

TABLE 1
Effect of suboptimal storage conditions on performance of Ames Dextrostix

	Blood glucose (mmol/L)			Coefficient of correlation
	N	\bar{x}	SD	
Reference group	40	9.08	6.11	
Group I	40	9.21	6.22	0.98
Group II	40	9.61	6.69	0.98

Second, the effect of storage conditions before use on the performance of Ames Dextrostix was assessed. We divided bottles of Dextrostix into two groups at ambient laboratory temperature (24°C): group I was stored capped and group II was stored uncapped. Over a period of 2 mo blood samples were assayed using strips from each group and the results compared with those obtained using strips from previously unopened bottles (reference group). Results from both groups were similar to those from the reference group (Table 1), indicating that storage of Dextrostix under less-than-ideal conditions does not significantly alter their accuracy.

Finally, we investigated the effect of storage conditions after use to determine if Ames Dextrostix would maintain their initial developed color; the ability to reread the strips some time after the initial reading to check the original result would be useful in some clinical situations. We found that the developed color of Dextrostix, stored after use at ambient temperature in dessicated bottles, was unstable and faded rapidly in a nonuniform fashion. After 24 h the strips read only $34 \pm 13\%$ of their initial value. However, when stored singly, dessicated in a bottle at -20°C , developed color was retained. Under the latter conditions, the readings 1 wk after use were $95 \pm 5\%$ of initial values. On removal of the strips from -20°C to ambient temperature, the developed color remained stable for up to 2 h. Although storage at -20°C tends to make rereading of Dextrostix inconvenient, it should be feasible in a hospital situation where strips used during the night could be checked the following morning. Patients on home glucose monitoring, who were in possession of a freezer, could have their results checked at a follow-up clinic visit.

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Dextrostix Reactivity Variation

Recalibration of the Dextrometer and Glucometer (Ames Division, Miles Laboratories, Elkhart, Indiana) whenever starting a new bottle of Dextrostix was recommended in a recent article in *DIABETES CARE*, and by the Ames Company. On the other hand, the manufacturers of Glucoscan (LifeScan, Mountain View, California), a rival meter, do not provide a method for recalibration and apparently believe that Dextrostix reactivity variation is not significant.

We recently evaluated Dextrostix reactivity variation in 14 Dextrostix supplied by our patients. The interval of time since the patient's opening of the container varied from 1 to 31 wk. Eight lot numbers were represented. The patient-supplied Dextrostix and 15 control Dextrostix from a single source were reacted with venous blood in random order, single-blinded, and measured by a Glucoscan meter.

The mean values of the patient-supplied Dextrostix and the control Dextrostix were 138 versus 141 mg/dl, respectively; the standard deviations were 16 versus 17 mg/dl, respectively; and the ranges of values were 122–149 versus 125–154 mg/dl, respectively. The values for variability of the control readings were similar to those previously reported in *DIABETES CARE*.

We conclude that variability in Dextrostix reactivity may be insignificant, especially when compared with variability of the operator technique. Further studies should be conducted to substantiate these findings since they affect patients' cost and selection of meters.

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Cutaneous Complication of CSII Therapy

The cutaneous complications of continuous subcutaneous insulin infusion (CSII) have recently been reviewed by Pietri and Raskin.¹ I have noted an additional complication, which seems worthy of mention since it responded to a specific form of therapy.

The patient, a 12-yr-old boy, was placed on CSII because of inadequate control on conventional therapy. He used the Auto-Syringe AS*6C pump (Auto-Syringe, Inc., Hooksett, New Hampshire) with U-36 insulin. The insulin was pre-

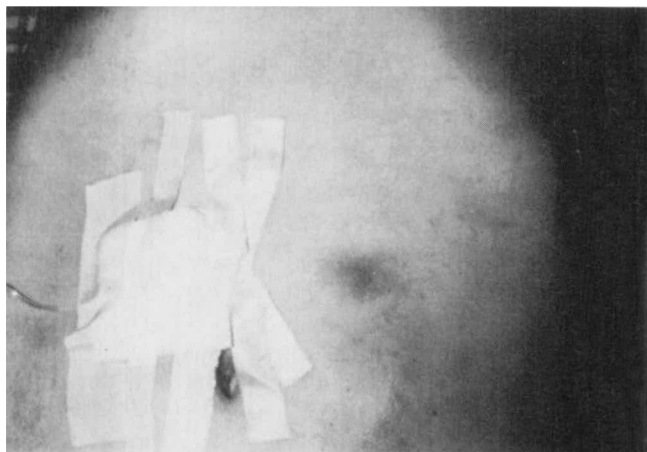


FIG. 1. A recent nodule seen above and to the right (patient's left) of the umbilicus. Two resolving nodules are below it.

pared by dilution of Squibb Regular mixed beef-pork U-100 insulin (E. R. Squibb & Sons, Princeton, New Jersey) with 0.9% saline. After about 2 mo of therapy, he began to get firm, indurated, painful, red nodules at the site of the indwelling needle (Figure 1), which came after about 24 h of infusion at a single site, and lasted several days after the needle was moved to another site. The pain necessitated moving the needle about once every 24 h. Several nodules were present at once, making it difficult to find suitable abdominal injection sites. The patient was afebrile; there were no signs of cellulitis, and erythromycin, prescribed by his general pediatrician, had no effect.

His insulin preparation was changed to Iletin I U-40 insulin (Eli Lilly and Company, Indianapolis, Indiana), which he then used without further dilution. The nodules resolved, and no new ones have occurred. The diluted insulin he had been using appeared slightly cloudy; when cultured, it grew a moderate number of *Klebsiella oxytoca*.

The specific cause of the nodules is not firmly established. Possible causes are the saline dilution and the bacterial contamination. The latter is of interest because of the recent report by Schade and Eaton documenting the bactericidal property of U.S.P. insulin.² Evidently, this property is lost on saline dilution. The brand of insulin was also changed, and this may have been a factor in the clinical improvement.

Because the patient was a child who had greatly suffered from the skin nodules, we did not rechallenge him to determine the specific cause of the untoward reaction. This case does, however, present an argument for avoiding use of diluted insulins in insulin pumps.

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¹ Pietri, A., and Raskin, P.: Cutaneous complications of chronic continuous subcutaneous insulin infusion therapy. *Diabetes Care* 4: 624-26, 1981.

² Schade, P. S., and Eaton, R. P.: Bactericidal properties of commercial U.S.P. formulated insulin. *Diabetes* 31: 36-39, 1982.

Cold Weather and CSII

The unusually cold weather experienced by most of the nation during the winter of 1982 has produced a system failure of continuous subcutaneous insulin infusion (CSII) therapy that has not been described previously. A 19-yr-old man with insulin-dependent diabetes mellitus, who was working part-time as a ski-lift operator and had been using CSII for 3 mo, began reporting frequent breakage of both Monoject (Sherwood Medical Industries, DeLand, Florida) and Autosyringe (Autosyringe, Inc., Hooksett, New Hampshire) 3-cc syringes at the luer. He also reported freezing of the diluted insulin in these syringes within 15 min of exposure to the cold. The patient was using the Autosyringe AS2C infusion pump and wearing the unit on his belt. Most of the unit, including the barrel of the syringe, was covered by a medium-length nylon ski jacket. The outside temperature and wind velocity were not recorded at these times; however, local weather reports suggested that the wind-chill factor was close to 0°F.

To investigate these "cold"-related CSII system failures, we subjected Monoject and Autosyringe 3-cc syringes, both empty and filled with the insulin-saline mixture used by our patient (115 U in 3-cc normal saline), to cold (0°C to -5°C) and wind (600-2000 rpm) in a temperature-controlled centrifuge and then applied light pressure to the luer end of the syringe. Although the force applied to the syringe was not quantitated, it was similar in intensity and direction to that which could be anticipated when accidentally bumping the AS2C unit against a steering wheel, door jamb, or desk.

Monoject syringes are designed to break easily at the luer for safety reasons. Consequently, it was not surprising that these syringes broke with little pressure at both room temperature and 0°C. Autosyringe syringes, however, are designed for use with Autosyringe pumps. The AS2C design requires the luer to extend beyond the syringe cradle, and therefore be subject to forces from all directions. The Autosyringe syringes did not break easily at room temperature, but broke as easily as those designed to snap apart when exposed to 0°C for 10 min.

Filling the syringes with the diluted insulin solution did not affect the results of the fragility testing. The solution used by our patient froze solidly in both syringes when exposed to 0°C to -5°C without wind for 30 min, but did not freeze during 15-min exposure to 0°C and 600 rpm. At the same temperature but faster speeds (2000 rpm) the solution in Monoject syringes froze within 15 min while only half of the filled Autosyringe syringes froze.