

"SENCELL"
Market Assumptions
and
Commercial Potential

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Introduction

Lifecare is a biosensor company with a proprietary and patented technology for monitoring changes in body analyte concentrations based on changes in the osmotic pressure. While Lifecare's technology, Sencell, represents a platform solution for measurement of various body analytes, Lifecare's primary strategic goal is to develop an implantable Continuous Glucose Monitoring system (CGM) that is smaller, cheaper, and longer lasting than existing commercially available CGM systems for diabetes patients.

The development of Sencell as a CGM system has progressed and we are currently on the verge to initiate first-in-human pilot clinical tests. We aim to achieve a CE mark in 2023, whereafter we plan for market penetration from 2023/2024, starting in the European Union. Our planning consists of Lifecare-controlled development, production, and distribution steps as a basis for organic global growth, although at any stage, we will consider partnering to increase the potential for optimized market impact.

This document contains key assumptions and reasoning as a basis for market potential and indicative revenue propositions for Lifecare's Sencell CGM system. We derive the potential gross value of the project targeted in defined markets in Europe, North America, as well as selected high-income countries.

Market Assumptions

Global Patient Population

We estimate that around 1/3rd of people with diabetes need to or should have insulin therapy. On this basis we assume that 1/3rd of the total global population suffering from diabetes are administering insulin and should continuously measure their glucose levels to optimize their insulin therapy. This group represents the primary patient group for Sencell.

For over 20 years, the International Diabetes Federation (IDF) has provided data on the global diabetes population. The 10th edition of Diabetes Atlas, published in December 2021, estimates that 1 in 10 adults worldwide, 537 million people, - are affected by diabetes per 2021. The global number of diabetes patients is estimated to grow to 643m by 2030 and 784m by 2040. These numbers are known to be conservatively projecting the future growth but are taken here for the further evaluation.

GLOBAL DIABETES PATIENT POPULATION DISTRIBUTION 2021

Europe	(EUR)	61m	(11%)
North America and Caribbean	(NAC)	51m	(9%)
Middle East and North Africa	(MENA)	73m	(14%)
South East Asia	(SEA)	90m	(17%)
Western Pacific	(WP)	206m	(38%)
South and Central America	(SACA)	32m	(6%)
Africa	(AFR)	24m	(4%)



According to the World Health Organization, diabetes is a global epidemic and is expected to be the 7th leading cause of death by 2030. The increasing global patient population represents a massive market for effective, affordable, and long-lasting CGM systems for better individual glucose control. It has the potential to significantly increase life-quality and decrease complications and consequently reduce monetary and non-monetary costs for individuals, public healthcare systems and the society in general.

In the 10th edition of the Diabetes Atlas, it is calculated that the direct costs of diabetes for adults reached USD 966 billion in 2021, estimated to grow to USD 1.03 trillion by 2030.

Assuming that 1/3rd of diabetes patients is eligible for insulin treatment, the potential market for CGM systems has a size of 179 million patients in 2021. With an estimated growth to 214 million in 2030 and 261 million in 2040, the CGM market is and will remain of significant size.

According to a business intelligence report from ResearchAndMarkets.com published in January 2022, the global CGM market size reached USD 4.623 billion in 2019 and is expected to grow to USD 31.102 billion in 2026

Target Markets

Currently available minimal invasive CGM systems are based on glucose sensors with limited lifetime. While Medtronic's device is approved for a 7-day duration, the sensor from Dexcom lasts for 10 days and Abbot's device can be worn for 14 days. The company Senseonics have brought a fully implantable CGM device with duration for 180 days to the market and obtained regulatory approval in Europe.

Due to device/sensor costs, the current global diabetes patient population with access to CGM is limited. Based on our knowledge and experience we assume that less than 20% of patients who need to or should have insulin therapy in the US, EU and other high-income areas have access to CGM today, while the vast majority of patients in most other parts of the world neither can afford nor has access to CGM technologies.

Two of the key benefits of Sencell are an expected lifespan of at least 6 months, and low costs compared to competitive CGM systems. On this basis, Sencell is positioned for an extensive market penetration when regulatory approvals, production capabilities and distribution are ensured.

Sencell is designed to be a CE class III medical device, and the aim is to meet the regulatory requirements for market entry in the EU in 2023. The basis for an implementation in North America will be depending on an FDA approval. Lifecare will progress with the aim to ensure FDA-approval once a CE mark is achieved. In addition, further regulatory processes in other parts of the world will be initiated and the runway to access additional markets can be expected to be accelerated.

Living with diabetes causes financial strain on individuals and healthcare systems. The ability to handle even the direct costs of CGM systems is less in low- and middle-income countries. To some extent, Sencell has the potential to bridge the financial gap because it will be an



affordable device compared to existing solutions. This is seen especially in context with the expected longevity of Sencell. To follow up on the potential to bridge some of the financial gap, Lifecare sees it most effective to first approach the markets in the worlds high-income countries and in parallel outline a program for increasing accessibility in low- and middle-income countries.

On this basis Lifecare currently envision market approach in the following geographical markets:

1. EU, UK, EEA and Switzerland Estimated patient population 2021: 36.20m

Lifecare targets CE-mark first, and will focus on the EU-market, including the UK, EEA and Switzerland. According to IDF Diabetes Atlas, this geographical market includes a total patient population of 36.2m as of 2021. Furthermore, the IDF estimate that in Region “Europe as a whole” (including many non-EU countries), the diabetes population is expected to grow from 61m in 2021, to 67m by 2030 and 69m by 2045.

2. USA and Canada Estimated patient population 2021: 35.20m

Lifecare aims to initiate the regulatory process for an FDA approval in 2023, and when achieved this will lead to market access in **USA and Canada**, where the patient population in 2021 includes 32.20m (USA) and 3m (Canada). By 2030 the IDF estimates that the patient population will increase to 34.24m (USA) and 3.17m (Canada).

3. High-income countries not in group 1 or 2 Estimated patient population 2021: 29.00m
High- income as defined by the World Bank (Gross national income per capita of more than US\$12.696 in 2021).

Based on achieving a CE-mark and an active approach to achieve an FDA approval, Lifecare will aim to target regulatory approval in certain high-income countries. The runway for regulatory approval will be individual per country but can be expected less complicated based on regulatory approval in EU.

For the purpose of market calculations, Lifecare has identified high-income countries with an estimated patient population in 2021 of 29m:

Western Pacific	Australia (1.50m), Japan (11m), South Korea (3.51m), New Zealand (0.27m), Singapore (0.71m), Taiwan (2.45m)
Middle East	Israel (0.53m), Kuwait (0,80m), Oman (0.44m), Qatar (0.40m), Saudi Arabia (4.27m), United Arab Emirates (0.99m)
South America	Chile (1.75m), Uruguay (0.28m)

Target Patient Population

From this point on, we will - unless otherwise stated - base the additional assumptions on patient population size as of 2021 in the defined geographical markets. Without going into regional details, it is based on the IDF predictions clear that the increase of diabetes will continue world-wide, although less extensively in Europe and North America compared to the

rest of the world. It is reasonable to assume a similar growth for the additional high-income countries (group 3).

The diabetes patient population numbers provided are total figures for both diagnosed and undiagnosed people. According to IDF 35,7% of people having diabetes in the region EUR (not limited to EU) are undiagnosed, while the number for NAC is 24,1%. In the rest of the world the IDF assumes that more than 1 in 2 adults are undiagnosed. It is fair to assume that the ratio of diagnosed vs. undiagnosed is lower in high-income countries, hence the ratio of undiagnosed vs. diagnosed in the countries defined in group 3 can be assumed in line with EUR and NAC.

It is unreasonable to assume that undiagnosed patients will buy diabetes-products. Hence, we narrow the patient population to only include those that are diagnosed by deducting 35.7% in of the patients in the estimated target market group 1, 24.1% in group 2 and 28.8% in group 3. Despite the expectation that awareness and detection of diabetes will improve, the proportion of undiagnosed patients is assumed as constant going forward.

This leaves us with diagnosed patient population:

1. EU, UK, EEA, and CH	23.2m
2. US and CA	26.7m
3. Defined high-income countries	20.7m

The long-term market potential for Lifecare is equivalent to the patient population that needs or should take insulin. To further narrow the patient population, we split the number of diagnosed patient population into patients with type 1 diabetes (T1) or type 2 diabetes (T2). Other types of diabetes are minimal compared to those with T1 or T2 and is not taken into account in our calculations. The IDF states in the 10th edition of the Diabetes Atlas that more than 90% of people with diabetes have T2 and hence we conservatively assume that 10% is T1, 90% are T2. The T1 diabetes population is the natural primary target due to several reasons:

- clearly expressed need and urgency of having access to glucose data 24/7 for advanced diabetes management
- mature segment with fast diffusion of messages and early adoption of products
- likely less price sensitive segment
- likely that doctors and other professionals are more inclined to recommend an implantable glucose sensor for this group

The T2 diabetes population represents the secondary target. T2 represent a heterogenous – and most of the total – patient population, but far from all the patients in this group are on an insulin-therapy and consequently, it is not relevant for all of the patients to continuously monitor the glucose level. We estimate that around 30-40% of the T2 diabetes population is on or would benefit from insulin therapy. We therefore deduct the non-insulin treated subgroup (70%) from further calculations.



Calculation Sencell Patient Population

On this basis we can calculate the total target patient populations in the defined geographical areas as shown in the table below:

TARGET PATIENT POPULATION SENCELL	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Total global diabetes population, m	537	548,78	560,56	572,33	584,11	595,89	607,67	619,44	631,22	643,00
Region Europe	61	61,67	62,33	63,00	63,67	64,33	65,00	65,67	66,33	67,00
EU, UK, EEA and CH: total, m	36,2	36,60	36,99	37,39	37,78	38,18	38,57	38,97	39,37	39,76
EU, UK, EEA and CH: un-diagnosed vs diagnosed, %	35,7%	35,7%	35,7%	35,7%	35,7%	35,7%	35,7%	35,7%	35,7%	35,7%
EU, UK, EEA and CH: un-diagnosed, m	12,92	13,06	13,21	13,35	13,49	13,63	13,77	13,91	14,05	14,19
EU, UK, EEA and CH: diagnosed, m	23,28	23,53	23,79	24,04	24,29	24,55	24,80	25,06	25,31	25,57
T1DM, %	10,00 %	10,00 %	10,00 %	10,00 %	10,00 %	10,00 %	10,00 %	10,00 %	10,00 %	10,00 %
T2DM, %	90,00 %	90,00 %	90,00 %	90,00 %	90,00 %	90,00 %	90,00 %	90,00 %	90,00 %	90,00 %
Other Types, %										
Primary target patient population, T1DM, m	2,33	2,35	2,38	2,40	2,43	2,45	2,48	2,51	2,53	2,56
Insulin-dependant T2DM, % of total T2DM population	30,00 %	30,00 %	30,00 %	30,00 %	30,00 %	30,00 %	30,00 %	30,00 %	30,00 %	30,00 %
Secondary target patient population, T1DM, m	6,28	6,35	6,42	6,49	6,56	6,63	6,70	6,77	6,83	6,90
Total EU, UK, EEA and CH patient population for Sencell, m	8,61	8,71	8,80	8,89	8,99	9,08	9,18	9,27	9,37	9,46
Region North America and Caribbean, m	51	51,67	52,33	53,00	53,67	54,33	55,00	55,67	56,33	57,00
US and CA: total, m	35,2	35,66	36,12	36,58	37,04	37,50	37,96	38,42	38,88	39,34
US and CA: un-diagnosed vs diagnosed, %	24,1%	24,1%	24,1%	24,1%	24,1%	24,1%	24,1%	24,1%	24,1%	24,1%
US and CA: un-diagnosed, m	8,48	8,59	8,70	8,82	8,93	9,04	9,15	9,26	9,37	9,48
US and CA: diagnosed, m	26,72	27,07	27,42	27,76	28,11	28,46	28,81	29,16	29,51	29,86
T1DM, %	10,00 %	10,00 %	10,00 %	10,00 %	10,00 %	10,00 %	10,00 %	10,00 %	10,00 %	10,00 %
T2DM, %	90,00 %	90,00 %	90,00 %	90,00 %	90,00 %	90,00 %	90,00 %	90,00 %	90,00 %	90,00 %
Other Types, %										
Primary target patient population, T1DM, m	2,67	2,71	2,74	2,78	2,81	2,85	2,88	2,92	2,95	2,99
Insulin-dependant T2DM, % of total T2DM population	30,00 %	30,00 %	30,00 %	30,00 %	30,00 %	30,00 %	30,00 %	30,00 %	30,00 %	30,00 %
Secondary target patient population, T1DM, m	7,21	7,31	7,40	7,50	7,59	7,69	7,78	7,87	7,97	8,06
Total US and CA patient population for Sencell, m	9,89	10,01	10,14	10,27	10,40	10,53	10,66	10,79	10,92	11,05
Defined high-income countries; AU, CL, IL, JP, KR, KW, NZ, OM, QA, SA, SG, TW, AE, UY										
Selection: total, m	29,0	29,35	29,70	30,06	30,41	30,76	31,11	31,47	31,82	32,17
Selection: un-diagnosed vs diagnosed, %	28,8%	28,8%	28,8%	28,8%	28,8%	28,8%	28,8%	28,8%	28,8%	28,8%
Selection: un-diagnosed, m	8,35	8,45	8,55	8,66	8,76	8,86	8,96	9,06	9,16	9,27
Selection: diagnosed, m	20,65	20,90	21,15	21,40	21,65	21,90	22,15	22,40	22,66	22,91
T1DM, %	10,00 %	10,00 %	10,00 %	10,00 %	10,00 %	10,00 %	10,00 %	10,00 %	10,00 %	10,00 %
T2DM, %	90,00 %	90,00 %	90,00 %	90,00 %	90,00 %	90,00 %	90,00 %	90,00 %	90,00 %	90,00 %
Other Types, %										
Primary target patient population, T1DM, m	2,06	2,09	2,11	2,14	2,17	2,19	2,22	2,24	2,27	2,29
Insulin-dependant T2DM, % of total T2DM population	30,00 %	30,00 %	30,00 %	30,00 %	30,00 %	30,00 %	30,00 %	30,00 %	30,00 %	30,00 %
Secondary target patient population, T1DM, m	5,57	5,64	5,71	5,78	5,85	5,91	5,98	6,05	6,12	6,18
Total Selection patient population for Sencell, m	7,64	7,73	7,83	7,92	8,01	8,10	8,20	8,29	8,38	8,48
TOTAL PATIENT POPULATION SENCELL, m	26,14	26,45	26,77	27,09	27,40	27,72	28,03	28,35	28,67	28,98

Sencell commercial potential

Target market penetration and unit sales

Lifecare plans to start first-in-human pilot clinical trials by end of 1H 2022. In 2H 2022 Lifecare plan to start the second round of clinical trials and aim to start regulatory clinical trials by end of year 2022. We assume that the CE mark will be achieved in 2023. First sales of the medical product can commence in 2023, but from the calculation perspective, we choose to define 2024 as the start of volume sales in the EU. The regulatory process to achieve FDA approval can be assumed more comprehensive compared to regulatory processes in other high-income countries, hence we aim for 2025 as the commerce of volume sales in high-income countries outside Europe and North America and 2026 as the start of volume sales in USA and Canada.

We estimate assumed market shares in the Primary market (T1 diabetes patients) and the Secondary market T2 (diabetes patients) as the market penetration for the geographical target markets. The market penetration is higher at the beginning of the sales-period, and we assume to reach peak market penetration in the 8th year of sales (by 2031). Furthermore, we assume the penetration to stay at peak until 2038, when our existing patents expire and hence the model get cut off at this point.

Capturing market shares depends on a range of factors that to an extent is not controlled by Lifecare as the developer and producer of the Sencell. On the basis that key benefits of the Sencell compared to existing CGM systems includes small size, long-lifetime and low cost, one could argue that the market penetration can be expected to be significant. For the purpose of this value proposition and assumption we choose to estimate on the conservative side, taking into account the range of market penetration factors not controlled by Lifecare.

Basis for the market penetration considerations is the following market share assumptions:

	Low case	Base case	High case
Primary market (T1)	3%	5%	10%
Secondary market (T2)	1%	3%	5%

Sencell is expected to have a lifetime of 6 months, hence we assume that every patient needs two devices per year.

This leads to sales for the base case of around 2m units annually in 2030.

Sales potential

CGM systems in the market have so-called minimal-invasive (“needle-sensors”) or implantable glucose sensors. The major players in this field are Dexcom, Medtronic and Abbott. In addition, we find it worth mentioning the CGM system Eversense, which is manufactured by Senseonice, the only provider of an implantable CGM system. Our research indicates that using the already available CGM systems is quite expensive for the patients. In addition, the existing minimal invasive devices require either rapid replacement (7-21 days duration), and repeated - in some cases daily – calibrations of the glucose measurement.

The following overview of pricing is based on an out-of-pocket private payer perspective, representing the total costs independent of private or public health insurance schemes. In addition, the overview is based on pricing in the US, as this represents the largest single market among the potential markets defined in this document.

The US health information website healthline.com presented a medically reviewed CGM cost overview on 10 May 2021. According to this overview, the average monthly cost for CGM’s can range from USD 130/month to more than USD 500/month. The estimated totals were as follows:

CGM	Estimated cost/year	Estimated cost/month
Dexcom	USD 4.173	USD 347
Medtronic	USD 4.208	USD 351

Abbott	USD 1.582	USD 132
Eversense	USD 6.400	USD 533

We target Sencell to be a cost-effective solution for patients. Thus, costs should be significantly lower than for the existing products in the market. We therefore **assume Sencell to have total annual sales price of EUR 650 per patient**. The annual estimated sales price includes the Sencell glucose sensors, read-out device and/or subscription fee for data transfer. This is a significant cost reduction compared to the costs of using the existing CGM products. No individual regional considerations have been included when assuming the total annual cost and it is likely that comprehensive market research, regional go-to-market strategies, potential partnering, and public/private reimbursement schemes will affect the product pricing. Deviations from the assumed total annual cost is likely to occur.

These assumptions lead to revenues in the target markets of around EUR 654m in 2030.

Target Market Potential Revenue Calculation

Market penetration Sencell Base Case	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Level of assumed market penetration - base case										
EU, UK, EEA and CH	0%	0%	0%	5%	20%	40%	80%	95%	100%	100%
US and CA	0%	0%	0%	0%	0%	10%	30%	50%	75%	95%
AU, CL, IL, JP, KR, KW, NZ, OM, QA, SA, SG, TW, AE, UY	0%	0%	0%	0%	2%	15%	40%	70%	95%	100%
Penetration, primary target patient population (T1DM) - base case	0,0%	0,0%	0,0%	0,1%	0,4%	1,1%	2,5%	3,6%	4,5%	4,9%
Penetration, secondary target patient population (T2DM) - base case	0,0%	0,0%	0,0%	0,1%	0,2%	0,7%	1,5%	2,2%	2,7%	3,0%
Units sold, primary target market, EU,UK,EEA and CH '000 (2 per patient per year)	0	0	0	12	49	98	198	238	253	256
Units sold, primary target market, US and CA '000 (2 per patient per year)	0	0	0	0	0	28	86	146	221	284
Units sold, primary target market, High Inc selection '000 (2 per patient per year)	0	0	0	0	4	33	89	157	215	229
Units sold, secondary target market, EU,UK,EEA and CH'000 (2 per patient per year)	0	0	0	19	79	159	321	386	410	414
Units sold, secondary target market, US and CA '000 (2 per patient per year)	0	0	0	0	0	46	140	236	359	460
Units sold, secondary target market, High Inc selection '000 (2 per patient per year)	0	0	0	0	7	53	144	254	349	371
Total units sold, '000	0	0	0	31	139	418	979	1417	1807	2013
Annual sales per patient for Sencell, EUR (325 eur per unit)				650	650	650	650	650	650	650
Revenues, EURm EU, UK, EEA and CH				10	41	84	169	203	216	218
Revenues, EURm US and CA				0	0	24	74	124	188	242
Revenues, EURm High Inc				0	4	28	75	134	183	195
Revenues, EURm	0	0	0	10	45	136	318	460	587	654