# Safety Monitoring Sheet

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Study Site Code: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | Participant ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | Device No.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| Enrollment Date: \_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_ (DD/MM/YY) | | | | | | | Birth Date: \_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_(DD/MM/YY) | | | | | | | Sex (circle one): 1=Male, 2=Female | | | | |
| \*Head circumference (cm): | | |  | |  | |  | |  | | |  | |  | |  | |  |
| Measured on (DD/MM/YY): | | |  | |  | |  | |  | | |  | |  | |  | |  |
| Which morbidity does this patient have? (check all that apply) | | | | | | | | | | | | | | | | | | |
| □ LBW □ Prematurity □ Birth asphyxia □ Sepsis □ Pneumonia □ Jaundice □ Other (please specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | | | | | | | |
| **SAFETY LOG** | | | | | | | | | | | | | | | | | | |
| Gently loosen the neoGuardTM device every 4 – 6 hours and examine the newborns’ forehead for any signs of skin irritation. If you observe any signs of an adverse event such as a rash or potential burn, please remove the device completely and inform the pediatrician/neonatologist or medical officer.  Please record your observations for every safety check performed by indicating the time and filling in the corresponding number code:  1 = No remarkable findings, 2 = Rash, 3 = Infection, 4 = Burn, 5 = Other skin irritation (please specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | | | | | | | |
|  | **Date** | **Time** | | **Observation** | | **Time** | | **Observation** | | **Time** | **Observation** | | **Time** | | **Observation** | | **Nurses Initials** | |
| 1. |  |  | |  | |  | |  | |  |  | |  | |  | |  | |
| 2. |  |  | |  | |  | |  | |  |  | |  | |  | |  | |
| 3. |  |  | |  | |  | |  | |  |  | |  | |  | |  | |
| 4. |  |  | |  | |  | |  | |  |  | |  | |  | |  | |
| 5. |  |  | |  | |  | |  | |  |  | |  | |  | |  | |
| 6. |  |  | |  | |  | |  | |  |  | |  | |  | |  | |
| 7. |  |  | |  | |  | |  | |  |  | |  | |  | |  | |
| 8. |  |  | |  | |  | |  | |  |  | |  | |  | |  | |
| 9. |  |  | |  | |  | |  | |  |  | |  | |  | |  | |
| 10. |  |  | |  | |  | |  | |  |  | |  | |  | |  | |

\*To ensure that the baby is comfortable, please measure his/her head circumference every 2 days and adjust the neoGuardTM headband as instructed in the band sizing chart.