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Guidelines on driving ability in patients with Diabetes mellitus

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Table of contents

Introduction

The prevalence of diabetes mellitus in Switzerland is 6.3% [1] and most of these people operate motor vehicles safely without creating any meaningful risk on the road for themselves or others. Having a diagnosis of diabetes, is, by itself, inadequate for determining a person's driving capability or safety. In addition, diabetes mellitus is only recorded on the driver's license if the diagnosis already existed at the time the driver's license was issued (this applies in particular to young patients with type 1 diabetes mellitus or monogenetic forms of diabetes). Otherwise, the diagnosis of diabetes is only recorded on the driver's license in the event of a motor vehicle accident or when assessing fitness to drive over the age of 75 years or when driving a motor vehicle professionally (cab, truck, bus driver). The majority of people with diabetes mellitus are, therefore, never registered by road traffic authorities. The treating physician has the right, but no obligation, to report patients with diabetes mellitus with a reduced fitness to drive to the relevant authorities.

Diabetes-related traffic accidents are rare for most drivers with diabetes mellitus and occur less frequently than for many other diseases that can impair driving performance and are tolerated by society. The incidence of hypoglycemia, which impairs the ability to drive, severe retinopathy (including macular edema) or cataract formation affecting visual acuity required to drive a motor vehicle, and peripheral neuropathy, which can severely impair sensation in the feet, is not as common as to justify restricting driving privileges for all drivers with diabetes mellitus.

Accident risk in patients with diabetes mellitus

Although the above-mentioned complications of diabetes mellitus can increase the risk of motor vehicle accidents, incapacitation from hypoglycemia poses the highest risk of accidents. The risk exists in people who are treated with insulin, sulfonylureas or glinides. A study in drivers treated with insulin concluded that 13% had developed hypoglycemia while driving in the previous year [2]. The analysis of various studies has shown that there is an increased risk of traffic accidents, but it is very modest [3]. A meta-analysis showed that the risk of traffic accidents among drivers with diabetes mellitus was not higher than among drivers without diabetes mellitus. Elderly people [4] and those on insulin therapy showed a trend towards an increased risk, but statistical significance was clearly missed [5]. Some published studies suggest that drivers with type 1 diabetes have a slightly higher risk of traffic accidents compared to drivers with type 2 diabetes (insulin and/or sulfonylureas). A driver with type 2 diabetes has the same risk as a driver without diabetes [6], but this has not been confirmed by other studies [7]. Case-control studies have shown that drivers with diabetes mellitus have only a slightly increased and, therefore, acceptable risk of motor vehicle accidents compared to drivers without diabetes, but many studies have significant limitations or are of poor quality. In particular, severe hypoglycemia is very common in a very small percentage of patients (especially with long duration of diabetes and under insulin therapy) and thus increases the risk of accidents in the entire group. Older studies may no longer be up to date due to changes in road conditions, motor vehicles and, above all, advances in the treatment of diabetes mellitus: more and more continuous blood glucose monitoring [8] in type 1 and type 2 diabetes, hybrid closed loop (HCL) insulin pumps in type 1 diabetes mellitus, no more use of sulfonylureas and much better ultra-long-acting insulins with a lower risk of hypoglycemia.. However, one question remains: How frequently does blood glucose need to be

measured? An observational study with CGMS has shown that with a blood or sensor glucose of ≥ 5 mmol/l at the start of driving, a blood glucose of < 3.9 mmol/l is reached within two hours in 13.8% of patients with type 1 and in 4.4% with type 2 diabetes mellitus treated with insulin. After 4 hours it is even 22% and 8.4% respectively [8].

In summary, most drivers with diabetes safely operate motor vehicles without creating any meaningful risk of injury to themselves or others. Diabetes mellitus alone is, therefore, not synonymous with impaired fitness to drive, and the increasing adoption of diabetes technologies and improved medications are likely to further reduce or prevent the frequency of hypoglycemia [9].

Legal basis for the guidelines on the fitness to drive in patients with diabetes mellitus compared to other diseases

For other diseases specific requirements have been defined by traffic medicine and the relevant professional associations, and such an approach has also been chosen for diabetes mellitus.

Legal basis

According to Art. 14 of the Road Traffic Act (SVG), anyone who fulfills the following criteria is allowed to drive a motor vehicle: minimum age, the necessary physical and mental capacity to drive motor vehicles safely, no addiction and a capacity, judged by their previous behavior, to follow the regulations as a motor vehicle driver. Fitness to drive describes the general, non-temporal and non-event-related suitability to drive a vehicle safely. On the other hand, **ability to drive** describes the event-related and time-limited ability to drive a vehicle safely, based on current physical and mental capacity.

Furthermore, Art. 7 Para. 1 of the Traffic Licensing Ordinance (VZV) states that anyone wishing to obtain a learner's permit, driver's license or a permit for professional passenger transport has to meet the **minimum medical requirements** set out in Annex 1 VZV.

In the first medical group (category A, B, A1, B1, F, G, M, subcategory D1, if acquired under old law (entry 106) and limited to 3.5 tons), the minimum requirement mandates that in the presence of diabetes mellitus there must be stable blood glucose control without hypoglycemia or hyperglycemia affecting driving ability. (VZV Annex 1).

In the second medical group (category C, D, C1, D1, if not acquired under old law, permit for professional passenger transport, traffic experts), mandate that drivers are excluded for category D or subcategory D1, if hypoglycemia may occur as a side effect of treatment or in which hyperglycemia may impair the ability to drive. A permit to drive for category C or sub-category C1, for professional passenger transport and for traffic experts, may be given under favorable circumstances. (VZV Annex 1).

The local authority may, as an **exception**, deviate from the medical minimum requirements according to Art. 7 Para. 3 VZV (Road Traffic Ordinance), if the applicant meets the driving suitability requirements under Art. 14 Para. 2 SVG (Road Traffic Act) and a doctor with a level 4 recognition

(Traffic Medicine Specialist SSLM) confirms this. This is always an individual case assessment by the authorities

According to the **reporting right** under Art. 15d Para. 3 SVG, doctors may report individuals with a reduced fitness to drive to the local road traffic authority without violating medical confidentiality.

In summary, there is a legal base for fitness to drive, medical minimum requirements for driver's license categories, and the possibility to obtain an exceptional permit, when deviating from the medical minimum requirements. Hypoglycemia is the most important factor that leads to a restriction of driving ability. Exceptions can be made for drivers with diabetes who can avoid hypoglycemia using the most advanced technological methods. Regardless of the reporting right, a doctor is obliged to inform their patients about driving suitability. The **medical duty of disclosure** is part of the safety counseling and pointing out measures to reduce hypoglycemia.

Hypoglycemia and driving ability

The most important factor in diabetes mellitus that leads to a restriction of driving ability is hypoglycemia. Hypoglycemia only occurs when patients are treated with insulin, sulfonylureas or glinides. The risk of hypoglycemia is higher for sulfonylureas with a longer half-life or with active metabolites. Short acting glinides and Gliclazide, which has no active metabolites and a relatively short half-life, have the lowest rate of hypoglycemia. The same applies to the ultra-long-acting insulins, Degludec (Tresiba®) and Glargin300 (Toujeo®) with more stable pharmacodynamic profiles [9].

A noticeable change in driving behavior was seen in the latest trials examining the influence of hypoglycemia (both in simulators and real cars). The lower the glucose concentration (venous blood sugar < 2.5 mmol/l and lasting more than 15 minutes), the more pronounced the reduction of the driving ability. Hypoglycemia in the range of 3.0 to 3.5 mmol/l reduced the driving ability to a lesser degree. Typical changes include less proactive driving behavior, reduced fine motor skills, and more abrupt reactions. It can be indirectly concluded that blood sugar levels above this range, and especially above 3.9 mmol/l with stable values, are unlikely to have a significant impact on driving behavior[10, 11]. This aligns with earlier research findings and corresponding international guidelines.

In England and Canada, a blood sugar level of 4.0 mmol/l before driving is considered safe for patients treated with insulin. For blood sugar < 4.0 mmol/l, it is recommended to immediately stop the vehicle, remove the ignition key, switch from the driver's seat to the passenger seat, correct the low blood sugar with rapidly acting carbohydrates, and wait 45 minutes before resuming the drive (https://www.diabetes.org.uk/for-professionals/get-involved/news-and-updates/driving-and-diabetes--what-healthcare-professionals-should-know). It should also be noted that CGM (Continuous Glucose Monitoring) systems may show a time delay in transmitting normal blood sugar values in the case of hypoglycemia (in case of doubt, capillary blood glucose measurement is recommended).

Factors in diabetes mellitus that impair the fitness to drive

Some micro- and macrovascular complications can lead to impaired driving ability over a prolonged period. The best predictive factor for development of these complications is glycemic exposure, expressed as HbA1c years (the annual average of HbA1c values is accumulated, and every HbA1c value > 6.0% is counted. A similar approach is used for smoking with "pack-years"). When reaching 50-70 HbA1c years, practically all microvascular complications are present. [12, 13]. Untreated arterial hypertension, hypercholesterolemia**,** smoking, and visceral obesity exacerbate these effects. Severe impairment of visual acuity and the visual field due to proliferative retinopathy and/or macular edema, or severe peripheral neuropathy of the lower extremities with loss of sensation, results in the inability to properly perceive and operate the gas, brake, or clutch pedals. Severe chronic kidney disease (eGFR < 30 ml/min) increases the risk of hypoglycemia when taking sulfonylurea or insulin.

Pregnancy and diabetes (gestational diabetes and pre-existing diabetes)

Gestational diabetes is now screened in all pregnant women between the 24th and 28th week of pregnancy using a 75g oral glucose tolerance test [14, 15]. If either the fasting glucose is ≥ 5.1 mmol/l**,** the 1-hour value is ≥ 10.0 mmol/l, or the 2-hour value is ≥ 8.5 mmol/l**,** gestational diabetes is diagnosed. Important: the blood glucose values must be measured venously and determined in a central laboratory. HbA1c is not suitable for the diagnosis of gestational diabetes. 15-17% of all pregnant women have gestational diabetes or a pre-existing diabetes mellitus [16].

If, during the first prenatal visit, the HbA1c value is ≥ 6.5%**,** fasting glucose is ≥ 7.0 mmol/l, or the 2-hour value is ≥ 11.1 mmol/l, a pre-existing diabetes mellitus is diagnosed. Gestational diabetes can only be diagnosed before the 24th week of pregnancy with a fasting blood glucose ≥ 5.1 mmol/l. [15].

During the first 16 weeks of pregnancy, insulin sensitivity is increased and potentially more hypoglycemia occurs with pre-existing type 1 or insulin-dependent diabetes [17], if the daily insulin dose is not reduced. , From the 20th week of pregnancy, insulin sensitivity decreases and the total insulin requirement increases accordingly

From the 20th week of pregnancy, the fetal pancreas begins to react to maternal blood sugar spikes [18-20]. The consequence of maternal hyperglycemia is hyperinsulinemia (in mother and child) and macrosomia (in the child). For this reason, the blood glucose target values in Switzerland from the 20th week of pregnancy have been set at <5.3 mmol/l while fasting and <8.0 mmol/l 1 hour postprandially (internationally 7.8 mmol/l; 140 mg/dl) [11]. As approximately 25% of women with gestational diabetes need to be treated with insulin to achieve these target levels, driving was difficult to manage with the 2017 recommendations (blood glucose should never be < 5.0 mmol/l before driving). As pregnant women need to measure blood glucose before every meal and 1 hour after eating and before sleeping, continuous glucose monitoring is now recommended in this situation, along with the use of an ultra-long-acting insulin and, if needed, a short-acting insulin. For women with pre-existing type 1 diabetes mellitus, therapy with an HCL insulin pump and continuous blood glucose monitoring is recommended. This increases the time in the target range during pregnancy of 3.5-7.8 mmol/l and reduces the number of hypoglycemic episodes <3.5 mmol/l during all trimesters and, thus, also the

rate of macrosomia of the child. The lower limit for driving ability of 4.0 mmol/l is the same as outside pregnancy.

Contribution of continuous glucose monitoring and HCL insulin pumps as well as ultra-long acting basal insulins to road safety

The information density of interstitial continuous glucose monitoring is several times higher than that of capillary self-monitoring of blood glucose values. With continuous glucose monitoring, interstitial glucose concentration is determined every five minutes and a 30-minute prediction is made. Today, all CGM systems issue a warning if the glucose is predicted to fall below a certain value, which can be set individually. As already mentioned, 2-4 hours after a glucose measurement ≥5.0 mmol/l before driving, the blood glucose drops to a value < 3.9 mmol/l in 13.8% of patients with type 1 and in 4.4% of patients with type 2 diabetes mellitus treated with insulin. After 4 hours it is even 22% and 8.4%, respectively [8]. This means that with the help of CGM, the driver can be warned of hypoglycemia and can correct the blood sugar with carbohydrates before hypoglycemia occurs. It is possible, therefore, to set the minimum blood glucose levels before driving lower for CGM user than those using capillary self-monitoring of blood glucose alone. The latest hybrid closed-loop insulin pumps also help to prevent hypoglycemia. Initially, when the hypoglycemia value (usually 3.9 mmol/l) was reached, the basal insulin application of the pump was stopped. A further development step led to the predictive switch-off of the insulin pump before the occurrence of hypoglycemia; today these pumps can automatically correct excessively high blood glucose levels and insulin delivery is automatically interrupted when the blood glucose level drops. The only step towards a fully automatic pump that is still missing is automatic insulin delivery before a meal without manual input. Today, the patient still has to inform the pump how much carbohydrate he/she is eating and the necessary amount of insulin is calculated and delivered based on the current blood glucose value (possibly corrective insulin is added) and the stored carbohydrate factor [21]. In the past, only the HbA1c value and the number of severe hypoglycemia (level 3; external help required, or unconsciousness) were used to assess blood glucose control. With the latest technologies, there are many factors that need to be considered (recommended values in brackets): HbA1c value (< 7.0%), hypoglycemia < 3.9 (level 1; < 4%) and < 3.0 mmol/l (level 2; < 1%), the coefficient of variation (< 36%) and the time spent in the target range (3.9-10 mmol/l; > 70%). It is even more efficient to assign a score from 1 (worst) to 4 (best) to each of these four factors and the individual points are added up to a single score [22](Figure 1).

Figure 1: Evaluation of CGMS blood glucose values [22]

HbA1c (%)	Coefficient of variation* (%)	Hypoglycaemia < 3.0 mmol/l (%)	Time in Range 3.9-10 mmol/l (%)	Points
≤ 6.5	≤ 25	< 1	≥ 80	4
6.5 - 6.9	26 - 35	1 - 4	70 - 79	3
7.0 - 8.0	36 - 49	5 - 10	51 - 69	2
> 8.0	≥ 50	> 10	≤ 50	1

Very good glycemic control:	**14 - 16 points**
Good glycemic control:	**11 - 13 points**
Sufficient glycemic control:	**9 - 10 points**
Insufficient glycemic control:	**< 9 points**

*Coefficient of variation = (Standard deviation*100)/glucose

The most modern CGM systems coupled with insulin pumps significantly reduce the number of hypoglycemic episodes and the coefficient of variation and, if the HbA1c is too high, also the HbA1c. This is the reason why certain restrictions on higher vehicle categories can now be removed as exceptions when using these technologies. Example of such an exception: A cab or truck driver with type 2 diabetes mellitus is treated with metformin, GLP-1 RA and SGTL-2 inhibitors with an HbA1c of 9.0%. He/she needs a basal insulin with the lowest risk of hypoglycemia (recommended Degludec or Glargine 300) and is willing to wear a CGM device. In this case, the diabetologist and the department of traffic medicine has to decide to give approval to this category, as a high HbA1c increases the risk of long-term consequences and a road traffic incident due to cardiovascular events becomes more likely. The same applies to streetcar and bus drivers and train drivers.

The new SSED recommendations for the treatment of type 2 diabetes mellitus changed as well. The use of sulfonylureas and glinides is no longer recommended. The recommended antidiabetic agents (metformin, SGLT-2 inhibitors, GLP-1 or GLP-1/GIP receptor agonists) given alone or in combination do not cause hypoglycemia. If insulin has to be used, the ultra-long-acting insulins Degludec and Glargine 300 are now recommended, which have a significantly lower hypoglycemic frequency than Glargine 100 or Detemir., or NPH insulin which has the highest risk for hypoglycemia among the long-acting insulins is no longer recommended. It has also been shown that with the co-formulated insulin Ryzodeg

(30% NovoRapid® and 70% Tresiba®), which is given once or twice daily with the main meals, the same HbA1c can be achieved as with a basal-bolus system, but with a much lower rate of hypoglycemia [9].

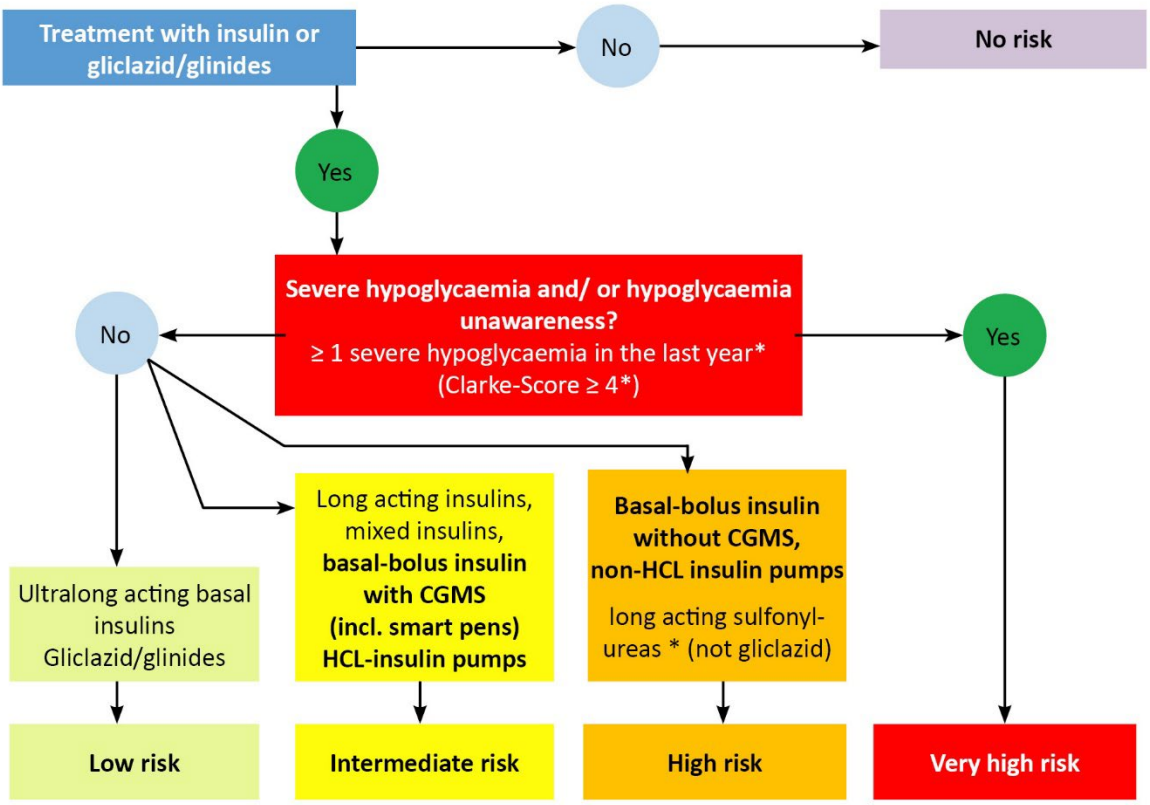
Basic guidelines for all driver license holders with diabetes mellitus

If diabetes mellitus is present, there must be stable blood sugar control without hypo- or hyperglycemia relevant to driving. There must be no other metabolic disorders with a significant impact on the ability to drive a motor vehicle safely. In particular, there must be no traffic-relevant secondary complications, which are specified in detail in the first and second medical group below, and no hyperglycemia.

In addition, the individual risk of hypoglycemia must be determined for all motor vehicle drivers depending on the type of treatment with particular emphasis on hypoglycemia unawareness (Fig.2, Tab.1). This results in different recommendations for action depending on the driver license category, which are listed in the following sections. Special consideration must be given to whether a CGM system is worn.

For the treating physician it is crucial to ask about severe hypoglycemia, since a very high percentage of patients do not mention hypoglycemia spontaneously. The Clarke score (in the appendix) can also be used to assess hypoglycemia awareness. It is the joint responsibility of the treating physician and the patient to avoid severe hypoglycemia, as this can also lead to serious consequences apart from driving: higher risk of dementia, more cardiovascular events (including sudden cardiac death), increased risk of thrombosis and more systemic inflammatory reactions [23].

Figure 2: Flow chart for assessing the risk of hypoglycemia during therapy with insulin or gliclazide/glinides



*particularly if > 70 years of age and with impaired renal function (eGFR< 30 ml/min) or with a diabetes duration > 20 years and impaired renal function

Table 1: Overview of risk categories for motor vehicle drivers with diabetes mellitus

Category	Therapy
No risk	• Metformin, GLP-1 receptor agonists, GLP-1/GIP-receptor agonists, DPP4-Inhibitors, SGLT-2 inhibitors or their combination and • No therapy with insulin, sulfonylureas or glinides
Low risk	• Ultralong-acting basal insulins (Degludec/ Glargin U300) or • Gliclazid or glinides
Intermediate risk	• Long-acting insulins (Glargin U100, Detemir) or • Co-formulated insulin Ryzodeg® 1-2x/daily or • Basal-bolus insulin therapy (incl. smart pens) with continuous glucose monitoring systems (CGMS) or • Hybrid-Closed-Loop Insulin pump systems (HCL)
High risk	• Basal-bolus insulin therapy without CGMS or • Non-Hybrid-Closed-Loop insulin pump systems or • Long acting Sulfonylureas (not gliclazid/glinides)
Very high risk	• ≥ 1 severe Hypoglycemia/year and/ or • Hypoglycemia unawareness (Clarke Score 4 or higher)

Guidelines for driver license holders of the first medical group (A, B, A1, B1, F, G, M and C1 for private use)

The following conditions must be met for initial registration or continued registration as a motor vehicle driver in the first medical group:

- No traffic-relevant diabetes complications (diabetic eye disease impairing vision, nephropathy, neuropathy, no traffic-relevant macrovascular complications)
- No traffic-relevant restrictions in the area of the cardiovascular system
- No significant long-term hyperglycemia (no approval or further approval with HbA1c > 10%)

Behavior before and during driving:

- In case of treatment with low risk of hypoglycemia (i.e. ultralong-acting basal insulin, gliclazide or glinides), blood glucose measurements before driving and during longer trips are not required. However, a blood glucose meter and carbohydrates as hypoglycemia prophylaxis has to be in the vehicle.

- In case of treatment with intermediate risk of hypoglycemia we differentiate between the following situations:
    - In the case of treatment with long-acting insulins (Glargine U100/Detemir), co-formulated insulin (70% Degludec and 30% Insulin Aspart [Ryzodeg®]), or if no continuous glucose monitoring system (CGMS) is used, blood glucose has to be measured before driving and regularly during longer trips (at least every 2 hours) [8]. If the blood sugar is < 4.0 mmol/L, it must be corrected by taking carbohydrates before starting or continuing driving. A 45-minute break must be taken. If the blood sugar is between 4-5 mmol/L, 10-20 g of carbohydrates have to be consumed
    - In the case of a basal-bolus insulin therapy with continuous glucose monitoring systems (CGMS) or hybrid closed-loop insulin pump systems (HCL), blood glucose measurements before or during the journey are not necessary, as these systems have an alarm function. If the CGMS shows a downward trend in blood glucose with a risk of hypoglycemia, this must be corrected early by taking carbohydrates. If the blood glucose is < 4.0 mmol/L, carbohydrates must be immediately administered. Afterwards, a waiting period of at least 45 minutes is required before driving can be continued (in case of doubt, a capillary blood glucose measurement is recommended).

- In case of treatments with high risk of hypoglycemia (Basal-Bolus-Insulin therapy without CGMS, non Hybrid-Closed-Loop insulin pump systems, long acting sulfonylureas), the blood glucose must be measured before driving and regularly (at least every 2 hours) [8] during longer car trips. If the blood glucose is < 5.0 mmol/L, it must be corrected by taking carbohydrates before starting or continuing the journey. Furthermore, for the initial or continued approval as a motor vehicle driver in the first medical group, in addition to the conditions mentioned in Chapter 1.1 (no traffic-relevant late complications, HbA1c < 10%), the following conditions must be met:
    - Stable blood glucose control over the past year without severe hypoglycemia (Grade III) and without hypoglycemia unawareness.
    - Stable ability to reliably avoid hypoglycemia while driving (i.e., the ability to measure blood glucose before driving and regularly on longer journeys).
    - Adherence to behavioral guidelines, particularly:
        - The blood glucose must be ≥ 5.0 mmol/L before driving and during longer trips (if no CGMS is used), or ≥ 4.0 mmol/L (if a CGMS is used).
        - If the blood glucose is < 5.0 mmol/L (without CGMS) or < 4.0 mmol/L (with CGMS), carbohydrates must be administered immediately. If blood glucose is < 4.0 mmol/L, a waiting period of at least 45 minutes is required before continuing driving (in case of doubt, a capillary blood glucose test is recommended).

At the beginning of a treatment with a higher risk of hypoglycemia, the fitness to drive is only considered valid once the aforementioned conditions are met and, in particular, it is ensured that hypoglycemia can be reliably avoided while driving a motor vehicle.

In case of very high risk of hypoglycemia (≥ 1 severe hypoglycemia grade III per year and/or hypoglycemia unawareness, a special assessment by a specialist in endocrinology/diabetology is required.
After an episode of severe hypoglycemia (grade III)[1] for holders of a driving license in the first medical group, ability to drive is only granted under the condition of wearing a continuous glucose monitoring system (CGMS) or performing 6-8 capillary blood glucose measurements daily *for at least one year*.

The measures required for each hypoglycemia risk level when driving motor vehicles for drivers in the first medical group are summarized in **Table 2:**

Table 2: Risk of hypoglycemia and und required measures, first medical group (A, B, A1, B1, F and C1 for private use)

Category	Therapy	Action
No risk	Metformin, GLP-1 receptor agonists, GLP-1/GIP-receptor agonists, DPP4-Inhibitors, SGLT-2 inhibitors or their combination	• No blood glucose measurement necessary before or during the journey
Low risk	Ultralong-acting basal insulins (Degludec/ Glargin U300) or gliclazid or glinides	• No blood glucose measurement necessary before or during each trip • Hypoglycemia prophylaxis and blood glucose meter in the vehicle
Intermediate risk	Long-acting insulins (Glargin U100, Detemir) or Ryzodeg® once or twice daily or basal-bolus insulin therapy (including smart pens) with continuous glucose monitoring systems (CGMS) or hybrid-Closed-Loop Insulin pump systems (HCL)	• Capillary blood glucose measurement before each trip • Hypoglycemia prophylaxis and blood glucose meter in the vehicle • CGMS: No capillary blood sugar measurements, due to provision of predictive low glucose alerts • If blood glucose < 4.0 mmol/L, correct with rapid-acting carbohydrates and wait for 45 minutes

High risk	Basal-bolus insulin therapy without CGMS or non-Hybrid-Closed-Loop insulin pump systems or long-acting sulfonylureas (not gliclazide/glinide)	• Capillary blood glucose measurement before driving and during longer trips • Hypoglycemia prophylaxis and blood glucose meter in the vehicle • If capillary blood glucose 4-5 mmol/l, correct with 10-20 g carbohydrates • No driving if capillary blood glucose < 4.0 mmol/l • If capillary blood glucose < 4.0 mmol/L, correct with rapid-acting carbohydrates and wait for 45 minutes
Very high risk	≥ 1 severe Hypoglycemia/year and/ or Hypoglycemia unawareness (Clarke Score 4 or higher)	• Assessment by a specialist in endocrinology/diabetology • Ability to drive only with continuous blood glucose monitoring (CGMS) or 6-8 capillary blood glucose measurements daily • Hypoglycemia prophylaxis and blood glucose meter in the vehicle • If blood glucose < 5.0 mmol/L, correct with carbohydrates • No driving if blood glucose < 5.0 mmol/L • If blood glucose < 4.0 mmol/L, correct with rapid-acting carbohydrates and wait for 45 minutes

Guidelines for driver license holders of the second medical group (D, D1, C, C1, professional passenger transport permit BPT, traffic experts)

For the initial or renewal of a driver license in the second group, the following conditions must be met for individuals with diabetes mellitus:

- No traffic-relevant diabetes complications (diabetic eye disease impairing vision, nephropathy, neuropathy, no traffic-relevant macrovascular complications).
- No traffic-relevant restrictions in the cardiovascular system and no traffic-relevant impairment of kidney function with a significant impact on general health.
- No significant hyperglycemic derangement (no issuance or renewal of the driving license, if HbA1c > 8.5%)

Therapy with risk of hypoglycemia:

Fitness to drive may be granted under particularly favorable circumstances under the same conditions as in the first medical group. Specifically, the following applies:

Categories D and D1

- According to medical minimum requirements, fitness to drive for categories D and D1 is excluded.
- Suitability to drive for categories D and D1 can be assessed by a permission level 4 physician as an exception permit according to Article 7, Paragraph 3 of the Road Traffic Ordinance (VZV), provided the following conditions are met:
  - Treatment and monitoring by a specialist in endocrinology and diabetology
  - Type 1 diabetes with Hybrid-Closed-Loop (HCL) insulin pump therapy and continuous glucose monitoring, or
  - Type 2 diabetes with ultra-long-acting basal insulin and the use of a CGM system
  - No severe hypoglycemia in the last twelve months
  - Hybrid-Closed-Loop (HCL) insulin pump therapy and continuous glucose monitoring (type 1 diabetes), or continuous glucose monitoring (type 2 diabetes) for at least three months
  - Preserved hypoglycemia awareness (Clarke Score < 4)
  - Confirmation from the treating specialist in endocrinology and diabetology that the affected person has been trained and is proficient in the use of Hybrid-Closed-Loop (HCL) insulin pump therapy and continuous glucose monitoring (for type 1 diabetes), or continuous glucose monitoring (for type 2 diabetes).

Categories C and C1, Permit for Professional Passenger Transport (BPT), Traffic Experts

For categories C and C1, for the permit for professional passenger transport, as well as for traffic experts, fitness to drive is granted under the following conditions:

- Stable glucose control with a therapy that does not result in hypoglycemia (no insulin, sulfonylureas/glinides)
- Stable ability to prevent hypoglycemia and regular glucose monitoring at low, medium, high, and very high hypoglycemia risk (see Table 3).
- There must always be an assessment by a specialist in endocrinology/diabetology and an evaluation by a traffic specialist (physician with at least permission level 3).

Table 3: Hypoglycemia risk and required measures, 2nd medical group (D, D1, C, C1, permit for professional passenger transport, traffic experts)

Category	Therapy	Action
No risk	Metformin, GLP-1 receptor agonists, GLP-1/GIP-receptor agonists, DPP4-Inhibitors, SGLT-2 inhibitors or their combination	• No blood glucose measurement necessary before or during the trip
Low risk	Ultralong acting basal insulins (Degludec/ Glargin U300) or gliclazid or glinides	• No suitability to drive for driving license categories D and D1; exception permit as mentioned above, traffic medical assessment by level 4 is mandatory • Capillary self-monitoring of blood glucose levels 3-4 times daily (or CGMS • No blood glucose measurement necessary before or during each trip • Hypoglycemia prophylaxis and blood glucose meter in the vehicle • Assessment by a specialist in endocrinology/diabetology and evaluation by a traffic specialist (physician with at least permission level 3)
Intermediate risk	Long-acting insulins (Glargin U100, Detemir) or Ryzodeg® once or twice daily or basal-bolus insulin therapy (including smart pens) with continuous glucose monitoring systems (CGMS) or hybrid-Closed-Loop Insulin pump systems (HCL)	• No suitability to drive for driving license categories D and D1; exception permit as mentioned above, traffic medical assessment by permission level 4 physician is mandatory • Blood glucose measurement before each trip • Hypoglycemia prophylaxis and blood glucose meter in the vehicle • CGMS: No capillary blood sugar measurements, since alarm function • If capillary blood glucose < 4.0 mmol/L, correct with rapid-acting carbohydrates and wait for 45 minutes

		• Assessment by a specialist in endocrinology/diabetology and evaluation by a traffic specialist (physician at least permission level 3)
High risk	Basal-bolus insulin therapy without CGMS or non-Hybrid-Closed-Loop insulin pump systems or long-acting sulfonylurea (not gliclazide/glinide)	• No suitability to drive for driving license categories D and D1 • Normally 3 months waiting time • Capillary blood glucose measurement before driving and during longer trips • Hypoglycemia prophylaxis and blood glucose meter in the vehicle • If capillary blood glucose 4-5 mmol/l, correct with 10-20 g carbohydrates • No driving if capillary blood glucose < 4 mmol/l • Assessment by a specialist in endocrinology/diabetology and evaluation by a traffic specialist (physician at least permission level 3)
Very high risk	≥ 1 severe Hypoglycemia/year and/ or Hypoglycemia unawareness (Clarke Score 4 or higher)	• No ability to drive for driving license categories D and D1 • Waiting time of normally 3 months without severe hypoglycemia • Use of a continuous glucose monitoring system (CGMS) • Capillary blood glucose measurement before driving and during longer trips • Hypoglycemia prophylaxis and blood glucose meter in the vehicle • No driving if capillary blood glucose < 5 mmol/l • Close monitoring and assessment by a specialist in endocrinology/diabetology and evaluation by a traffic specialist (permission level 4 physician)

Required intervals for issuing a certificate for road traffic authorities

The control interval for diabetes management is determined by the treating physician. The better the glycaemic control, the longer the control interval can be. The following general guidelines apply:

A) Newly diagnosed type 2 diabetes without insulin or sulfonylurea treatment: Check-ups with the doctor to determine HbA1c, assess self-monitoring of blood glucose or CGMS every 3-4 months, annual measurement of eGFR and albuminuria, and peripheral neuropathy using a reflex hammer, vibration test at the base joint of the big toe (first metatarsal joint) and with a monofilament. Annual to every two year report from the ophthalmologist, including visual acuity, visual field, and retinopathy grade. A certificate for the road traffic authority every 3 years is sufficient. With optimal conditions, this interval can be extended to 5 years.

B) Newly diagnosed type 1 diabetes mellitus: Motivation for the use of CGMS (Continuous Glucose Monitoring System) and also the use of an HCL (Hybrid Closed Loop) insulin pump. Check-ups as in A), but with a diabetologist. First ophthalmologist's report to be requested after 5 years, and thereafter, depending on the ophthalmologist's assessment, at least once every 1-2 years. The interval for the certificate to the road traffic authority is initially 1 year, with optimal conditions and no severe hypoglycemia, every 3 years, and in the best case, every 5 years.

C) For long-standing type 1 or type 2 diabetes: Check-ups with the diabetologist (for type 1 diabetes) or with the general practitioner (for type 2 diabetes) every 3 to 4 months, along with monitoring the parameters mentioned above. At least once a year, a report from the ophthalmologist is required. The interval for the certificate to the road traffic authority depends on the existing complications of diabetes, blood sugar control, and severe hypoglycemia: ideally every 5 years, otherwise every 3 years, and annually if blood sugar control is insufficient.

D) Higher categories (second medical group; except C1 for private use): Certificate interval annually.

Summary and conclusions

In recent years, several pharmacological and technological innovations revolutionized diabetes care. The CGMS (Continuous Glucose Monitoring System) technology was developed in 1999, but it has only recently become increasingly integrated into diabetes therapy. Today, except for insulin, no treatment for type 2 diabetes mellitus is recommended that causes hypoglycemia, and the risk of hypoglycemia with ultralong-acting insulins is lower. As a result, recommendations for driving motor vehicles have had to be adjusted [9]. Since hypoglycemia is the greatest risk factor for impaired driving ability, the latest technology (CGMS coupled with Hybrid-Closed-Loop (HCL) insulin pumps), is able to reduce the number of hypoglycemic events and blood glucose fluctuations. In addition, HbA1c and time in target range can be improved. Patients with type 1 diabetes mellitus are now, in exceptional cases, allowed to higher vehicle categories.

With the analysis of CGMS data, an objective assessment of the frequency of hypoglycemia grade 1 and 2 is now possible (Figure 1), which was previously only partially possible with blood glucose logs (not all hypoglycemia episodes were recorded, particularly nocturnal hypoglycemia or were not entered in the glucose control logs).

The Federal Office of Public Health has thus far set the indications for reimbursement of CGM systems rather high. However, as the prices of these systems have fallen or are expected to fall further, this working group believes that every patient with type 1 diabetes mellitus who accepts technology should have access to an HCL pump coupled with CGMS. Likewise, patients who are treated with insulin should also have the opportunity to use a CGMS. This also applies to gestational diabetes and diabetes during pregnancy. Since these systems warn of impending hypoglycemia, they will also improve road safety, and the safety margin for blood glucose, which was previously set at 5 mmol/l, can be lowered to 4 mmol/l. With these new recommendations, all driving license holders are able to achieve the blood glucose control recommendations of the SSED (Swiss Society for Endocrinology and Diabetes), including pregnancy; for CGMS users, blood glucose measurements every 2 hours while driving are no longer necessary.

If hypoglycemia occurs during driving, the vehicle must immediately be pulled over to the side of the road, the hazard lights turned on, the car key removed, and the driver must move to the passenger seat. The hypoglycemia should be corrected with rapid acting carbohydrates (emergency supply in the car). Since the brain takes longer to fully regain its responsiveness after prolonged hypoglycemia, a waiting period of 45 minutes is required before continuing driving. With the use of technology, such situations should become significantly rarer (especially when CGMS is coupled with HCL insulin pumps).

Appendix

a) Clarke-Score

b) Medical certificate: Ability to drive and diabetes mellitus

c) Information sheet: Drivers with diabetes mellitus

Clarke Score for verification of the hypoglycemia awareness *(adapted for Switzerland)*

1. Choose a statement that best describes you (only one answer)!

❑ „I always experience symptoms, when my blood sugar is low"

❑ „ I sometimes experience symptoms, when my blood sugar is low."

❑ „ I never experience symptoms, when my blood sugar is low."

2. When your blood sugar is low, do you experience less symptoms than you used to?

❑ no ❑ yes

3. How often, in the last six months, did you experience severe hypoglycemia, during which you felt confused and were not capable of correcting the hypoglycemia without losing consciousness?

❑ never ❑ 1 or 2x ❑ every other month ❑ monthly ❑ more than 1x/month

4. How many severe hypoglycemia episodes did you experience during the last year, during which you lost consciousness or had seizures or needed a glucagon or glucose injection?

❑ none ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6

❑ 7 ❑ 8 ❑ 9 ❑ 10 ❑ 11 ❑ 12 or more

5. How often, during the last 4 weeks, did you experience blood sugar values< 3.9 mmol/l with symptoms?

❑ never ❑ 1-3x ❑ 1x per week ❑ 2-3x per week ❑ 4-5x per week ❑ almost daily

6. How often, during the last 4 weeks, did you experience blood sugar values< 3.9 mmol/l without symptoms?

❑ never ❑ 1-3x ❑ 1x per week ❑ 2-3x per week ❑ 4-5x per week ❑ almost daily

7. How low must your blood sugar be, in order to feel any symptoms?

❑ 3.3 – 3.8 mmol/l

❑ 2.8 – 3.3 mmol/l

❑ 2.2 – 2.7 mmol/l

❑ below 2.2 mmol/l

8. How reliable are you at recognizing, based on your symptoms, that your blood sugar is low?

❑ never ❑ barely ❑ sometimes ❑ often ❑ always

Assessment Clarke Score for verification of the hypoglycemia awareness:

Questions 1 – 4: All answer apart from 1. answer = 1 point

Questions 5 und 6: If answer 5 < answer 6 = 1 point

Question 7: Answers 3 and 4 = 1 point

Question 8: First 3 answers = 1 point

(Maximum: 8 points)

0 – 2 points: Normal
4 – 8 points: reduced awareness of hypoglycemia

References

1. Kaiser, A., et al., *Prevalence, awareness and treatment of type 2 diabetes mellitus in Switzerland: the CoLaus study.* Diabet Med, 2012. **29**(2): p. 190-7.
2. Graveling, A.J., R.E. Warren, and B.M. Frier, *Hypoglycemia and driving in people with insulin-treated diabetes: adherence to recommendations for avoidance.* Diabet Med, 2004. **21**(9): p. 1014-9.
3. Inkster, B. and B.M. Frier, *Diabetes and driving.* Diabetes Obes Metab, 2013. **15**(9): p. 775-83.
4. Kagan, A.H., G.; Korner-Bitensky, N., *Diabetes Fitness to Drive: A Systematic Review of the Evidence with a Focus on Older Drivers.* Canadian Journal of Diabetes, 2010. **34**(3): p. 233-242.
5. Hostiuc, S., I. Negoi, and M. Hostiuc, *Diabetes and collision risk. A meta-analysis and meta-regression.* Int J Clin Pract, 2016. **70**(7): p. 554-68.
6. Cox, D.J., et al., *Diabetes and driving mishaps: frequency and correlations from a multinational survey.* Diabetes Care, 2003. **26**(8): p. 2329-34.
7. Stork, A.D., T.W. van Haeften, and T.F. Veneman, *Diabetes and driving: Desired data, research methods and their pitfalls, current knowledge, and future research.* Diabetes Care, 2006. **29**(8): p. 1942-9.
8. Rayman, G., J. Kroger, and J. Bolinder, *Could FreeStyle Libre() sensor glucose data support decisions for safe driving?* Diabet Med, 2018. **35**(4): p. 491-494.
9. Gastaldi, G.L., B; Thalmann, S; Alder, S; Laimer, M; Brändle, M; Wiesli, P; Lehmann, R, *Swiss Recommendations of the Society for Endocrinology and Diabetes (SGED/SSED) for the Treatment of Type 2 Diabetes Mellitus (2023)* Swiss Med Wkly, 2023. **153**: p. in press.
10. Lehmann, V., et al., *Machine learning for non-invasive sensing of hypoglycemia while driving in people with diabetes.* Diabetes Obes Metab, 2023. **25**(6): p. 1668-1676.
11. Lehmann, V.Z., T., Maritsch, M., Notter, M., Schallmoser, S., Bérubé, C., Albrecht, C., Kraus, M., Feuerriegel, S., Fleisch, E., Kowatsch, T., Lagger, S., Laimer, M., Wortmann, F., Stettler, C., *Machine learning to infer a health state using biomedical signals – detection of hypoglycemia in people with diabetes while driving real cars,.* New England Journal of Medicine, 2024 **390**: p. in press.
12. Orchard, T.J., et al., *Prevalence of complications in IDDM by sex and duration. Pittsburgh Epidemiology of Diabetes Complications Study II.* 1990. **39**(9): p. 1116-1124.
13. Hatz, K., et al., *The prevalence of retinopathy in patients with type 1 diabetes treated with education-based intensified insulin therapy and its association with parameters of glucose control.* Diabetes Res Clin Pract, 2019. **148**: p. 234-239.
14. Lehmann, R., A. Troendle, and M. Brandle, *[New insights into diagnosis and management of gestational diabetes mellitus: recommendations of the Swiss Society for Endocrinology and Diabetes].* Therapeutische Umschau. Revue therapeutique, 2009. **66**(10): p. 695-706.
15. Sweeting, A., et al., *A Clinical Update on Gestational Diabetes Mellitus.* Endocr Rev, 2022. **43**(5): p. 763-793.
16. Group, H.S.C.R., *Hyperglycemia and Adverse Pregnancy Outcome (HAPO) Study: associations with neonatal anthropometrics.* Diabetes, 2009. **58**(2): p. 453-9.
17. Nielsen, L.R., et al., *Hypoglycemia in pregnant women with type 1 diabetes: predictors and role of metabolic control.* Diabetes Care, 2008. **31**(1): p. 9-14.
18. Grasso, S., et al., *Human fetal insulin secretion in response to maternal glucose and leucine administration.* Pediatr Res, 1980. **14**(5): p. 782-3.
19. Obenshain, S.S., et al., *Human fetal insulin response to sustained maternal hyperglycemia.* N Engl J Med, 1970. **283**(11): p. 566-70.
20. Jovanovic, L., *Medical nutritional therapy in pregnant women with pregestational diabetes mellitus.* J Matern Fetal Med, 2000. **9**(1): p. 21-8.

21. Kowalski, A., *Pathway to artificial pancreas systems revisited: moving downstream.* Diabetes Care, 2015. **38**(6): p. 1036-43.
22. Lehmann, R., *Technologie bei der Behandlung des Diabetes mellitus Typ 1: Ersetzt das künstliche Pankreas das traditionelle Basis-Bolus-System?* Diabetes, Stoffwechsel und Herz, 2019. **28**(2): p. 98-101.
23. Snell-Bergeon, J.K. and R.P. Wadwa, *Hypoglycemia, diabetes, and cardiovascular disease.* Diabetes Technol Ther, 2012. **14 Suppl 1**(Suppl 1): p. S51-8.