

Dräger Medical AG & Co. KGaA, Morslinger Allee 53-55, D-23558 Lübeck

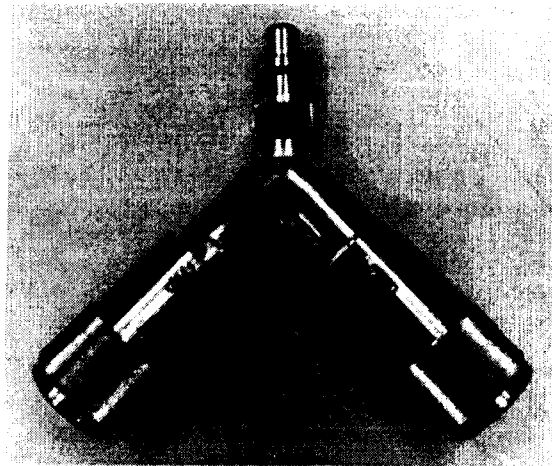
Date
February 2005

To all customers and users using AIR dual plug connectors as additional taps for medical compressed air

Important safety notice! **Exchange of AIR dual plug connectors, part number G01166**

Dear Sir or Madam,

In the course of our product testing we have discovered that AIR dual plug connectors manufactured up to the year 2000 allow the possibility of connecting to a vacuum hose, resulting in a short-time pressure surge.



AIR dual plug connector, to be replaced

These connectors are used to provide additional taps in centralised gas supply systems for medical compressed air.

The identified cause of the fault was a dimensional non-conformance inside the AIR socket. We are not aware of any confusion occurring in day-to-day clinical practice.

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Konto-Nr.: 7 053 002 797
BLZ 210 500 05
Swift Code KILADE 22

Deutsche Bank AG, Lübeck
Konto-Nr.: 030 209 100
BLZ 230 707 00
Swift Code DEUTDE 22
Commerzbank AG, Lübeck
Konto-Nr.: 328 014 579 500
BLZ 230 403 22
Swift-Code COBA DE FF 230

Vorsitzender des Aufsichtsrats:
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Vorstand:
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Roland Jaksch

Our investigations revealed that if the VAC and AIR sockets are confused by the user the possibility of a connection being made cannot be excluded.

The potential effects are as follows:

When the vacuum regulator is plugged into the AIR connector it does not lock in, but there is a brief pressure surge in the connected scavenging system. The fault is directly detectable by a loud whistling. In the Dräger cylinder packs for bronchial suction and continuous drainage the pressure is immediately relieved again, as the cap of the receiving cylinder opens. On cylinders with so-called cough valves, the cough valve also opens. Our investigations have revealed that patients may be exposed to pressure surges of around 50 to 100 mbar for short periods of time.

User action:

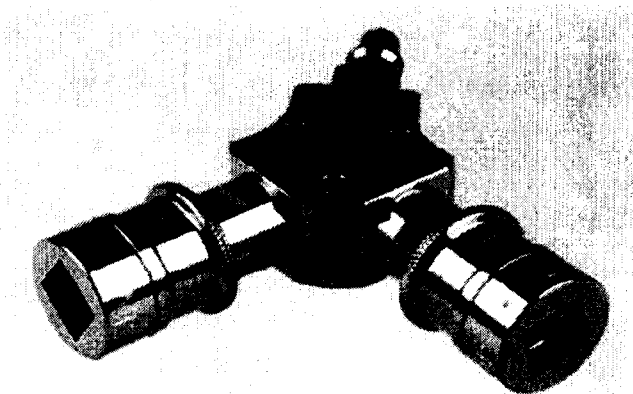
The scavenging and drainage systems should always be connected to the central vacuum supply first and then tested, and only after that should the connection be made to the patient. This sequence must also be followed during patient transports.

Manufacturer action:

Although we can exclude the possibility of the fault occurring on the patient if the user action is carried out as stipulated, we consider it necessary to replace the AIR dual plug connectors concerned free of charge.

As the dual plug connectors concerned cannot be assigned to any fixed unit location, we require your assistance. We would therefore request you to notify your relevant personnel of the above issues, the stipulated user action and the exchange of the AIR dual plug connector shown, and to check your stocks of it.

Please use the enclosed reply form to indicate how many of the affected dual plug connectors you have in total. We will then send you the corresponding number of new connectors promptly and at no charge (see picture).



New AIR dual plug connector

On receipt of the new connectors please return the old ones to Dräger Medical, otherwise we will be forced to charge for the new issue. We hope you will understand our reasons for this, as we wish to ensure that the dual plug connectors with the fault described are not re-used. We will notify you of the return address to use when we send the replacement connectors.

The exchange period will end on June 30th, 2005. On receipt of the replacement issue, and notwithstanding that in all cases by no later than June 30th, 2005, the old AIR dual plug connectors as described must no longer be used.

We regret any inconvenience caused, but consider this action essential for the sake of patient safety. Consequently, we would ask you to assist us as indicated.

If you have any queries your usual contacts at Dräger Sales and Service will be glad to help.

Best regards,

Dräger Medical AG & Co. KGaA
Manager, Anaesthesia Business Unit


pp. Oliver Rosenthal

Enclosure

Reply form/stock report for AIR dual plug connector exchange