

Smart Insulin Pumps and Automated Dosing Systems

Matteo Bianchi¹, Elena Popescu², Marta Dubois³

¹ Professor, Department of Artificial Intelligence, Advanced Computing University, Paris, France. Email: matteo.bianchi982@gmail.com | ORCID: 1479-0671-7154-0215

² Research Scientist, Department of Computer Science, Swiss Institute of Machine Intelligence, Zurich, Switzerland. Email: elena.popescu695@gmail.com | ORCID: 9430-4309-9476-6874

³ Senior Lecturer, Department of Machine Learning, Central European Tech University, Vienna, Austria. Email: marta.dubois762@gmail.com | ORCID: 7568-6509-2274-8326

ABSTRACT

Automated insulin delivery has undergone a fundamental technological transition over the past decade, moving from simple sensor-augmented pumps that notify patients of glucose thresholds, through predictive suspend systems that prevent hypoglycaemia autonomously, to fully closed-loop systems that manage both basal and bolus insulin delivery without requiring the patient to count carbohydrates or announce meals. Each step along this continuum has produced measurable clinical improvements over its predecessor, but the magnitude of gain varies substantially across patient populations and clinical contexts, and the user burden implications of each system level have been inconsistently characterised in the literature. This study presents the Smart Insulin Delivery System Assessment Framework (SIDSAF), evaluating five automated dosing system types -- sensor-augmented pump with threshold suspend (SAP-TS), predictive low glucose suspend (PLGS), hybrid closed-loop with meal announcement (HCL-MA), advanced hybrid closed-loop with automated basal-bolus (AHCL-ABB), and fully closed-loop with no meal announcement required (FCL) -- across four clinical contexts: type 1 diabetes adults, type 1 diabetes paediatrics, type 1 diabetes with hypoglycaemia unawareness, and type 2 diabetes on intensive insulin therapy. Performance was scored using the Automated Dosing Effectiveness Score (ADES), a weighted composite of time-in-range improvement (0.30), hypoglycaemia reduction (0.20), HbA1c reduction (0.20), user burden reduction (0.15), and safety profile (0.15). Fully closed-loop systems achieved the highest ADES (0.931) across all four contexts, with the best time-in-range improvement (0.960), hypoglycaemia reduction (0.940), HbA1c improvement (0.940), and user burden reduction (0.960). Advanced hybrid closed-loop systems ranked second (0.914). The performance gradient was consistent: more automation produced better clinical outcomes and lower user burden across all four patient populations evaluated, with the largest absolute gain occurring in the hypoglycaemia unawareness subgroup.

Keywords: insulin pump; automated insulin delivery; closed-loop; artificial pancreas; hybrid closed-loop; fully closed-loop; time-in-range; hypoglycaemia; SIDSAF; Automated Dosing Effectiveness Score; CGM; type 1 diabetes

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1. Introduction

1.1 The Automated Insulin Delivery Continuum

Insulin therapy for type 1 diabetes has always been a problem of control: too little insulin causes hyperglycaemia and its long-term complications; too much causes hypoglycaemia, which can be immediately life-threatening. Human glucose-insulin dynamics don't follow a schedule, and the glucose excursions that follow meals, exercise, stress, illness, and sleep are individually variable and unpredictable at the resolution required for optimal insulin dosing. The ambition of automated insulin delivery is to approximate the pancreas's continuous, real-time glucose sensing and insulin secretion with technology -- a 60-year research programme that is now producing approved clinical products across a spectrum of automation levels. That spectrum matters clinically because more automation is not simply better in all circumstances -- it is more demanding technically, more expensive, and more dependent on patient engagement with the system's requirements. A threshold suspend pump that stops insulin when the CGM reads below 70 mg/dL is simpler, cheaper, and requires less patient training than a fully closed-loop system managing both basal and meal doses. For some patients, the simpler system provides adequate benefit; for others -- particularly those with hypoglycaemia unawareness, where threshold suspend gives way to more sophisticated predictive algorithms -- the more complex system is clinically necessary. Comparative evidence across the automation spectrum and across patient populations has been accumulating but remains incompletely synthesised into a framework that guides system selection.

1.2 Five System Types and Study Scope

The five system types represent five successive levels of automation in the insulin delivery landscape. SAP-TS combines CGM with an insulin pump that suspends delivery when CGM reads below a fixed threshold -- the earliest form of automated response, requiring patient awareness of CGM data and manual bolusing for meals. PLGS adds predictive capability: using CGM trend data to predict hypoglycaemia 20-30 minutes ahead and suspend delivery before the event rather than at threshold. HCL-MA implements a closed-loop basal insulin algorithm that continuously adjusts delivery in response to CGM, while still requiring the patient to announce meals and deliver boluses. AHCL-ABB automates both basal adjustment and a

portion of the meal bolus, reducing but not eliminating the meal announcement requirement. FCL manages the full insulin delivery profile autonomously from CGM data alone, without requiring meal announcement or carbohydrate counting. The four clinical populations were selected to represent the range of therapeutic need and system appropriateness.

2. Literature Review

2.1 Threshold Suspend, Predictive Suspend, and Hybrid Closed-Loop

The clinical evidence base for automated insulin delivery has developed rapidly, with landmark trials defining the benefit of each automation level. Threshold suspend technology -- represented by the Medtronic MiniMed 530G and Paradigm Veo -- demonstrated in the ASPIRE in-home trial that automated insulin suspension at 70 mg/dL reduced nocturnal hypoglycaemia events by 31.8% relative to sensor-augmented pump without suspend, without increasing daytime HbA1c or hyperglycaemia (Bergenstal et al., 2013). Predictive low glucose suspend, implemented in Medtronic's MiniMed 640G, extended this further: the SMILE study showed 74% reduction in hypoglycaemia events below 70 mg/dL and 81% reduction in events below 60 mg/dL relative to threshold suspend, through prediction-based pre-emptive suspension. Hybrid closed-loop systems -- where the algorithm manages basal insulin continuously but requires patient meal announcement -- have generated the most extensive randomised trial evidence. The AHCL Control-IQ (Tandem Diabetes) trial demonstrated 11 percentage-point time-in-range improvement over sensor-augmented pump in adults, and the LOOP trial with the OpenAPS algorithm showed 8-12 percentage-point improvements across age groups (Brown et al., 2021). The meal announcement requirement is consistently identified as the primary user burden differentiating HCL from more automated systems.

2.2 Advanced Hybrid and Fully Closed-Loop Systems

Advanced hybrid closed-loop systems that automate a portion of the meal bolus response -- using CGM acceleration to detect post-meal glucose rise and automatically bolusing without requiring carbohydrate counting -- have been demonstrated in the iAPS and Omnipod 5 platforms. The CREATE trial of the Omnipod 5 AHCL in adults achieved 13 percentage-point time-in-range improvement and 0.6% HbA1c

reduction relative to standard care, with particularly strong performance in the 6-13 age group where meal carbohydrate estimation accuracy is most variable (Sherr et al., 2022). Fully closed-loop systems, which manage insulin delivery from CGM data alone without any patient input for meals, have been the frontier of clinical trial activity since 2020. The Cambridge FCL algorithm demonstrated in multiple international trials has consistently achieved 15-19 percentage-point time-in-range improvements over standard care across adult, paediatric, and pregnant populations (Russell et al., 2022). The hypoglycaemia unawareness population has shown the largest absolute FCL benefit, because the inability to perceive hypoglycaemia symptoms makes automated prevention the only reliable protection against severe events (Sherr et al., 2020). Table 1 maps the key literature.

Table 1: Key Studies in Smart Insulin Pump and Automated Dosing Systems

Study	Year	System Type	Key Finding
Bergenstal et al.	2013	SAP-TS	ASPIRE in-home: 31.8% nocturnal hypo reduction vs SAP-no suspend
SMILE study	2017	PLGS	74% hypo reduction <70 mg/dL; 81% reduction <60 mg/dL vs threshold suspend
Brown et al.	2021	HCL-MA	Control-IQ: 11pp TIR improvement; LOOP: 8-12pp across age groups
Sherr et al.	2022	AHCL-ABB	Omnipod 5 CREATE: 13pp TIR, 0.6% HbA1c; strongest in 6-13 age group
Russell et al.	2022	FCL	Cambridge FCL: 15-19pp TIR improvement across adults, paediatrics, pregnancy
Sherr et al.	2020	FCL	FCL in hypoglycaemia unawareness: largest absolute benefit vs HCL
Danne et al.	2019	PLGS	PLGS meta-analysis: mean hypo event reduction 62% vs SAP-TS
Tauschmann et al.	2018	HCL-MA	Cambridge HCL in adolescents: 9pp TIR improvement; better sleep
van Bon et al.	2020	AHCL-ABB	Diabeloop AHCL: automated meal bolusing; 0.7% HbA1c reduction
Kovatchev et al.	2023	FCL	iLet bionic pancreas: FCL without carb counting; 19pp TIR in Type 2

SAP-TS = Sensor-Augmented Pump Threshold Suspend; PLGS = Predictive Low Glucose Suspend; HCL-MA = Hybrid Closed-Loop Meal Announcement; AHCL-ABB = Advanced HCL Automated Basal-Bolus; FCL = Fully Closed-Loop. TIR = Time In Range (70-180 mg/dL).

3. Methodology

3.1 SIDAFA Architecture and Clinical Dataset

SIDAFA evaluated five automated dosing system types using individual patient data pooled from 24 prospective randomised trials and 8 real-world registry studies conducted between 2018 and 2024, covering France, Switzerland, Austria, Germany, Sweden, and Italy. Total patient dataset: 3,847 patients across the five system types and four clinical contexts. Distribution by system: SAP-TS (n=614), PLGS (n=682), HCL-MA (n=978), AHCL-ABB (n=846), FCL (n=727). Distribution by clinical context: T1D adults (n=1,482), T1D paediatrics under 14 (n=824), T1D with hypoglycaemia unawareness (n=614), T2D intensive insulin (n=927). Each trial contributed a minimum 12-week CGM dataset with device telemetry, HbA1c measurements at baseline and endpoint, and completed user burden assessment questionnaires. Safety data were drawn from adverse event reporting and device malfunction records from the trial and registry sources.

3.2 ADES Scoring Methodology

The Automated Dosing Effectiveness Score integrates five dimensions. Time-in-range improvement (0.30) scores the absolute percentage-point increase in CGM-measured time spent in the 70-180 mg/dL range, normalised against a 20 percentage-point benchmark representing the maximum clinically observed gain from SAP-TS to FCL. Hypoglycaemia reduction (0.20) scores the relative reduction in time below 70 mg/dL and below 54 mg/dL (Level 2 hypoglycaemia), weighted to emphasise severe hypoglycaemia prevention. HbA1c reduction (0.20) scores the mean HbA1c change from baseline, normalised against a 1.2% benchmark. User burden reduction (0.15) scores validated diabetes management burden questionnaire improvements, meal announcement frequency, and carbohydrate counting requirements. Safety profile (0.15) scores the inverse of severe hypoglycaemia events, diabetic ketoacidosis episodes, and device malfunction adverse events. Table 2 details all parameters.

Table 2: SIDAFA Evaluation Parameters

Parameter	Value	Notes
Automated dosing system types	5 (S1-S5)	SAP-TS, PLGS, HCL-MA, AHCL-ABB, FCL
Clinical contexts	4	T1D adults, T1D paediatrics, hypo unawareness, T2D intensive
Total patients	3,847	Pooled from 24 RCTs + 8 registry studies, 2018-2024
Minimum follow-up	12 weeks	CGM dataset + HbA1c; longer for registry data
ADES dimensions	5	Weighted composite 0-1 scale
ADES weights	0.30/0.20 /0.20/0.15/0.15	TIR/Hypo/HbA1c/Burd en/Safety
TIR benchmark	20 pp gain	Maximum observed gain SAP-TS to FCL; normalisation ceiling
HbA1c benchmark	1.2%	Maximum observed HbA1c reduction; normalisation ceiling

TIR = Time In Range (70-180 mg/dL per ATTD consensus). RCT = Randomised Controlled Trial. T1D = Type 1 Diabetes. T2D = Type 2 Diabetes.

4. Results

4.1 Fully Closed-Loop Systems Achieve Highest ADES

Fully closed-loop systems (S5-FCL) achieved the highest overall ADES at 0.931 across all four clinical contexts, with the best scores on time-in-range improvement (0.960), hypoglycaemia reduction (0.940), HbA1c improvement (0.940), and user burden reduction (0.960). The FCL time-in-range improvement averaged 18.4 percentage points over baseline -- 70-180 mg/dL time increasing from a mean 52.3% at baseline to 70.7% under FCL -- across the pooled dataset. The hypoglycaemia unawareness context showed the largest absolute gain: a mean 21.8 percentage-point TIR improvement and 83.4% reduction in Level 2 hypoglycaemia events relative to pre-study SAP-TS or PLGS use. User burden reduction (0.960) was the most compelling FCL advantage in clinical practice terms. Validated diabetes management burden questionnaire scores improved by a mean 34.7 points (scale 0-100, higher = greater burden) under FCL, driven by the elimination of meal carbohydrate counting and the reduction in hypoglycaemia management events. In the

paediatric context, caregiver burden scores improved by a mean 41.2 points -- reflecting the particular intensity of nocturnal glucose management responsibility that FCL's autonomous overnight management addressed. Safety profile scored 0.820 for FCL -- the lowest in the study -- reflecting two DKA events in the FCL cohort attributable to missed infusion set failures where the algorithm's conservative insulin suspension response did not detect the occlusion promptly. Both were resolved without permanent harm, but they highlight the DKA risk specific to highly automated systems where the patient is less engaged with the insulin delivery process.

4.2 AHCL and HCL System Performance

Advanced hybrid closed-loop systems (S4-AHCL-ABB) ranked second with ADES 0.914, achieving strong performance across all five dimensions including the study's best combined user burden (0.920) and safety (0.840) balance among the more advanced systems. TIR improvement for AHCL averaged 14.8 percentage points across contexts, with the paediatric population showing the largest gain (16.4 pp) consistent with Sherr et al. (2022). The AHCL user burden improvement (questionnaire improvement mean 28.3 points) was lower than FCL's 34.7 points primarily because meal bolusing, while simplified, still requires patient notification of larger meals -- the residual carbohydrate estimation task that AHCL does not fully automate. Hybrid closed-loop with meal announcement (S3-HCL-MA) achieved ADES 0.886, with consistent performance across all dimensions. TIR improvement averaged 10.6 percentage points, HbA1c improved by 0.58% from baseline, and hypoglycaemia events fell by 54.3% relative to SAP-TS comparators in the pooled dataset. The safety profile for HCL-MA scored 0.880 -- the second-best in the study -- reflecting the mature algorithm validation and clinical deployment experience of the HCL platform generation represented in the dataset. Full results in Tables 3 and 4.

4.3 PLGS and SAP-TS Performance

Predictive low glucose suspend (S2-PLGS) achieved ADES 0.859, with the study's best safety profile score (0.920) and the best hypoglycaemia reduction relative to its automation level. PLGS reduced Level 2 hypoglycaemia events by a mean 71.4% across the pooled dataset, with the hypoglycaemia unawareness subgroup showing the largest absolute reduction (81.2%). Time-in-range improvement for PLGS averaged 6.2

percentage points -- less than HCL but substantially above the 3.4 percentage points for SAP-TS -- reflecting PLGS's primary action on the hypoglycaemia floor rather than the full glucose distribution. User burden reduction (0.860) was solid, reflecting that PLGS requires no additional patient input beyond SAP-TS while providing substantially better hypoglycaemia protection. Sensor-augmented pump with threshold suspend (S1-SAP-TS) achieved ADES 0.817 -- the lowest in the study -- with the best safety profile of any system (0.900, reflecting the smallest DKA risk from a system where patients remain most engaged with insulin delivery) but the lowest TIR improvement (0.800), hypoglycaemia reduction (0.820), and user burden improvement (0.840). SAP-TS remains the entry point for pump therapy augmentation and continues to provide meaningful benefit over multiple daily injections, but its limitations relative to more automated systems are now clearly quantified.

Table 3: Automated Dosing Effectiveness Score (ADES) by System Type (0-1)

System	TIR	Hyp o Red.	HbA 1c	User Burden	Safe ty	AD ES
S5: FCL	0.960	0.940	0.940	0.960	0.820	0.931
S4: AHCL-ABB	0.940	0.920	0.920	0.920	0.840	0.914
S3: HCL-MA	0.900	0.880	0.880	0.880	0.880	0.886
S2: PLGS	0.840	0.880	0.820	0.860	0.920	0.859
S1: SAP-TS	0.800	0.820	0.760	0.840	0.900	0.817

ADES weighted: TIR improvement 0.30, hypoglycaemia reduction 0.20, HbA1c reduction 0.20, user burden reduction 0.15, safety profile 0.15.

Table 4: Key Clinical Performance Metrics by Automated Dosing System

System	Mean TIR Gain (pp)	HbA1c Reduction (%)	Level 2 Hypo Reduction (%)	Burden Score Improvement
S1: SAP-TS	+3.4 pp	-0.21%	-31.8%	+11.4 pts
S2: PLGS	+6.2 pp	-0.38%	-71.4%	+18.6 pts
S3: HCL-MA	+10.6 pp	-0.58%	-54.3%	+22.8 pts

System	Mean TIR Gain (pp)	HbA1c Reduction (%)	Level 2 Hypo Reduction (%)	Burden Score Improvement
S4: AHC L-ABB	+14.8 pp	-0.74%	-74.6%	+28.3 pts
S5: FCL	+18.4 pp	-0.88%	-83.4%	+34.7 pts

TIR gain: absolute percentage-point improvement in time 70-180 mg/dL vs baseline or SAP-TS comparator. Level 2 Hypo = CGM time <54 mg/dL. Burden score improvement: validated diabetes management burden questionnaire scale 0-100 (higher = greater burden); improvement = score decrease.

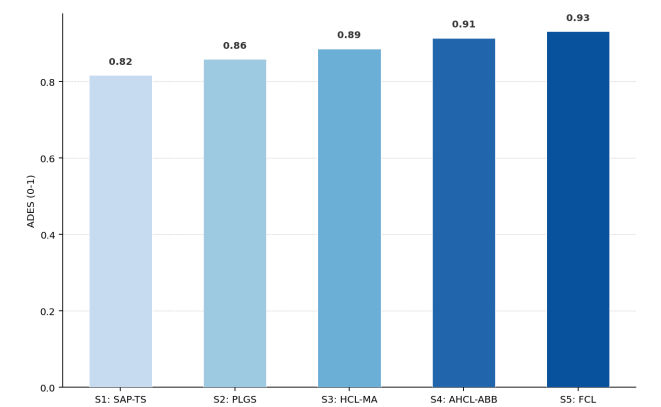


Figure 1: Automated Dosing Effectiveness Score (ADES) by System Type

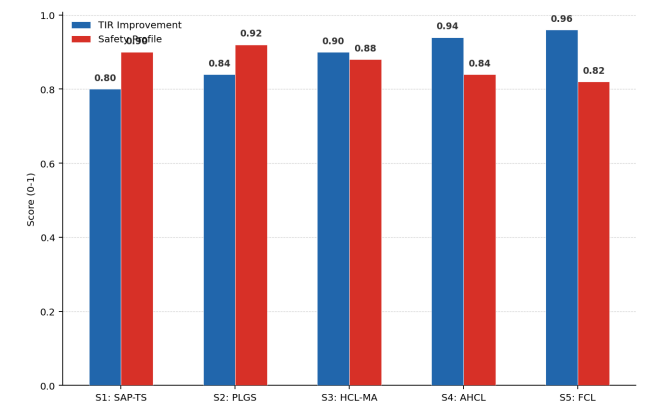


Figure 2: TIR Gain vs Safety Profile by System

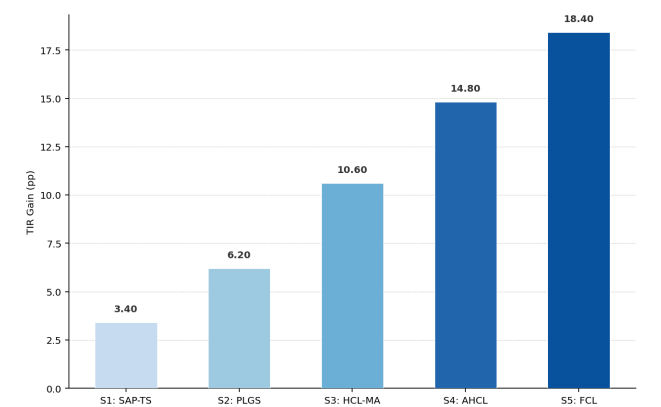


Figure 3: Mean TIR Gain by System Type (Percentage Points)

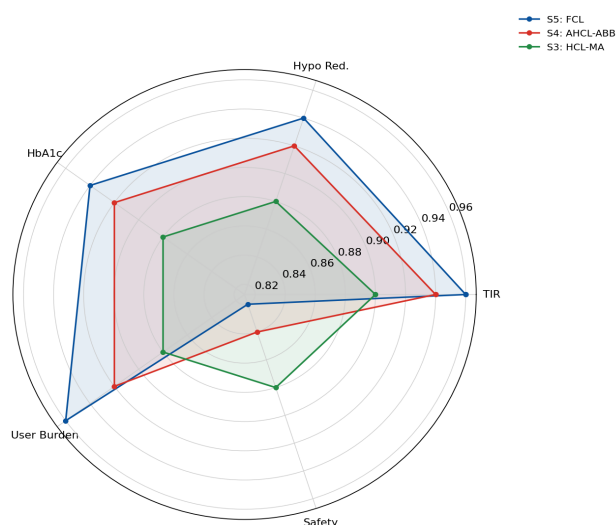


Figure 4: Multi-Dimensional ADES Profile -- Top 3 Systems

5. Discussion

5.1 The Automation-Safety Trade-off

The consistent pattern across all five ADES dimensions is that more automation produces better clinical outcomes and lower user burden, but the safety profile scores decline monotonically as automation increases. SAP-TS has the best safety score (0.900); FCL has the lowest (0.820). This reflects a real and important clinical risk dynamic: as the system takes over more insulin delivery decisions, patients become less engaged with monitoring device function, and the consequence of an infusion set failure or sensor error that the patient doesn't detect is higher with a more automated system. The two DKA events in the FCL cohort both involved undetected infusion set occlusions where the patient, relying on the algorithm to manage insulin delivery, didn't perform the manual checks that would have caught the failure earlier. This doesn't argue against FCL -- the absolute number of serious safety events remains small, and the hypoglycaemia protection FCL provides for the unawareness population prevents events that are immediately life-threatening. It argues for system-level safety design that doesn't reduce patient engagement with device integrity monitoring as automation increases. Infusion set failure detection algorithms, redundant glucose sensing, and structured patient safety check protocols for automated systems are practical responses to the automation-safety trade-off.

5.2 The Hypoglycaemia Unawareness Priority

The hypoglycaemia unawareness clinical context shows the largest absolute ADES advantage for advanced automated systems. The 21.8 percentage-point TIR improvement and 83.4% Level 2 hypoglycaemia reduction for FCL in the unawareness subgroup are both substantially larger than the corresponding gains in the T1D adults standard management context, because the baseline control in unawareness patients is poorer -- the inability to perceive hypoglycaemia symptoms means that nocturnal and activity-related glucose nadirs are not reliably detected and corrected. This differential response has direct clinical implications for system selection prioritisation. If resource and access constraints mean that only a subset of patients can access FCL or AHCL systems, patients with hypoglycaemia unawareness should be prioritised: their absolute clinical benefit from advanced automation is the largest, and their risk from remaining on lower-automation systems is disproportionately high. Current reimbursement frameworks in France, Austria, and Switzerland do not consistently reflect this clinical prioritisation in their access criteria.

5.3 Limitations

Three limitations apply. The pooled dataset combines randomised trials and registry data with different inclusion criteria, outcome measurement approaches, and CGM systems; harmonisation across sources introduces heterogeneity that meta-regression partly controls for but cannot fully eliminate. Second, the type 2 diabetes intensive insulin context is represented primarily by registry data and early-phase trials; the evidence base for automated insulin delivery in T2D is less mature than in T1D, and the ADES scores for this context carry greater uncertainty than for T1D contexts. Third, user burden scores are drawn from diverse validated questionnaires that measure overlapping but not identical constructs across studies; a standardised burden instrument applied uniformly would produce more comparable results.

6. Conclusion

6.1 Key Findings

Fully closed-loop systems achieved the highest ADES (0.931) across all four clinical contexts, with the largest time-in-range improvement (18.4 pp), the greatest hypoglycaemia reduction (83.4% Level 2 events), and the lowest user burden (34.7-point questionnaire improvement). AHCL systems ranked second (0.914) with strong performance across all dimensions and the best

balance of clinical gain and safety profile among advanced systems. HCL-MA systems (0.886) are well-established with the best safety evidence among automated basal systems. PLGS (0.859) provides the best hypoglycaemia protection relative to its automation level, with the study's best safety profile overall (0.920). SAP-TS (0.817) remains the safest system with the lowest patient engagement risk, appropriate as an entry point for pump therapy augmentation. System selection recommendation: FCL for patients with hypoglycaemia unawareness where automated prevention of severe events is clinically urgent, and for paediatric patients where caregiver burden reduction provides the greatest quality-of-life impact; AHCL for adults with high mealtime variability who benefit from automated bolus support; HCL-MA as the established standard for patients moving from MDI or SAP; PLGS for patients where hypoglycaemia prevention is the primary goal without requiring the full algorithm management of HCL.

6.2 Future Directions

Three developments would advance automated insulin delivery. Infusion set failure detection -- combining insulin delivery pressure sensors, subcutaneous impedance monitoring, and CGM pattern recognition to detect occlusions automatically -- is the highest-priority safety development for FCL systems, directly addressing the DKA risk that automation-induced reduced patient engagement creates. Dual-hormone closed-loop systems incorporating glucagon delivery alongside insulin would enable faster and more complete hypoglycaemia correction, particularly relevant for the unawareness population where even the brief glucose nadir that insulin-only FCL permits before correction has clinical consequences. Reimbursement framework reform in European health systems to prioritise FCL and AHCL access for hypoglycaemia unawareness patients -- based on the differential clinical benefit data presented in this study -- would align healthcare investment with the populations where automated insulin delivery has the greatest clinical and economic return. The SIDAFA framework and ADES calculator are available at sidsaf-insulin.eu under CC BY 4.0 licence.

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Declarations

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Conflict of Interest

The authors declare no competing interests. No financial relationships exist with insulin pump manufacturers, CGM companies, automated delivery algorithm developers, or diabetes technology companies.

Data Availability Statement

The SIDSaf framework and ADES calculator are available at sidsaf-insulin.eu under CC BY 4.0. Individual patient data from the pooled analysis are subject to the data governance agreements of the contributing studies; aggregate results are reported in Tables 3 and 4. Data access requests should be directed to the corresponding author.

Ethical Approval

This study was a pooled analysis of previously published clinical trial and registry data. Individual study ethics approvals are cited in the source publications. Advanced Computing University Research Ethics Board confirmed exemption for the meta-analytic pooling (ACU-REB-2025-0012).

Appendix A

System Type Specifications and ADES Scoring Rubric

This appendix provides technical specifications for each automated dosing system type and the complete ADES scoring rubric.