OPEN TO CLOSED-LOOP TRANSITION SCHEMES
FOR IN VIVO GLUCOSE CONTROL

F. Garelli[1,2], E. Fushimi[1,2], N. Rosales[2], H. De Battista[1,2]

[1] Consejo Nacional de Investigaciones Científicas y Técnicas CONICET, Argentina.
[2] Group of Control Applications, LEICI-Facultad de Ingeniería, Universidad Nacional de La Plata, Buenos Aires, Argentina.
fabricio@ing.unlp.edu.ar — http://www.gca.ing.unlp.edu.ar

ABSTRACT

In this work, a safety layer called the SAFE loop [1] is reformulated to be employed during clinical trials in two different ways: the Time Enable mode, which gives a criterion for the transition between open and closed-loop therapy in hybrid configurations, and the Amplitude Enable mode, which diminishes the risk of an hypoglycemic event when testing fully closed-loop algorithms by delimiting the Insulin-On-Board (IOB) profile of the new control algorithm with the IOB profile corresponding to the usual open-loop therapy of the patient (or a factor of it).
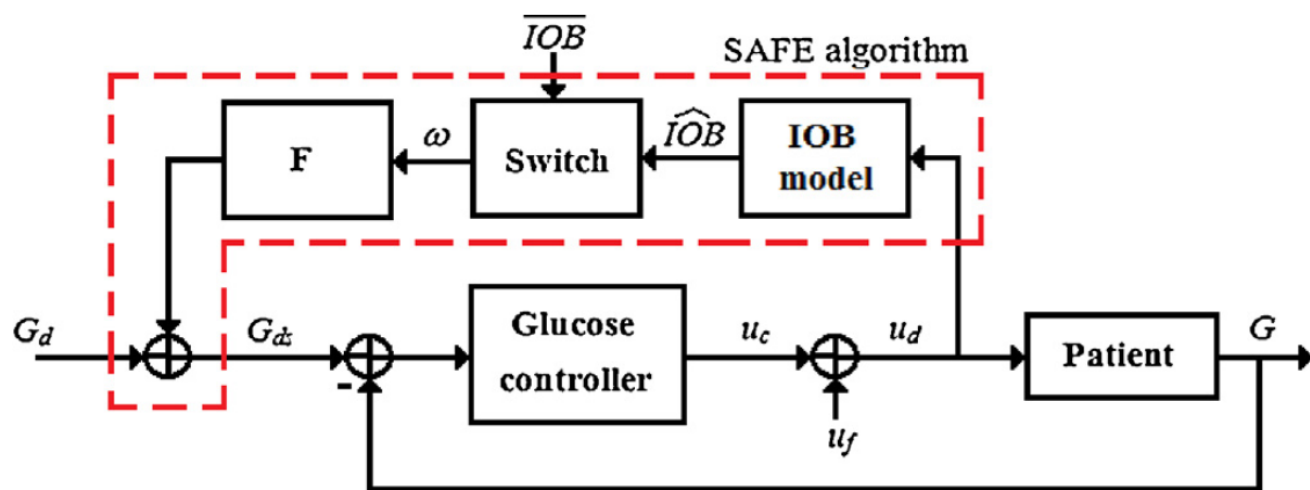
The SAFE Layer

Fig. 1. Basic scheme of a glucose control loop with the SAFE algorithm.

TIME and AMPLITUDE ENABLE

- **TIME ENABLE** MODE:

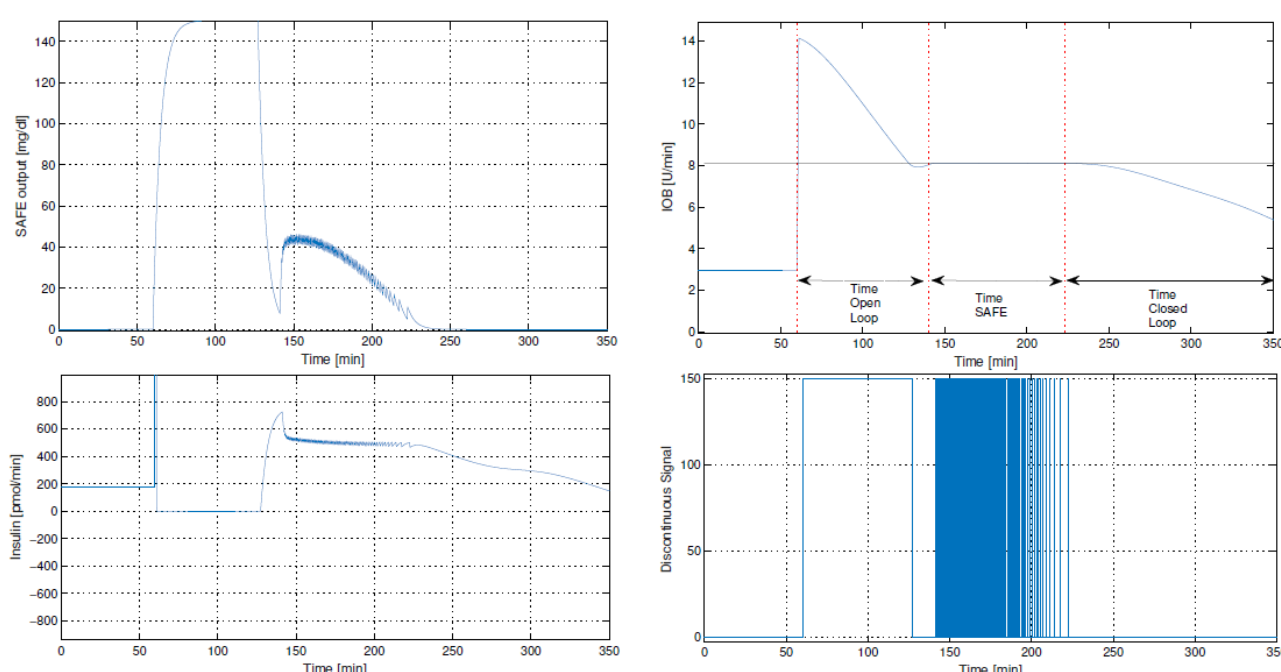$$\overline{IOB} = \left(1 - \frac{T_{OL}}{DIA}\right) \cdot I : CHO \cdot [CHO]$$

Fig. 2. Time Enable: Main signals of mode of operation on Adult 10 of UVA/Padova simulator

- **AMPLITUDE ENABLE** MODE:

$$\overline{IOB} = \text{Open-loop IOB profile}$$
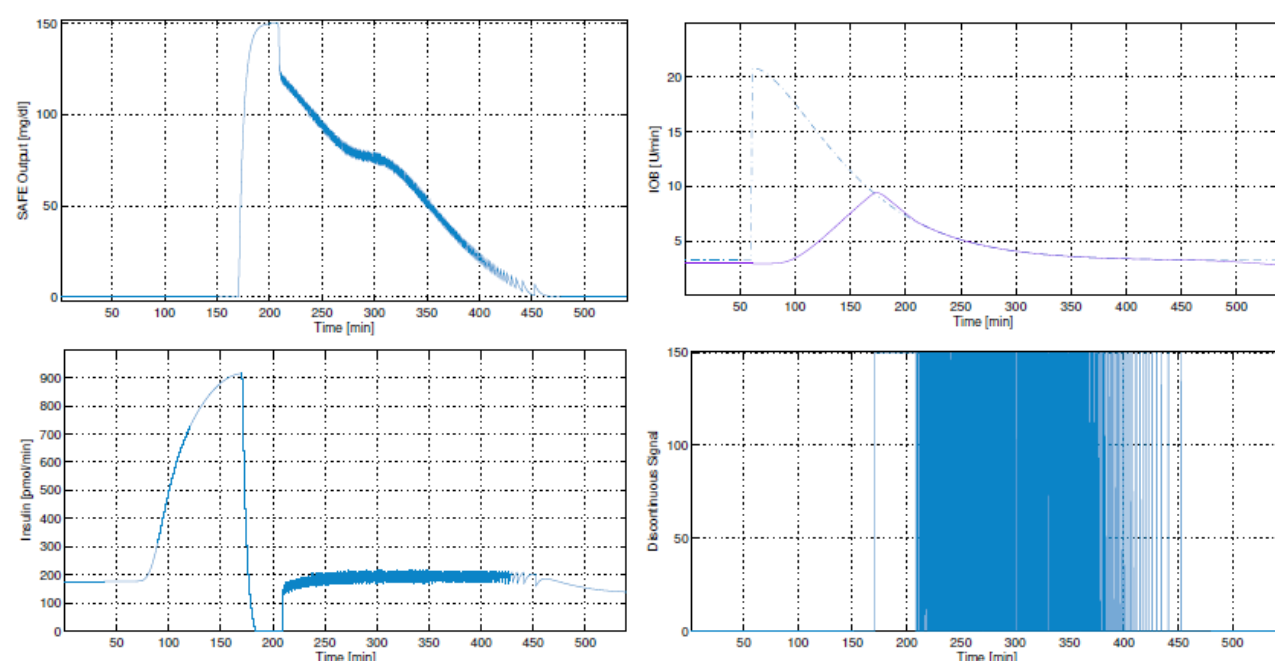(or a bigger-than-1 factor of it).

Fig. 3. Amplitude Enable: Main signals of mode of operation on Adult 10 of UVA/Padova simulator

RESULTS

In-silico trials show how using the **Time Enable** method the transition from open (bolus) to closed-loop is made automatically and gradually, resulting in a bumpless mechanism which improves the controller response.
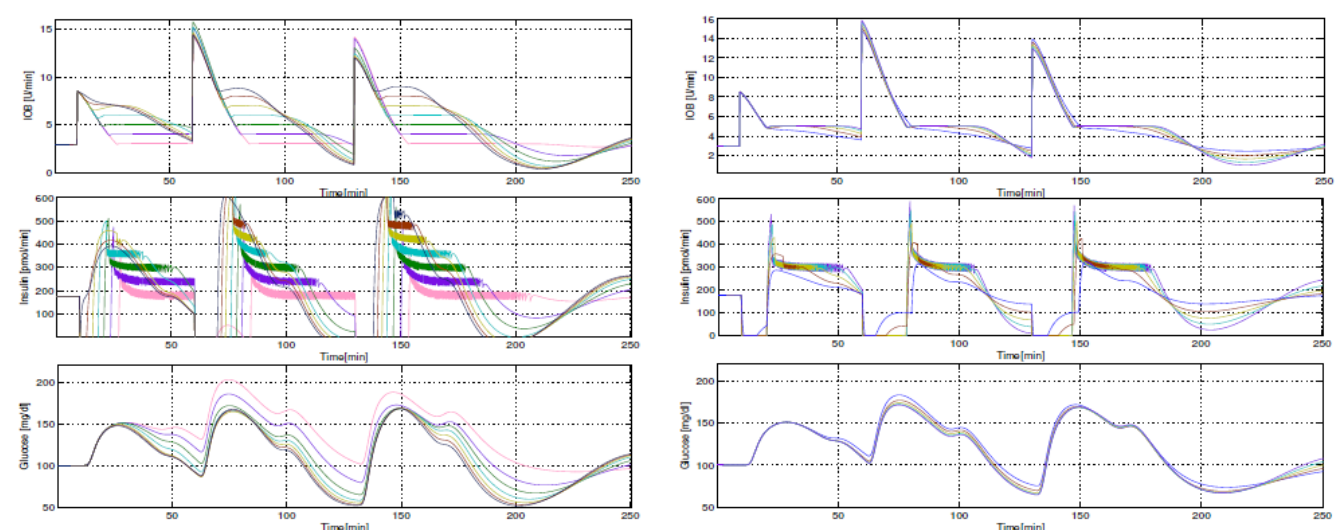

Fig. 4. Time Enable: Time evolution when performing an IOB sweep (left) and a Kp sweep (right)

Tabla 1. $\overline{IOB}$ sweep. Time Enable.

$IOB[U]$	T_{OL} [min]	T_{SAFE} [min]	T_{CL} [min]
3	392	746	362
4	342	615	543
5	277	525	698
6	242	396	862
7	202	202	1096
8	178	154	1170
9	116	57	1327

Tabla 2. k_p sweep. Time Enable.

$k_p[\%]$	T_{OL} [min]	T_{SAFE} [min]	T_{CL} [min]
−70%	290	0	1210
−50%	285	210	1005
−30%	284	352	864
−10%	280	452	768
+10%	277	505	718

In the case of the **Amplitude Enable** mode, the results show how the patient is protected from hypoglycemia even when controller gain is disproportionally large, as shown below.
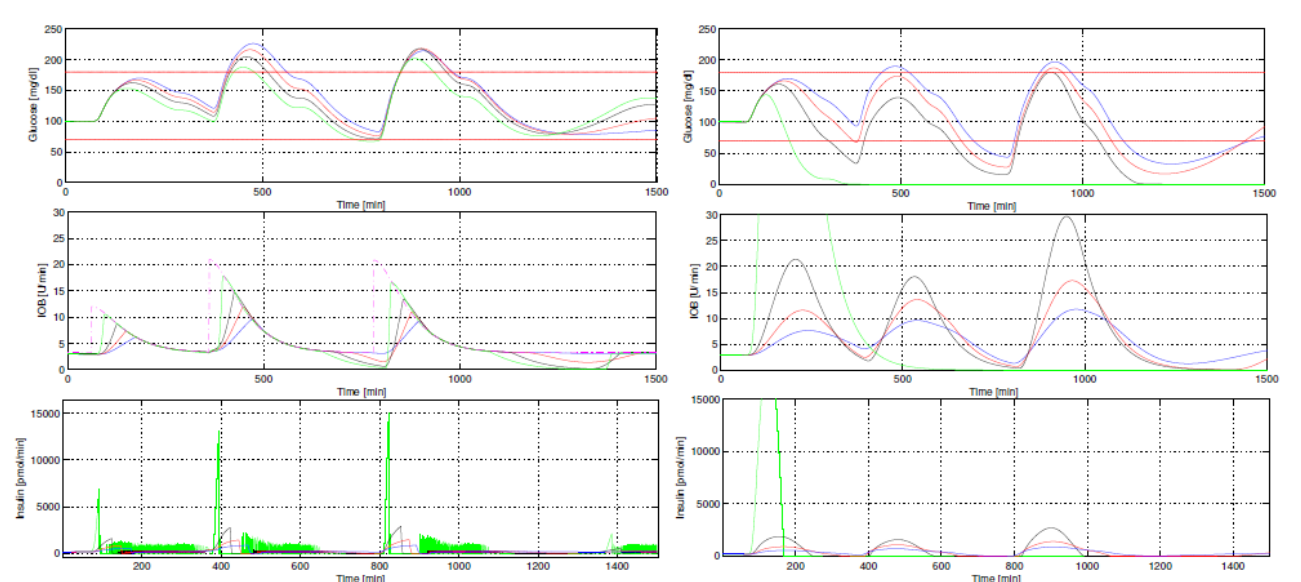

Fig. 5. Amplitude Enable: Time evolution when performing a Kp sweep with (left) and without (right) the SAFE layer

Tabla 4. k_p sweep. PID with Amplitude Enable.

$k_p[\%]$	Time in hypoglycemia [%]	Time in normoglycemia [%]	Time in hyperglycemia [%]
100%	0	81	19
200%	0	83	17
500%	0	85,65	14,35
7500%	4,64	85,8	9,56

Tabla 3. k_p sweep. PID without Amplitude Enable.

$k_p[\%]$	Time in hypoglycemia [%]	Time in normoglycemia [%]	Time in hyperglycemia [%]
100%	31	57,9	11,1
200%	36,15	60,3	3,55
500%	50	48,35	1,65
7500%	87,9	12,1	0

CONCLUSIONS

- Two IOB constraint profiles are proposed for its use in clinical trials, giving rise to a safe mechanism for in vivo testing both hybrid and fully closed-loop controllers.

REFERENCES

[1] A. Revert, F. Garelli, J. Picó, H. De Battista, P. Rossetti, J. Vehi, J. Bondía. *Safety Auxiliary Feedback Element for the Artificial Pancreas in Type 1 Diabetes*, IEEE Transactions on Biomedical Engineering, 60(8), 2113- 2122, Aug. 2013.