

Optimizing diabetes outcomes in children\* & teens with T1D

# Clinical studies supporting the proven clinical benefit of FreeStyle Libre 2 system<sup>†1-3</sup>

## Improved time spent in target range & reduced A1c<sup>‡3</sup>

- Children and teens (N=76) stayed in target range almost 10% longer than BGM at baseline
- A1c reductions, especially notable in teens, didn't impact hypoglycemic risk
- Time in hyperglycemia was reduced by 1.2 (±3.3) hr/day (p=0.004)

Age:	4-6 Children	7-12 Children	13-17 Teens	
				<b>1hr/day</b> more time in range (70 mg/dL-180 mg/dL) p=0.005
<b>Time in Target Range</b>	<b>+1.6</b> ±2.6 hr/day (70 mg/dL-180 mg/dL) p=0.035	<b>+0.5</b> ±3.1 hr/day (70 mg/dL-180 mg/dL) p=0.33 not statistically significant	<b>+1.2</b> ±2.5 hr/day (70 mg/dL-180 mg/dL) p=0.025	
				<b>0.4%</b> average A1c reduction p<0.0001
<b>A1c Reduction</b>	<b>0.3%</b> ±0.5% p=0.02	<b>0.3%</b> ±0.5% p=0.005	<b>0.7%</b> ±0.6% p<0.0001	

## Increased treatment satisfaction<sup>‡3</sup>

- FreeStyle Libre 2 system demonstrated safe home use without device training or insulin-adjusted algorithms
- Children, teens, and their caregivers agreed on the following attributes:

**91%**  
FreeStyle Libre 2 system is the preferred way to check glucose<sup>§</sup>

**90%**  
FreeStyle Libre 2 system does not get in the way of daily activities<sup>§</sup>

**99%**  
FreeStyle Libre 2 system is easier to use than BGM<sup>§</sup>

**94%**  
of teens made their own dosing decisions



\*FreeStyle Libre 2 system is indicated for use in people with diabetes age 4 and older. †Data from these studies were collected with the outside US version of FreeStyle Libre 14 day system. FreeStyle Libre 2 has the same features as FreeStyle Libre 14 day system with optional, real-time glucose alarms. Therefore, the study data is applicable to both products. ‡Short-term, single arm study in 76 children and teens with T1D age 4-17 using insulin pump or multiple daily injection therapy. Primary efficacy endpoint was the equivalence (non-inferiority) of Time in Range (TIR) (70-180 mg/dL hr/day) utilizing FreeStyle Libre device and blood glucose monitoring (BGM) during the final 14 days of the treatment phase (days 57-70) compared to BGM use only during baseline (days 1-14). §Questionnaire was completed by children or their caregiver. Diaries were completed by the teenagers.

1. Al Hayek, A. Clinical Medicine Insights: *Endocrinology and Diabetes* (2017): <https://doi.org/10.1177/1179551417746957>. 2. Al Hayek, A. *Diabetes Therapy* (2020): <https://doi.org/10.1007/s13300-020-00793-2>. 3. Campbell, F. *Pediatric Diabetes* (2018): <https://doi.org/10.1111/pedi.12735>.

### Reduced frequency of hypoglycemia\*<sup>1</sup>

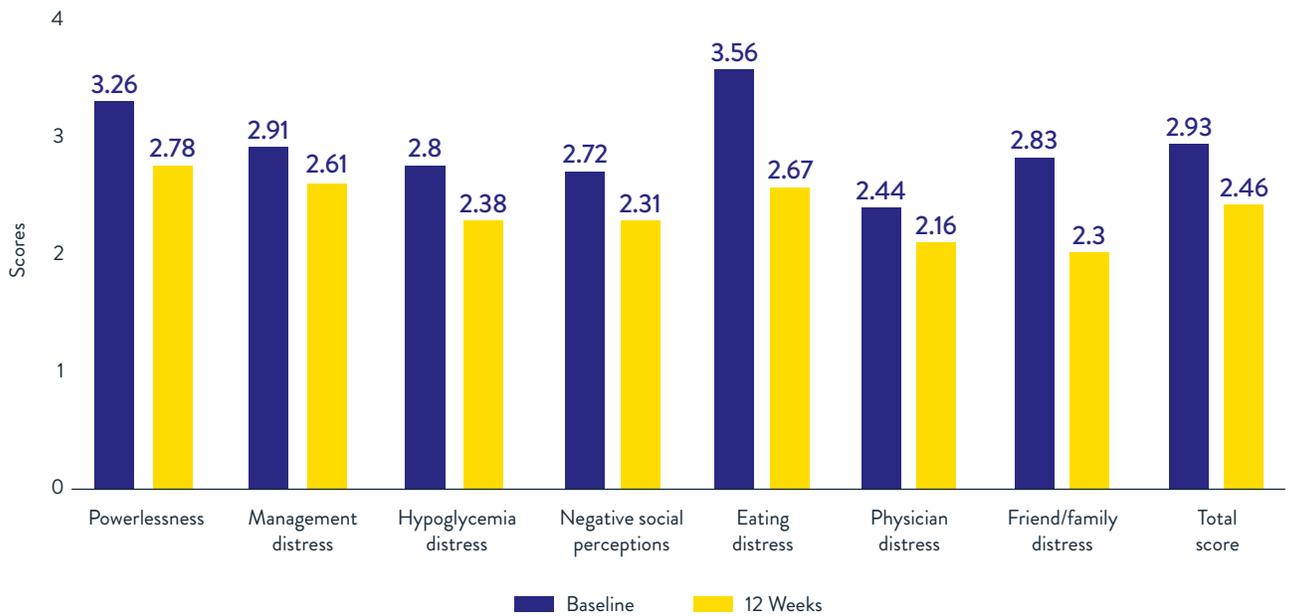
- Monthly hypoglycemic episodes significantly decreased ( $p=0.023$ ) in teens ( $N=47$ ) after 3 months of use vs BGM at baseline

### Improved behavior & improved quality of life (QoL)\*<sup>1</sup>

- Significant positive differences were seen in the behavior ( $N=47$ ) of fear of hypoglycemia ( $p=0.0001$ ), worry ( $p=0.0001$ ), and QoL ( $p=0.002$ ), helping teens to be less anxious and more in control of their diabetes management after 3 months vs BGM at baseline

### Reduced diabetes-related distress in teens<sup>†2</sup>

- Teens ( $N=187$ ) felt considerably less distress from diabetes management after 3 months vs BGM at baseline, based on significant decrease in 7 different subdomains ( $p=0.0001$ )



By improving their glucose control and QoL, FreeStyle Libre 2 system users saw improved clinical outcomes and reduced diabetes-related distress<sup>1-3</sup>



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\*Results from 47 teens with T1D age 13-17 using the Hypoglycemia Fear Survey-Child (HFS-C) to measure anxiety-provoking aspects of hypoglycemia and the specific behaviors adopted by teens to avoid hypoglycemia. The survey comprises a 10-item behavior subscale (HFS-B), a 15-item worry subscale (HFS-W), and 7 questions about response to hypoglycemia under special circumstances. HFS-W measured anxiety-provoking aspects, whereas the HFS-B measured the specific behaviors. †Results from 187 teens with T1D age 13-19 based on the T1-Diabetes Distress Scale (T1-DDS), which comprises 7 concepts of health wherein 5 questions deal with powerlessness, 4 questions relate to management distress (disappointment with self-care efforts), 4 relate to hypoglycemia distress, 4 deal with negative social perceptions (worry about other people's possible negative judgments), 3 with eating distress (anxiety that eating is out of control), 4 with physician distress (disappointment with the healthcare professionals currently managing their treatment), and 4 relate to friend/family distress (perception of too much focus on diabetes among their loved ones).

1. Al Hayek, A. Clinical Medicine Insights: *Endocrinology and Diabetes* (2017): <https://doi.org/10.1177/1179551417746957>. 2. Al Hayek, A. *Diabetes Therapy* (2020): <https://doi.org/10.1007/s13300-020-00793-2>. 3. Campbell, F. *Pediatric Diabetes* (2018): <https://doi.org/10.1111/ pedi.12735>.

#### Important Safety Information

Failure to use FreeStyle Libre 2 system as instructed in labeling may result in missing a severe low or high glucose event and/or making a treatment decision, resulting in injury. If glucose alarms and readings do not match symptoms or expectations, use a fingerstick value from a blood glucose meter for treatment decisions. Seek medical attention when appropriate or contact Abbott at 855-632-8658 or <https://www.FreeStyle.abbott/us-en/safety-information.html> for safety info.