



VITALS

A Weekly Safety Newsletter For Medical Transport Professionals

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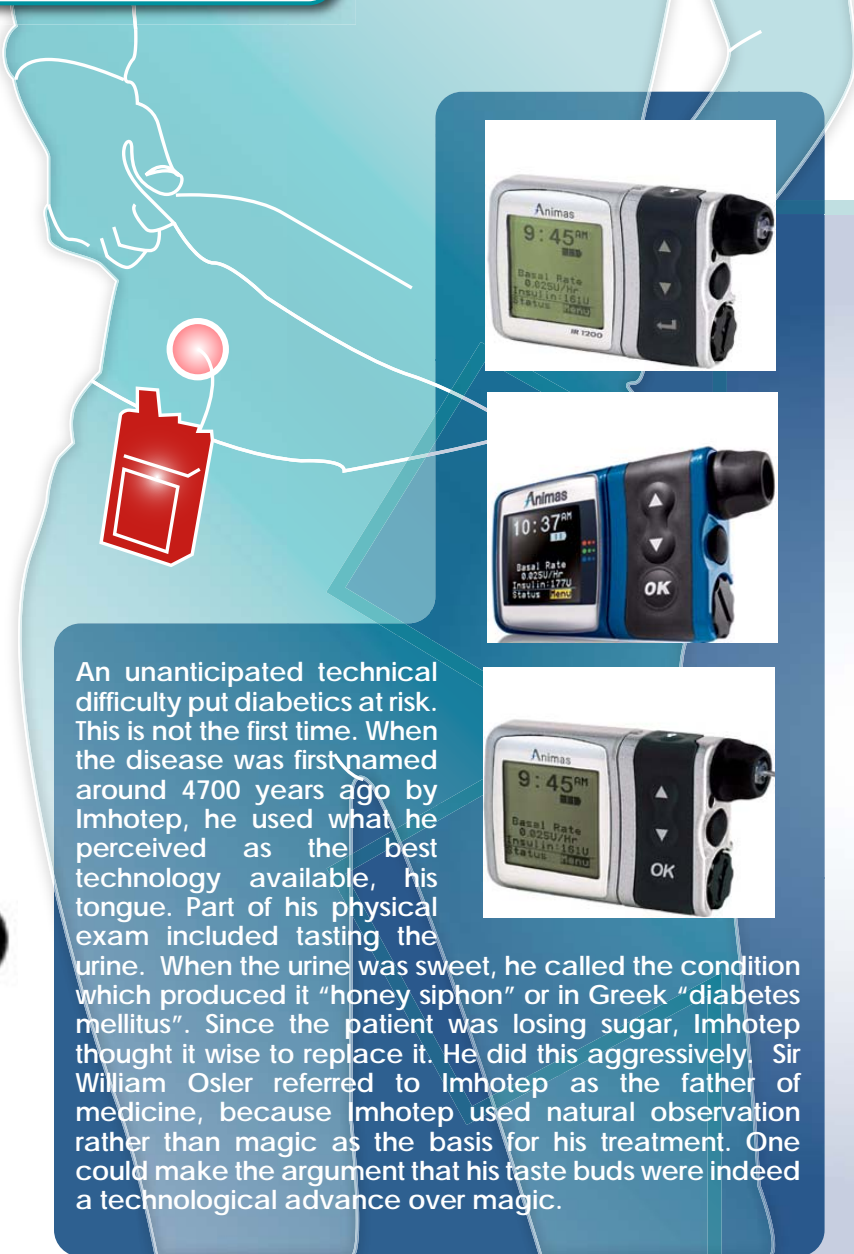
FDA Class I Recall of Animas Corporation Battery Caps

Class I recalls are the most serious type. There is a reasonable probability that the use of these products will cause serious injury or death. The products are the: Animas Corporation, Battery Caps Used with the OneTouch Ping System, Animas 2020 Insulin Pump, Animas IR1200 Insulin Pump, and the Animas IR1250 Insulin Pump.

These insulin pumps all use the same type of battery cap. The company cited the following as the reason for the Recall:

"There may be an intermittent loss of contact between the battery cap and the battery compartment in the pump which may result in the device resetting. This can cause the device to stop administering insulin, which could result in an excess level of glucose in the blood (hyperglycemia). Additionally, this failure may lead to user confusion in the amount of insulin administered, contributing to errors in future doses, which may result in lower than normal level of glucose in the blood."

To rectify the situation, the company sent each customer a letter describing the problem and a replacement battery cap. This could have impacted both emergency and nonemergency transports. Of course if the sugar was too high or low, symptoms may have occurred which prompted a request for emergency services. Conversely, how many diabetics on dialysis could have been transported for a routine dialysis trip and gotten ill en route?



An unanticipated technical difficulty put diabetics at risk. This is not the first time. When the disease was first named around 4700 years ago by Imhotep, he used what he perceived as the best technology available, his tongue. Part of his physical exam included tasting the urine. When the urine was sweet, he called the condition which produced it "honey siphon" or in Greek "diabetes mellitus". Since the patient was losing sugar, Imhotep thought it wise to replace it. He did this aggressively. Sir William Osler referred to Imhotep as the father of medicine, because Imhotep used natural observation rather than magic as the basis for his treatment. One could make the argument that his taste buds were indeed a technological advance over magic.



The technology of today is so sophisticated that at times it may appear magical, but without appropriate maintenance, calibration and vigilance our efforts may ultimately be as misdirected as Imhotep's.

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