CLIA Waiver by Application Approval Determination

Decision Summary

A. Document Number

CW220002

B. Parent Document Number

K220272

C. CLIA Waiver Type:

Dual 510(k) and CLIA Waiver by Application (Dual Submission)

D. Applicant

Roche Diagnostics

E. Proprietary and Established Names

cobas® pulse blood glucose monitoring system

F. Measurand (analyte)

Glucose

G. Sample Type(s)

Arterial whole blood, neonatal arterial whole blood, and neonatal heel stick whole blood anticoagulated with lithium heparin.

H. Type of Test

Quantitative amperometric assay (FAD-dependent glucose dehydrogenase)

I. Test System Description

The cobas® pulse glucose monitoring system consists of a hand-held, battery powered cobas® pulse instrument, instrument charging station, and single use cobas® GLU test strips. The GLU QC kit is sold separately. The system utilizes amperometric detection as the test principle utilizing FAD-dependent glucose dehydrogenase (FAD-GDH) for the quantitative determination of glucose concentrations in arterial, neonatal arterial, and heel stick samples. Glucose in the blood reacts with the reagent in the test strip, and this produces a small electric current (amperometry). The magnitude of the resultant current is proportional to the glucose concentration in the sample. The detected current signal is then calculated by the meter and the glucose concentration is displayed on the meter. The meter reports plasma equivalent glucose concentrations.

J. Demonstrating "Simple"

- The cobas pulse blood glucose monitoring system consists of the fully automated cobas pulse instrument and single-use cobas GLU test strips.

- The cobas pulse blood glucose monitoring system uses direct, unprocessed whole blood samples and requires no sample manipulation before performing the test.

- There is no reagent handling. Reagents are secured within the test strip. The meter provides the user with step-by-step prompts on the touch screen describing how to run a glucose test. Once the test strip is inserted into the meter the sample is applied directly to the test strip and the test result is displayed. There are no further procedural steps.

- The cobas pulse blood glucose monitoring system provides direct readout of quantitative results that require no interpretation, or calculation by the operator. No operator intervention is required during the analysis steps.

- The cobas pulse blood glucose monitoring system does not require calibration or coding by the user. The cobas® pulse instrument is factory calibrated.

- The cobas pulse blood glucose monitoring system requires no technical or specialized training with respect to troubleshooting or interpretation of multiple or complex error codes. Error messages are unambiguous and include easy-to-interpret solutions.

- The cobas pulse blood glucose monitoring system requires no electronic or mechanical maintenance. Maintenance consists of changing batteries, and external cleaning and disinfection of the instrument.

- The cobas pulse blood glucose monitoring system includes a quick reference guide (QRG) and instructions for the CLIA waived user in the user manual are written at no higher than a 7th grade comprehension level.

K. Demonstrating "Insignificant Risk of an Erroneous Result"- Failure Alerts and Fail-safe Mechanisms

1. Risk Analysis

   A comprehensive risk analysis was conducted by the sponsor for the cobas pulse system to assess the risks of providing incorrect patient results and the safety risks to the patient or operator associated with the operation of the system and to demonstrate that the system is robust to known sources of error. All risks of harm to the patient or operator were mitigated to an acceptable level, and the system was demonstrated to be robust to known sources of error.

2. Fail-Safe and Failure Alert Mechanisms

   a. Error Messages and Lock-outs:

      The cobas pulse system was designed with several failure alert mechanisms and procedural controls intended to reduce the risk of device malfunction and procedural errors when performing the assay. The system will provide an error message, or a lockout function will occur and will not allow output of test results for example:

      - **B-AA**: Invalid barcode. The user is advised to try again and if the problem persists to contact their system administrator or they can contact the Roche customer support if they do not have a system administrator onsite.
      - **B-AB**: Scan timeout. If the barcode scanning period has timed out the error message is displayed and the user is advised to restart scanning the barcode.
      - **D-AA**: Test strip error. If there is a test strip error due to wrong position of the test strip, damaged test strip, dirty test strip, the user is advised to repeat the test with a new test strip.
      - **D-AB**: Lot expired. If the test strip lot has expired, the error will be displayed and the user is advised to repeat the test with a test strip from a valid lot.
      - **D-AE:** Material expired. If the QC material is expired the error message will be displayed. The user is advised to use a valid QC lot, to check expiry date and try again. If the problem persists, the user is instructed to contact their system administrator or they can contact the Roche customer support if they do not have a system administrator onsite.
      - **D-AF:** Test strip error. If there is a test strip error due to an already used strip or test strip container left open the user is advised to repeat the test with a new test strip and to contact system administrator or they can contact the Roche customer support if they do not have a system administrator onsite
      - **D-AG:** Insertion error. If the test strip is not inserted completely, the user is advised to eject the test strip and insert it again ensuring that it is fully pushed inside the instrument.
      - **D-AH:** Unknown lot. If the instrument does not recognize the test strip lot, the user is advised to ensure that a correct test strip lot is used and to try again. If the problem persists, the user is instructed to contact their system administrator or

they can contact the Roche customer support if they do not have a system administrator onsite.

- **D-AJ:** QC test required. If QC testing is required to be performed, the user is advised to perform a QC test.
- **D-AK:** Insertion error. If the test strip is inserted incorrectly, the error message is displayed and the user is advised to eject the test strip and insert it again and to wait for the screen instruction before inserting the test strip.
- **D-AL:** Test strip error. The error is displayed if the test strip was removed during testing. The user is advised to repeat the test with a new test strip and warned to not remove the test strip during processing. The user is advised to always use the eject button to remove the test strip.
- **D-AN:** Unknown kit lot. If an unknown QC kit lot is used, the user is advised to ensure that a correct QC kit lot is used and to contact their system administrator or they can contact the Roche customer support if they do not have a system administrator onsite.
- **D-AO:** Test strip error. The error message is displayed if the eject button was not used to remove the test strip. The user is advised to use the eject button to remove the test strip and to repeat the test with a new test strip.
- **E-AA:** Temperature too low. If the temperature is too low, the error will be displayed. The user is advised to use the instrument at a higher temperature and to ensure the room temperature is at least 12°C or 54°F. The user is advised to try again and to contact their system administrator or they can contact the Roche customer support if they do not have a system administrator onsite if the problem persists.
- **E-AB:** Temperature too high. If the temperature is too high, the error will be displayed. The user is advised to ensure that the room temperature is below 40°C or 104°F and to make sure the instrument is not exposed to direct sunlight. The user is advised to try again and to contact their system administrator or they can contact the Roche customer support if they do not have a system administrator onsite if the problem persists.
- **G-AA:** Instrument error. The error is displayed if there is an error with the instrument. The user is advised to turn off and restart the instrument. The user is advised to try again and to contact their system administrator or they can contact the Roche customer support if they do not have a system administrator onsite if the problem persists.
- **G-AC:** Process error. The user is advised to repeat the test with a new test strip when the error is displayed. The user is advised to try again and to contact their system administrator or they can contact the Roche customer support if they do not have a system administrator onsite if the problem persists.
- **G-AE:** Instrument error. When the message is displayed the user is to contact their system administrator or they can contact the Roche customer support if they do not have a system administrator onsite.
- **H-AC:** Low battery. If the battery is low the error is displayed and the user is advised to charge the instrument.
- **H-AF:** Date/time lost. When the message is displayed, the user it advised to enter the date and time before performing new tests.

- **H-AG:** Ejection error. The user is advised to eject the test strip using the eject button when the message is displayed. The user is also advised to remove the test strip manually if the problem persists.
- **S-AB:** Sample application error. If there is a sample application error, the error message is displayed and the user is advised to repeat the test with a new test strip and to apply the sample when requested, without removing the test strip.
- **S-AD:** Sample type error. If this message is displayed, the user is advised to repeat the test with a new test strip and to ensure they are using one of the following sample types: arterial, neonate arterial, neonate heel stick whole blood, or QC material for a QC test.
- **S-AF:** Sample error. The user is advised to repeat the test with a new test strip when the error is displayed. The user is advised to try again and to contact their system administrator or they can contact the Roche customer support if they do not have a system administrator onsite if the problem persists.
- **U-AE:** Invalid patient ID . If the patient ID is too long and/or contains invalid characters the message is displayed. The user is advised to re-enter the patient ID.
- **U-AG:** Unexpected bottle. When the message is displayed, the user is advised to first Scan bottle: QC, Level 1 or Scan bottle: QC, Level 2 then to scan the requested bottle again. The user is advised to contact their Roche representative if the problem persists,
- **'Hi'**: is displayed when the glucose test result is greater than 600 mg/dL.
- **'Lo'**: is displayed when the glucose test result is less than 10 mg/dL.

b. External control material:

i. The use of external quality control material is recommended to demonstrate that the cobas pulse system is working properly. The labeling states that the user should perform quality control testing only with the Roche QC (cobas® GLU QC kit) Solutions.

ii. The frequency of running quality controls is stated in the labeling. It is recommended to run both levels of quality controls at least once every 24 hours of patient testing and during the following circumstances:

- Before using the instrument for patient testing the first time.
- At shorter QC intervals if established by the healthcare facility.
- When a new test strip container is opened.
- If there is doubt about the patient's glucose result.
- To test the correct performance of the system.
- If the instrument was dropped

iii. A QC Lockout period ensures that QC is run frequently. By default, the QC lockout configuration is set to every 24 hours. The instrument cannot be used for patient testing while the device is in QC Lockout. QC tests must be completed successfully before the instrument can be used for glucose testing.

iv. Directions for use are clearly stated in the labeling (QRG, user manual and test strip insert).

v. Storage and stability are stated in labeling. The user should follow the manufacturer's instructions for storage and stability. An error code (D-AE) is displayed if the QC material has expired.

vi. Two levels of ready-to-use liquid control solutions are available for use (Level 1, Level 2)

vii. Manufacturer: Roche

3. Flex Studies

The robustness of the cobas pulse glucose monitoring system was demonstrated in conditions where its operational limits were stressed due to potential operator errors, factors affecting specimen or test system integrity, or environmental factors. The following flex studies were performed based on the identification of potential errors from the sponsor's risk assessment that may contribute to erroneous results when the cobas pulse glucose monitoring system is used in intend use settings:

a. Environmental Factors

i. System Operating Conditions Testing:

To assess the performance of the cobas pulse glucose monitoring system when used under various operating temperature and humidity conditions, the system was tested at different temperature and relative humidity (RH) conditions including 10°C/45%RH, 42°C/45% RH, 12°C/10%RH, 12°C/90%RH, 30°C/90%RH and 40°C/10%RH. Each condition was tested with five glucose concentrations (30-50 mg/dL, 51-110 mg/dL, 111-150 mg/dL, 151-250 mg/dL, 251-400 mg/dL). The results from the cobas pulse blood glucose monitoring system under each test condition were compared to those from the nominal control condition. The study results support the labeled operating conditions claim of 12°C to 40°C (54 to 104°F) and relative humidity range of 10% to 90%.

ii. Altitude Study:

To assess the effect of high altitude on the performance of the cobas pulse glucose monitoring system, the system was tested at an altitude of about 15420 ft (4700 meters) above sea level. Whole blood samples adjusted to 3 glucose concentrations (50-65 mg/dL, 100-120 mg/dL, and 200-250 mg/dL) were tested. The results obtained from the candidate system at 15,420 ft were compared to those obtained at an altitude of 295 ft (90 m) above sea level. The results of the study support the claim that the cobas pulse glucose monitoring system can be operated at altitudes of up to 15420 ft (4700 meters).

b. Reagent integrity

Test Strip Stability Testing:
Test strip stability was assessed using real time stability studies. Protocols and acceptance criteria were reviewed and found to be acceptable to support the labeling claims of a 24 month closed vial shelf life and open vial use life when stored at 4 - 30°C (39 - 86°F) and relative humidity of 10 - 90%. The labeling instructs the users not to freeze the test strips.

c. Operator Error/Human Factors

i. Sample Volume Study:

The sponsor conducted a sample volume study using whole blood samples at 3 glucose concentrations (50-65, 100-120 and 200-250 mg/dL) tested at 5 sample volumes (0.2, 0.4, 0.6, 1.2, and 2.4 μL). Values obtained using the candidate system were compared to those obtained using the comparator method (cobas 6000 system). Results support the claimed minimum sample volume of 0.6 μL for the system. The meter has an error message displayed if enough blood is not added to the test strip. This feature was validated and was shown to function as intended.

ii. Sample Perturbation Study:

A sample perturbation study was conducted to assess the effect of events such as wicking away of blood from the test strip, flipping the test strip, squeezing the test strip, blowing on the test strip, moving the test strip, or hitting the test strip on the center or the side after applying the sample and during measurement on the cobas pulse glucose monitoring system. Whole blood samples at 3 glucose concentrations (50-65, 100-120 and 200-250 mg/dL) were tested for each of the perturbation methods. Values obtained were compared to a control condition (no external perturbation of the test strip). The results of the study demonstrate that the cobas pulse glucose monitoring system is robust to sample perturbation.

iii. Intermittent Sampling:

An intermittent sampling study was conducted to assess the effect of adding a second sample dosing to a cobas test strip after starting glucose measurement of an initial short sample on the cobas pulse system. Whole blood samples at 3 glucose concentrations (50-65, 100-120 and 200-250 mg/dL) were tested and values obtained were compared to a one-time sample dose. The results of the study demonstrate that that the cobas pulse glucose monitoring system is robust to intermittent sampling.

iv. Testing with Used Test Strips:

A study was performed to assess the response of the cobas pulse instrument when a pre-used cobas GLU test strip is inserted. Test strips pre-dosed with whole blood samples at concentrations of 50-65 mg/dL, 100-120 mg/dL, 200-250 mg/dL and two levels of control solution (L1 and L2) were tested. Measurements were taken under three used test strip conditions, wet (recently used test strip), dried for 15 minutes, and dried for 3 days and were compared to values obtained using fresh test strips. In all cases the cobas pulse glucose monitoring system displayed an error result (D-AA: Test strip error), demonstrating that insertion of a used test strip into the blood glucose meter does not provide glucose measurement results to the user.

v. Messages for Samples Outside the Measuring Range:

A study was conducted using whole blood samples to demonstrate that the cobas pulse glucose monitoring system provides the appropriate error codes when measured glucose concentrations are outside of the system's claimed measuring range. If the concentration of a sample is less than 10 mg/dL glucose, the result is flagged by the meter as "Lo". If a sample exceeds 600 mg/dL glucose, the result is reported by the meter as "Hi". The "Lo" and "Hi" functions were validated and demonstrated to function as intended.

vi. Cleaning and Disinfection:

The device is intended for multiple-patient use. Disinfection efficacy studies were performed on the exterior meter materials by an outside commercial testing laboratory, demonstrating complete inactivation of Hepatitis B Virus (HBV) with the chosen disinfectants, Clorox Germicidal Wipes (EPA Reg. No. 67619-12) and Super Sani-Cloth Germicidal Disposable Wipe (EPA Registration Number 9480-4). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 12,045 cycles of cleaning and disinfection cycles using the chosen disinfectants. The robustness studies were designed to simulate cleaning and disinfection over the 3-year multi-patient use life of the meter. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

d. Hardware, Software and Electronics Integrity

The following testing was performed to validate that the cobas pulse glucose meter is insensitive to performance variation under the following electrical stress conditions:

i. Environment resistance:

As part of the hardware verification for the instrument, a study was performed to confirm that there are no problems with the functionality of the cobas pulse glucose meter in a temperature range of +12°C up to 40°C (54 to 104°F) and a

humidity range of 10% up to 90%. All of the verification results were within the criteria limits and no deterioration in functionality of the hardware was observed.

ii. Transport testing:

A study was performed using the instrument to confirm the extreme exposure limits for transport of -20°C (-4°F) to 50°C (122°F), and noncondensing humidity up to 93%. The cobas pulse glucose instrument was also tested to demonstrate the instrument was robust to the impact by mechanical shock and vibration expected during transport.

iii. Physical trauma to the meter:

A study was conducted to assess the impact of dropping on the cobas pulse instrument. The meter was dropped from a height of 1 meter and 2 meters such that the meter made impact with a concrete floor. All of the verification results were within the criteria limits and no deterioration in functionality was observed for the 1 meter drop and the meter returned the appropriate error code for the 2 meter drop, preventing further use of the device.

iv. Electromagnetic Interference and Electrical Safety:

The sponsor provided documentation certifying that acceptable electrical safety and electromagnetic compatibility (EMC) testing had been performed and the system was found to be compliant.

L. Demonstrating "Insignificant Risk of an Erroneous Result" –Accuracy

To demonstrate that the cobas pulse glucose monitoring system poses an insignificant risk of erroneous results in the hands of intended users and when performed in CLIA waived-type settings, the sponsor submitted a clinical study which was also used to support FDA clearance under K220272.

1. Comparision Study

a. Study Design

i. Study Sites

The performance of the cobas pulse glucose monitoring system was assessed in professional healthcare settings at 14 clinical sites that included patients from the general ward, operating rooms, medical intensive care units, surgical intensive care units, pediatric intensive care units, neonatal intensive care units and nurseries.

ii. Operators

Results from the cobas pulse glucose monitoring system were obtained during the clinical study by a total of 75 untrained operators who were untrained in the use of the cobas pulse glucose monitoring system.

iii. Instructions for Use

The operators were given the user guide, test strip insert, and the Quick Reference Guide. No other materials or instructions were provided and the operators received no training in the use of the test.

iv. Subjects (Patients)

A total of 873 patients were enrolled and participated in the arterial, neonate arterial, and neonate heel stick studies. Arterial blood was collected from 622 adult and pediatric patients, neonate arterial blood was collected from 104 patients, and heel stick blood was obtained from 147 neonates. All heel stick studies were performed with neonatal samples <28 days old. Samples from patients, less than 24 hours old to over 81 years of age, were analyzed throughout the study. The glucose levels of the patient samples were as follows (according to the comparator method; cobas 6000 system): 49.0 to 461.9 mg/L for all arterial (24 samples <80 mg/dL and 10 samples >300 mg/dL); 49.0 to 461.9 mg/L (16 samples <80 mg/dL and 4 samples >300mg/dL) for neonate arterial; 18.5 mg/dL to 176.8 mg/dL (85 samples <80 mg/dL) for neonatal heel stick. In addition to glucose levels, patient conditions, medication information, pO2, sodium, and hematocrit were collected during the study. This study included patients with 1617 different patient conditions and diagnoses. Patients received a total of 709 different medications administered within 24 hours of blood draw. Please see the k220002 decision summary for a detailed list of patient medications and medical conditions.

v. Samples

Lithium heparin arterial, neonate arterial and neonate heel stick whole blood samples. Refer to section L.1.b.i.1 for information on sample type limitations.

vi. Comparative Method (CM)

Roche cobas 6000 system (K191899)

b. Results and Analysis

i. Data Analysis

1. The results of the cobas pulse glucose monitoring system compared with the comparator method can be found in the tables below for each specimen type (all arterial results combined, neonate arterial, and neonate heel stick):

Arterial Whole Blood (combined)

Glucose concentrations < 75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±12 mg/dL	Within ±15 mg/dL	Exceeds ±15 mg/dL
6/16 (37.5%)	15/16 (93.8%)	16/16 (100.0%)	16/16 (100.0%)	0/16 (0.0%)

Glucose concentrations ≥75 mg/dL

Within ±5% mg/dL	Within ±10% mg/dL	Within ±12% mg/dL	Within ±15% mg/dL	Within ±20% mg/dL	Exceeds ±20% mg/dL
423/606 (69.8%)	571/606 (94.2%)	585/606 (96.5%)	596/606 (98.3%)	600/606 (99.0%)	6/606 (1.0%)

Neonatal Arterial Study

Glucose concentrations < 75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±12 mg/dL	Within ±15 mg/dL	Exceeds ±15 mg/dL
4/10 (40/0%)	9/10 (90.0%)	10/10 (100.0%)	10/10 (100.0%)	0/10 (0.0%)

Glucose concentrations ≥75 mg/dL

Within ±5% mg/dL	Within ±10% mg/dL	Within ±12% mg/dL	Within ±15% mg/dL	Within ±20% mg/dL	Exceeds ±20% mg/dL
49/94 (52.1%)	87/94 (92.6%)	91/94 (96.8%)	93/94 (98.9%)	93/94 (98.9%)	1/94 (1.1%)

Neonatal Heel Stick Study

Glucose concentrations < 75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ±12 mg/dL	Within ±15 mg/dL	Exceeds ±15 mg/dL
27/69 (39.1%)	61/69 (88.4%)	66/69 (95.7%)	68/69 (98.6%)	1/69 (1.4%)

Glucose concentrations ≥75 mg/dL

Within ±5% mg/dL	Within ±10% mg/dL	Within ±12% mg/dL	Within ±15% mg/dL	Within ±20% mg/dL	Exceeds ±20% mg/dL
43/78 (55.1%)	70/78 (89.7%)	74/78 (94.9%)	74/78 (94.9%)	78/78 (100.0%)	0/78 (0.0%)

Capillary Fingerstick and Venous Whole Blood Limitations

The sponsor includes limitations against the use of the cobas pulse with capillary finger stick and venous whole blood. The labeling states the following limitation:

This system is not intended for use with capillary finger stick, venous whole blood, or neonate cord blood specimens.

- In comparing capillary whole blood glucose measurements using the cobas® pulse to venous plasma measurements using the comparator method, a large percentage of samples had significant bias to the comparator method.
- In comparing venous whole blood on the cobas® pulse to venous plasma on the comparator method for samples with glucose less than 75 mg/dL, 2 outliers showed significant bias to the comparator method, and protocol deviations led to a large number of venous sample exclusions resulting in uncertainty in the study.

These limitations were put in place due risks posed by the performance if this device in these two sample types. The results of the cobas pulse glucose monitoring system were compared with those obtained on the comparator method and are as follows for each specimen type:

For capillary fingerstick samples, 54.5% (12/22) of samples with glucose concentrations <75 mg/dL were within ±12 mg/dL and 45.5% (10/22) exceeded a difference of ±15 mg/dL relative to the comparator method result. Additionally, for capillary fingerstick samples with glucose concentrations ≥75 mg/dL, 82.2% (562/684) of the samples were within ±12 mg/dL and 7.0% (48/684) exceeded a difference of ±20% relative to the comparator method results.

For venous whole blood samples, 94.6% (35/37) of samples with glucose concentrations <75 mg/dL were within ±12 mg/dL and 5.4% (2/37) exceeded a difference of ±15 mg/dL relative to the comparator method result. Additionally, protocol deviations led to the exclusion of more than 10% of venous whole blood samples from the study resulting in uncertainty in the results from this study.

ii. Allowable Total Error (ATE) and Limits for Erroneous Results (LER)

The study performed to support CLIA waiver for the cobas pulse glucose monitoring system was analyzed to evaluate whether the clinical data would meet clinically appropriate ATE and LER zones for the sponsor's intended use population. The analysis demonstrates that the percentage of results over the entire measurement range that falls within the ATE zone (within ±12 mg/dL for glucose concentrations < 75 mg/dL or within ±12% for glucose concentrations ≥75 mg/dL) is ≥95%. None of the results were in the LER zone.

2. Operator Questionnaire

Upon completion of the clinical studies, operators completed a questionnaire to evaluate the ease of understanding of the test procedure. The participants found the cobas pulse glucose monitoring system easy to use and the instructions in the user manual and QRG clear and easy to follow.

M. Labeling for Waived Devices

The labeling consists of:

1. Quick Reference Instructions
2. User Manual that contains information for the CLIA waived user
3. Test Strips Package Insert
4. Test strip box
5. Instrument box
6. User Assistance that contains information for the non-CLIA waived user
7. Addendum to the User Manual with clinical study information (medical conditions, medications etc.) for the non-CLIA waived user

2. The following elements are appropriately present:

The labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10.

- The Quick Reference Guide and instructions in the User Manual for the CLIA waived user are written at no higher than a 7th grade reading level.
- The User's Manual and Quick Reference Guide identify the test as CLIA waived.
- The User Manual and Test Strip Package Insert contain a statement that a Certificate of Waiver is required to perform the test in a waived setting.
- The User Manual and Quick Reference Guide contain a statement that laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test as required per 42 CFR 493.15(e)(1).

- The User Manual, Test Strip Package Insert and Quick Reference Guide provide instructions for conducting quality control procedures.

N. Conclusion:

The submitted information in this CLIA waiver application supports a CLIA waiver approval decision.