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Beyond the Device

The “Tennis Player Paradox” and non-mitigable residual risk in fitness-for-duty assessment for safety-critical railway tasks in workers with diabetes mellitus

UIMC Congress, Lisbon, October 2026

Agenda

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The position, and the question it raises

Reg. (EU) 2019/773 · Legislative Decree 247/2010 · RFI Provision 55/2006 · Reg. (EU) 2017/745

What the Position Paper states

Advanced technologies — insulin pumps, CGM, closed-loop systems — reduce the risk of a sudden acute event without eliminating it

They cannot therefore be a sufficient basis for compatibility with safety-critical duties

Diabetes is never in itself a ground for exclusion: every judgement remains individual

What this contribution asks

Does the most recent technological evolution weaken that position — or strengthen it?

We test it against the single most favourable configuration available

And we propose an interpretative category for technologically mediated residual risk

Method: three lines of evidence, one index case

Narrative review — not a systematic review

- ***Clinical literature***

persistence of severe hypoglycaemia and impaired awareness in technology-assisted populations; accuracy and limits of CGM-derived metrics

- ***Human factors literature***

automation bias and automation-induced complacency, transferred from aviation and clinical decision support

- ***Regulatory analysis***

European and national railway certification framework, and medical device vigilance under Reg. (EU) 2017/745

- ***Index case***

publicly documented, analysed in anonymised form, selected for paradigmatic value and not for statistical representativeness

A best case, by every criterion we use

The index case — June 2026

The subject

Type 1 diabetes since early childhood · excellent metabolic control · maximal adherence

Dedicated specialist team · CGM in use for over a decade with no prior malfunction

Task risk profile known, reproducible and rehearsed hundreds of times

The sequence

The sensor returned a falsely elevated glucose reading

An insulin dose grossly disproportionate to actual need was administered on that reading

Acute hypoglycaemia in competition: ~350 g of rapid carbohydrate in the first hour, and medical intervention on court

The decisive point

Section 4 — the index case

The device did not fail to warn. The device produced the risk.

Not a false negative — the failure mode our assessment framework already knows how to describe — but a false positive that triggered an iatrogenic therapeutic chain.

The Tennis Player Paradox

Proposed construct — Section 5.1

In a subject under maximal therapeutic and technological control, operating within a known and reproducible risk profile, residual risk is not abolished but transformed: it migrates from the biological to the technological system, concentrates into a single point of failure, and becomes less predictable — because the device shifts from a monitoring tool to a determinant of therapeutic decision-making.

The best-controlled subject is not the subject with the lowest residual risk. He is the subject whose residual risk is hardest to characterise.



Four mechanisms, separately documented

Anatomy of the paradox — Section 5.2

- ***Risk migration***

residual risk ceases to be biological and becomes technological: sensor accuracy and drift, interference, connectivity, algorithm, interface. None of it reachable by clinical history

- ***Single point of failure***

railway safety is built on redundancy; growing trust in the device retires the autonomous barriers (self-monitoring, cross-checking, symptom perception) as redundant

- ***Device as decision driver***

a sensor that informs leaves the verification chain intact; a sensor feeding bolus calculation or closed-loop delivery suppresses it

- ***Automation bias and perceptual delegation***

reliable automation lowers operator vigilance; in diabetes, attention disinvests from prodromal symptoms

Severe hypoglycaemia persists despite technology

Supporting evidence — Section 6

1. Severe hypoglycaemic events and impaired awareness persist in adults with type 1 diabetes despite CGM and AID use — Sherr et al., Diabetes Care 2024;47(6):941–947

2. Persistence of severe hypoglycaemia is observed regardless of the insulin delivery method adopted — Laffel et al., Diabetes Care 2025;48(2):273–278

3. Recent observational data show persistence of severe hypoglycaemia even among users of advanced technologies, hence the need for ongoing surveillance of hypoglycaemic risk — ADA Standards of Care in Diabetes 2026

A regulatory precedent already exists

Section 6.1 — UK driver licensing guidance

Dependence on the device is already treated as a risk condition in its own right.

UK guidance provides that monitoring-device alarms must supplement — not replace — the individual's own ability to recognise hypoglycaemia and their active self-monitoring; and that a driver who has become dependent on those alarms to recognise lows must stop driving and notify the authority.

To our knowledge this is the first explicit normative recognition of perceptual delegation. It qualifies reliance on the device not as an advantage but as an independently relevant risk condition — and it is available to us by analogy.



Dependence on the alarm is a reportable condition, not a credential.

The perfect dossier problem

Section 5.3 — false reassurance of the fitness judgement

What the file shows

High time in range, low time below range, optimal HbA1c

No documented severe events; favourable specialist report

All of it truthful, and none of it contestable in itself



asymmetry

What the file does not show

Any information on the behaviour of the man–device system under fault conditions

Which is precisely what a safety-critical judgement has to assess

An asymmetry: apparent dossier quality rises while characterisability of residual risk falls



What can be governed

Not the event — but the assessment process

What to assess, and what to track

Proposed operational criteria — Sections 7.1 and 7.2 · not yet validated

At initial certification

System reliability and redundancy: device and algorithm type, failure history, feasible back-up plan, documented independent capillary self-monitoring

Hypoglycaemia awareness by validated instruments (Gold, Clarke, HypoA-Q), including the share of awareness delegated to the device

History of severe and near-severe events, including lows self-resolved only because an alarm fired

Behavioural interaction profile: alarm response, manual override frequency, cross-checking of anomalous values

At follow-up

Time in range and time below range, read with their documented transferability limits

Number, type and temporal distribution of alarms, as an indirect index of delegation

Sensor failures, signal loss, early replacements, sensor-versus-capillary discrepancies

Concordance between sensor-detected and self-reported hypoglycaemia — an early, measurable marker of perceptual delegation

From terminal certifier to active vigilance node

Section 7.4 — an open proposal to the UIMC community

Step 1

Detection

During fitness assessment the physician intercepts a sensor or algorithm malfunction

Output

A clinical datum that is also a potentially reportable device incident

Step 2

Today

The information stops in the health record and goes no further

Output

Vigilance value of the finding is lost

Step 3

Proposed

A structured reporting flow from fitness assessment to the device vigilance system, Reg. (EU) 2017/745

Output

Benefit extending beyond the railway to the whole population of device users



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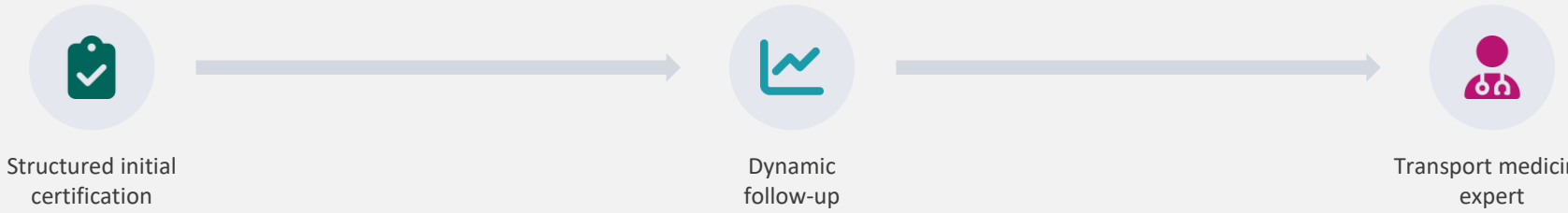
Technology is necessary. It is not sufficient.

In the most favourable configuration imaginable the acute event still occurred — and it occurred through the technology, not despite it. This corroborates, rather than weakens, the precautionary position of the RFI Direzione Sanità.

A structured initial certification, extended to the relationship between patient and device

A dynamic follow-up built on downloaded data and read with explicit awareness of their limits

Ownership of the process vested in the transport medicine expert, as a permanent interface with the scientific community and with the device vigilance system



What this work does not establish

Limitations — Section 8

On the case

Single, publicly sourced and not clinically verifiable

Its role is to make a documented mechanism legible — not to demonstrate it

It carries illustrative, not probative, value

On the method

Narrative review, with no formal appraisal of evidence quality

Transfer from general clinical populations to a railway workforce requires caution: selection, surveillance and motivation differ

The operational criteria proposed are not validated and require prospective testing

Key message

Beyond the device



The ultimate safeguard is not the device, but the professional judgement that interprets it.

Railway safety, protection of the worker and protection of the public remain convergent and complementary objectives. The paradox does not place them in tension.

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Thank you

