

Draft Consumer LETTER D-TRON/Battery issue Version April 19 2006

XYZ
XYZ Town
Country XYZ

Location, April XY, 2006

Important information on power pack failure risk of batteries for D-TRONplus and Accu-Chek D-TRONplus insulin pump family

Dear XYZ,

The purpose of this letter is to inform you about a potential risk with some insulin pump power packs where specific battery power packs are in use for the D-TRONplus or Accu-Chek D-TRONplus. The measure relates solely to the power pack lots numbers 4017120// 4017121// 4017242 // and 6020002.

Via its sales forces and Customer Service Centers, we are in close touch with our customers and have received global complaints reporting a sudden shut-down of the D-TRONplus insulin pump family.

Subsequent investigation has shown a cell failure of the affected power packs to cause a rare shutdown of the insulin pumps – in some occasions without giving an alarm. This malfunction may lead to an undetected insulin under-delivery.

Although few complaints have been reported, the possibility exists of thus affected power packs already in circulation. The potentially affected lots are: 4017120 // 4017121 // 4017242 and 6020002. We hereby kindly ask you to check your power pack stock of D-TRONplus or Accu-Chek D-TRONplus insulin pump- **you find the lot number printed on the metal power pack casing itself and at the top of the blister backside.** Any potentially affected power packs with the given lot numbers will be replaced immediately, free of charge.

Management of patient therapy with the D-TRONplus or Accu-Chek D-TRONplus insulin pump can be continued as usual

We should like to thank you in advance for your assistance. If you require additional information, please do not hesitate to contact our colleagues at the Customer Service Center 0123456789 at any time.

Yours faithfully,

Roche Diagnostics

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XYZ
XYZ Town
Country XYZ

Location, April XY, 2006

Important information on power pack failure risk of batteries for D-TRONplus and Accu-Chek D-TRONplus insulin pump family

Dear XYZ,

The purpose of this letter is to inform you about a potential risk with some insulin pump power packs where specific batheried power packs are in use for the D-TRONplus or Accu-Chek D-TRONplus. The measure relates solely to the power pack lots numbers 4017120// 4017121// 4017242 // and 6020002.

Via its sales forces and Customer Service Centers, we are in close touch with our customers and have received global complaints reporting a sudden shut-down of the D-TRONplus insulin pump family.

Subsequent investigation has shown a cell failure of the affected power packs to cause a rare shutdown of the insulin pumps – in some occasions without giving an alarm. This malfunction may lead to an undetected insulin under-delivery.

Although few complaints have been reported, the possibility exists of thus affected power packs already in circulation. The potentially affected lots are: 4017120 // 4017121 // 4017242 and 6020002. We hereby kindly ask you to check your power pack stock of D-TRONplus or Accu-Chek D-TRONplus insulin pump- **you find the lot number printed on the metal power pack casing itself and at the top of the blister backside.** Any potentially affected power packs with the given lot numbers will be replaced immediately, free of charge.

Management of patient therapy with the D-TRONplus or Accu-Chek D-TRONplus insulin pump can be continued as usual

We should like to thank you in advance for your assistance. If you require additional information, please do not hesitate to contact our colleagues at the Customer Service Center 0123456789 at any time.

Yours faithfully,

Roche Diagnostics

Draft Pharmacist LETTER D-TRON/Battery issue Version April 19 2006

XYZ Pharmacy
XYZ Town
Country XYZ

Location, April XY, 2006

Information on potential failure of power packs for D-TRONplus and Accu-Chek D-TRONplus insulin pump family

Dear XYZ,

The purpose of this letter is to inform you about a potential risk with some insulin pump power packs where specific power packs (special battery) are in use for the D-TRONplus or Accu-Chek D-TRONplus. The measure relates solely to the power pack lots **4017120// 4017121// 4017242 // and 6020002.**

Via its sales forces and Customer Service Centers, we are in close touch with our customers and have received global complaints reporting a sudden shutdown of the D-TRONplus insulin pump family.

Subsequent investigation has shown a cell failure of the affected power packs to cause the shut-down of the insulin pumps – in some occasions without giving an alarm. This malfunction may lead to an undetected insulin under-delivery.

Although few complaints have been reported, the possibility exists of thus affected power packs already in circulation. The potentially affected lots are as follows: **4017120 //4017121 // 4017242 and 6020002.**

We hereby wish to ask you to **check your power pack stocks** of D-TRONplus or Accu-Chek D-TRONplus insulin pump. Any potentially affected power packs with the given lot numbers will be replaced immediately, free of charge and contact may be made either with our customer service center or via your sales representative.

Management of patient therapy with the D-TRONplus or Accu-Chek D-TRONplus insulin pump can be continued as usual. All involved customer segments incl. healthcare professionals are also being notified henceforth.

We should like to thank you in advance for your assistance. If you require additional information please do not hesitate to contact our colleagues at the Customer Service Center **0123456789** or our sales force at any time.

Yours faithfully,

Roche Diagnostics