

# Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs  
and Drug Control  
MUSCAT



سلطنة عمان  
وزارة الصحة  
المديرية العامة للصيدل  
والرقابة الدوائية  
مسقط

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.....<sup>29</sup>..... dated .....<sup>09/02/20</sup>..... Regarding TGA recall of Stellar 100 and Stellar 150 ventilators from (Mfr: Resmed)

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

# Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs  
and Drug Control  
MUSCAT



سلطنة عمان  
وزارة الصحة  
المديرية العامة للصيدل  
والرقابة الدوائية  
مسقط


Circular No. 29/2020

15 -03-1441 H

09 -02-2020

Ref: 17/2020

## Recall of Stellar 100 and Stellar 150 ventilators from Resmed

Source of Recall	Therapeutic Goods Administration (TGA) <a href="http://apps.tga.gov.au/Prod/sara/arn-detail.aspx?k=RC-2019-RN-01749-1">http://apps.tga.gov.au/Prod/sara/arn-detail.aspx?k=RC-2019-RN-01749-1</a>
Product	Stellar 100 and Stellar 150 ventilators
Manufacturer	Therapeutic Goods Administration (TGA)
Local Agent	Global Source trading L.L.C
The affected products	Product number: 24156, 24164, 24147, 24162 Serial Number: 20160123307, 22171057208
Reason for Recall	Consumers and health professionals are advised that ResMed, in consultation with the TGA, has initiated a recall for product correction in relation to its Astral 100 and Astral 150 ventilators due to an internal battery issue.
Action	<ol style="list-style-type: none"><li>1. Kindly check your stock, contact your local agent for remedial action</li><li>2. Stellar should be used consistent with the indications for use (i.e Stellar is not a life support device)</li><li>3. Prior to use, customers should perform a functional test including alarms as described in the 'Starting therapy' section in the User guide. Press the power switch at the back of the device once to turn on the device; and</li><li>4. Customers should check that the alarm sounds a test beep and the LEDs (visual indicator) for the alarm signal and the Alarm mute button flash.</li></ol>
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 Director of Medical Device Control contact E-mail <a href="mailto:dg-padc@moh.gov.om">dg-padc@moh.gov.om</a>

Directorate General of Pharmaceutical Affairs & Drug Control  
Sultanate of Oman

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

