

# Problem with D-TRON adapter

## Roche announce recall of D-TRON adapters

Roche – the new owners of the Disetronic range of insulin pumps, now branded as **Accu-Chek** – have reported a problem (or "quality issue") with some adapters for the D-TRON and D-TRONplus range of insulin pumps. This can result in up to 1.8 units of extra insulin being given without your realising it within 15 minutes of changing an adapter.

Roche in the UK will recall all D-TRON adapters, but they are starting with children (13 years or younger) and people using less than 18 units of insulin per day. People on higher insulin doses are for the moment invited to "follow good practice of testing your blood sugar 1-2 hours after you have inserted a new adapter and cartridge".

The **US Food and Drugs Administration** (FDA) says only lots 4013674 to 4022628 are affected.

The following statement has been issued by Roche:

Dear Pump User

We are writing to advise you that we have experienced a quality issue with the Disetronic D-Tron adapter that is used by pump users on the Disetronic D-Tron, Disetronic D-TronPlus and the Accu-Chek D-TronPlus. If you use an H-Tron or AccuChek Spirit, this issue will not affect you and you need not read further.

Although this issue has led to a product recall for specific pump users, we would like to assure you that we have had no safety related events due to this issue thus far, and our actions are precautionary in nature.

Pump users that are at most risk are those that have a very small insulin demand of less than 18 units per day. Our key concern is that the adapter may lose pressure and deliver an extra once-off insulin dose of up to a theoretical maximum of 1.8 units more than planned within a 15 minute period following the use of a new adapter. (If this occurs it will only be within the first 15 minutes and not thereafter). During testing, this maximum was never actually achieved. This unplanned delivery will be accompanied by an A4 alarm but will continue to deliver the insulin. In patients with small insulin demand this could cause blood sugars to run lower than planned and if not managed, may cause hypoglycaemia. We believe that up to 2% of Disetronic D-Tron Adapters may have this quality issue.

### Required Action

1. If you care for a child on a D-Tron pump who is 13 years old or less, you must contact the Accu-Chek Pump Care Line on 0800 731 2292 and request replacement Accu-Chek Adapters immediately.
2. Pumpers with current daily insulin requirements of less than 18 units must contact the Accu-Chek Pump Care Line for replacement Accu-Chek Adapters immediately.
3. If you are an adult pumper and your insulin requirement is greater than 18 units per day, please continue to use the same adapter as normal but ensure that you follow good practice of testing your blood sugar 1-2 hours after you have inserted a new adapter and cartridge.

### We need your help

Please do not panic as we have had no actual patient safety events thus far and as this is a precautionary measure, please may we ask you to continue using your current adapters if your current daily insulin dose is greater than 18 units. Please follow the recommended practice of checking your blood glucose 1-2 hours after a new adapter has been fitted, and do not change your adapter before you go to bed. This will allow us to focus our efforts on those most at risk; children 13 years or under and other pump users with low insulin requirements. We will ensure that everyone has access to the new adapters as soon as we possibly can.

We apologise for the inconvenience that our precautionary actions for the Disetronic D-Tron Adapters may cause you. At Roche Diagnostics we understand that safety is key for everyone involved in managing their diabetes and would like to reassure you that we take every measure necessary to provide you with the safest devices with which to deliver your insulin needs.

If you have further questions or would like to confirm your understanding of this matter, please call us on our Accu-Chek Pump Care Line on 0800 731 2291.

Yours sincerely

Roche Diagnostics Ltd

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