

# 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

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...214..... dated 14/10/3119 regarding  
Accu-Chek Insight Insulin Pumps.

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

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**Circular No. 24 / 2019**

07 -03-1440 H

14 -03-2019

## Accu-Chek® Insight Insulin Pumps

Mfr: Roche Diabetes Care

The Medicines & Healthcare Products Regulatory Agency of the United Kingdom has recently issued a Medical Device Alert concerning the above mentioned product. As per the alert, the key lock function of the pump locks only the buttons on the front of the insulin pump. It does not lock the quick bolus keys on the top of the pump.

The manufacturer has received reports of unintended boluses being delivered. The company is providing users with key frames to fit onto all affected Accu-Chek Insight Pumps (i.e. pumps with serial numbers below 32100000 to further reduce the risk of accidental bolus delivery.

You are requested to check the availability of these models and if available to report to the agent for their necessary action.

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

Directorate General of Pharmaceutical Affairs & Drug Control

Ministry of Health, PO Box 393, Muscat, PC-100, Sultanate of Oman

**Dr. Mohammed Hamdan Al Rubaie**  
**DIRECTOR GENERAL**

