


Urgent Safety Communication

Urgent Safety notice of Fabius devices Manufactured by Draeger Medical Systems Inc.

Device/ Product Name:	Fabius GS Premium, Tiro, Tiro D-M, MRI, plus, plus XL
Lot numbers/Serials:	Affected are only Fabius devices with the serial numbers specified in the attached file below.
Manufacturer:	Draeger Medical Systems Inc.
Problem:	Saudi FDA would like to bring to your attention that Draeger Medical Systems Inc. has issued a safety notice about potential failure of automatic and manual Ventilation of Fabius devices.
Recommendation/Actions:	<ul style="list-style-type: none"> - Draeger currently producing replacement motors for the potentially affected devices. - Draeger Service will contact you and arrange an appointment for replacing the motor, free of Charge. - If you have concerns regarding the affected product, contact the Authorized representative listed below.
Devices/Products photo:	 <p style="text-align: center;"><i>Approximate image</i></p>

Authorized Representative Details	Company name:	Draeger Arabia Co. Ltd.
	Contact Person:	Ahmed Algarni
	Phone:	+966 508463646
	Email:	Ahmed.Algarni@draeger.com;

For further information, please see the notification letter below or [Click Here](#).

Healthcare Professionals should **report** any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.

Medical Devices Sector

Saudi Food and Drug Authority

Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)

North Ring Road - Al Nafal Unit (1)

Riyadh 13312 - 6288

Tel: +966 (11) 2038222 Ext: 2406, 2412

Fax: +966 (11) 2757245

For latest published Recalls/Alerts, please visit ([NCMDR Website](#))

Sincerely,
NCMDR Team

Drägerwerk AG & Co. KGaA, 23542 Lübeck

**To our customers of the Dräger anesthesia machines
Fabius GS Premium, Tiro, Tiro D-M, MRI, plus, plus XL**

February 2018

Important safety notice!!!

**Potential failure of automatic and manual ventilation of Fabius devices.
Affected are only Fabius devices with the serial numbers specified in the enclosure.
Other anesthesia devices are NOT affected!**

Dear Sir / Madam,

As part of our global market monitoring, we have become aware of a case in which the automatic ventilation of a Fabius failed during operation. Ventilation of the patient was continued by means of the ManSpont mode and a manual resuscitator. No injury was reported. Our investigation revealed that in this individual case excess oil from a production step interfered with the position detection of the ventilator motor during operation. We cannot completely rule out that the devices specified in the enclosure also contain excess oil which may, in the worst case, interfere with the position detection of the ventilator motor. According to our records, you have been supplied with one or more of the devices with the affected serial numbers.

If the position detection of the motor is disturbed, the automatic ventilation may fail and the device alerts the user by displaying the message "VENTILATOR FAIL!!!". Although this has not occurred yet, manual ventilation may also fail if the ventilator cover is damaged.

We are currently producing replacement motors for the potentially affected devices. Our Dräger Service will contact you and arrange an appointment for replacing the motor, free of charge.

Drägerwerk AG & Co. KGaA
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23558 Lübeck, Germany
Postal address:
23542 Lübeck, Germany
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Fax +49 451 882-2080
info@draeger.com
www.draeger.com
VAT ID: DE135082211

Bank information:
Commerzbank AG, Lübeck
IBAN: DE95 2304 0022 0014 6795 00
SWIFT code: COBA DE FF 230
Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
SWIFT code: NOLADE21SPL

Company headquarters: Lübeck
Commercial register:
Municipal Court Lübeck HRB 7903 HL
General partner:
Drägerwerk Verwaltungs AG
Company headquarters: Lübeck
Commercial register:
Municipal Court Lübeck HRB 7395 HL

Chairman of the Executive Board of
Drägerwerk AG & Co. KGaA and
Drägerwerk Verwaltungs AG:
Prof. Dr. Nikolaus Schweickart
Board of Directors:
Stefan Dräger (Chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

Until then, please continue to operate your devices with the usual attention and make sure that a manual resuscitator for emergency ventilation is kept ready according to our instructions for use.

We regret any inconveniences this may cause.

With best regards,



Serial Number List

ASKF-0151	ASKF-0207	ASKH-0007	ASKH-0047	ASKH-0086
ASKF-0156	ASKF-0208	ASKH-0008	ASKH-0048	ASKH-0087
ASKF-0162	ASKF-0209	ASKH-0009	ASKH-0049	ASKH-0088
ASKF-0163	ASKF-0210	ASKH-0010	ASKH-0050	ASKH-0089
ASKF-0164	ASKF-0211	ASKH-0011	ASKH-0051	ASKH-0090
ASKF-0165	ASKF-0212	ASKH-0012	ASKH-0052	ASKH-0091
ASKF-0167	ASKF-0213	ASKH-0014	ASKH-0053	ASKH-0092
ASKF-0168	ASKF-0214	ASKH-0015	ASKH-0054	ASKH-0093
ASKF-0172	ASKF-0215	ASKH-0016	ASKH-0055	ASKH-0094
ASKF-0175	ASKF-0216	ASKH-0017	ASKH-0056	ASKH-0095
ASKF-0177	ASKF-0217	ASKH-0018	ASKH-0057	ASKH-0096
ASKF-0178	ASKF-0218	ASKH-0019	ASKH-0058	ASKH-0097
ASKF-0180	ASKF-0219	ASKH-0020	ASKH-0059	ASKH-0098
ASKF-0181	ASKF-0220	ASKH-0021	ASKH-0060	ASKH-0099
ASKF-0182	ASKF-0221	ASKH-0022	ASKH-0061	ASKH-0100
ASKF-0183	ASKF-0222	ASKH-0023	ASKH-0062	ASKH-0101
ASKF-0184	ASKF-0223	ASKH-0024	ASKH-0063	ASKH-0102
ASKF-0185	ASKF-0224	ASKH-0025	ASKH-0064	ASKH-0103
ASKF-0186	ASKF-0225	ASKH-0026	ASKH-0065	ASKH-0104
ASKF-0187	ASKF-0226	ASKH-0027	ASKH-0066	ASKH-0105
ASKF-0188	ASKF-0227	ASKH-0028	ASKH-0067	ASKH-0106
ASKF-0189	ASKF-0228	ASKH-0029	ASKH-0068	ASKH-0107
ASKF-0190	ASKF-0229	ASKH-0030	ASKH-0069	ASKH-0108
ASKF-0191	ASKF-0230	ASKH-0031	ASKH-0070	ASKH-0109
ASKF-0192	ASKF-0231	ASKH-0032	ASKH-0071	ASKH-0110
ASKF-0193	ASKF-0232	ASKH-0033	ASKH-0072	ASKH-0111
ASKF-0194	ASKF-0233	ASKH-0034	ASKH-0073	ASKH-0112
ASKF-0195	ASKF-0234	ASKH-0035	ASKH-0074	ASKH-0113
ASKF-0196	ASKF-0235	ASKH-0036	ASKH-0075	ASKH-0115
ASKF-0197	ASKF-0236	ASKH-0037	ASKH-0076	ASKH-0116
ASKF-0198	ASKF-0237	ASKH-0038	ASKH-0077	ASKH-0117
ASKF-0199	ASKF-0238	ASKH-0039	ASKH-0078	ASKH-0119
ASKF-0200	ASKF-0239	ASKH-0040	ASKH-0079	ASKH-0122
ASKF-0201	ASKH-0001	ASKH-0041	ASKH-0080	ASKH-0130
ASKF-0202	ASKH-0002	ASKH-0042	ASKH-0081	ASKH-0131
ASKF-0203	ASKH-0003	ASKH-0043	ASKH-0082	ASKH-0132
ASKF-0204	ASKH-0004	ASKH-0044	ASKH-0083	ASKH-0133
ASKF-0205	ASKH-0005	ASKH-0045	ASKH-0084	ASKH-0134
ASKF-0206	ASKH-0006	ASKH-0046	ASKH-0085	ASKH-0135

Serial Number List

ASKH-0136	ASKJ-0192	ASKK-0009	ASKK-0040	ASKK-0080
ASKH-0137	ASKJ-0193	ASKK-0009	ASKK-0041	ASKK-0081
ASKH-0138	ASKJ-0194	ASKK-0010	ASKK-0042	ASKK-0082
ASKH-0139	ASKJ-0195	ASKK-0011	ASKK-0043	ASKK-0086
ASKH-0140	ASKJ-0196	ASKK-0011	ASKK-0044	ASKK-0089
ASKH-0142	ASKJ-0197	ASKK-0012	ASKK-0045	ASKK-0092
ASKH-0143	ASKJ-0199	ASKK-0013	ASKK-0046	ASKK-0111
ASKH-0144	ASKJ-0200	ASKK-0013	ASKK-0047	ASKK-0111
ASKH-0146	ASKJ-0202	ASKK-0014	ASKK-0048	ASKK-0112
ASKH-0147	ASKJ-0205	ASKK-0014	ASKK-0049	ASKK-0114
ASKH-0150	ASKJ-0206	ASKK-0015	ASKK-0050	ASKK-0115
ASKH-0151	ASKJ-0207	ASKK-0016	ASKK-0051	ASKK-0119
ASKH-0158	ASKJ-0208	ASKK-0016	ASKK-0052	ASKK-0157
ASKH-0159	ASKJ-0210	ASKK-0017	ASKK-0053	ASKK-0180
ASKH-0164	ASKJ-0211	ASKK-0017	ASKK-0054	ASKK-0183
ASKH-0166	ASKJ-0212	ASKK-0018	ASKK-0055	ASKL-0001
ASKH-0168	ASKJ-0213	ASKK-0019	ASKK-0057	ASKL-0002
ASKH-0169	ASKJ-0214	ASKK-0020	ASKK-0058	ASKL-0003
ASKJ-0007	ASKJ-0215	ASKK-0020	ASKK-0059	ASKL-0005
ASKJ-0159	ASKJ-0216	ASKK-0021	ASKK-0060	ASKL-0006
ASKJ-0170	ASKJ-0217	ASKK-0021	ASKK-0061	ASKL-0007
ASKJ-0171	ASKJ-0218	ASKK-0022	ASKK-0062	ASKL-0008
ASKJ-0173	ASKJ-0219	ASKK-0022	ASKK-0063	ASKL-0009
ASKJ-0174	ASKJ-0220	ASKK-0023	ASKK-0064	ASKL-0009
ASKJ-0175	ASKJ-0221	ASKK-0024	ASKK-0065	ASKL-0010
ASKJ-0177	ASKJ-0222	ASKK-0025	ASKK-0066	ASKL-0018
ASKJ-0178	ASKJ-0223	ASKK-0026	ASKK-0067	ASKL-0054
ASKJ-0179	ASKJ-0224	ASKK-0027	ASKK-0068	ASKL-0070
ASKJ-0180	ASKJ-0225	ASKK-0029	ASKK-0069	ASKL-0079
ASKJ-0181	ASKJ-0226	ASKK-0030	ASKK-0070	ASKL-0080
ASKJ-0182	ASKJ-0227	ASKK-0031	ASKK-0071	ASKL-0082
ASKJ-0183	ASKK-0001	ASKK-0032	ASKK-0072	ASKL-0090
ASKJ-0184	ASKK-0002	ASKK-0033	ASKK-0073	ASKL-0099
ASKJ-0186	ASKK-0003	ASKK-0034	ASKK-0074	ASKL-0111
ASKJ-0187	ASKK-0004	ASKK-0035	ASKK-0075	ASKL-0112
ASKJ-0188	ASKK-0005	ASKK-0036	ASKK-0076	ASKL-0113
ASKJ-0189	ASKK-0006	ASKK-0037	ASKK-0077	ASKL-0116
ASKJ-0190	ASKK-0007	ASKK-0038	ASKK-0078	ASKL-0119
ASKJ-0191	ASKK-0008	ASKK-0039	ASKK-0079	ASKL-0126

Serial Number List

ASKL-0165	ASKM-0031	ASKM-0114	ASKM-0195	ASKM-0293
ASKL-0166	ASKM-0032	ASKM-0115	ASKM-0198	ASKM-0297
ASKL-0168	ASKM-0032	ASKM-0116	ASKM-0201	ASKM-0298
ASKL-0169	ASKM-0033	ASKM-0117	ASKM-0202	ASKM-0299
ASKL-0173	ASKM-0034	ASKM-0118	ASKM-0205	ASKN-0002
ASKL-0174	ASKM-0034	ASKM-0119	ASKM-0206	ASKN-0003
ASKL-0175	ASKM-0035	ASKM-0120	ASKM-0208	ASKN-0010
ASKL-0176	ASKM-0043	ASKM-0121	ASKM-0210	ASKN-0011
ASKL-0177	ASKM-0044	ASKM-0122	ASKM-0211	ASKN-0013
ASKL-0178	ASKM-0045	ASKM-0123	ASKM-0212	ASKN-0013
ASKL-0187	ASKM-0046	ASKM-0124	ASKM-0213	ASKN-0014
ASKL-0189	ASKM-0047	ASKM-0125	ASKM-0217	ASKN-0015
ASKL-0190	ASKM-0048	ASKM-0126	ASKM-0221	ASKN-0017
ASKL-0191	ASKM-0049	ASKM-0127	ASKM-0223	ASKN-0018
ASKL-0192	ASKM-0050	ASKM-0128	ASKM-0228	ASKN-0019
ASKL-0193	ASKM-0051	ASKM-0129	ASKM-0230	ASKN-0026
ASKL-0194	ASKM-0052	ASKM-0131	ASKM-0231	ASKN-0031
ASKL-0195	ASKM-0053	ASKM-0132	ASKM-0232	ASKN-0041
ASKL-0197	ASKM-0056	ASKM-0136	ASKM-0234	ASKN-0042
ASKL-0199	ASKM-0057	ASKM-0139	ASKM-0235	ASKN-0069
ASKM-0004	ASKM-0058	ASKM-0141	ASKM-0236	ASKN-0070
ASKM-0007	ASKM-0059	ASKM-0143	ASKM-0240	ASKN-0085
ASKM-0008	ASKM-0063	ASKM-0144	ASKM-0242	ASKN-0106
ASKM-0011	ASKM-0064	ASKM-0145	ASKM-0245	ASLA-0003
ASKM-0011	ASKM-0065	ASKM-0146	ASKM-0246	ASLA-0004
ASKM-0013	ASKM-0066	ASKM-0147	ASKM-0247	ASLA-0019
ASKM-0014	ASKM-0067	ASKM-0148	ASKM-0248	ASLA-0028
ASKM-0014	ASKM-0068	ASKM-0150	ASKM-0249	ASLA-0041
ASKM-0015	ASKM-0069	ASKM-0151	ASKM-0250	ASLA-0046
ASKM-0020	ASKM-0082	ASKM-0152	ASKM-0252	ASLA-0053
ASKM-0021	ASKM-0086	ASKM-0167	ASKM-0261	ASLA-0055
ASKM-0023	ASKM-0088	ASKM-0169	ASKM-0265	ASLA-0056
ASKM-0025	ASKM-0089	ASKM-0172	ASKM-0266	ASLA-0057
ASKM-0026	ASKM-0104	ASKM-0173	ASKM-0269	ASLA-0060
ASKM-0027	ASKM-0105	ASKM-0176	ASKM-0280	ASLA-0061
ASKM-0028	ASKM-0106	ASKM-0179	ASKM-0283	ASLA-0071
ASKM-0029	ASKM-0107	ASKM-0184	ASKM-0286	ASLA-0078
ASKM-0030	ASKM-0109	ASKM-0187	ASKM-0288	
ASKM-0031	ASKM-0113	ASKM-0193	ASKM-0292	