

Appendix 2: safety parameters of the Pregnolia System

- Vaginal or cervical blood loss (directly after measurement)
- Patient discomfort or dissatisfaction during Pregnolia® measurement(scaled 0 to 10)
- Preterm Prelabour Rupture Of Membranes (PPROM) (directly after measurement)
- Preterm labour (directly after measurement)
- Infections within seven days of measurement (Urinary Tract Infections, Vaginal infections, Intra-uterine infections)
- Irritation and sensitization of mucosal tissue
- Infection of the vaginal or mucosal tissue
- Tissue abrasion and vaginal discharge
- Spotting, light bleeding
- Superficial lacerations or minor tissue abrasions