TRAINING UPDATE

Lab Location:	SGMC and WOMC	**Date Implemented:**	12/8/2021
Department:	Blood Bank	**Due Date:**	12/31/2021

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Rad Source RS3400 Blood Irradiator

Description of change(s):

Added instructions for irradiating syringes.

- Use syringe holder
- Place syringe in holder so it is pointing to the bottom of the canister
- Place the syringe flange in the flange lock slot
- Add a rubber band for stabilization when irradiating the 30cc syringe
- Push the syringe holder all the way into the canister, until it touches the bottom of the canister
- Orient the canister in the irradiator so the syringe is at the bottom
- Irradiate

SGMC.BB 4001 Rad Source RS3400 Blood Irradiator

Copy of version 2.0 (approved and current)

Last Approval or Periodic Review Completed	12/7/2021
Next Periodic Review Needed On or Before	12/7/2023
Effective Date	12/7/2021

Controlled Copy of a Manual ID 20556

Location SGMC & WOMC BB vol 5

Organization Adventist HealthCare

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	12/7/2021	2.0	Nicolas Cacciabeve	
Approval	BB approval	12/7/2021	2.0	Stephanie Codina	
Approval	QA approval	12/6/2021	2.0	Leslie Barrett (104977)	
Approval	Lab Director	4/7/2021	1.0	Nicolas Cacciabeve	
Approval	BB approval	4/7/2021	1.0	Stephanie Codina	
Approval	QA approval	4/6/2021	1.0	Leslie Barrett	

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
2.0	Approved and Current	Major revision	12/6/2021	12/7/2021	Indefinite
1.0	Retired	Initial version	4/6/2021	4/14/2021	12/7/2021

Linked Documents

- AG.F 577 RS 3400 Irradiation Log Sheet
- AG.F 578 RS 3400 Irradiator Maintenance Log

Non-Technical SOP

Title	**Rad Source RS3400 Blood Irradiator**
Prepared by	Stephanie Codina Date: 3/11/2021
Owner	Stephanie Codina Date: 3/11/2021

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

TABLE OF CONTENTS

1. PURPOSE

The RS 3400 is a medical device which uses x-ray irradiation to inactivate T-cells in cellular blood products to prevent transfusion-associated graft-versus-host disease (TA-GVHD). Individual canisters are rotated around a single x-ray source for a specific period of time which delivers irradiation to the contents in the canisters.

2. SCOPE

Cellular blood products including red cells, whole blood, and non-PRT platelets must be irradiated in the following situations:

- When requested by the treating physician for a hospital-approved reason or with pathologist approval.
- When the recipient is receiving HLA-matched and/or crossmatched platelets
- When red cells and non-PRT platelets are provided for neonatal transfusion, including exchanges and intrauterine transfusion.

The SGMC blood bank will irradiate blood products for other AHC sites.

3. RESPONSIBILITY

All blood bank staff members must understand and adhere to this procedure for irradiating cellular blood products and maintaining the irradiator.

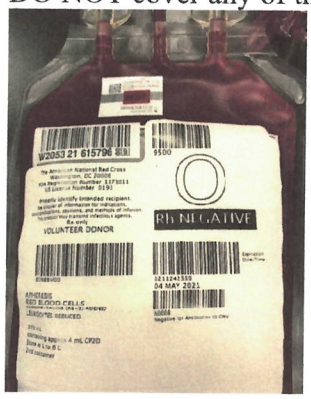
4. DEFINITIONS

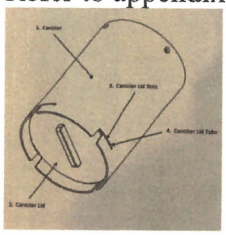
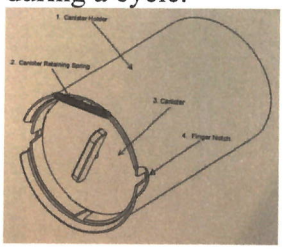
- Radiation is energy in the form of waves or particles. The nature of the radiation used in the irradiator is x-ray. The intensity of radiation depends on flux of photons, measured in Gy/min. The x-ray is distributed in a spherical field with a Bremsstahlung spectrum.
- Gy = Gray. Gray x 100 = Rad. The real dose of energy per gram of tissue (blood product) delivered by irradiation.

5. PROCEDURE

A. General Use

Step	Action
1	Determine if the recipient needs blood product irradiation. A. When the physician requests irradiated blood products for the recipient for the first time, a. Verify the reason for irradiation is an appropriate indication per hospital-defined criteria outlined in appendix C. Pathologist approval is required for irradiation outside of hospital-defined criteria. b. Enter the irradiation marker into the patient's blood bank administrative data file per procedure. Once the irradiation marker has been added, all subsequent transfusions must be irradiated until a physician send a written order to blood bank indicating transfusion of irradiated blood products is no longer clinically necessary. B. All HLA-matched and/or crossmatched platelets will be irradiated. C. All granulocyte products will be irradiated. D. All red blood cell and non-PRT platelet products provided to neonates under 120 days in age will be irradiated. This includes neonatal, exchange, and intrauterine transfusions. NOTE: Irradiation applies to cellular products only (red blood cells, non-PRT platelets, and granulocyte products). Non-cellular products such as plasma and cryoprecipitate are not routinely irradiated.
2	Select a blood product that meets all patient criteria including blood type, antigen status, and any other special attributes.
3 	Check to see if the condition light is illuminated. Perform a condition if the condition light is illuminated.

Step	Action
4	Complete the Irradiation Log Sheet by filling in the following information. A. Tech performing irradiation B. Date of irradiation C. Unit number or donor identification number (DIN) D. Product code prior to irradiation (write NA if irradiated as part of aliquot preparation) E. Product code following irradiation F. Division G. Expiration date of original product H. Expiration date of irradiated product (28 days from date of irradiation or original expiration date; whichever is first) I. Time out of the storage container (refrigerator)
5	Place a Rad-Sure indicator on each blood product that will be irradiated (refer to appendix B). A. Verify the lot number and expiration date of the rad-sure indicators. Place the sticker containing the rad sure lot number and expiration date on the log sheet. B. Verify that the word "NOT" is showing on each rad-sure indicator to be used. Document verification on the irradiation log. C. Place the label on the front of the blood product below the product label. D. DO NOT cover any of the base label during application. 
6	Ensure the key is in the cycle mode (all the way to the right).

Step	Action
7	Load the blood product into the canister. A. Prepare the canister by verifying the canister bottom is securely in place and remove the canister lid with the handle, so you have access to the canister for loading the blood product. B. Carefully insert the blood product into the canister. The canister lid slots mark the volume lines for each canister. Blood products must fit between the lid and the bottom of the canister. C. Refer to appendix A for syringe loading. 
8	Load the canister containing the blood product into the irradiation compartment. A. Open the chamber door by holding the door release button and pulling the chamber door handle simultaneously until the chamber door is open and the canister holders are accessible. B. Visually inspect the chamber to ensure nothing is inside the chamber and nothing in any of the canister holders. C. Place the loaded canister into an available canister holder by slightly pushing the canister retaining spring up (the canister itself may be used for this purpose) and inserting the canister all the way into the canister holder so that the canister retaining spring returns to its original position, gently securing the canister in the canister holder. a. Orient the canister so the canister lid slots are not located at the canister retaining spring. The spring may catch on the slots during removal. b. The canister must be inserted fully into the canister holder in order for the blood products to be in the proper irradiation field. The canister retaining spring should never be compromised in any way and must always be present. c. Ensure the canister lid is secure prior to loading the canister into the canister holder. Do not rotate the canister within the canister holder once it has been loaded into the canister holder. This could cause the canister lid to become loose and fall of during a cycle. 

Step	Action
9	Once all the canisters have been loaded, visually inspect he chamber again. Ensure the canister retaining spring on each canister is in a horizontal position and the handles on the canister lids are facing the operator.
10	Close the chamber door gently ensuring the door latching magnet engages to lock the door tight. The chamber door should be operated gently and never slammed or rapidly opened/closed.
11	Verify the cycle time display is illuminated with the cycle time (280 seconds). Watch for a few seconds to ensure the timer is counting down towards zero one second at a time.
12	Press the start button. The x-ray indicator lights will illuminate together indicating the RS 3400 is checking components for proper operation. This will occur for a few seconds. Then, the x-rays will begin, and the x-ray indicator lights will flash throughout the cycle. The cycle time display will count down seconds and display the seconds remaining until the cycle is complete. Never interrupt a cycle once it has been started, except in the event of an emergency. An interruption will result in an incomplete cycle and the blood products will not have been fully irradiated. Blood products that have not been properly irradiated ***cannot*** be exposed to another cycle.
13	The cycle has successfully completed when the buzzer and its indicator light activate. The cycle has not properly completed if this does not occur, and the blood products should ***not*** be used as irradiated blood products.
14	Open the chamber door to retrieve the blood products by depressing the door release button and pulling the chamber door handle simultaneously to open.
15	Remove all canisters from the chamber and assure the chamber is empty. Gently close the chamber door. Do not use the canister lid holders to remove the canister from the holder. Use the finger notches to move the canister.
16	Remove all the blood products from the canisters and inspect the irradiation indicators for completeness. If the work 'NOT" is visible, the unit did not receive the proper amount of radiation and cannot be issued when the patient/situation requires irradiated blood products. Do not re-irradiated units.
17	Complete the "Irradiation Log Sheet" by filling in the following information. A. Indicate whether the word "NOT" is obscured on the rad-sure indicator label. B. Time returned the refrigerator or other storage container.
18	The irradiator requires a cool down period of at least 5 minutes before switching the irradiator off.

B. LIS Documentation

Step	Action
1	Access Sunquest function "Blood Component Preparation."
2	At the "Value" prompt, type the irradiation function that corresponds to the unit you are irradiating then press the "Tab" key. This is generally "I" plus the E code.
3	Press the "Tab" key to default the current date and time as the irradiation time. Enter the date and time on which the product was irradiated if irradiation took place at an early time (such as during computer downtime).
4	Click the "Continue" button.
5	A second "Blood Component Prep" screen will appear. A. At the "Unit #" prompt scan the DIN (unit number) of the unit that was irradiated. B. At the "Component?" prompt, scan the product code form the product that was irradiated. This will autofill both the product code and division fields.
6	For red blood cell or whole blood products, enter the expiration date and time of the irradiated unit. A. The new expiration date will be 28 days from the date of irradiation or the original expiration date, whichever is sooner. a. Sunquest will calculate the 28-day expiration if you type "T+28" in the expiration date field. b. Compare the original expiration to the 28-day expiration and choose the date that is sooner. The new expiration should never exceed the original expiration. B. The expiration time will be 2359 or the original expiration time, if sooner.
7	Click the "Save" button.
8	A "Preview Output/New Units" screen will appear. Review the information to ensure accuracy, then click on the "Finish" button to generate new product/expiration labels for the irradiated product(s).
9	Adhere the new label(s) to the unit(s) and perform a blood label check of each unit per procedure.
10	Return the unit to storage and document the time on the log sheet.

C. Condition Mode

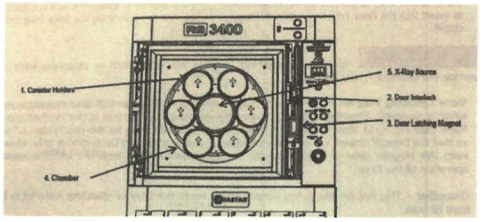
Step	Action
1 	Condition mode is a non-operating mode. Use of condition mode allows the x-ray source to be put through a periodic maintenance sequence. **The condition light will illuminate when this mode needs to be performed.**
2	Check the chamber to ensure it is completely empty. No blood products or canisters should be inside.
3	Close the chamber door gently, so that it engages with the door latching magnet.
4	Make sure the fault light is "off." Clear the fault per instructions if the fault light is on.
5	Turn the key to "Condition" mode from the off or cycle mode position. Press the start button within 3 second to start the condition mode. A. If more than 3 seconds pass, the start button is deactivated ant the process must be repeated. B. The cycle time display does not display and should remain completely blank in condition mode. You are in "cycle" mode if the display comes on. Turn the key switch back one click, counterclockwise to return the irradiator to condition mode.
6	Once the start button is pressed and the condition mode starts, the following will occur: A. The x-ray indicator light will come on and will begin to flash anytime x-rays are being produced. B. The condition mode will continue for 10-15 minutes. C. The condition mode has successfully completed when the buzzer and its small red indicator light activates for approximately 15 seconds. The condition light will turn off if it was on.

D. Clearing a Fault

Step	Action
1	The RS 3400 monitors multiple internal operations. When the system detects that any of the internal operations are functioning outside of their set parameters a fault may result. The Fault Light will illuminate when a fault occurs and the fault buzzer will sound. The fault buzzer and light will remain on until the operator follows the instructions below to clear.

Step	Action
2 	If the fault occurs during a cycle, the operator can attempt to complete the cycle. Note: This occurs when the door latching magnet is not fully engaged when the start button is pressed. A. Do *not* disturb anything to permanently terminate the cycle such as opening the chamber door, shutting the device off, pushing the E-stop button, etc. B. Wait at least 30 seconds from the time the fault light illuminates. C. Press the start button to resume the cycle.
3	The device will first check monitored components. During this time, both x-ray indicator lights will come on and the cycle time display will remain static until all items are checked by the device. Once the device checks all items, the cycle will resume, and the cycle time display will count down. Note: Do not attempt to resume more than twice in a single cycle to avoid damaging the device.

E. Routine Maintenance

Step	Action
1	The irradiator should be periodically wiped (at least monthly) with an approved hospital disinfectant wipe. Do not allow cleaners or water to drip into panels or chamber. A. Do not spray or pour liquid onto the device. B. Do not use bleach or other caustic chemicals on the device.
2	Door interlock mechanism (Perform monthly) Verify that the interlock "tongue" attached to the chamber door has no obvious defects, cracks, or missing hardware and that it inserts into the door interlock freely and properly. Remove the irradiator from service if the door interlock fails. 
3	Power cord (Perform monthly) Visually inspect the power cord to ensure there are no cuts or failures in the insulation and the cord is not damaged or frayed. Remove the irradiator from service if the cord is damaged frayed.

Step	Action
4	Timer Check (Perform monthly) A. Obtain a stopwatch and document the serial number on the QC form. B. Verify the stopwatch by comparing it to the US Naval Observatory (USNO) Master Clock. a. Dial the USNO master clock at 202-762-1401. b. Start the timer. c. Stop the timer at 60 seconds. d. Determine how much time elapsed on the USNO master clock. e. Compare the stopwatch to the master clock. The two must agree exactly to verify the stopwatch. f. Document results and interpretations on the QC form. C. Begin an irradiation cycle (Never run an empty irradiator. You can use a wasted component if needed). D. Start the verified stopwatch when the irradiator time begins to count down. E. Stop the verified stopwatch when the irradiator timer reaches zero. F. The time listed on the stopwatch should be between 278-282 seconds. G. Record the results on the QC form. H. Remove the irradiator from service if the timer check is out of range.
5	Annual maintenance is required by a field services representative. Contact Rad Source Technologies, Inc at 678-765-7900 or service @radsource.com
6	Dose verification of the irradiator is performed by a contracted vendor. The irradiator will be removed from service is the dose verification fails. A. Semi-annually B. After major repairs C. When the irradiator is installed D. When the irradiator is moved

F. Generator Testing

Step	Action
1	The operator must turn the key to the off position before the generator test is performed. The operator may resume normal operation after the generator test is completed. Note: SGMC routinely performs generator testing every third Thursday of the month between 0400 and 0600.

G. Emergency STOP

Step	Action
1 	All processes immediately stop when the emergency stop button is pressed. **This button should only be pressed for emergencies that involve smoke, water, and fire.** If the button is pressed while an irradiation cycle is running, the cycle is void and incomplete and the blood products should not be considered irradiated.
2	Allow the emergency stop button to remain depressed until the emergency is resolved.
3	To clear, A. Turn the key to the off mode. B. Wait 10 seconds. C. Turn the key to cycle mode to resume normal operations.

6. RELATED DOCUMENTS

Form: Irradiation Log Sheet (AG.F577)
Form: RS 3400 Irradiator Maintenance Log (AG.F578)
SOP: Blood Label Check

7. REFERENCES

- RadSource. RS 3400 Operator's Manual. Document F-354, Revision 14. July 2020. RadSource Technologies, Inc: Buford, GA.
- RadSource. RS 3400 Syringe Holder Operator's Manual. Document MKT004-2/18, Version 3. 2018. RadSource Technologies, Inc: Buford, GA.

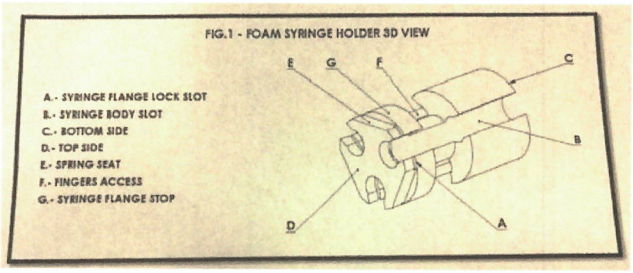
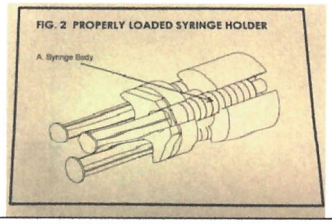
8. REVISION HISTORY

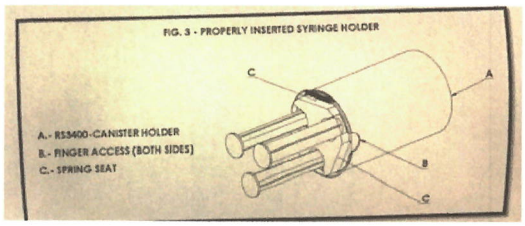
Version	Date	Reason for Revision	Revised By	Approved By
1	12/3/21	Section 5: Added reference to appendix A (A.7) Section 9: Added instructions for using the syringe holder for neonatal products (App.A), re-numbered subsequent appendices	SCodina	NCacciabeve

9. ADDENDA AND APPENDICES

A Syringe Loading
B Rad-Sure Irradiation Indicators Type XR 15 Gy
C Indications for Irradiation
D Irradiation Functions

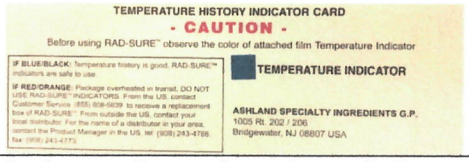
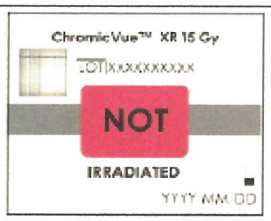
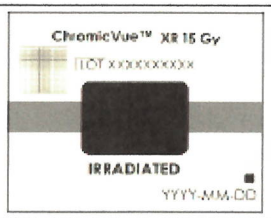
Appendix A
Syringe Loading

Step	Action
1	The syringe holder is used for holding syringes in the RS 2400 Canister Holders. The syringe holder is designed to hold standard 30mL and 50mL syringes drawn up to full capacity. 
2	Push the syringe body into the syringe body slot so that the syringe flange fits within the syringe flange lock slot. A. The syringe flange should sit in contact with the syringe flange stop. B. The syringe body should be completely within the syringe body slot, so it will not impede the insertion of the loaded syringe holder into the RS 3400 canister holder. C. Place a rubber band around the syringe body in the syringe holder when 30 mL syringes are used to help secure the syringes. The rubber band is not necessary for 50mL syringes. D. The tip of the syringe should not extend beyond the bottom of the syringe. E. Avoid handling the syringe plungers when inserting the syringes into the holder. 
3	The syringe holder will accommodate up to three syringes at once, but can be used for one, two, or three. When only one syringe is contained in the syringe holder, the syringe holder should be oriented so that the syringe is toward the bottom of the canister holder.

Step	Action
4	Once the syringe(s) is/are within the syringe holder, the syringe holder can then be placed into the RS 3400 canister holder by handling the syringe holder at the syringe flange sop, or main body of the syringe holder. The syringe holder must be oriented in the canister holder so that the spring retains the syringe holder at the spring seat portion of the syringe holder. 
5	The syringe holder can be gently removed from the canister holders by using two hands to draw out the syringe holder by using the finger access slots on each side of the canister holder. This allows the operator to avoid handling the syringe plungers.
6	Once the syringe holder is out, the syringes can be removed by holding the syringe holder by the syringe flange stop (or main body of the syringe holder) and gently pulling the syringe out by the syringe body.

Appendix B
Rad-Sure Irradiation Indicators Type XR 15 Gy

When attached to blood products, Rad-Sure ChromicVue type XR 15 Gy indicators show whether the blood products have been irradiated. Rad-Sure XR indicators only indicate that irradiation has occurred. They do not measure the dose from an irradiator. Rad-Sure XR indicators should only be used with x-ray irradiators that are working properly and are properly calibrated. Variations in lighting conditions, product batches, and user eyesight may affect interpretation of the indicator.

Step	Action
1	Observe the color of the film temperature indicator prior to using a Rad-Sure indicator. A. Indicators must be stored at or below 25°C and away from all radiation sources to include gamma rays, x-rays, electron devices, and microwaves. B. If the indicator is Blue/Black, the temperature history is good, and the Rad-Sure indicators are safe to use. C. If the indicator is Red/Orange, the indicators have been overheated and should not be used. 
2	Pull the clear strip on the box to forward a rad sure indicator.
3	Look for the word "NOT" in the window of each indicator. Do not use any indicator unless the word "NOT" is clearly visible.
4	Observe the product expiration date on the indicator. Do not use indicators that are beyond the printed expiration date.
5	Peel the indicator from its backing. Avoid touching the adhesive layer with gloves. Apply the indicator to the blood product by pressing firmly.
6	Irradiate the blood product per procedure.
7	After irradiation, check the indicator to verify that the window is black and obscures the work "NOT." The indicator should now read "IRRADIATED." Notify a supervisor is the word "NOT" remains visible.  

Reference: Rad-sure chromic Vue type Xr 15 Gy and type XR 25 Gy Blood Irradiation Indicator Use Instructions. Revised Jun 2019.

Appendix C
Indications for Irradiation

For All Patients	For Pediatric Patients	For Patients with Congenital Immune Deficiency
• Malignant lymphoma, from diagnosis to death • Currently or previously on purie analogue treatment (fludarabine, cladribine, 2-CDA, pentastatin) • Products from first- or second-degree relatives • HLA-matched components • Granulocyte components • Chronic graft-vs-host disease (GVHD) • on purine analogue drugs • Allogeneic marrow transplant from start of conditioning to end of GVHD prophylaxis • 7 days before harvesting of autologous stem cell transplant to 3 months after transplant or 6 months if total body irradiation is used • Aplastic anemia • Undiagnosed pancytopenia • ALL or AML for stem cell transplant	• All red cell and platelet transfusions given to infants <4 months of age • Intrauterine transfusions (IUT) of red cells or platelets • "Top-up" transfusions if previous IUT • Exchange transfusions (ET) or platelet transfusions following IUT • Any ET if delay for irradiation does not compromise care • Small blue cell tumors in childhood • Acute lymphoblastic leukemia (ALL) • Acute myeloblastic leukemia (AML) • Burkitt's lymphoma/leukemia • Solid tumors, eg o Ewing's sarcoma o Hepatoblastoma o Neuroblastoma o Osteogenic sarcoma o Retinoblastoma o Rhabdomyosarcoma • Langerhan's cell histiocytosis • Open-heart surgery in patient <6 months old	• Di George's syndrome • Congenital heart deficiency or open-heart surgery in patient <6 months old • Congenital cell-mediated immune deficiency • Severe combined immune deficiency • Wiskott-Aldrich syndrome • Purine nucleoside phosphorylase deficiency • Reticular dysgenesis • Adenosine deaminase deficiency • Major histocompatibility complex (HLA) I or II deficiency • Leukocyte adhesion molecular deficiency • Cell-mediated deficiency, not otherwise specified

Berte LM. Transfusion Service Manual of Standard Operating Procedures, Training Guides, and Competence Assessment Tools, 2nd ed. 2007. AABB Press: Bethesda, Maryland.

Appendix D
Irradiation Functions

Original Product	Component Prep Function	Final (Irradiated) Product
E0167	IE0167	E0178
E0181	IE0181	E0179
E0212	IE0212	E0223
E0226	IE0226	E0224
E0276	IE0276	E0274
E0316	IE0316	E0331
E0336	IE0336	E0332
E0366	IE0366	E0378
E0382	IE0382	E0379
E0404	IE0404	E0419
E0424	IE0424	E0420
E0605	IE0605	E4537
E0678	IE0678	E0661
E0685	IE0685	E0668
E0686	IE0686	E0669
E0693	IE0693	E0676
E0694	IE0694	E0677
E4519	IE4519	E4521
E4520	IE4520	E4522
E4531	IE4531	E4526
E4532	IE4532	E4527
E4533	IE4533	E4528
E4536	IE4536	E0660
E4543	IE4543	E4538
E4544	IE4544	E4539
E4545	IE4545	E4540
E4546	IE4546	E4539
E4547	IE4547	E0677