Neonatal Jaundice –Transcutaneous Bilirubin (TcB) measurement

This LOP is developed to guide safe clinical practice in Newborn Care Centre (NCC) at The Royal Hospital for Women. Individual patient circumstances may mean that practice diverges from this Local Operations Procedure (LOP).

1. INTRODUCTION

Transcutaneous bilirubin (TcB) devices are widely used in term and near-term infants for estimation of bilirubin in combination with total serum bilirubin (SBR) levels.[1,2,3]
TcB readings are instant and can avoid delays in treatment and/or discharge as well as indicate the need for formal SBR testing.
Use of TcB has been shown to reduce SBR testing in infants ≥ 32 weeks gestation by 30% with reductions in the pain and stress of heel pricks as well as healthcare costs.[4,5]
There is increasing evidence for the accuracy of TcB in premature infants < 32 weeks gestation.[6,7]

2. SCOPE

This guideline outlines use of the Dräger Air-Shields JM103/JM105 TcB devices in infants of all gestations.
Infants < 32 weeks gestation require simultaneous SBR measurements because of their increased risk of jaundice and the increased susceptibility of their brain to moderate/high bilirubin levels.
The device is not to be used when infants are receiving overhead phototherapy but can be used for babies on the Bilisoft blanket.[8]

3. AIM

To guide appropriate TcB use in infants nursed in RHW.

4. PATIENT

Infants with jaundice

5. STAFF

Medical officers, nurses and midwives

6. CLINICAL PRACTICE

All clinicians require training with use of the Dräger JM-105 and Dräger Airshields JM-103 and use of these TcB guidelines.
Midwives and nursing staff will carry out the daily light calibration and document in the JM-105 (Appendix 1) or JM-103 (Appendix 2) Resource Manuals prior to the morning round. Both the values for the long and short optical paths should read within ±1.0 of the reference value on the unit cover.

6.1 Practical instructions for using the DRÄGER Jaundice Meters JM-105

1. Remove the Jaundice Meter JM-105 from the docking station.
2. Clean the probe with an alcohol swab prior to use.
3. Press the “switch-on” power button.
4. Check that the green “ready” light is on.
5. Select “Menu”, select “Measure”. Press “OK.” The letters “AVE” with the number of measurements selected appears on the display.
6. Place the jaundice meter probe tip **flat** against the infant’s skin.
7. Press lightly until an audible click occurs.
8. Lift the jaundice meter from the skin.
9. Wait for the green light and repeat the procedure.
10. Consult the result with the RMO to decide whether a total serum bilirubin pathology test is required.
11. Clean the probe with an alcohol swab after use.

…./2

Neonatal Jaundice –Transcutaneous Bilirubin (TcB) measurement cont'd

Practical instructions for using the DRÄGER Jaundice Meters JM-103:

1. Clean the probe with an alcohol wipe.
2. Switch power ON. Ready light illuminates and n-3 will appear on the display.
3. Place probe tip flat against the baby's skin and press down gently until you hear a click. (If measurement over the forehead is not possible the sternum can be used).
4. Avoid any bruises or discoloured areas of skin.
5. Lift meter from the skin between measurements and wait until the green ready light comes on.
6. **Repeat the test x 3. Once the three tests have been done the average of the three measured values appears on the display.**
7. Switch to the 'Off' position.
8. Clean the measuring probe with an alcohol swab.
9. Place the Jaundice Meter on the charger unit when is not in use.
10. The upper limit of the TCB meter measurement range is 340 µmol/L. Above this measured level the display will show "---".
11. The RESET button deletes the currently displayed measured value and prepares for the next measurement

6.2 Guidelines once TcB level is obtained:

- **Perform urgent SBR on all infants < 24 hours of age presenting with jaundice** (regardless of whether a TcB has been done).[9]
- Perform TcB (± SBR depending on gestation and rate of rise) every 6-24 hours in the first 72 hours of life for any visible jaundice appearing after 24 hours of age.
- Look for risk factors such as Prematurity, Isoimmune haemolytic disease, Asphyxia, Polycythaemia, Cephalhaematoma/bruising, Temperature instability, Sepsis or acidosis, Maternal diabetes, History of sibling with significant jaundice, Low serum albumin < 30g/L, East Asian race or ethnic group at risk for G6PD deficiency. *These may lower your threshold for phototherapy &/or increase the frequency of TcB/SBR testing.*

6.3 TcB levels in Infants < 38 weeks gestation

- All infants < 32 weeks gestation require a simultaneous total serum bilirubin (SBR) and TcB.
- Infants 32-37 weeks gestation with a TcB level above the TcB gestational threshold line on the TcB chart for gestation require an SBR measurement.[7] (Perform SBR when TcB is within 50 µmol/L of phototherapy line).
- For infants 33-37 weeks gestation with a TcB below the gestational line for an SBR – continue regular TcB. These infants may not need phototherapy providing they are well.[7]

6.4 TcB levels in Term Infants ≥ 38 weeks gestation

- An SBR is required when the TcB is above the TcB threshold line for phototherapy as plotted on the ≥ 38 weeks gestation TcB jaundice chart (Perform SBR when TcB is within 50 µmol/L of phototherapy line).

7. DOCUMENTATION

- TcB chart appropriate to gestational age
- Observation Chart
- NICUS database
- Infants <32 weeks: write TcB & SBR results on the TcB threshold graphs (see Appendix 3).

8. EDUCATIONAL NOTES

- Transcutaneous bilirubin (TcB) devices estimate serum bilirubin non-invasively. The JM-103/JM-105 devices determine the yellowness of an infant's subcutaneous tissue by measuring the difference in the optical densities for light in the blue (450 nm) and green (550 nm) wavelength regions. The measuring probe has two optical paths. This method allows for a more precise measurement of yellowness in an infant's subcutaneous tissue by minimizing the influences of the melanin pigment and the skin maturity. The device does not have a user calibration. The system does include a checker that measures the intensity of light from the device to ensure the light output is within range.

Neonatal Jaundice –Transcutaneous Bilirubin (TcB) measurement cont'd

- TcB measurements have demonstrated good linear correlation with SBR in term neonates.[11]
- The JM-103 TcB device has been shown to correlate well in multi-racial groups though may overestimate SBR in African infants.[10,12,13]
- Data were collected on 8319 TcB measurements at 27 nursery sites in the US; 925 total SBR levels were matched to a TcB value.[7] The mean TcB – TSB difference was 14.4 µmol/L ± 30.4 µmol/L & the correlation between paired measurements was 0.78. In the multivariate analysis TcB – SBR differences were 11.5 µmol/L higher in African-American newborns than in neonates of other races (P < .001). The TcB – SBR difference also varied significantly based on brand of TcB meter used and hour of age of the infant (the tendency for TcB to underestimate SBR increased with advancing newborn age). TcB levels were less accurate at higher levels: At SBR ≥ 256 µmol/L, corresponding TcB value averaged 24 µmol/L lower with substantial variability often > 34 µmol/L. At lower SBR levels, TcB tended to overestimate the value.
- The use of TcB compared to visual inspection in infants ≥ 35 weeks gestation in acute-care and community settings has been associated with significant improvements in laboratory utilization, patient care, convenience, and safety.[14] A prospective cohort study compared neonatal hyperbilirubinemia-related outcomes of 14,796 healthy infants ≥ 35 weeks gestation by using locally validated nomograms relative to a historical cohort of 14,112 infants assessed by visual inspection alone. After implementation of routine TcB measurements there was a 54.9% reduction in the incidence of SBR ≥ 342 µmol/L. TcB implementation was associated with reductions in the number of SBR samples taken (p< 0.001) and overall phototherapy rate (p < 0.001) & a reduced age at readmission for phototherapy (104 ± 52 vs 89 ± 70 hours, P < .005).[14]
- In some cases what appear to be falsely low TcB levels could be due to erroneously high SBR measurements.[15]
- TcB > 206–240 µmol/L appears to underestimate bilirubin concentrations and at the clinician's discretion an SBR should be done.[11]
- Data pertaining to TcB in preterm infants suggests a high correlation between TcB and SBR. A systematic review comparing TcB with SBR found good correlation of TcB with SBR in infants < 32 weeks gestation (r = 0.89 [95% CI: 0.82–0.93]).[6] Two studies from the meta-analysis provided separate data for infants ≤ 28 weeks gestation & reported correlation coefficients of 0.92-0.94.[16,17]
- Another systematic review compared TcB devices in near term & term infants receiving phototherapy or in the post-phototherapy phase.[8] Pooled estimates of correlation coefficients (r) during phototherapy were: covered sites 0.71 (95% CI 0.64-0.77, 11 studies), uncovered sites 0.65 (95% CI 0.55-0.74), 8 studies), forehead 0.70 (95% CI 0.64-0.75, 12 studies) and sternum 0.64 (95% CI 0.43-0.77, 5 studies). Correlation coefficients improved marginally in the post-phototherapy phase (r = 0.72, 95% CI 0.64-0.78, 4 studies). Correlation was only moderate. Further research is needed before TcB devices can be recommended for these settings.[8]
- Potential harms associated with using invasive blood tests include: Infant pain and discomfort, risk of infection and maternal distress.[18,19]
- The potential harms associated with under diagnosis include: Auditory neuropathy spectrum disorder and bilirubin induced neurologic damage (BIND).[20,21]
- Risk of a ≥ 50 µmol/L underestimation of SBR by TcB was significantly increased in newborns with birth weights < 2500g.[10] Failing to identify significant hyperbilirubinemia is the worst outcome of TcB screening. Therefore, TcB results need to be interpreted cautiously in newborns with birth weights < 2500g, particularly in the first 48 hours of life.

9. RELATED POLICIES / PROCEDURES / CLINICAL PRACTICE LOP

- RHW Neonatal Jaundice – Management in infants <32 weeks Feb 2017
- NSW Health 2016. Doc Number GL2016_027. Neonatal Jaundice - Identification and management in neonates ≥32 weeks gestation
- Exchange Transfusion

10. RISK RATING

- Medium

11. NATIONAL STANDARD

- Standard 12: Provision of Care.

Neonatal Jaundice –Transcutaneous Bilirubin (TcB) measurement cont'd

REFERENCES

1. NICE. (2016). Jaundice in newborn babies under 28 days. https://www.nice.org.uk/guidance/cg98
2. Maisels MJ, Bhutani VK, Bogen D, Newman TB, Stark AR, Watchko JF. (2009) Hyperbilirubinemia in the newborn infant ≥ 35 weeks' gestation: an update with clarifications. Pediatrics. Oct;124(4):1193-8.
3. Srinivas GL, Cuff CD, Ebeling MD, Mcelligott JT. (2016) Transcutaneous bilirubinometry is a reliably conservative method of assessing neonatal jaundice. J Matern Fetal Neonatal Med. 29(16):2635-9.
4. Briscoe L, Clark S & Yoxall CW. Can transcutaneous bilirubinometry reduce the need for blood tests in jaundiced full term babies? (2002) Archives of Disease in Childhood Fetal & Neonatal Edition, 2002; 86: (3), F190-192.
5. RPA Newborn Care Guidelines: Bilirubinometer Policy (2006) http://www.slhd.nsw.gov.au/rpa/neonatal%5Ccontent/pdf/guidelines/bilirubinometer.pdf
6. Nagar G, Vandermeer B, Campbell S, Kumar M. (2013) Reliability of transcutaneous bilirubin devices in preterm infants: a systematic review. Pediatrics. Nov;132(5): 871-81.
7. Maisels MJ, Coffey MP, Kring E. (2015). Transcutaneous bilirubin levels in newborns < 35 weeks gestation J Perinatol. Sep;35(9):739-744.
8. Nagar G, Vandermeer B, Campbell S, Kumar M. (2016) Effect of Phototherapy on the Reliability of Transcutaneous Bilirubin Devices in Term and Near-Term Infants: A Systematic Review and Meta-Analysis. Neonatology;109(3):203-12.
9. Jackson GL, Saumur M, Chandwani V, Engle WD. (2015) Evaluation of Early Transcutaneous Bilirubinometry to Predict Subsequent Hyperbilirubinemia in Neonates Admitted to a Well-Baby Nursery. Am J Perinatol. Aug;32(10):944-51.
10. Taylor JA, Burgos AE, Flaherman V, Chung EK, Simpson EA, Goyal NK, Von Kohorn I, Dhepyasuwan N; (2015) Discrepancies between transcutaneous and serum bilirubin measurements. Better Outcomes through Research for Newborns Network. Pediatrics. Feb;135(2):224-31
11. El-Beshbishi SN, Shattuck KE, Mohammad AA, Petersen JR. (2009) Hyperbilirubinemia and transcutaneous bilirubinometry. Clin Chem. 2009 Jul;55(7):1280-7
12. Raimondi F, Lama S, Landolfo F, Sellitto M, Borrelli AC, Maffucci R, Milite P, Capasso L. (2012) Measuring transcutaneous bilirubin: a comparative analysis of three devices on a multiracial population. BMC Pediatr. 2012 Jun 14;12:70.
13. Olusanya BO, Imosemi DO, Emokpae AA. (2016) Differences Between Transcutaneous and Serum Bilirubin Measurements in Black African Neonates. Pediatrics. Sep;138(3).
14. Wainer S, Parmar SM, Allegro D, Rabi Y, Lyon ME. (2012) Impact of a transcutaneous bilirubinometry program on resource utilization and severe hyperbilirubinemia. Pediatrics. Jan;129(1):77-86
15. Maisels MJ. Transcutaneous bilirubin measurement: does it work in the real world? (2015) Pediatrics. Feb;135(2):364-6.
16. Schmidt ET, Wheeler CA, Jackson GL, Engle WD. (2009) Evaluation of transcutaneous bilirubinometry in preterm neonates. J Perinatol. 2009;29(8):564–569
17. Ahmed M, Mostafa S, Fisher G, Reynolds TM. (2010) Comparison between transcutaneous bilirubinometry and total serum bilirubin measurements in preterm infants <35 weeks gestation. Ann Clin Biochem;47(pt 1):72–77
18. Shah VS, Taddio A, Bennett S & Speidel BD. (1997) Neonatal pain response to heel stick vs venepuncture for routine blood sampling. Archives of Disease in Childhood Fetal & Neonatal Edition. 77: (2), F143-144.
19. Lidow MS. (2002) Long-term effects of neonatal pain on nociceptive systems. Pain ;99:377–383
20. Olds C, Oghalai JS. (2015) Audiologic impairment associated with bilirubin-induced neurologic damage. Semin Fetal Neonatal Med. Feb; 20(1): 42–46.

Neonatal Jaundice –Transcutaneous Bilirubin (TcB) measurement cont'd

21. Gamaleldin R, Iskander I, Seoud I, Aboraya H, Aravkin A, Sampson P, Wennberg R. (2011) Risk Factors for Neurotoxicity in Newborns With Severe Neonatal Hyperbilirubinemia. Pediatrics. 2011 Oct; 128(4): e925–e931.
22. Van den Esker-Jonker B, den Boer L, Pepping RM, Bekhof J. (2016) Transcutaneous Bilirubinometry in Jaundiced Neonates: A Randomized Controlled Trial. Pediatrics. Dec;138(6).
23. Varvarigou A, Fouzas S, Skylogianni E, Mantagou L, Bougioukou D, Mantagos S. (2009) Transcutaneous Bilirubin Nomogram for Prediction of Significant Neonatal Hyperbilirubinemia Pediatrics;124;1052-1059.
24. Maisels MJ, Kring E. (2006) Transcutaneous bilirubin levels in the first 96 hours in a normal newborn population of ≥ 35 weeks' gestation. Pediatrics.;117(4):1169 –1173

AUTHORS:

Original version Date: 20/06/2017	**Author/s: John Smyth, Keshni Nanthakumar**
Current Version number: 1.0	**Version Date:** 20/06/2017
Risk Rating: Medium	**Due for Review:** 20/06/2020
Approval by: NCC Quality Committee	**Approval Date: 3/07/2017**

Appendix 1

Performing Daily Operational Light calibration on Draeger JM-105:
The light output of the device should be checked once daily as follows to ascertain the meter light output is within range.

- Remove the Jaundice Meter JM-105 from the docking station.
- Switch on the power.
- Select CHECKER and select OK to save selection.
- Open the checker lid on the charging unit.
- When the green READY light illuminates, place the tip of the Jaundice Meter perpendicular on the reading checker circle. Press down until you hear a click.
- The display screen shows the “L” (long), “S” (short), and Delta values. The meter must read within the reference values posted under the checker lid. If so, the unit is ready to use. If not, clean the tip and repeat. If values are still out of range, do not use the unit (contact biomed).

Configuring the JM-105:

- Press the power switch on.
- If you want to change your file storage option, configure the device as desired by selecting CONFIG > MEMORY > OK > your desired setting (OFF, MEM ONLY, or LINK ON) > OK. If not, go to next step.
- Press the MENU button to exit the CONFIG screen.
- To determine whether or not you want to average your measurements and how many measurements you want to take.
- Configure the device as desired by selecting CONFIG > AVERAGE > OK > your desired setting (SINGLE through 5 TIMES) > OK.

Appendix 2

Performing Daily Operational Light calibration on the JM-103:

- Hold the Reset button down, and set the Power switch to the On position.
- After CHE appears on the display window, immediately release the Reset button. If the Reset button is held down for longer than 15 seconds, switch the unit of measurement back to its previous setting
- Visually confirm that CHE appears in the display and that the Ready lamp illuminates.
- Open the cover of the checker (on the base unit). Use only the checker supplied with the Jaundice Meter (JM-103).
- Place the measuring probe perpendicular to the checker, and push it gently until a click sounds.
- The display interchanges between the L-value, the measured value of the long-optical path, and the S-value, the measured value of the short-optical path. When the L-value is displayed, "**•**" appears in the upper left-hand corner of the display
- Confirm the measured value. If both the L-value and the S-value are within ± 1.0 of the reference values indicated on the checker, the values are acceptable.
- If the measured value exceeds ± 1.0 of the reference value, perform the following:
  a. Clean both the checker and the measuring probe.
  b. Place the measuring probe perpendicular to the checker, and push it gently until a click sounds.
  c. If the measured value still exceeds ± 1.0 of the reference value, contact biomed dept
- Close the cover of the checker. Set the Power switch to the Off position.

Troubleshooting the JM-103:

1. Selecting the Unit of Measurement (this should be set on µmol/L, not mg/dL)

- To convert back to µmol/L - Hold down the Reset button, and turn on the Power switch. Do not release the Reset button. While continuing to press the Reset button, allow approximately 15 secs for the unit of measurement to switch from mg/dL to µmol/L or vice versa. Once the display has changed release the Reset button. The Ready lamp will then light up indicating that the instrument is ready to take a measurement.

2. Setting the Number of Average Measurements back to n-3 if this has changed:

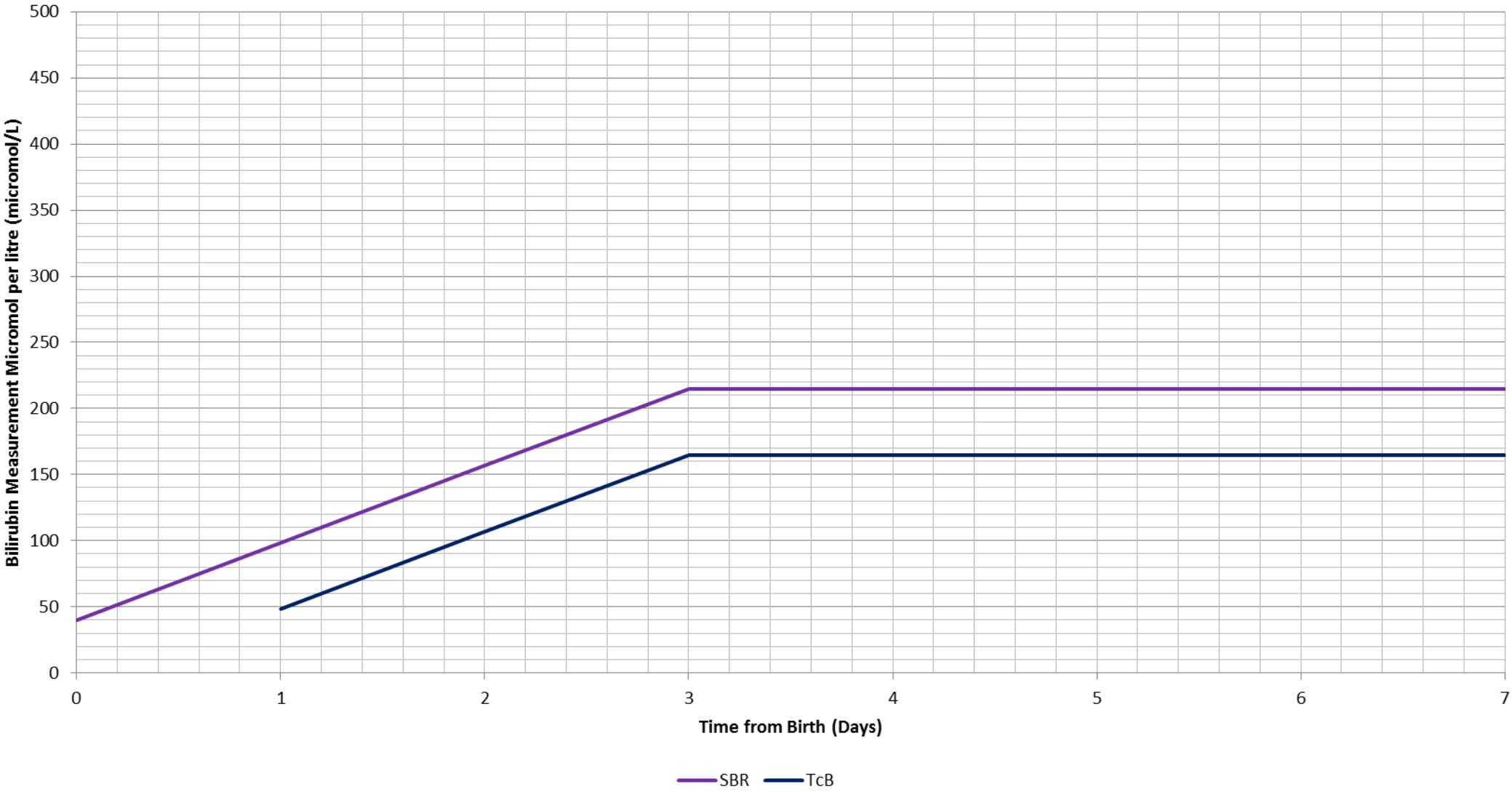
- Set the Power switch to On or press the Reset button to prepare the instrument for measurement. n-1, n-2, and so on (up to n-5) will appear.
- Press the Reset button for 5 secs. The number of average measurements will switch as follows: n-1→ n-2 → n-3 → n-4 → n-5.
- Release the Reset button when the required number of average measurements is displayed.

3. Error Messages:

- Er1: the measured value is abnormal. In the case of an averaging measurement, the measurement fluctuation is excessively large. Place the measuring probe perpendicular to the infant's forehead or sternum, and take the measurement again. If Er1 still appears, contact the biomedical dept.
- Er2 – Er6: A measurement error may have occurred during an averaging measurement, or the hardware is not functioning properly. Set the Power switch to the Off position, and then return it to the On position. If the warning still appears, contact the biomedical dept.
- With a fully charged battery, approximately 400 measurements can be taken. With 6 hrs worth of charging, approximately100 measurements can be taken. Allow approximately 32 hrs for charging to complete.

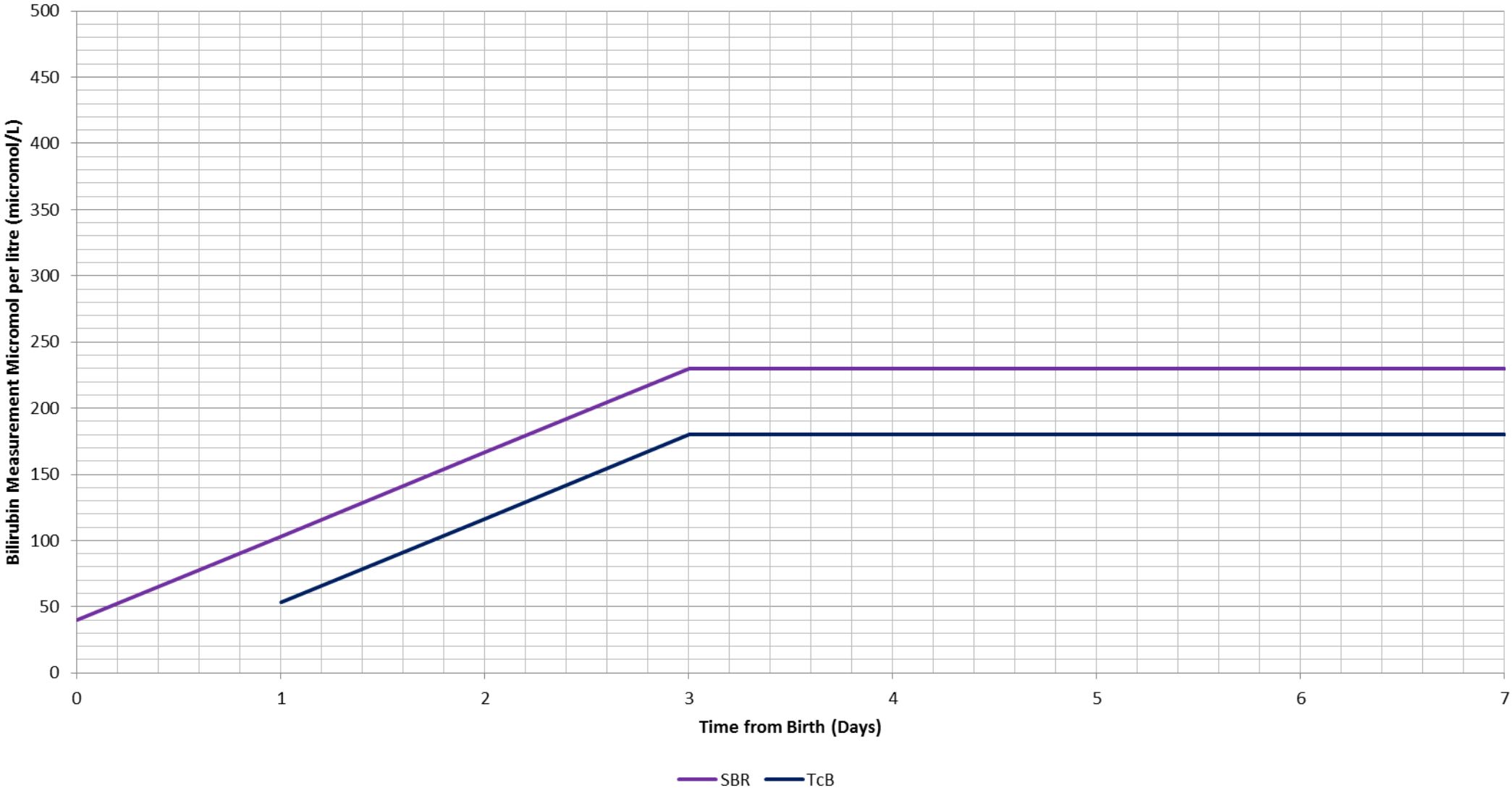
RHW NCC: TcB Threshold Graph for 32 Week Gestation Infants

- **Lower line is TcB level: If TcB is above this level for age a blood SBR measurement is required**
- **Upper line is TcB/serum SBR Phototherapy threshold (as per NSW Jaundice chart)**



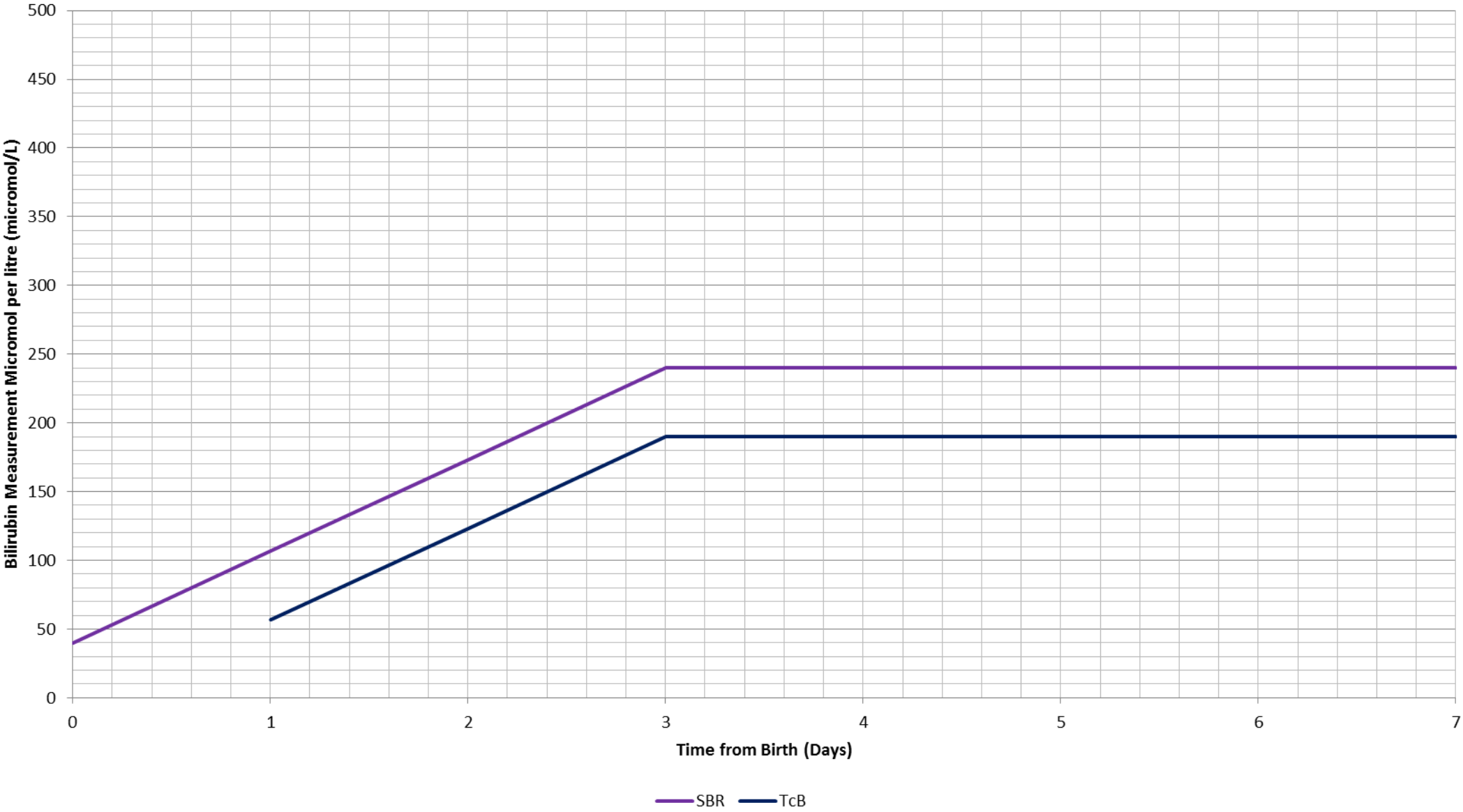
RHW NCC: TcB Threshold Graph for 33 Week Gestation Infants

- **Lower line is TcB level: If TcB is above this level for age a blood SBR measurement is required**
- **Upper line is TcB/serum SBR Phototherapy threshold (as per NSW Jaundice chart)**



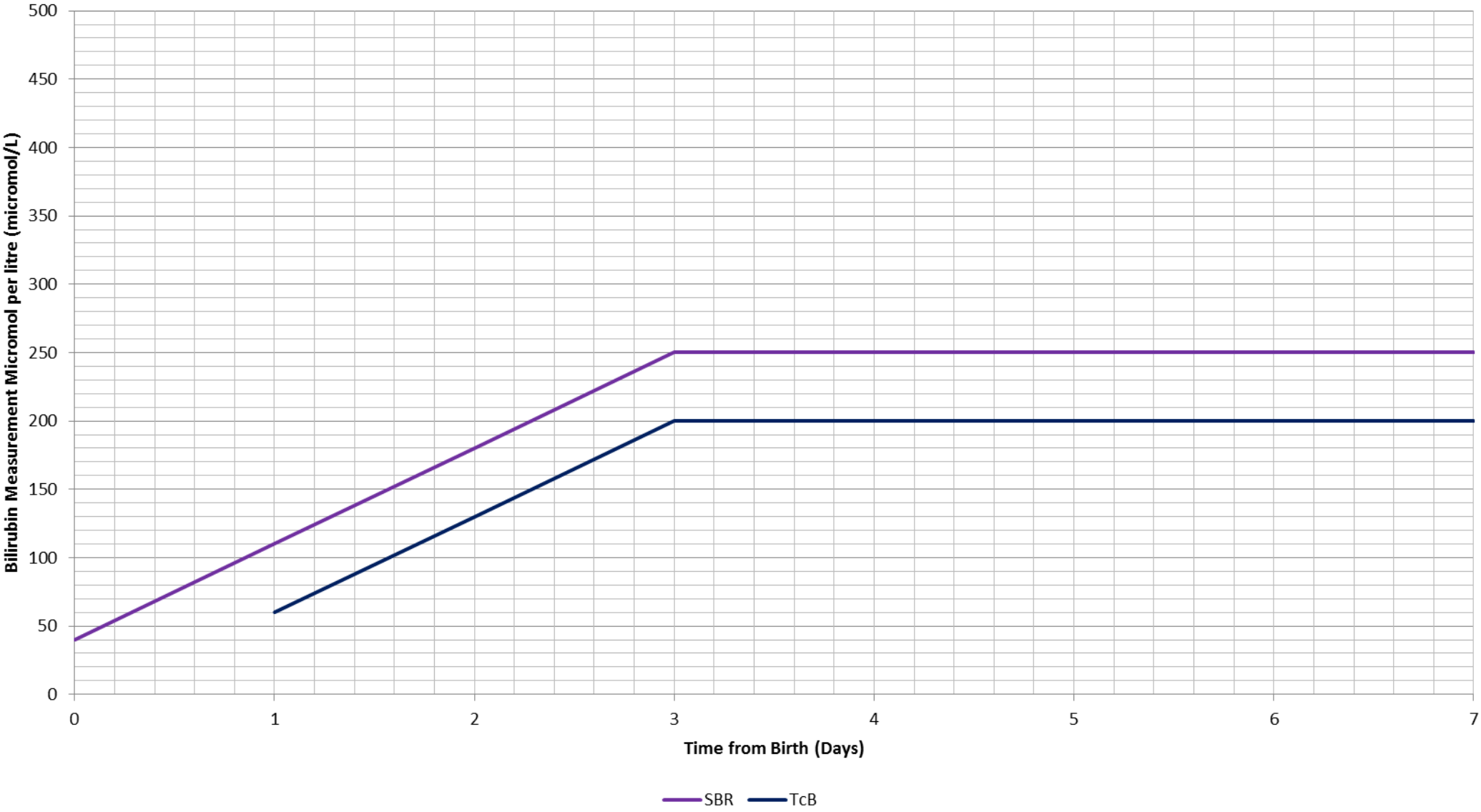
RHW NCC: TcB Threshold Graph for 34 Week Gestation Infants

- **Lower line is TcB level: If TcB is above this level for age a blood SBR measurement is required**
- **Upper line is TcB/serum SBR Phototherapy threshold (as per NSW Jaundice chart)**



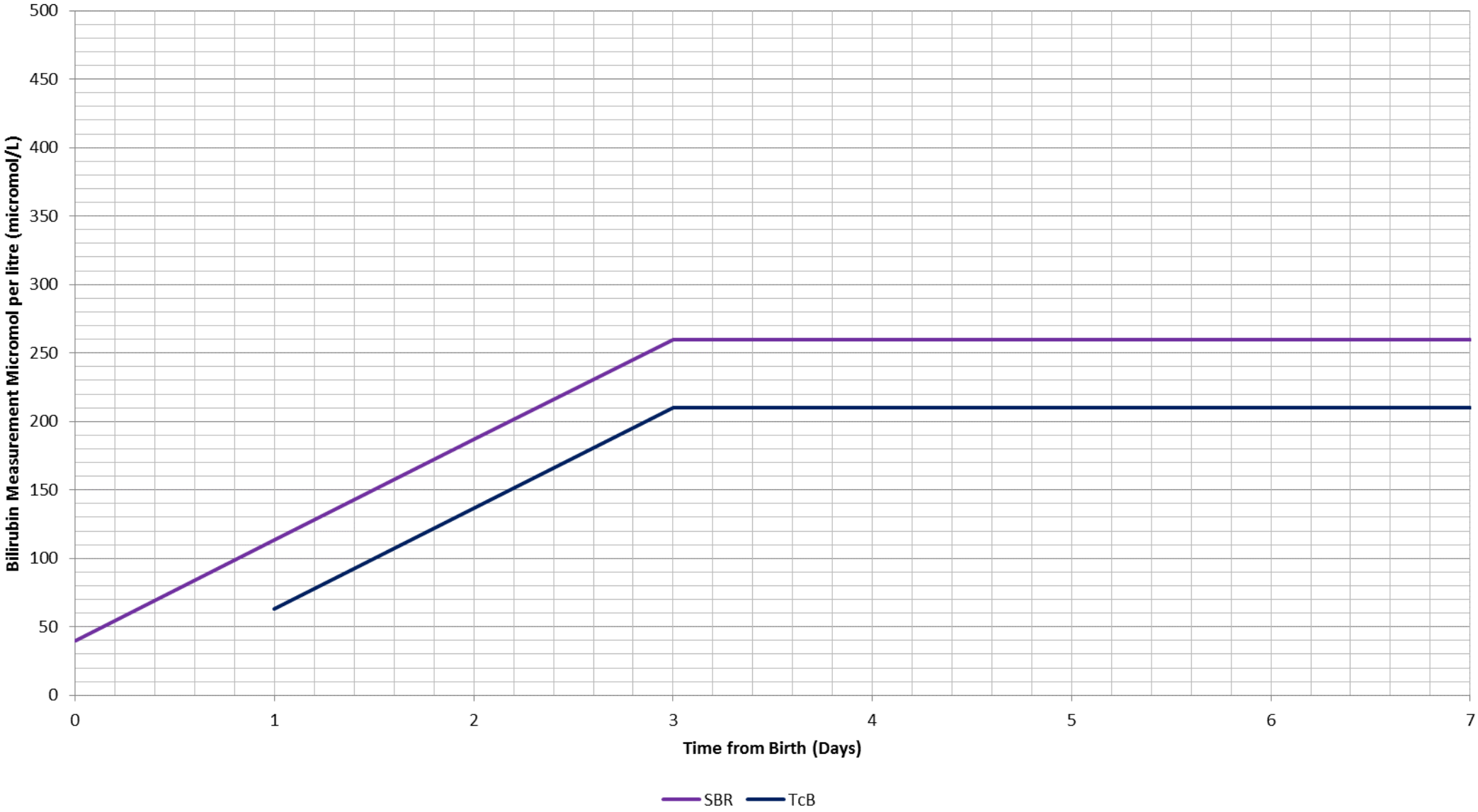
RHW NCC: TcB Threshold Graph for 35 Week Gestation Infants

- **Lower line is TcB level: If TcB is above this level for age a blood SBR measurement is required**
- **Upper line is TcB/serum SBR Phototherapy threshold (as per NSW Jaundice chart)**



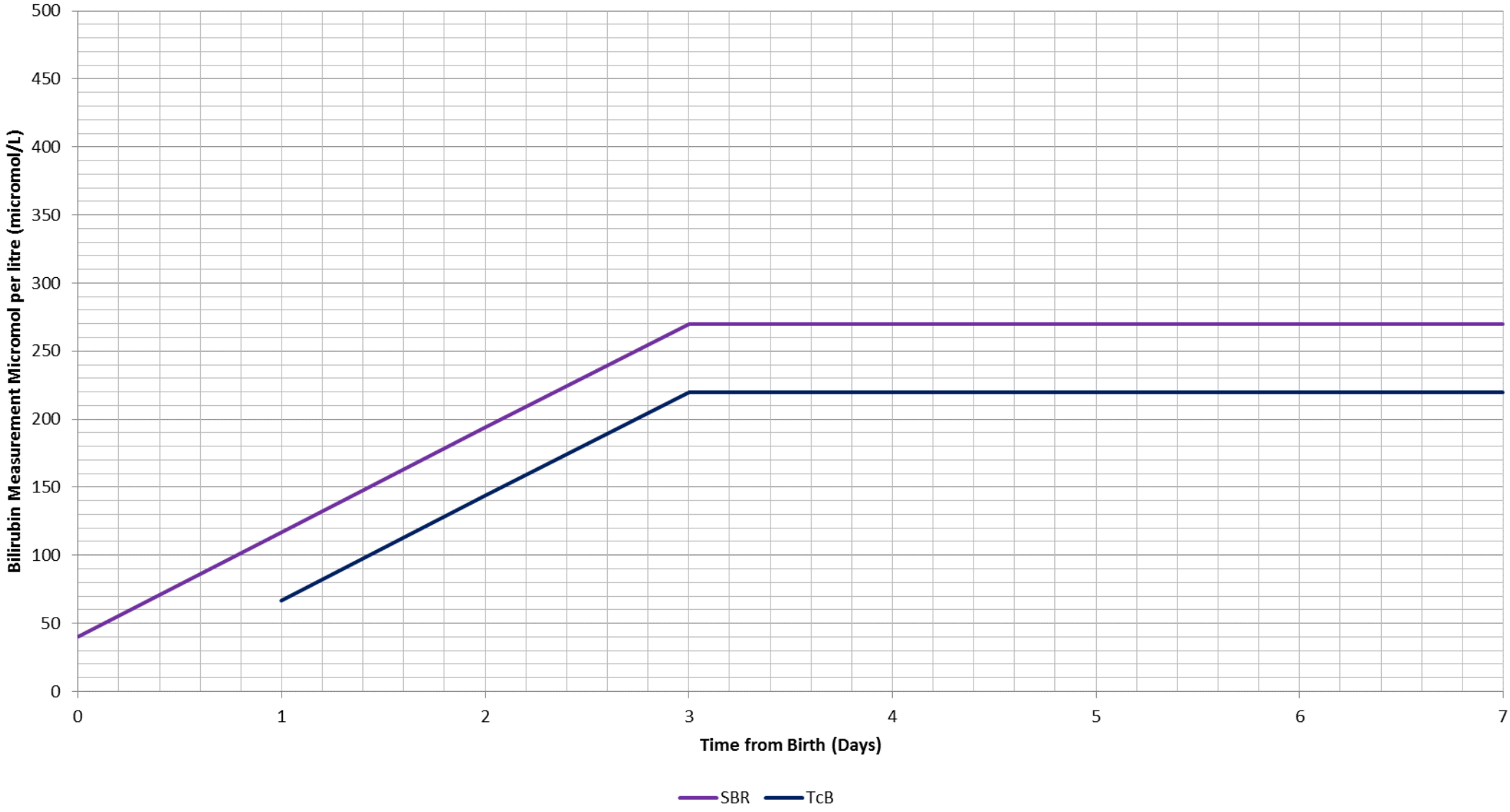
RHW NCC: TcB Threshold Graph for 36 Week Gestation Infants

- **Lower line is TcB level: If TcB is above this level for age a blood SBR measurement is required**
- **Upper line is TcB/serum SBR Phototherapy threshold (as per NSW Jaundice chart)**



RHW NCC: TcB Threshold Graph for 37 Week Gestation Infants

- **Lower line is TcB level: If TcB is above this level for age a blood SBR measurement is required**
- **Upper line is TcB/serum SBR Phototherapy threshold (as per NSW Jaundice chart)**



RHW NCC: TcB Threshold Graph for ≥ 38 week Gestation Infants

- **Lower line is TcB level: If TcB is above this level for age a blood SBR measurement is required**
- **Upper line is TcB/serum SBR Phototherapy threshold (as per NSW Jaundice chart)**