued by Philips Medical Systems on May 29, 2009 (see Attachment 1).

General Information: These gas modules were manufactured by Dräger for Philips Medical from June 2007 to December 2008. Full details of the affected serial numbers are provided in Attachment 1. Philips has classified this FCO as “Action for Performance – Retrofit on Failure”. Thus, they will provide the repair exchange service only after being notified of a failure.

Further investigation determined that Dräger, the Original Equipment Manufacturer (OEM) of the module has found the same issue with some Dräger products manufactured between June 2007 and November 2008. Their Technical Service Bulletin released May 7, 2009, describes the addition of a Flow Restrictor to the tubing circuit which bypasses the defective component (see Attachment 2). Despite the language in the Technical Service Bulletin, Dräger will provide this repair service at no charge. Dräger will contact the facilities to arrange the corrective action.

In addition to the device failures, several operational problems were discovered by staff using the products. Users were positioning the sample port of the line tubing system upside down, resulting in excessive amounts of moisture being drawn into the sample line. This required changing the water traps very frequently, sometimes twice during a case, compared to the recommended every two week exchange. If the water trap cannot remove the fluids, the system can become occluded and cannot perform the gas analysis. In addition, the output line from the gas module to the anesthesia scavenging

system included a Gas Exhaust Return Filter that was not supposed to be used with a scavenging system. The use of that filter in the scavenging system has no negative impact but was unnecessary and had been used since the initial installation as a result of verbal instructions from the manufacturer's representative.

Actions:

1. By close of business (COB) June 17, 2009, the **Facility Director (or designee)** will ensure that all applicable Anesthesia staff and Biomedical Engineering staff are made aware of this safety risk.

2. By COB, June 18, 2009, the **Anesthesia Director** must do the following:
   a. Assign staff to assess their inventory, determine if they have the affected models from either manufacturer, and if affected, verify with calibration gases that the gas concentration measurements are accurate. If the gas concentration measurements are not accurate, the staff must report the problem to Biomedical Services to arrange for appropriate service.
   b. Assure that staff is assigned to check the performance of the affected gas modules and monitors daily. If the automatic ZERO calibration fails, obvious data inaccuracies occur or the INOP messages listed in the Attachments occur, users must report the problem to Biomedical Services to arrange for appropriate service.
   c. Assure that staff is assigned to review the manufacturer's written Instructions For Use (IFU) for the affected gas modules, anesthesia machines, and gas monitors, and assure that the sample port tubing configuration is correct, that water traps are changed at the recommended intervals and that any extraneous Gas Exhaust Return Filters are removed from the gas scavenging circuit.

3. By COB, June 29, 2009, **Biomedical Engineering staff** shall ensure that an "off schedule" Preventive Maintenance Inspection (PMI) is performed on the affected devices to determine if they require an unusually high (greater than 220 ml/min) flow rate to calibrate. If so, Biomedical Engineering staff shall coordinate repair of the device.

4. By COB June 30, 2009, the **Patient Safety Manager** shall document the status of this Patient Safety Alert on the VHA Hazardous Recalls/Alerts website. http://vaww.nbc.med.va.gov/visn/recalls/index.cfm.

Source: Two VA Medical Centers

Attachments:
1. Philips Medical Systems Field Change Order FCO86201007A
2. Dräger Technical Service Bulletin No. 139

Contacts: Tom Bauld, VA National Center for Patient Safety (NCPS): (734) 930-5890, or Paul Sherman, VHA Center for Engineering & Occupational Safety and Health (CEOSH): (314) 894-6100, ext. 66072.

ATTACHMENT 1 Philips Medical Systems Field Change Order FCO86201007A

Philips Medical Systems

FIELD CHANGE ORDER Service

Issued by : Heinrich Schmanns, PM-B
Supersedes : N/A
Publication No. : N/A

FCO Ref No. : FCO86201007A
Date : May 29, 2009
Product Group(s)**:** N/A

CLASSIFICATION: *Specify one classification.*
____ Mandatory Action
____ Action for Performance – Proactive
__X_ Action for Performance – Retrofit on Failure
____ Service Recommendation

APPLIES TO: **Geography** : Worldwide

Traceable Item Identification

PMS Number:	451261003781	451261003781	451261003791
	451261003791	451261003801	451261003801
	451261003811	451261003811	451261012171
	451261012171	451261012181	451261012181
Part Number:	M1013-68010	M1013-68010	M1013-68020
	M1013-68020	M1013-68030	M1013-68030
	M1013-68040	M1013-68040	M1019-68050
	1019-68050	M1019-68060	M1019-68060

Range of Serial Numbers
M1013A and M1019A ARYF-0001 to ARZN-0070

M1019A ARXN-0072 ARXC-0014 ARXE-0039
ARXK-0173 ARXM-0177 ARXM-0203

M1013A ARXA-0058

Physical Main Block Number(s) (PB), Physical Sub Block Number(s) (SB) and System Code(s) (SC)
N/A

(Identification where the affected item could be present)

Commercial (Sales) Product Number PMS Number:	862165	862227
Part Number:	M1013A	M1019A

TITLE:
FCO86201007A: M1013A/M1019A G1/G5 Gas Module – Too high sample flow

LIST OF PAGES & DRAWINGS: N/A

ATTACHMENT 1 (cont)

INTRODUCTION:

Symptom : Gas Analyzers M1013A and M1019A, **exclusively** with factory production code between ARYF-0001 to ARZN-0070, may show in seldom cases a high sample flow rate up to 420ml/min instead of 200 ml/min ±20 ml/min.
Due to the high flow rate, the primarily number of the affected units will fail ZERO calibration and/or show additionally other technical alarms (INOPs) as listed below:

- "GM COMPONENT MALF"
- One, two or all three INOPs "CO2 UNABLE TO MEAS" , "O2 UNABLE TO MEAS", "N2O UNABLE TO MEAS"
- "O2 ZERO FAILED";
- "GM ACCURACY?" and "O2 ZERO FAILED",
- "GM ZERO FAILED" and one, two or all three INOPs "CO2 UNABLE TO MEAS" , "O2 UNABLE TO MEAS", "N2O UNABLE TO MEAS"

In some cases, the high flow occurs without any INOP indication and may be identified by flow measurement and unusual loud pump noise. For all suspect devices, the flow rate can be measured easily according the service instruction manual on the water-trap inlet.

Note:
If the high flow problem occur and one or more of the INOPs mentioned above are displayed, single gases or even all gases are no longer available as numeric on the IntelliVue Monitor. Instead of the numeric, a question mark "-?-" is shown.
Nevertheless, if high flow occurs without any INOP shown, single gases might be displayed as numeric. The measurement accuracy of the specific gases is within the ISO specification. In all cases described above, the numeric value is not shown or it is within the ISO specification.

Cause : The M1013A and M1019A Gas Modules contain a pneumatic subcomponent with a pump to generate the flow to withdraw sample gas from the patient circuit. This flow is managed by a closed-loop control. In some cases a cold crack may occur on single individual devices of the production code series between

M1013A and M1019A	ARYF-0001 to	ARZN-0070 and				
M1019A	ARXN-0072	ARXC-0014	ARXE-0039	ARXK-0173	ARXM-0177	ARXM-0203
M1013A	ARXA-0058.					

Due to the cold crack on single individual devices inside the pneumatic circuitry, this flow control management for the pump is short circuited. Therefore resulting in a high sample flow and as a followup of this high flow the technical alarms are coming up.

Remedy : Exchange the unit. Do **not** adjust the high flow. Adjustment will not resolve the specific problem on a long term basis.

MANPOWER / TIME TO COMPLETE:
Philips' Installable:
00 hours 45 minutes for 01 engineers
Customer Installable:
00 hours 45 minutes for 01 engineers

TOOLS & TEST EQUIPMENT:
Service maintenance Digital Mass FlowMeter for flow check – M1026-60144 / 453563230731

MODIFICATION KIT / PARTS REQUIRED:
Modification kit: N/A
Containing:
Ordering Info:

PROCEDURE:
If symptoms are observed as described above, check the flow as described in Service Manual (M1013-9301C / 451261020481). If flow exceeds the allowed maximum of 220 ml/min and/or the described INOPs are present, exchange the unit.

ATTACHMENT 1 (cont)

M1013A
M1013-68010 M1013-68020 M1013-68030 M1013-68040 M1019A M1019-68050 M1019-68060
For this specific case, do **not** adjust the flow. This is only affecting units in the serial number range from
M1013A and M1019A
ARYF-0001 to ARZN-0070
(manufactured from June 2007 to December 2008, **not** the shipment or installation date) and
M1019A
ARXN-0072
ARXC-0014
ARXE-0039
ARXK-0173
ARXM-0177
ARXM-0203
M1013A
ARXA-0058.

Location Category: __X__ On-site __X__ Philips Medical CRC
__X__ Customer Installable _____ Remote

Verification Procedure(s):
• V : P
• PO: P
• P : P
• if in doubt, please follow the whole Preventive Maintenance procedure as described in Service Manual (M1013-9301C / 451261020481)

PARTS DISPOSAL:
__X__ Return _____Scrap _____Other

DOCUMENTATION:
B300-2009-

ATTACHMENT 2 Dräger medical Technical Service Bulletin No. 139

Dräger medical
A Dräger and Siemens Company

Technical Service Bulletin

5000.008
Multi-Unit TSB

05/2009 Küpper TSB No. 139
Released on 07.05.2009

Status: Field Quality Improvement Action (Class 2)
Countries affected: See Device list
Re: Anaesthetic gas metering

Reason:
- Increased extraction rate of anesthetic gas metering
- Frequent occurrence of 'Water trap / Scavenging line' message
- Zeroing error of Pato O2 sensor with error code 6014
- Pump error code 3705 (pressure drop too small)

Solution/Procedure:
1. Units under service contract: Installation of a new flow restrictor
2. Units without service contract: Installation of new flow restrictor in case of repair

Device affected: All gas metering modules from June 2007 to November 2008, see Device List

- Primus, Pallas (PGM 1, PGM 2, PGM 3):
- Apollo (PGM 2)
- Zeus
- Scio Four
- Vamos
- Vamos2

ATTACHMENT 2 (cont)

Technical Service Bulletin

Timing/When:

Re 1: Installation of the flow restrictor must be completed by 31.07.2010
Re 2: N/A

Order no.:

Upgrade kit Flow 200 ml : 6872195 (gold housing)
(Primus, Pallas (PGM 1, PGM 2, PGM 3), Apollo (PGM 2), Zeus, Scio Four, Vamos2)

Upgrade kit Flow 150 ml : 6872185 (silver housing)
(Vamos)

(The upgrade kits can be ordered free of charge)

Costs:

This TSB explicitly stipulates that only units under service contract are to be upgraded. The period was purposely chosen to be so long in order to ensure that during that time every unit under contract can be visited at least once within the normal service interval. Consequently, contrary to the remuneration procedure otherwise, only the work time will be reimbursed, and no travel time.

Re 1: Subsidiaries (units under service contract)

I The manufacturer bears the cost of the field corrective action. Costs are reimbursed only on completion in the countries concerned. The amount reimbursed is calculated on the basis of a flat rate per device multiplied by the number of devices affected. The rate per device is indicated specific to each country in the following Livelink folder: Project Workspace: FCA. For cost reimbursement purposes, the device manufacturer issues a credit note for the subsidiary concerned on receipt of a notice of completion.

Re 2: Subsidiaries (units without service contract)

For units **without** service contract, repairs and the relevant Flow upgrade kit are chargeable outside of the warranty period.

The recommended price for the repair is:

Upgrade kit € 99 each + work time and travel cost

Distributors: (units under service contract)

Distributors shall prepare an invoice stating the services rendered, **excluding** travel costs, as direct net costs (work times according to in-house rates) after conclusion of the field action.

ATTACHMENT 2 (cont)

Technical Service Bulletin

Recipient of invoice (only for distributors):
Dräger Medical AG & Co. KG
Peter Küpper, cost center 4030
Moislinger Allee 53-55
23558 Lübeck, Germany

Hours worked: 1 h

Test: See upgrading instructions in the two upgrade kits

Job report: Each country shall report completion of the action by filling out and returning the job report form ("Confirmation of completion"). The job report form is attached as an annex to the TSB.

Additional info: The Device List includes units **with** and **without** service contract.

Please specify on the job report form how many units under service contract have been upgraded.

Important Notice!
When implementing this TSB please take account of the following class 3 TSB:

- **Field action 129 - New SW for gas modules (SW PGM1.36 / MFM 3.01)**
- **Field action 138 – Installation of Nafion tube on PGM 2 with Pato.**
  (The Nafion tube forms part of service kit 1 y with immediate effect)

R&D Life Cycle Engineering
Original signed by

Original signed by

Jürgen Mess