

نتقدم بثقة
Moving Forward
with Confidence

رؤية عمان
2040
Oman Vision

To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 155 dated 24/7/2023 Regarding NCMDR FSN of Dispenser DP 30 from (mfr: Nouvag AG).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information



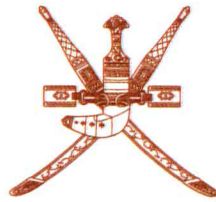
PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489

Twitter: dgpa_dc Email: dg-padc@moh.gov.om



Circular No. 155/2023


06 -01-1445 H

24 -07-2023

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Field Safety Notice of Dispenser DP 30 from Nouvag AG

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19622
Product	Dispenser DP 30.
Description	Surgical equipment/ Anaesthesia - surgical equipmen.
Manufacturer	Nouvag AG.
Local Agent	Diamond Mountains International.
The affected products	Dispenser DP30 (Art.No.4180 / 4180-115ang/ 4180-230ang/ 4180cov / 4180int / 4180med).
Reason	Information for the market to adapt the intended patient group regarding the above dispenser (adjustment of the age of the intended patient and additional specifications for tumescent anesthesia infiltration parameters).
Action	1. Inform all relevant customers/users about this change (see attachment). 2. Contact the local agent for remedial action.
Product Image	
Comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General



Urgent safety information

Information for the market to adapt the intended patient group regarding Dispenser DP 30 (REF 4180)

03.07.2023

Dear Ladies and Gentlemen,

We, Nouvag AG, hereby inform you of a voluntary Field Safety Notice concerning the following listed products and our records show that you have received one or more items of the affected products.

Sender (Published by):

Nouvag AG
St. Gallerstrasse 25, 9403 Goldach, Switzerland
PRRC: Christian Micheletti, c.micheletti@nouvag.com
Tel. +41 71 846 66 79

Addressee:

This urgent safety information concerns all distributors, users and relevant staff of health care facilities who use and distribute the above-mentioned product.

Identification of the medical devices concerned:

- Dispenser DP 30 (Art.No.4180 / 4180-115ang / 4180-230ang / 4180cov / 4180int / 4180med)

Description of the problem including the identified cause:

1. In the context of the update of the clinical evaluation, an adjustment of the intended use was made due to the lack of evidence of a possible use in underage patients: adjustment of the age of the intended patient.

Specification so far: Use on patients of all ages.
New: Use exclusively on adult patients.

Result: Exclusion of patients who have not yet reached the age of majority.

2. In the context of the update of the clinical evaluation, additional specifications were added regarding tumescent anesthesia infiltration parameters.

Specification so far: max. concentration of anesthetic and type of solution to be used.
New: added max. recommended flow and max. lidocaine dose, as well as expected flows for different operating settings.



There is no technical adaptation or malfunction of the product. There are no risks for patients, users or third parties in the further use of the product. There are no risks for underage patients who have already been treated.



What measures are to be taken by the addressee?

- Inform all relevant customers/users about this change. Affected products do not need to be replaced.
- Advise users/customers to contact the manufacturer (See return address or letterhead) if they have any uncertainties, problems or concerns.
- The measures are valid immediately and do not require an implementation period.
- Observe this safety notice until the measure has been completed at your site. Keep a copy of this safety instruction.

Information on vigilance:

The competent national authorities have been informed about this voluntary safety measure.

Please inform Nouvag AG of any adverse event related to the affected products or any item related to the product. Use <https://nouvag.com/en/contact-us> or your Area Sales Manager to report any incident.

We apologise for any inconvenience this may cause. If you have any further queries, please do not hesitate to contact us.

Contact person (EU):

Nouvag Dental- und Medizintechnik GmbH (EC REP)
DE-AR-000005643

Schulthaisstrasse 15, 78462 Konstanz - Germany
Phone. +49 (0)7531 1290-0

Info-de@nouvag.com


Responsible person (Art. 15, 2017/745 (EU)):

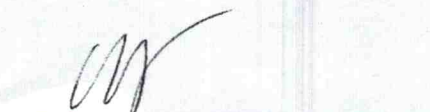
Sandra Conzelmann

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Goldach, 03.07.2023


Christian Gerlach, CEO
Nouvag AG


Christian Micheletti, PRRC
Nouvag AG