i-STAT G3+ Cartridge

Intended for use with the i-STAT 1 Analyzer (REF 04P75-01 & 03P75-06)

NAME

i-STAT G3+ Cartridge – REF 03P78-50

INTENDED USE

The i-STAT G3+ cartridge with the i-STAT 1 System is intended for use in the *in vitro* quantification of pH, oxygen partial pressure, and carbon dioxide partial pressure in arterial or venous whole blood.

Analyte	Intended Use
pH	pH, ***P***O_2, and ***P***CO_2 measurements are used in the diagnosis, monitoring, and treatment of respiratory disturbances and metabolic and respiratory-based acid-base disturbances. Bicarbonate is used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.
Oxygen Partial Pressure (***P***O_2)	
Carbon Dioxide Partial Pressure (***P***CO_2)	

SUMMARY AND EXPLANATION/CLINICAL SIGNIFICANCE

Measured:

pH

pH is an index of the acidity or alkalinity of the blood with an arterial pH of <7.35 indicating an acidemia and >7.45 alkalemia. [1]

Oxygen Partial Pressure (***P***O_2)

PO_2 (partial pressure of oxygen) is a measurement of the tension or pressure of oxygen dissolved in blood. Some causes for decreased values of ***P***O_2 include decreased pulmonary ventilation (e.g., airway obstruction or trauma to the brain), impaired gas exchange between alveolar air and pulmonary capillary blood (e.g., bronchitis, emphysema, or pulmonary edema), and alteration in the flow of blood within the heart or lungs (e.g., congenital defects in the heart or shunting of venous blood into the arterial system without oxygenation in the lungs).

Carbon Dioxide Partial Pressure (***P***CO_2)

PCO_2 along with pH is used to assess acid-base balance. ***P***CO_2 (partial pressure of carbon dioxide), the respiratory component of acid-base balance, is a measure of the tension or pressure of carbon dioxide dissolved in the blood. ***P***CO_2 represents the balance between cellular production of CO_2 and ventilatory removal of CO_2 and a change in ***P***CO_2 indicates an alteration in this balance. Causes of primary respiratory acidosis (increase in ***P***CO_2) are airway obstruction, sedatives and anesthetics, respiratory distress syndrome, and chronic obstructive pulmonary disease. Causes of primary respiratory alkalosis (decreased ***P***CO_2) are hypoxia (resulting in hyperventilation) due to chronic heart failure, edema and neurologic disorders, and mechanical hyperventilation.

TEST PRINCIPLE

The i-STAT System uses direct (undiluted) electrochemical methods. Values obtained by direct methods may differ from those obtained by indirect (diluted) methods. [2]

Measured:

pH

pH is measured by direct potentiometry. In the calculation of results for pH, concentration is related to potential through the Nernst equation.

***P*O₂**

***P*O₂** is measured amperometrically. The oxygen sensor is similar to a conventional Clark electrode. Oxygen permeates through a gas permeable membrane from the blood sample into an internal electrolyte solution where it is reduced at the cathode. The oxygen reduction current is proportional to the dissolved oxygen concentration.

***P*CO₂**

***P*CO₂** is measured by direct potentiometry. In the calculation of results for ***P*CO₂**, concentration is related to potential through the Nernst equation.

Temperature "Correction" Algorithm

pH, ***P*O₂**, and ***P*CO₂** are temperature-dependent quantities and are measured at 37°C. The pH, ***P*O₂**, and ***P*CO₂** readings at a body temperature other than 37°C can be 'corrected' by entering the patient's temperature on the chart page of the analyzer. In this case, blood gas results will be displayed at both 37°C and the patient's temperature.

pH, ***P*O₂**, and ***P*CO₂** at the patient's temperature (T_p) are calculated as follows: [3]

$$pH(T_p) = pH - 0.0147(T_p - 37) + 0.0065(7.4 - pH)(T_p - 37)$$

$$PO_2(T_p) = PO_2 \times 10^{\frac{5.49\times10^{-11} PO_2{}^{3.88} + 0.071}{9.72\times10^{-9} PO_2{}^{3.88} + 2.30}(T_p - 37)}$$

$$PCO_2(T_p) = PCO_2 \times 10^{0.019(T_p - 37)}$$

Calculated:

HCO_3, TCO_2, and BE

- HCO_3 (bicarbonate), the most abundant buffer in the blood plasma, is an indicator of the buffering capacity of blood. Regulated primarily by the kidneys, HCO_3 is the metabolic component of acid-base balance.
- TCO_2 is a measure of carbon dioxide which exists in several states: CO_2 in physical solution or loosely bound to proteins, bicarbonate (HCO_3) or carbonate (CO_3) anions, and carbonic acid (H_2CO_3). Measurement of TCO_2 as part of an electrolyte profile is useful chiefly to evaluate HCO_3 concentration. TCO_2 and HCO_3 are useful in the assessment of acid-base imbalance (along with pH and ***P*CO₂**) and electrolyte imbalance.
- The calculated TCO_2 provided by the i-STAT System is determined from the measured and reported values of pH and ***P*CO₂** according to a simplified and standardized form of the Henderson-Hasselbalch equation. [3]
- This calculated TCO_2 measurement is metrologically traceable to the i-STAT pH and ***P*CO₂** measurements, which are in turn traceable to primary standard reference materials for pH and ***P*CO₂**. Like all calculated parameters reported by the i-STAT System, the user can independently determine TCO2 values from the reported pH and ***P*CO₂** measurements using a combination of the equation for HCO_3 given in the ***P*CO₂**.

- Base excess of the extracellular fluid (ECF) or standard base excess is defined as the concentration of titratable base minus the concentration of titratable acid when titrating the average ECF (plasma plus interstitial fluid) to an arterial plasma pH of 7.40 at $\boldsymbol{P}CO_2$ of 40 mmHg at 37 °C. Excess concentration of base in the average ECF remains virtually constant during acute changes in the $\boldsymbol{P}CO_2$ and reflects only the non-respiratory component of pH-disturbances.

When a cartridge includes sensors for both pH and $\boldsymbol{P}CO_2$, bicarbonate (HCO_3), total carbon dioxide (TCO_2) and base excess (BE) are calculated. [3]

$\log HCO_3 = pH + \log \boldsymbol{P}CO_2 - 7.608$
$TCO_2 = HCO_3 + 0.03\ \boldsymbol{P}CO_2$
$BE_{ecf} = HCO_3\text{-}24.8 + 16.2(pH\text{-}7.4)$
$BE_b = (1 - 0.014*Hb) * [\ HCO3 - 24.8 + (1.43 * Hb + 7.7) * (pH - 7.4)\ ]$

sO_2

- sO_2 (oxygen saturation) is the amount of oxyhemoglobin expressed as a fraction of the total amount of hemoglobin able to bind oxygen (oxyhemoglobin plus deoxyhemoglobin).
- sO_2 is calculated from measured $\boldsymbol{P}O_2$ and pH and from HCO_3 calculated from measured $\boldsymbol{P}CO_2$ and pH. However, this calculation assumes normal affinity of oxygen for hemoglobin. It does not take into account erythrocyte diphosphoglycerate (2,3-DPG) concentrations which affect the oxygen dissociation curve. The calculation also does not take into account the effects of fetal hemoglobin or dysfunctional hemoglobins (carboxy-, met-, and sulfhemoglobin). Clinically significant errors can result from incorporation of such an estimated sO_2 value for oxygen saturation in further calculations, such as shunt fraction, or by assuming the value obtained is equivalent to fractional oxyhemoglobin.

$$sO_2 = 100\ \frac{(X^3 + 150X)}{X^3 + 150X + 23400}$$

where $X = \boldsymbol{P}O_2 \bullet 10^{(0.48[pH-7.4]-0.0013[HCO_3-25])}$

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels in vivo. [4] If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

REAGENTS

Contents
Each i-STAT cartridge contains one reference electrode, sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. A list of reactive ingredients relevant for the i-STAT G3+ cartridge is indicated below:

Sensor	Reactive Ingredient	Biological Source	Minimum Quantity
pH	Hydrogen Ion (H^+)	N/A	6.66 pH
$\boldsymbol{P}CO_2$	Carbon Dioxide (CO_2)	N/A	25.2 mmHg

Warnings and Precautions

- For *in vitro* diagnostic use.
- Cartridges are intended for single-use only. Do not reuse.
- Refer to the i-STAT 1 System Manual for all warnings and precautions.

Storage Conditions

- Refrigerated at 2-8°C (35-46°F) until expiration date.
- Room Temperature at 18-30°C (64-86°F). Refer to the cartridge box for shelf life.

INSTRUMENTS

The i-STAT G3+ cartridge is intended for use with the i-STAT 1 analyzer REF 04P75-01 (Model 300-G) and REF 03P75-06 (Model 300W).

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

Arterial or venous whole blood.
Sample Volume: 95 µL

Blood Collection Options and Test Timing (time from collection to cartridge fill)

Analyte	Syringes	Test Timing	Evacuated Tubes	Test Timing
pH ***P***CO_2 ***P***O_2	Without anticoagulant	3 minutes	Without anticoagulant	3 minutes
	With balanced heparin anticoagulant or lithium heparin anticoagulant (syringe must be filled per manufacturer's recommendation) • Maintain anaerobic conditions. • Remix thoroughly before filling cartridge.	10 minutes	With lithium heparin anticoagulant (tubes must be filled per manufacturer's recommendation) • Maintain anaerobic conditions. • Remix thoroughly before filling cartridge,	10 minutes

PROCEDURE FOR CARTRIDGE TESTING

Each cartridge is sealed in a foil pouch for protection during storage--do not use if pouch has been punctured.

- A cartridge should not be removed from its protective pouch until it is at room temperature (18-30 °C or 64-86 °F). For best results, the cartridge and analyzer should be at room temperature.
- Since condensation on a cold cartridge may prevent proper contact with the analyzer, allow refrigerated cartridges to equilibrate at room temperature for 5 minutes for a single cartridge and 1 hour for an entire box before use.
- Use a cartridge immediately after removing it from its protective pouch. Prolonged exposure may cause a cartridge to fail a Quality Check.
- Do not return unopened, previously refrigerated cartridges to the refrigerator.
- Cartridges may be stored at room temperature for the time frame indicated on the cartridge box.

Filling and Sealing the Cartridge (after cartridge has been equilibrated and blood sample has been collected)

1. Place the cartridge on a flat surface.
2. Mix the sample thoroughly. Invert a lithium heparin blood collection tube at least 10 times. If sample was collected into a syringe, invert syringe for 5 seconds then roll the syringe between the palms (hands parallel to the ground) for 5 seconds, flip and roll for an additional 5 seconds. The blood in the hub of the syringe will not mix, therefore expelling 2 drops before filling a cartridge is desired. Note that it may be difficult to properly mix a sample in a 1.0 mL syringe.

3. Fill the cartridge immediately after mixing. Direct the hub of syringe or tip of the transfer device (pipette or dispensing tip) into the sample well of the cartridge.
4. Slowly dispense sample into the sample well until the sample reaches the fill mark indicated on the cartridge. Cartridge is properly filled when the sample reaches the 'fill to' mark and a small amount of sample is in the sample well. The sample should be continuous, no bubbles or breaks (see System Manual for details).
5. Fold the snap closure of the cartridge over the sample well.

Performing Patient Analysis

1. Press the power button to turn on the handheld.
2. Press 2 for *i-STAT Cartridge*.
3. Follow the handheld prompts.
4. Scan the lot number on the cartridge pouch.
5. Continue normal procedures for preparing the sample, and filling and sealing the cartridge.
6. Push the sealed cartridge into the handheld port until it clicks into place. Wait for the test to complete.
7. Review the results.

For additional information for cartridge testing, refer to the i-STAT 1 System Manual located at www.pointofcare.abbott.

Analysis Time

Approximately 130–200 seconds

Quality Control

The i-STAT quality control regimen has four aspects, resting on the foundation of a system design, which reduces the opportunity for the type of error which traditional quality control regimens are designed to detect:

1. A series of automated, on-line quality measurements that monitor the sensors, fluidics and instrumentation each time a test is performed.
2. A series of automated, on-line procedural checks monitors the user each time a test is performed.
3. Liquid materials are available to be used to verify the performance of a batch of cartridges when they are first received or when storage conditions are in question. The performance of this procedure is not a manufacturer's system instruction.
4. Traditional quality control measurements verify the instrumentation using an independent device, which simulates the characteristics of the electrochemical sensors in a way which stresses the performance characteristics of the instrumentation.

Calibration Verification

Calibration Verification is a procedure intended to verify the accuracy of results over the entire measurement range of a test. The performance of this procedure is not a manufacturer's system instruction. However, it may be required by regulatory or accreditation bodies. While the Calibration Verification Set contains five levels, verification of the measurement range could be accomplished using the lowest, highest and mid-levels.

EXPECTED VALUES

TEST	UNITS *	REPORTABLE RANGE	REFERENCE RANGE *(arterial)*	*(venous)*
MEASURED				
pH		6.50 - 8.20	7.35 - 7.45 [5]	7.31 -7.41**
PO_2	mmHg	5 - 800	80 - 105 [6]***	

TEST	UNITS *	REPORTABLE RANGE	REFERENCE RANGE *(arterial)*	*(venous)*
	kPa	0.7 – 106.6	10.7 - 14.0 [6]***	
PCO_2	mmHg	5 - 130	35 - 45 [5]	41 - 51
	kPa	0.67 – 17.33	4.67 - 6.00	5.47 - 6.80
CALCULATED				
Bicarbonate/ HCO_3	mmol/L (mEq/L)	1.0 – 85.0	22 – 26**	23 – 28**
TCO_2	mmol/L (mEq/L)	5 - 50	23 - 27	24 - 29
Base Excess/ BE	mmol/L (mEq/L)	(-30) – (+30)	(-2) – (+3) [5]	(-2) – (+3) [5]
sO_2	%	0-100	95 - 98	

***** The i-STAT System can be configured with the preferred units. Not applicable for pH test.

****** Calculated from Siggard-Andersen nomogram. [1]

******* The reference ranges shown are for a healthy population. Interpretation of blood gas measurements depend on the underlying condition (e.g., patient temperature, ventilation, posture and circulatory status).

Unit Conversion:
P*O$_2$ and *P*CO$_2$:** To convert ***PO_2 and ***P***CO_2 results from mmHg to kPa, multiple the mmHg value by 0.133.

The reference ranges programmed into the analyzer and shown above are intended to be used as guides for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

METROLOGICAL TRACEABILITY

The measured analytes in the i-STAT G3+ cartridge are traceable to the following reference materials or methods. The i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods.

pH

The i-STAT System test for pH measures the hydrogen ion amount-of-substance concentration in the plasma fraction of arterial or venous whole blood (expressed as the negative logarithm of the relative molal hydrogen ion activity) for *in vitro* diagnostic use. pH values assigned to i-STAT System controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference materials SRMs 186-I, 186-II, 185, and 187.

***P*O$_2$**

The i‑STAT System test for oxygen partial pressure measures oxygen partial pressure in arterial or venous whole blood (dimension kPa) for *in vitro* diagnostic use. ***P***O_2 values assigned to i‑STAT System controls and calibration verification materials are traceable to U.S. National Institute of Standards and Technology (NIST) standard reference materials via commercially available certified specialty medical gas standards.

***P*CO$_2$**

The i‑STAT System test for carbon dioxide partial pressure measures carbon dioxide partial pressure in arterial or venous whole blood (dimension kPa) for *in vitro* diagnostic use. ***P***CO_2 values assigned to i‑STAT System controls and calibration verification materials are traceable to U.S. National Institute of Standards and Technology (NIST) standard reference materials via commercially available certified specialty medical gas standards.

Additional information regarding metrological traceability is available from Abbott Point of Care Inc.

PERFORMANCE CHARACTERISTICS

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision

Precision data was collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Test	Units	Aqueous Control	Mean	SD (Standard Deviation)	CV (%) [Coefficient of Variation (%)]
pH		Level 1	7.165	0.005	0.08
		Level 3	7.656	0.003	0.04
$\boldsymbol{P}O_2$	mmHg	Level 1	65.1	3.12	4.79
		Level 3	146.5	6.00	4.10
$\boldsymbol{P}CO_2$	mmHg	Level 1	63.8	1.57	2.5
		Level 3	19.6	0.40	2.0

Method Comparison

Method comparison data were collected using CLSI guideline EP9-A. [7]

Deming regression analysis [8] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site-specific variables.

* The usual warning relating to the use of regression analysis is summarized here as a reminder. For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid". [8] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

pH		IL BGE	Radiometer ICA 1	Nova STAT Profile 5	Radiometer ABL500
Venous blood samples were collected in evacuated tubes and arterial samples were collected in blood gas syringes with lithium heparin anticoagulant. All samples were analyzed in duplicate on the i-STAT System and on the comparative methods within 10 minutes of each other. Arterial blood samples were collected from hospital patients in 3 mL blood gas syringes and were analyzed in duplicate on the i-STAT System and the comparative method within 5 minutes of each other.	n	62	47	57	45
	Sxx	0.005	0.011	0.006	0.004
	Syy	0.009	0.008	0.008	0.008
	Slope	0.974	1.065	1.058	1.0265
	Int't	0.196	-0.492	-0.436	-0.1857
	Sy.x	0.012	0.008	0.010	0.0136
	Xmin	7.210	7.050	7.050	----
	Xmax	7.530	7.570	7.570	----
	r	0.985	0.990	0.9920	0.986

Oxygen Partial Pressure/PO_2 (mmHg)		Radiometer ABL500	Radiometer ABL700	Bayer 845
Arterial blood samples were collected from hospital patients in 3 cc blood gas syringes and were analyzed in duplicate on the i-STAT System and the comparative method within 5 minutes of each other.	n	45	29	30
	Sxx	3.70	2.04	3.03
	Syy	2.78	2.64	3.28
	Slope	1.023	0.962	1.033
	Int't	-2.6	1.2	-2.9
	Sy.x	2.52	3.53	3.44
	Xmin	----	39	31
	Xmax	----	163	185
	r	0.996	0.990	0.996

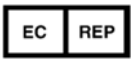
Carbon Dioxide Partial Pressure/ PCO_2 (mmHg)		IL BGE	Radiometer ABL500
Venous blood samples were collected in blood gas syringes. All samples were analyzed in duplicate on the i-STAT System and on the comparative methods within 10 minutes of each other. Arterial blood samples were collected from hospital patients in 3 cc blood gas syringes and were analyzed in duplicate on the i-STAT System and the comparative method within 5 minutes of each other.	n	62	29
	Sxx	0.69	0.74
	Syy	1.24	0.53
	Slope	1.003	1.016
	Int't	-0.8	1.1
	Sy.x	1.65	0.32
	Xmin	30.4	28
	Xmax	99.0	91
	r	0.989	0.999

FACTORS AFFECTING RESULTS

Factor	Analyte	Effect
Exposing the sample to air	PO_2	Exposure of the sample to air will cause an increase in PO_2 when values are below 150 mmHg and a decrease in PO_2 when values are above 150 mmHg (approximate PO_2 of room air).
	pH	Exposing the sample to air allows CO_2 to escape which causes PCO_2 to decrease and pH to increase and HCO_3 and TCO_2 to be under-estimated.
	PCO_2	
	HCO_3	
	TCO_2	
Venous stasis	pH	Venous stasis (prolonged tourniquet application) and forearm exercise may decrease pH due to localized production of lactic acid.
Hemodilution	pH	Hemodilution of the plasma by more than 20% associated with priming cardiopulmonary bypass pumps, plasma volume expansion or other fluid administration therapies using certain solutions may cause clinically significant error on sodium, chloride, ionized calcium and pH results. These errors are associated with solutions that do not match the ionic characteristics of plasma. To minimize these errors when hemodiluting by more than 20%, use physiologically balanced multi-electrolyte solutions containing low-mobility anions (e.g. gluconate).
Cold temperature	PO_2	Do not ice samples before testing as PO_2 results may be falsely elevated in cold samples. Do not use a cold cartridge as PO_2 results may be falsely decreased if the cartridge is cold.
Allowing blood to stand (without exposure to air)	pH	pH decreases on standing anaerobically at room temperature at a rate of 0.03 pH units per hour. [1]
	PO_2	Standing anaerobically at room temperature will decrease PO_2 at a rate of 2–6 mmHg per hour. [1]
	PCO_2	Standing anaerobically at room temperature will increase PCO_2 by approximately 4 mmHg per hour.

Factor	Analyte	Effect
	HCO_3	Allowing blood to stand (without exposure to air) before testing allows ***P***CO_2 to increase and pH to decrease, which will cause HCO_3 and TCO_2 to be over-estimated, due to metabolic processes.
	TCO_2	
Under fill or partial draw	***P***CO_2	The use of partial draw tubes (evacuated tubes that are adjusted to draw less than the tube volume, e.g., a 5 mL tube with enough vacuum to draw only 3 mL) is not recommended due to the potential for decreased ***P***CO_2, HCO_3 and TCO_2 values. Underfilling blood collection tubes may also cause decreased ***P***CO_2, HCO_3 and TCO_2 results. Care must be taken to eliminate "bubbling" of the sample with a pipette when filling a cartridge to avoid the loss of CO_2 in the blood.
	HCO_3	
	TCO_2	
Method of calculation	sO_2	Calculated sO_2 values from a measured *P*O_2 and an assumed oxyhemoglobin dissociation curve may differ significantly from the direct measurement. [3]
Clinical conditions	HCO_3	Causes of primary metabolic acidosis (decrease calculated HCO_3) are ketoacidosis, lactate acidosis (hypoxia), and diarrhea. Causes of primary metabolic alkalosis (increase calculated HCO_3) are vomiting and antacid treatment.
Propofol (Diprivan®) or thiopental sodium	***P***CO_2	The use of G3+ cartridge is recommended, which is free from clinically significant interference at all relevant therapeutic doses.
PO_2 sensitivity	***P***CO_2	In patient samples where the ***P***O_2 is > 100 mmHg above the normal range (80-105 mmHg), an increase in ***P***CO_2 of approximately 1.5 mmHg (with a range of 0.9 to 2.0 mmHg) may be observed for every 100 mmHg increase in ***P***O_2. For example, if an oxygenated patient has a measured ***P***O_2 of 200 mmHg, and a normal ***P***O_2 is 100 mmHg, the impact to the ***P***CO_2 result may be increased by approximately 1.5 mmHg.

KEY TO SYMBOLS

Symbol	Definition/Use
	2 months room temperature storage at 18-30^{0}C
	Use by or expiration date. An expiration date expressed as YYYY-MM-DD means the last day the product can be used.
	Manufacturer's lot number or batch code. The lot number or batch will appear adjacent to this symbol.
	Sufficient for <n> tests
	Authorized representative for Regulatory Affairs in the European Community.
	Temperature limitations. The upper and lower limits for storage are adjacent to upper and lower arms.
	Catalog number, list number, or reference
	Do not reuse.
	Manufacturer
	Consult instructions for use or see System Manual for instructions.
	*In vitro* diagnostic medical device
	Compliance to the European directive on *in vitro* diagnostic devices (98/79/EC)
	For prescription use only.

Additional Information: To obtain additional product information and technical support, refer to the company website at www.pointofcare.abbott.

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