

Drägerwerk AG & Co. KGaA, 23542 D-Lübeck

**To our customers of the Dräger anesthesia machines
Fabius, Apollo, and Perseus with mech. mixer**

May 2018

Important safety notice!!!

Possible failure of the O2 minimum dosage module (S-ORC)

Only devices specified in the attached serial number list are affected.

Other anaesthesia machines are NOT affected!

Dear Sir / Madam,

In the course of conducting production quality checks, we became aware of a device where it was possible to dose 100% N₂O. To date, we are not aware of any reports of this occurring in devices currently in distribution.

The above-mentioned anaesthesia machines are equipped with a mechanical O₂ minimum dosage module (S-ORC). This safety feature prevents the user from inadvertently setting hypoxic gas mixtures (with less than 21% oxygen) at the fresh gas mixer when N₂O is selected as one of the carrier gases.

Our investigation determined that the root cause was a burr not being removed from an internal component of the S-ORC during the production process. The production process has already been corrected. Nevertheless, we cannot completely rule out that the devices listed in the attached serial number list are equipped with an S-ORC module which also has a burr which, in the worst case can impair the mechanics of the module. According to our records, you have been supplied with one or more of the devices with the affected serial numbers.

In the event of a fault, the S-ORC module would not prevent setting an N₂O flow that would result in a hypoxic mixture from being dosed to the patient. The device would then deliver exactly the set gas composition, which can be read on the electronic fresh gas flow displays. A hypoxic gas mixture would be immediately visible on the basis of the O₂ monitoring. In addition, a visual and audible alarm would be generated if the inspiratory oxygen concentration (FiO₂) low alarm limit is violated.

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Executive Board
Stefan Dräger (Chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

We are currently manufacturing replacement parts for all potentially affected devices, which will be installed as part of the next service. Our Service dept. will contact you to arrange the replacement Free of Charge

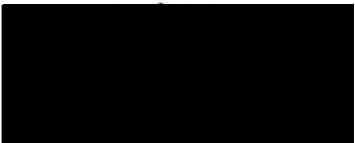
In the meantime, you can continue to use the installed devices. The device doses and measures the administered medical gases according to its purpose. However, it is important to ensure that the instructions, notes and warnings in the relevant instructions for use are observed and that the alarms are not disabled on the corresponding O2 and N2O monitoring devices. Always set gas flows so that at least 21% oxygen is dosed. If your anaesthesia machine drops below the low alarm limit for FiO₂ and generates an alarm, please check your settings and adjust them as required.

We regret any inconvenience caused by this measure but consider it necessary as a preventive measure to ensure patient and user safety. Please inform all affected users in your facility.

With kind regards



Hans Ulrich Schöler
Head of Product Management
Anesthesiology



Oliver Möller
Post Market Surveillance
Quality and Regulatory Affairs

Attachment:

Serial number list

Serial Number List

Apollo		Perseus	Fabius GS Premium	
ASKN-0041	ASKN-0113	ASKM-0197	ASKM-0226	ASKN-0011
ASKN-0111	ASKN-0114	ASKN-0006	ASLA-0019	ASKN-0014
ASLA-0026	ASKN-0116	ASKN-0007	ASLA-0022	ASKN-0016
ASLA-0027	ASKN-0138	ASKN-0008	ASLA-0029	ASKN-0017
ASKN-0117	ASKN-0139	ASKN-0009	ASLA-0030	ASKN-0018
ASLA-0122	ASKN-0143	ASKN-0013	ASLA-0193	ASKN-0096
ASLA-0123	ASKN-0144	ASKN-0014	ASLA-0132	ASKN-0097
ASKM-0152	ASKN-0148	ASKN-0015	ASLA-0134	ASLA-0024
ASKM-0193	ASKN-0150	ASKN-0021	ASLA-0150	ASLA-0025
ASKM-0202	ASKN-0151	ASKN-0026	ASLA-0151	ASLA-0026
ASKM-0203	ASKN-0152	ASKN-0027	ASLA-0152	ASLA-0027
ASKM-0211	ASKN-0163	ASKN-0028	ASLA-0154	ASLA-0028
ASKM-0212	ASKN-0164	ASKN-0029	ASLA-0156	ASLA-0033
ASKM-0213	ASKN-0165	ASKN-0030	ASLA-0157	ASLA-0034
ASKM-0214	ASLA-0001	ASKN-0031	ASLA-0161	ASLA-0051
ASKM-0221	ASLA-0002	ASKN-0034	ASLA-0164	ASLA-0052
ASKM-0222	ASLA-0003	ASKN-0035	ASLA-0165	ASLA-0054
ASKM-0227	ASLA-0092	ASKN-0036	ASLA-0167	ASLA-0062
ASKM-0228	ASLA-0121	ASKN-0037	ASLA-0168	ASKM-0153
ASKM-0246	ASLA-0124	ASKN-0038	ASLA-0172	ASKM-0160
ASKM-0269	ASLA-0131	ASKN-0039	ASLA-0174	ASKM-0162
ASKM-0272	ASLA-0132	ASKN-0040	ASLA-0180	ASKM-0163
ASKM-0328	ASLA-0145	ASKN-0042	ASLA-0181	ASKM-0164
ASKM-0332	ASLA-0146	ASKN-0045	ASLA-0185	ASKM-0171
ASKM-0333	ASLA-0152	ASKN-0046	ASLA-0188	ASKM-0172
ASKM-0337	ASLA-0153	ASKN-0048	ASLA-0189	ASKM-0174
ASKM-0339	ASLA-0154	ASKN-0049	ASLA-0018	ASKM-0175
ASKM-0340	ASLA-0163	ASKN-0050	ASKM-0147	ASKM-0178
ASKM-0360	ASLA-0164	ASKN-0053	ASKM-0148	ASKM-0179
ASKM-0362	ASLA-0165	ASKN-0054	ASKM-0237	ASKM-0114
ASKM-0366	ASLA-0166	ASKN-0055	ASKN-0015	ASKM-0116
ASKM-0370	ASLA-0173	ASLA-0009	ASKN-0019	ASKM-0120
ASKM-0371	ASLA-0174	ASLA-0010	ASKN-0020	ASKM-0121
ASKM-0408	ASLA-0175		ASKM-0248	ASKM-0122
ASKM-0409	ASLA-0179		ASKM-0249	ASKM-0123
ASKM-0415	ASLA-0180		ASKM-0251	ASKM-0145
ASKN-0012	ASLA-0181		ASKM-0253	ASKM-0146
ASKN-0035	ASLA-0182		ASKN-0001	ASKM-0150
ASKN-0039	ASLA-0183		ASKN-0002	ASKM-0151
ASKN-0040			ASKN-0008	ASKM-0152

Serial Number List

Fabius GS Premium				Fabius MRI
ASKM-0161	ASKN-0128	ASKM-0252	ASKM-0202	ASKN-0024
ASKM-0225	ASKN-0129	ASKN-0031	ASKM-0204	ASKN-0025
ASKM-0227	ASKN-0130	ASKN-0035	ASKM-0205	ASLA-0017
ASKN-0024	ASLA-0076	ASKN-0070	ASKM-0207	ASLA-0018
ASKN-0025	ASLA-0077	ASKN-0071	ASKM-0208	ASLA-0019
ASKN-0026	ASLA-0078	ASKN-0072	ASKM-0215	ASLA-0020
ASKN-0027	ASLA-0090	ASKN-0082	ASKM-0219	
ASKN-0028	ASLA-0091	ASKN-0083	ASKM-0220	
ASKN-0029	ASLA-0092	ASKN-0086	ASKM-0221	
ASKN-0030	ASLA-0093	ASKN-0089	ASKM-0222	
ASLA-0194	ASLA-0094	ASLA-0010	ASKM-0223	
ASKN-0131	ASLA-0095	ASLA-0182	ASKM-0224	
ASKN-0132	ASLA-0096	ASKM-0154	ASKM-0229	
ASKN-0134	ASLA-0099	ASKM-0155	ASKN-0061	
ASKN-0135	ASLA-0100	ASLA-0175	ASKN-0090	
ASKN-0136	ASLA-0101	ASKN-0092	ASLA-0035	
ASKN-0060	ASLA-0106	ASKM-0102	ASLA-0046	
ASLA-0063	ASLA-0108	ASKM-0103	ASLA-0047	
ASLA-0064	ASLA-0109	ASKM-0124	ASLA-0048	
ASKM-0107	ASLA-0111	ASKM-0125	ASLA-0049	
ASKM-0108	ASLA-0115	ASKM-0129	ASLA-0050	
ASKM-0112	ASLA-0116	ASKM-0132	ASLA-0053	
ASKM-0113	ASLA-0118	ASKM-0133	ASLA-0070	
ASLA-0082	ASLA-0122	ASKM-0134	ASLA-0071	
ASKN-0103	ASLA-0127	ASKM-0135	ASLA-0072	
ASKN-0104	ASLA-0128	ASKM-0136	ASLA-0073	
ASKN-0106	ASLA-0040	ASKM-0137	ASLA-0074	
ASKN-0107	ASLA-0041	ASKM-0138	ASLA-0075	
ASKN-0109	ASLA-0042	ASKM-0139	ASLA-0129	
ASKN-0110	ASKM-0140	ASKM-0189	ASLA-0131	
ASKN-0111	ASKM-0142	ASKM-0190	ASLA-0133	
ASKN-0112	ASKM-0143	ASKM-0191	ASLA-0140	
ASKN-0113	ASKM-0144	ASKM-0192	ASLA-0141	
ASKM-0095	ASKM-0149	ASKM-0193	ASLA-0159	
ASKM-0243	ASKM-0167	ASKM-0194	ASLA-0199	
ASKN-0123	ASKM-0242	ASKM-0195	ASLA-0200	
ASKN-0124	ASKN-0133	ASKM-0198	ASLA-0201	
ASKN-0125	ASKN-0137	ASKM-0199	ASLA-0218	
ASKN-0126	ASKM-0241	ASKM-0200		
ASKN-0127	ASKM-0250	ASKM-0201		

Serial Number List

Fabius Plus				
ASKN-0056	ASKM-0281	ASLA-0026	ASKM-0083	ASKM-0238
ASKN-0086	ASKM-0282	ASLA-0029	ASKM-0181	ASKM-0239
ASKN-0087	ASKM-0283	ASKN-0072	ASKN-0115	ASKN-0055
ASKM-0205	ASKM-0284	ASLA-0005	ASKN-0027	ASKN-0120
ASKN-0025	ASKM-0288	ASLA-0041	ASKN-0028	ASKM-0111
ASKM-0116	ASKM-0289	ASKM-0279	ASKN-0029	
ASKM-0117	ASKN-0040	ASKM-0287	ASKN-0030	
ASKL-0022	ASKN-0053	ASLA-0044	ASKN-0031	
ASKM-0119	ASKN-0054	ASLA-0045	ASKN-0032	
ASKM-0121	ASKN-0059	ASLA-0046	ASKN-0033	
ASKM-0123	ASKN-0060	ASKN-0116	ASKN-0034	
ASKM-0131	ASKN-0061	ASKN-0121	ASKN-0035	
ASKM-0247	ASKN-0082	ASKM-0144	ASKN-0036	
ASKM-0251	ASKN-0084	ASKN-0026	ASKN-0037	
ASKM-0252	ASKN-0108	ASKN-0105	ASKN-0038	
ASKM-0253	ASKN-0109	ASKN-0123	ASKN-0039	
ASKM-0254	ASKM-0107	ASLA-0006	ASKN-0057	
ASKM-0255	ASKM-0194	ASLA-0027	ASKN-0062	
ASKM-0258	ASKM-0195	ASLA-0047	ASKN-0063	
ASKM-0259	ASKM-0196	ASKM-0285	ASKN-0064	
ASKM-0260	ASKM-0197	ASKM-0209	ASKN-0065	
ASKM-0261	ASKM-0215	ASKN-0058	ASKN-0066	
ASKM-0262	ASLA-0007	ASKL-0127	ASKN-0067	
ASKM-0263	ASLA-0008	ASKL-0129	ASKM-0256	
ASKM-0264	ASLA-0009	ASKM-0091	ASKM-0257	
ASKM-0265	ASLA-0010	ASKM-0092	ASKN-0083	
ASKM-0266	ASLA-0011	ASKM-0093	ASKN-0088	
ASKM-0267	ASLA-0012	ASKM-0094	ASKN-0089	
ASKM-0268	ASLA-0013	ASKM-0095	ASKN-0090	
ASKM-0269	ASLA-0014	ASKM-0219	ASKN-0091	
ASKM-0270	ASLA-0015	ASKM-0220	ASKN-0092	
ASKM-0271	ASLA-0016	ASKM-0221	ASKN-0094	
ASKM-0272	ASLA-0018	ASKM-0222	ASKN-0095	
ASKM-0273	ASLA-0019	ASKM-0224	ASKN-0096	
ASKM-0274	ASLA-0020	ASKM-0225	ASKM-0207	
ASKM-0275	ASLA-0021	ASKN-0004	ASLA-0062	
ASKM-0276	ASLA-0022	ASKN-0006	ASLA-0063	
ASKM-0277	ASLA-0023	ASLA-0052	ASLA-0064	
ASKM-0278	ASLA-0024	ASKM-0079	ASLA-0065	
ASKM-0280	ASLA-0025	ASKM-0080	ASKM-0237	

Serial Number List

Fabius Plus XL			Fabius Tiro	
ASKM-0016	ASKM-0021	ASKM-0143	ASKM-0203	ASKM-0257
ASKM-0015	ASKM-0022	ASLA-0071	ASKM-0197	ASKN-0003
ASKM-0246	ASKM-0053	ASKM-0050	ASKM-0233	ASKN-0005
ASKN-0106	ASKM-0081	ASKM-0051	ASKM-0236	ASKN-0006
ASKL-0133	ASKM-0082	ASKM-0052	ASKM-0238	ASKN-0009
ASKL-0142	ASKM-0084	ASKM-0056	ASKM-0239	ASKN-0105
ASKL-0146	ASKM-0085	ASKM-0057	ASKM-0240	ASKN-0108
ASKM-0234	ASKN-0111	ASKM-0088	ASKM-0247	ASKN-0114
ASKM-0235	ASKN-0112	ASKM-0089	ASKM-0081	ASKN-0118
ASKM-0236	ASKM-0184	ASKM-0200	ASKM-0082	ASKN-0119
ASKM-0241	ASKN-0110	ASKM-0210	ASKM-0084	ASKN-0065
ASKM-0242	ASKM-0145	ASKM-0213	ASLA-0190	ASKN-0066
ASKM-0243	ASKM-0148	ASKN-0085	ASLA-0191	ASKM-0254
ASKM-0244	ASKM-0151	ASLA-0078	ASLA-0192	ASKM-0255
ASKM-0245	ASKM-0152	ASKN-0104	ASLA-0198	ASKN-0004
ASKM-0250	ASKM-0146	ASKM-0240	ASKM-0115	ASKN-0007
ASKN-0043	ASKM-0147	ASKM-0086	ASKM-0118	ASKN-0010
ASKN-0044	ASKM-0149	ASKM-0290	ASKM-0126	ASKN-0012
ASKN-0045	ASKM-0150	ASKM-0291	ASKM-0128	ASKN-0013
ASKN-0046	ASKN-0069	ASKM-0183	ASKM-0131	ASKN-0021
ASKN-0047	ASKN-0070	ASKN-0015	ASKM-0165	ASKN-0022
ASKN-0048	ASLA-0061	ASKN-0102	ASKM-0166	ASKN-0023
ASKN-0049	ASKL-0193	ASKN-0103	ASKM-0170	ASKN-0099
ASKN-0050	ASKL-0195	ASKN-0114	ASKN-0058	ASKN-0100
ASKN-0051	ASKM-0031	ASLA-0079	ASKN-0059	ASKM-0181
ASKN-0052	ASKM-0033		ASKN-0063	ASKM-0182
ASKN-0071	ASKM-0035		ASKN-0064	ASKM-0185
ASKN-0073	ASLA-0095		ASKN-0067	ASKM-0210
ASKN-0074	ASLA-0096		ASKM-0231	ASKM-0211
ASKN-0075	ASLA-0097		ASKN-0076	ASLA-0008
ASKN-0076	ASLA-0098		ASKM-0104	ASLA-0012
ASKN-0077	ASLA-0099		ASKM-0105	ASLA-0013
ASKN-0078	ASLA-0113		ASKM-0106	ASLA-0014
ASKN-0079	ASLA-0114		ASKM-0109	ASLA-0015
ASKN-0080	ASKL-0161		ASKM-0117	ASKM-0097
ASKN-0081	ASKL-0162		ASKM-0119	ASKM-0098
ASLA-0028	ASKM-0043		ASKM-0127	ASKM-0099
ASKM-0017	ASKM-0045		ASKM-0130	ASKM-0100
ASKM-0018	ASKM-0046		ASKM-0168	ASKN-0079
ASKM-0020	ASKM-0068		ASKM-0169	ASLA-0016

Serial Number List

Fabius Tiro		
ASLA-0017	ASKN-0102	ASLA-0009
ASLA-0056	ASKM-0141	ASLA-0021
ASLA-0137	ASKM-0176	ASLA-0023
ASLA-0138	ASKM-0177	ASLA-0031
ASLA-0139	ASKM-0234	ASLA-0032
ASLA-0148	ASKN-0115	ASLA-0123
ASLA-0149	ASKN-0116	ASLA-0130
ASLA-0219	ASKN-0046	ASLA-0135
ASLA-0220	ASLA-0036	ASLA-0136
ASLA-0221	ASLA-0037	ASLA-0147
ASLA-0223	ASLA-0038	ASLA-0155
ASKM-0230	ASKM-0256	ASLA-0158
ASKN-0047	ASLA-0196	ASLA-0163
ASKN-0048	ASKM-0101	ASLA-0166
ASKN-0049	ASKM-0173	ASLA-0170
ASKN-0050	ASKM-0212	ASLA-0195
ASKN-0051	ASKN-0052	
ASKN-0053	ASKN-0056	
ASKN-0054	ASKN-0057	
ASKN-0055	ASKM-0074	
ASKM-0088	ASKM-0075	
ASKM-0089	ASKM-0077	
ASKN-0120	ASKM-0078	
ASKN-0121	ASLA-0055	
ASKN-0078	ASLA-0162	
ASKN-0117	ASKM-0110	
ASKM-0218	ASKM-0111	
ASKN-0044	ASKM-0196	
ASLA-0057	ASKM-0209	
ASLA-0058	ASKM-0232	
ASLA-0059	ASKM-0244	
ASLA-0060	ASKM-0246	
ASLA-0061	ASKN-0032	
ASKN-0038	ASKN-0033	
ASKN-0039	ASKN-0034	
ASLA-0160	ASKN-0037	
ASLA-0124	ASKN-0041	
ASLA-0125	ASKN-0043	
ASLA-0126	ASKN-0068	
ASKN-0101	ASKN-0093	