QUALITY AUDIT STANDARD **QAS3002** MEASUREMENT PROTOCOLS

2.5g one-shot bottles of polydisperse glass-bead transfer standard, Part No.CRM0014.

Suitable for:

Hydro LV, Hydro EV, Aero S, Aero M, DIF2012, QSpec MU, Hydro 2000 MU, Hydro 2000G, Scirocco 2000, Scirocco 2000 M, MAM2460, MAM2461.

Autosampler 2000 with Hydro 2000G using 2 bottles per test.

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Introduction

Malvern's QAS3002 Quality Audit Standard (bottle part number CRM0014) has been produced to provide users of Malvern particle size analysers with a one-shot, polydisperse transfer standard that enables them to check the performance of their sample dispersion units on a regular basis.

Compliance with International Standards

QAS3002 complies with the recommendations of ISO13320, USP <429> and EP 2.9.31 relating to the validation of laser diffraction systems. The glass bead particles present within QAS3002 are spherical, cover a decade in size and have precisely defined optical properties. In addition, the standard is used in conjunction with a clear measurement procedure, as outlined in this datasheet. As such, QAS3002 provides a reliable means of checking and documenting the consistent operation of a laser diffraction system, as part of FDA or other international laboratory accreditation schemes (e.g. ISO, NAMAS, and IAF).

Sample Variability

Polydisperse particle sizing standards are prone to segregation during transit, which can lead to sampling errors. To overcome this, Malvern's Quality Audit Standards are produced by Whitehouse Scientific Ltd., who use an extremely efficient riffle-splitting process to ensure that each one-shot sample is representative of the entire batch.

Random sampling of QAS3002 bottles has shown that the relative standard deviation for the median (Dv50) particle size is of the order of 0.3%. This confirms that, as long as the entire contents of the bottle are used during a measurement in accordance with the instructions included on this datasheet, reproducible results can be obtained.

Shelf Life and Batch Numbering

Malvern's Quality Audit Standards are made of inert glass beads and are stored in sealed containers. For this reason they have an indefinite shelf life. It has also been possible to provide many years of continuous supply from a single, large master batch. As a result, the only batch number for QAS3002 is 02.

Traceability

The pass/fail specifications set for Malvern's Quality Audit Standards have been developed via a fully documented programme of testing using reference laser diffraction systems which have been verified using NIST-traceable polystyrene latex standards. As such, although these standards are transfer standards, they are indirectly traceable to NIST.

Establishing Pass/Fail criteria and measurement procedures

An ongoing programme of dispersion unit testing is carried out by Malvern in order to characterize each Quality Audit Standard and establish the pass/fail criteria referenced on this datasheet. As testing continues, Malvern constantly assesses the average measurement values obtained over the entire population of dispersion units. As the population increases, slight adjustments to the pass/fail criteria may be required in order to ensure that these accurately reflect the expected performance of all units. Changes may also be made to the measurement procedure in order to ensure robust measurements can be made.

Given the above, it is important that the latest version of this datasheet is used, especially when carrying out an annual system OQ or PV. In case of doubt, the latest version number ((MRK665-nn) can be verified by visiting Malvern's website. If there is any disagreement between the datasheet and the latest OQ procedure, the OQ certificate and specification should be considered to take precedence over the datasheet.

Expected Results

QAS3002 has been designed for use with the following dispersion units:

Mastersizer 3000	Hydro LV, Hydro EV, Aero S (all venturis), Aero M (Standard Venturis only)
Mastersizer 2000	Hydro 2000G, Hydro 2000G with autosampler, Hydro 2000MU, Scirocco 2000, Scirocco 2000M
Mastersizer S	DIF2012, QSpec MU, MAM2460, MAM2461, MAM2461C

DIF2012, Hydro 2000G, Hydro 2000G with autosampler, Hydro 2000MU and QSpec MU dispersion units

The specifications for the Mastersizer 2000 and Mastersizer S wet dispersion units are set at ± 3% for the Dv50 and ± 5% for the Dv10 and Dv90.

	Dv10 / µm	Dv50 / µm	Dv90 / µm
Lower Limit	35.326	59.995	85.473
Target Value	37.185	61.850	89.972
Upper Limit	39.044	63.706	94.471

MAM2460, MAM2461, MAM2461C, Scirocco 2000, Scirocco 2000M dispersion units

The specifications for the Mastersizer 2000 and Mastersizer S dry dispersion units are set at ± 3% for the Dv50 and ± 5% for the Dv10 and Dv90.

	Dv10 / µm	Dv50 / µm	Dv90 / µm
Lower Limit	36.631	61.360	85.515
Target Value	38.559	63.258	90.016
Upper Limit	40.487	65.156	94.517

Hydro LV and Hydro EV dispersion units

The specifications for the Mastersizer 3000 wet dispersion units are set at ± 2.5% for the Dv50, ±3% for the Dv10 and ±4% Dv90.

	Dv10 / µm	Dv50 / µm	Dv90 / µm
Lower Limit	35.597	60.054	85.928
Target Value	36.698	61.594	89.508
Upper Limit	37.799	63.134	93.088

Aero S & Aero M dispersion units

The specifications for both the Mastersizer 3000 Aero S and Aero M dry dispersion units are set at ± 2.5% for the Dv50, ±3% for the Dv10 and ±4% Dv90.

For the stainless steel and ceramic versions of the Aero S and Aero M standard venturi disperser, the specifications are as follows:

	Dv10 / µm	Dv50 / µm	Dv90 / µm
Lower Limit	36.388	60.625	85.786
Target Value	37.513	62.179	89.360
Upper Limit	38.638	63.733	92.934

The specifications for the stainless steel and ceramic versions of the Aero S (only) high-energy venturi disperser are as follows:

	Dv10 / µm	Dv50 / µm	Dv90 / µm
Lower Limit	37.512	61.682	86.672
Target Value	38.672	63.264	90.283
Upper Limit	39.832	64.846	93.894

Material Safety Data Sheet [MSDS]

1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY/UNDERTAKING
Product Name: Malvern Quality Audit standards
Cas-Number: 65997-17-3
EINECS-Number: 2660460
Product Code: 0390
Synonyms: GLASS BEADS
Use/description of product: Soda Lime Glass
Company: Whitehouse Scientific Ltd.
Chester, CH3 7PB, England
Tel: +44 (0) 1244 332626
Fax: +44 (0) 1244 335098
email: info@whitehousescientific.com

2. COMPOSITION / INFORMATION ON INGREDIENTS
Hazardous Ingredients: SODA LIME GLASS 100.000%
EINECS: 2660460
CAS: 65997-17-3

3. HAZARDS IDENTIFICATION
Main Hazards: No significant hazard.

4. FIRST AID MEASURES (SYMPTOMS)
Skin contact: There may be mild irritation at the site of contact
Eye contact: There may be irritation and redness.
Ingestion: No Symptoms.
Inhalation: Exposure may cause coughing or wheezing.

4. FIRST AID MEASURES (ACTIONS)
Skin contact: Wash immediately with plenty of soap and water.
Eye contact: Bathe the eye with running water for at least 15 minutes. Advice should be sought if irritation persists, consult a specialist.
Ingestion: Wash out mouth with water.
Inhalation: Remove to fresh air.

5. FIRE FIGHTING MEASURES
Extinguishing Media: Non-Flammable substance, not applicable. Suitable extinguishing media for the surrounding fire should be used.
Protection of fire-fighters: Wear self-contained breathing apparatus. Wear protective clothing to prevent contact with skin and eyes.

6. ACCIDENTAL RELEASE MEASURES
Personal Precautions: Refer to section 8 below for personal protection details.
Clean-Up Procedure: Transfer to a suitable container. Material can create slippery conditions underfoot. Avoid creating dust.

7. HANDLING AND STORAGE
Handling Requirements: Ensure that there is sufficient ventilation of the area. Avoid direct contact with the substance. Avoid the formation or spread of dust in the air.
Storage Conditions: Store in cool, well ventilated area.
Keep bottles tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION
Hazardous ingredients: SODA LIME GLASS
TWA (8hr exposure limit): Short: OES
Engineering Methods: Ensure that there is exhaust ventilation of the area.
Respiratory Protection: Respiratory protective device with particle filter.
Hand protection: Protective gloves.
Eye Protection: Safety glasses. Ensure eye bath is to hand.
Skin Protection: Protective clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES
State: Solid.
Colour: White.
Odour: Odourless.
Melting Point/Range°C: Approximately 730°C
Relative Density: 2.6 g/cm3 (20°C)

10. STABILITY AND REACTIVITY
Stability: Stable under normal conditions.

11. TOXICOLOGICAL INFORMATION
Chronic Toxicity: Overexposure to dust may cause irritation of eyes and throat.
Routes of Exposure: No data available.

12. ECOLOGICAL INFORMATION
Mobility: No data available.
Persistence and degradability: No data available.
Bioaccumulative Potential: No data available.

13. DISPOSAL CONSIDERATIONS
Disposal Operations: Contact waste disposal services.
Disposal of Packaging: Contact waste disposal services.

NB: The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

14. TRANSPORTATION INFORMATION
ADR / RID
UN No: -
Shipping Name: "NOT SUBJECT TO ADR"
IMDG / IMO
UN No: -
IATA / ICAO
UN No: -

15. REGULATORY INFORMATION
Hazard Symbols:
No significant hazard.
Note: The regulatory information given above only indicates the principal regulations specifically applicable to the product described in the safety data sheet. The user's attention is drawn to the possible existence of additional provisions which complete these regulations. Refer to all applicable national, international and local regulations or provisions.

16. OTHER INFORMATION
Other Information:
Complies with Directives (2001/58/EC), (1999/45/EC), (91/155/EEC), (67/548/EEC) as amended and Chemicals (hazard information and packaging for supply) 2002 (CHIP3) Regulation, EH40.

Legal Disclaimer:
The information contained in this safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and it is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process unless specified in the text.

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START

Ensure the cell windows and any lenses (if applicable) are clean and free from scratches

For the wet dispersion units, flush and drain the accessory at least 2 times in order to eliminate any contamination from other samples.

Which sample dispersion unit is being used?

Hydro LV and Hydro EV on the Mastersizer 3000

If mains water has been used to rinse the unit before measurement, ensure that the final 3 rinses (two rinses and one top-up) are performed using de-ionised water.

With the beaker/sample tank filled, turn the pump/stirrer on to full speed and then turn it off for about 3 sec to allow air to dissipate. Then, set the pump speed to 3000rpm.

Setup or create an SOP with the following settings:

Sample:

Particle Type:
Spherical

Material:
Material Name: glass beads (typical)
Refractive index: 1.52
Absorption index: 0.00
Density: 2.45
Different blue-light properties: unchecked

Dispersant:
Refractive index: 1.33

Sample:

Instructions Before Measurement:

Check that the part No. of the standard being measured is QAS3002 (CRM0014). Enter bottle number for the standard into the sample details. Ensure that the entire contents of the sample bottle is emptied into the tank at the 'add sample' stage. Half fill the empty bottle with deionised water, replace the cap, shake well and empty the contents into the tank. Allow 30 to 50 seconds for the sample to disperse before performing the first measurement starting within 1 minute of adding the sample. If due to water quality issues, glass beads are observed on the surface of the liquid following sample addition, it may be necessary to add 4-5 drops of 5% Igepal to the tank to aid dispersion.

Measurement:

Duration:
Background measurement duration (sec): 15
Sample measurement duration (sec): 15
Don't perform blue light measurement: checked

Sequence:
Number of measurements: 3
Delay between measurement (s): 0
Pre-measurement delay (s): 0

Obscuration:
Obscuration lower limit (%): 10
Obscuration higher limit (%): 30
Auto start measurement, when obscuration is in range: unchecked
Enable filtering: unchecked

Sample Dispersion:

Accessory:
Stirrer Speed: 3000 rpm
Tank Fill Behaviour: Manual. Degas after fill enabled. (Hydro LV SOP only).
Ultrasound Mode: None

Cleaning:
Clean type: Normal
Ultrasonication: Enable 'No ultrasound during clean'

Data Processing:

Analysis Mode:
Analysis Model: Narrow Modes
Advanced...: Single Mode: checked
Number of inner detectors to kill: 0

Results:
Limit the result size range: unchecked
Result Type: Volume Distribution (recommended)

User Sizes:
Use default sizes

Run the SOP and follow the on-screen instructions. Average the results to obtain the final result.

STOP

Aero S (all venturi dispersers) Aero M (Standard venturis only) on the Mastersizer 3000

Setup or create an SOP with the following settings:

Sample:

Particle Type: Spherical
Material:
Material Name: glass beads (typical)
Refractive index: 1.52
Absorption index: 0.00
Density: 2.45

Sample:

Instructions Before Measurement:

Check that the part no. of the standard being measured is QAS3002 (CRM0014). Ensure that the sample area is clean and dry, that the tray and venturi are correctly fitted.

For Aero S set the hopper gap to 1mm, empty the entire contents of the bottle into the sample hopper and close the lid of the dispersion unit firmly.

For Aero M set the gate gap to 1mm, empty the entire contents of the bottle into the centre of the circular end of the tray and close the lid of the dispersion unit firmly.

Measurement:

Duration:
Background measurement duration (sec): 10
Sample measurement duration (seconds): 30

Sequence:
Number of measurements: 1

Obscuration:
Obscuration lower limit: 0.1%

Obscuration higher limit: 10%

Auto start measurement, when obscuration is in range: checked.

Stabilisation time (seconds): 0

Enable filtering: checked

Time out (seconds): 5

Sample Dispersion:

Accessory:
Air pressure: 1 bar g

Feed rate: 40%

Venturi Type: Select as appropriate

Tray type: General purpose tray

Hopper gap (Aero S) : 1mm

Gate gap (Aero M) : 1mm

Cleaning:
Clean type: Normal

Data Processing:

Analysis Mode:
Analysis Model: Narrow Modes
Use fine powder mode: unchecked

Advanced...: Single Mode: checked
Number of inner detectors to kill: 0

Results:
Limit the result size range: unchecked
Result Type: Volume Distribution (recommended)

User Sizes:
Use default sizes

Run the SOP and follow the on-screen instructions. If you are working to compendial procedures, repeat the measurement process until 3 QAS samples have been successfully measured.

If multiple QAS samples have been measured, average the results to obtain the final result.

STOP

Hydro 2000G, Hydro 2000M/MU with 1000ml beaker on the Mastersizer 2000

If mains water has been used to rinse the unit before measurement, ensure that the final 3 rinses (two rinses and one top-up) are performed using deionised water.

If ultrasonics are available, turn off the pump/stirrer and turn on the ultrasonics for 30sec to allow air bubbles to dissipate.

With the beaker/sample tank filled, turn the pump/stirrer on to full speed and then turn it off for about 10 sec to allow air to dissipate. Then, set the pump speed to 2000rpm (Hydro 2000G) or 3000rpm (Hydro2000M/MU).

Setup or create an SOP with the following settings:

Materials Tab:

Particle: Glass Beads (Typical). RI 1.52, Absorption 0.00

Dispersant: Water, RI 1.33

Model: Single mode spherical

Labels Tab:

Instructions Before Measurement: Check that the part no. of the standard being measured is QAS3002 (CRM0014). Enter the serial number of the dispersion unit into the samples details along with the bottle number for the standard. Ensure that the entire contents of the sample bottle is emptied into the tank at the "add sample" prompt. Allow 30 to 50 seconds for the sample to disperse before performing the first measurement, with the first measurement starting within 1 minute of adding the sample. If, due to water quality issues, glass beads are observed on the surface of the liquid following sample addition, the addition of 4-5 drops of 5% Nonidet P40 to the tank may be necessary to aid dispersion.

Measurement Tab:

Background measurement time: 12 seconds

Measurement time: 12 seconds

Sampler Settings Tab:

Pump: 3000 rpm for Hydro 2000MU/M; 2000rpm for Hydro 2000G

Stirrer: 800rpm for Hydro 2000G
Ultrasound: None
Tank Fill: Manual for Hydro 2000G

Cycles Tab:

Select a single aliquot and 3 measurement cycles. Select 'Create Average result'.

Run the SOP and follow the on-screen instructions.

STOP

Scirocco 2000 with a ceramic or stainless steel venturi on the Mastersizer 2000

Setup or create an SOP with the following settings:

Materials Tab:

Particle: Glass Beads (Typical). RI 1.52, Absorption 0.00

Model: Single mode, Fine Powder

Labels Tab:

Instructions Before Measurement: On the General Purpose sample tray, set the sample feed gate gap to 10mm. Ensure that the sample area is clean and dry. Check that the part no. of the standard being measured is QAS3002 (CRM0014). Enter the serial number of the dispersion unit into the sample details along with the bottle number for the standard. Empty the entire contents of the bottle onto the front half of the feed tray, closest to the feed slit.

If the Scirocco 2000 with a cement sample feed hopper is being used with a horizontal feed slit, set the feed slit aperture to 2.5mm.

Measurement Tab:

Background measurement time: 12 seconds

Measurement time: 30 seconds

Lower Obscuration Limit (Advance Option): 0.5%

Upper Obscuration Limit (Advance Option): 6.0%

Obscuration Filtering (Advanced Option): Enabled

Obscuration Filtering - Time Out (Advanced Option): 0 min 45sec

Sampler Settings Tab:

Sampler Tray: General Purpose

Air Pressure: 1bar

Feed Rate: 50%

Note that the suggested feed rate is an average setting which should ensure that the obscuration falls within the specified limits and that all the sample is consumed within the measurement time specified for the sample. This may be adjusted to allow for local conditions.

Cycles Tab:

Select a single aliquot and 1 measurement cycle.

Run the SOP and follow the on-screen instructions.

STOP

Scirocco 2000M with a ceramic or stainless steel venturi on the Mastersizer 2000

Setup or create an SOP with the following settings:

Materials Tab:

Particle: Glass Beads (Typical). RI 1.52, Absorption 0.00

Model: Single mode, Fine Powder

Labels Tab:

Instructions Before Measurement: On the sample tray, set the sample feed gate gap to 10mm. Ensure that the sample area is clean and dry. Check that the part no. of the standard being measured is QAS3002 (CRM0014). Enter the serial number of the dispersion unit into the samples details along with the Bottle Number for the standard. Empty the entire contents of the bottle onto the back half of the feed tray, furthest from the feed slit.

Measurement Tab:

Background measurement time: 12 seconds

Measurement time: 30 seconds

Lower Obscuration Limit (Advance Option): 0.5%

Upper Obscuration Limit (Advance Option): 6.0%

Obscuration Filtering (Advanced Option): Enabled

Obscuration Filtering - Time Out (Advanced Option): 0 min 45sec

Sampler Settings Tab:

Sampler Tray: General Purpose

Air Pressure: 1.2bar

Feed Rate: 35%

Note that the suggested feed rate is an average setting which should ensure that the obscuration falls within the specified limits and that all the sample is consumed within the measurement time specified for the sample. This may be adjusted to allow for local conditions.

Cycles Tab:

Select a single aliquot and 1 measurement cycle.

Set the Air Pressure and Feed Rate values referenced above using the adjustment knobs on the front of the dispersion unit. Then, set the Mode Selector knob to 'Airflow'.

Run the SOP, enter the sample details and carry out the background measurement and alignment.

Once the background has finished and the Measure Sample screen is displayed, switch the Mode Selector knob on the dispersion unit to 'Feed'. The measurement will start automatically.

Adjust the feed rate if necessary in order to ensure that the sample is fed gradually through the feed slit into the feeder basket, and that the correct measurement obscuration is achieved

STOP

Hydro 2000G with Autosampler 2000 using deionised water on the Mastersizer 2000

Add the contents of two bottles of QAS3002 (CRM0014) to an autosampler pot, and load the pot onto the Autosampler tray.

If mains water has been used to rinse the Hydro 2000G unit before measurement, ensure that the final 3 rinses (two rinses and one top-up) are performed using de-ionised water.

With the dispersion unit filled, turn the pump off and turn on the ultrasonics for 30 sec. Turn off the ultrasonics and allow any air bubbles to dissipate.
Next, adjust the pump and stirrer speed to maximum and then turn the pump and stirrer off for about 3 sec to allow air to dissipate.
After 10 sec set the pump speed to 2000rpm.

Setup or create an SOP with the following settings:

Materials Tab:

Particle: Glass Beads (Typical). RI 1.52, Absorption 0.00

Dispersant: Water, RI 1.33

Model: Single mode spherical

Labels Tab:

Enter the serial number of the Hydro 2000G and Autosampler into the samples details along with the Bottle Numbers for the standards.

Measurement Tab:

Background measurement time: 12 seconds

Measurement time: 12 seconds

Autosampler Settings Tab:

Sample Quantity: 3ml

Sample Transfer: By volume

Sub-sample volume: 15ml

In-pot mixing time: 15 sec

Dispersal Delay: 15 sec

Dispersant equilibration delay: 30 sec

Sampler Settings Tab:

Pump: 2000 rpm

Stirrer: 800rpm

Ultrasound: None

Cycles Tab:

Select a single aliquot and 3 measurement cycles.

Select a full wash with one clean cycle for the autosampler and Hydro 2000G

Select 'Create Average result'

Associate the sample on the autosampler tray with the SOP using the autosampler schedule. Run the measurement in accordance with the instructions in the autosampler manual.

STOP

DIF2012, QS-M/MU on the Mastersizer S with 1000ml beaker

Ensure the 300RF lens is fitted

If mains water has been used to rinse the unit before measurement, ensure that the final 3 rinses (two rinses and one top-up) are performed using deionised water.

If ultrasonics are available, turn off the pump/stirrer and turn on the ultrasonics for 30sec to allow air bubbles to dissipate.

With the beaker/sample tank filled, turn the pump/stirrer on to full speed and then turn it off for about 10 sec to allow air to dissipate.

For DIF2012 unit, set the pump and stirrer speeds to 80%. For the QS M/MU unit, set the pump speed to 3000rpm.

Set the following measurement and analysis parameters:

Number of measurement sweeps: 12000

Number of background sweeps: 12000

Presentation Code: 3OAD

Analysis Model: Monomodal

Killdata channels: 0

In the document notes, record the bottle number of the standard and the serial number of the dispersion unit being tested.

Check that the part no. of the standard being measured is QAS3002 (CRM0014). At the Inspect measurement stage, ensure that the entire contents of the sample bottle is emptied into the dispersion unit. Allow 30 to 50 seconds for the sample to disperse before performing the first measurement, with the first measurement being within 1 minute of adding the sample.

If, due to water quality issues, glass beads are observed on the surface of the liquid following sample addition, the addition of 4-5 drops of 5% Nonidet P40 to the tank may be necessary to aid dispersion. Carry out 3 measurements in total, saving the data from each measurement.

Flush the system.

STOP

MAM2460, MAM2461 and MAM2461C on the Mastersizer S

Ensure the 300F lens is fitted.

Set up the dispersion unit as follows:

Dispersion Pressure: 1.2bar

Feed Rate: 40%

Tray Gate Span: 10mm

Ensure the sample area is clean and dry.

Note that the suggested feed rate is an average setting which should ensure that the obscuration falls within the specified limits and that all the sample is consumed within the sample. This may be adjusted to allow for local conditions.

Set the following measurement and analysis parameters:

Number of measurement sweeps: 20000

Number of background sweeps: 20000

Obscuration Triggering: On

Lower Sweep Obscuration Limit: 1%

Upper Sweep Obscuration Limit: 6%

Timeout: At least 5 mins

Presentation Code: 3RAA

Analysis Model: Monomodal

Killdata channels: 0

Set up a measurement sequence,

enabling the following options:

Document

Align

Background

Sample (no Inspect stage needed)

Set up a process with the Calculate and Save options enabled.

Ensure QAS3002 (CRM0014) is being measured.

In the document notes, record the bottle number of the standard and the serial number of the dispersion unit being tested.

Set the feeder to Airflow mode and run the measurement sequence.

Following the background, the software will state that the sampling is being measured. Set the feeder to the 'Standby' mode and empty the entire contents of the bottle onto the back of the sample tray, furthest from the feed slit.

Set the feeder to the 'Feed' mode.

Adjust the feed rate if necessary in order to ensure that the sample is fed gradually through the feed slit into the feeder basket, and that the correct measurement obscuration is achieved.

STOP