

# BASAL RATES DELIVERED ACCORDING TO TYPICAL CIRCADIAN PROFILES WITH BOLUSES: ACCURACY OF DIFFERENT INSULIN PUMPS

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## BACKGROUND AND AIMS

Insulin pumps are commonly used in the therapy of persons with type 1 diabetes. EN 60601-2-24 describes test settings and procedures for evaluating infusion pumps with constant flow rates; however, most basal rates follow a circadian pattern and boluses are given in addition. In this study, accuracy of different insulin pumps was evaluated in an experimental setting based on EN 60601-2-24.

## METHOD

The insulin pumps Accu-Chek<sup>®</sup> Insight, Accu-Chek<sup>®</sup> Spirit Combo, MiniMed<sup>®</sup> 640G, MiniMed<sup>®</sup> 670G, OmniPod<sup>®</sup> and mylife<sup>™</sup> YpsoPump were tested. Evaluations were based on the weight increase of a water-filled, oil-covered beaker placed on an electronic balance into which insulin was delivered. Pumps were installed outside of the balance with infusion sets or a steel pipe (for patch pump), respectively, connected to the beaker. After priming, a circadian basal rate profile (20U/24h) was run for 48h. In addition, three insulin boluses (8, 10 and 15U) were delivered during the first 24h. Each pump was tested 9 times; total deviations over 48h and percentages of individual 1-h-windows inside of a target range of  $\pm 15\%$  were calculated.

## RESULTS

Over 48h, mean total deviations from target ranged from -0.3% to +1.9% for the different systems (Table 1). Percentages of 1-h-windows within  $\pm 15\%$  of target ranged from 63.9% to 94.4% during the first 24h (with included boluses) and from 69.0% to 100% during the second 24h.

## CONCLUSION

In this study, accuracy markedly differed between the insulin pumps over short time windows with included boluses, although deviations from target were small for all pumps over the total observation period.

TABLE 1: Total deviation and percentage of 1-h-windows within  $\pm 15\%$  of target for each system (1-6) during different time ranges.

#	Insulin pump (Infusion set)	Total deviation [%] / Percentage of 1-h-windows within $\pm 15\%$ of target		
		1-24 h (with boluses)	25-48 h (without boluses)	1-48 h
1	Accu-Chek <sup>®</sup> Insight (Accu-Chek Insight Flex)	-0.4 / 94.4	0.0 / 100	-0.3 / 97.2
	Accu-Chek <sup>®</sup> Spirit			
2	Combo (Accu-Chek FlexLink)	0.2 / 88.4	-1.6 / 98.1	-0.3 / 93.3
3	MiniMed <sup>®</sup> 640G (Quick-set <sup>®</sup> )	1.8 / 90.3	-0.9 / 99.5	1.0 / 94.9
4	MiniMed <sup>®</sup> 670G (Quick-set <sup>®</sup> )	1.0 / 93.5	-0.4 / 99.5	0.6 / 96.5
5	OmniPod <sup>®</sup>	1.7 / 63.9	1.0 / 69.0	1.5 / 66.4
6	mylife <sup>™</sup> YpsoPump (Orbit soft)	2.3 / 92.1	1.0 / 98.6	1.9 / 95.4

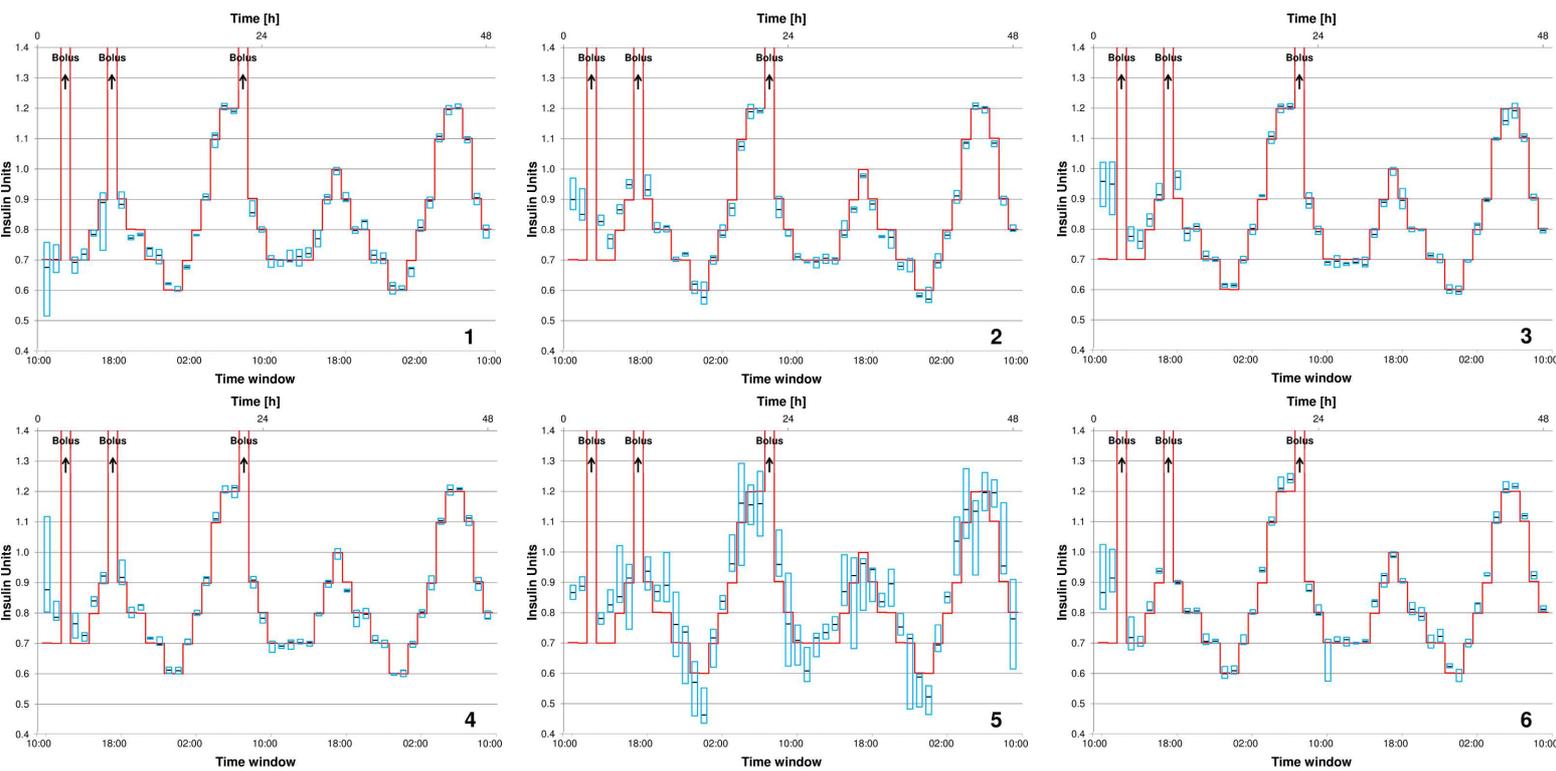


FIGURE 1: Median delivery (black dashes), 50% of values (blue boxes) and target (red line) over 1-h windows in course of time; for each insulin pump system (1-6).

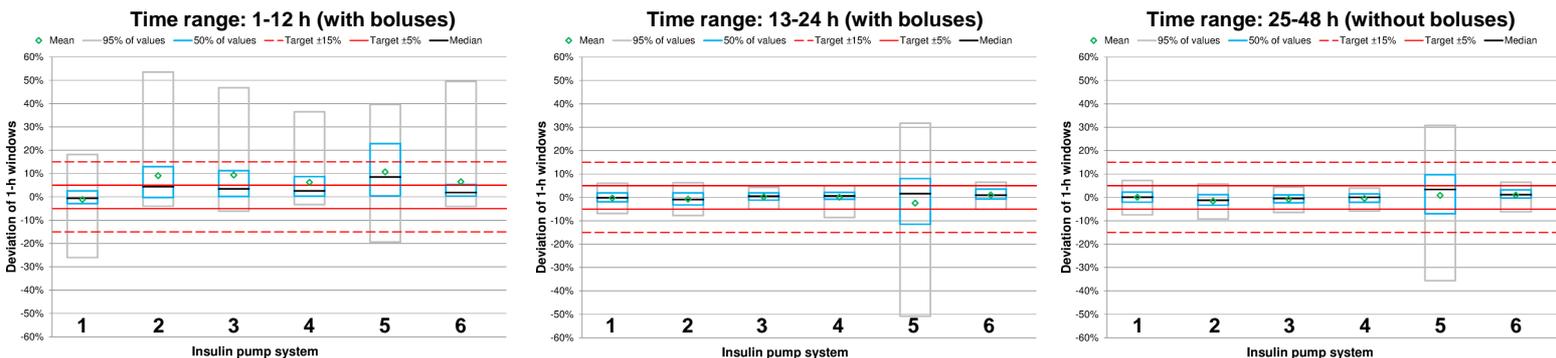


FIGURE 2: Percentage deviation of 1-h windows for each system (1-6) during different time ranges: Left: hours 1-12 (with 2 boluses), middle: hours 13-24 (with 1 bolus), right: hours 25-48 (no boluses).