

Metabolic Control RCT
Skin Assessment Form

tbIPSkinAssess

PtID	1. Patient ID: _____
Namecode	2. Namecode: _____
Visit	3. Visit: <input type="checkbox"/> 2wk <input type="checkbox"/> 6wk <input type="checkbox"/> 3m <input type="checkbox"/> 6m <input type="checkbox"/> 9m <input type="checkbox"/> 12m <input type="checkbox"/> 15m <input type="checkbox"/> 18m <input type="checkbox"/> 21m <input type="checkbox"/> 24m <input type="checkbox"/> 30m <input type="checkbox"/> 36m <input type="checkbox"/> 42m <input type="checkbox"/> 48m

SkinAssessNotDone	<input type="checkbox"/> Not Done
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Skin Assessment

SkinChanges	1. Are there any areas of acute (erythema or edema) or chronic (scabbing, dry skin, hypo or hyperpigmentation or scarring) skin changes related to sensor use that are greater than usual (by investigator judgment)? <input type="checkbox"/> No <input type="checkbox"/> Acute <input type="checkbox"/> Chronic <input type="checkbox"/> Acute and Chronic
AcuteSev	1a. If acute changes present, complete the following: 1a1. Severity* <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe (If Severe, complete an Adverse Event Form) Severity Definitions: ▪ Mild: Observation is present, but not necessarily well defined or immediately noticeable to the subject. ▪ Moderate: Observation is clearly defined or bothers the subject intermittently. ▪ Severe: Observation is extremely noticeable and bothersome to subject. May indicate infection or risk of infection or potentially life-threatening allergic reaction
AcuteDs	1a2. Describe the changes, including location(s): _____
ChronicSev	1b. If chronic changes present, complete the following: 1b1. Severity* <i>Show Definitions</i> <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe (If Severe, complete an Adverse Event Form) Severity Definitions: ▪ Mild: Observation is present, but not necessarily well defined or immediately noticeable to the subject. ▪ Moderate: Observation is clearly defined or bothers the subject intermittently. ▪ Severe: Observation is extremely noticeable and bothersome to subject. May indicate infection or risk of infection or potentially life-threatening allergic reaction
ChronicDs	1b2. Describe the changes, including location(s): _____

*For severity, indicate the highest level if skin changes are present in more than one location. If "Severe" is selected, please complete an Adverse Event Form.

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