

Field Action Notice



Product: ABL800, ABL9, ABL90 and AQT90

December 12, 2025

Subject: Cybersecurity vulnerabilities

Background: Radiometer has identified three potential vulnerabilities within the above analyzers. Please refer to MyRadiometer.com under the specific analyzer type, e.g., "ABL800", and then select "Cybersecurity documentation".

An attacker with physical access to the analyzer could circumvent the analyzer's kiosk mode and start the Windows Task Manager.

An attacker could gain remote control over the analyzer if it is running on either Windows XP or Windows 7, by exploiting all three vulnerabilities in combination. Gaining remote control over analyzers running on Windows 8 and Windows 10 is not possible.

The remote control can be utilized, for example, to make the analyzer unavailable for use or as an attack point against the network to which the analyzer is connected. The attacker will be able to view patient data and measurement results, but will not be able to alter the encrypted data; hence, the vulnerabilities will not lead to a hazardous situation.

Affected Product: ABL800 analyzers in the following combinations:

- Windows XP and all application software versions
- Windows 7 and all application software versions
- Windows 10 and application software lower than SW version 6.20 MR2

ABL9 analyzers in the following combinations:

- Windows 8 and all application software versions
- Windows 10 and application software lower than SW version 1.5.0

ABL90 analyzers in the following combinations:

- Windows XP and all application software versions
- Windows 7 and all application software versions
- Windows 10 and application software lower than SW version 3.5 MR11

AQT90 analyzers in the following combinations:

- Windows XP and all application software versions
- Windows 7 and all application software versions
- Windows 10 and all application software versions.

User Action: Per the customer advisory letter:

To continue using the analyzer, Radiometer kindly requests that you ensure that:

1. Only authorized people can physically access the analyzer.
2. The network is secure, and access follows best practices.

If the network requirements are not met, users are requested to perform additional actions. These additional actions depend on the analyzer type, installed OS, and analyzer application software version. Please refer to the individual customer advisory letters.

Additionally, please complete the Recall Response Form (supplied with this letter) and return it to your Radiometer representative within two weeks of receiving this letter.

Action:**Please carry out the following actions for existing customers:**

1. Translate the customer advisory letters and recall response forms into your local language(s) and print them on your official company paper.
2. Compose a complete lists of affected customers and analyzers (documented in the relevant "Field Action Effectiveness Data Sheets").
3. Provide the relevant version "A" customer advisory letter(s) and recall response form to each affected customer as follows,
 - Submit the customer advisory letter(s) and a recall response form to the customers, or
 - Visit the customers to hand over the customer advisory letter(s) and the recall response form, and explain the problem.
4. Collect and consolidate recall response forms in the relevant "Field Action Effectiveness Data Sheets" (Excel) enclosed with this FAN. Please note that a response must be received from all affected customers.
5. Contact affected customers to explain the permanent solution and schedule a visit to implement it in the analyzer(s).
6. Visit the affected customers to implement the permanent solution in the analyzer(s) as follows:

ABL800:***RXPE:***

- Remove the possibility of connecting remotely (if not already done by the customer).
- Remove access to the Task Manager (registry change), please refer to Appendix 1.
The registry change also prevents an FSE from accessing the OS, and the only way to gain access is to reinstall the OS.

RWEST:

- Upgrade the application software to version 6.20 MR2.
- Remove access to Task manager (registry change), please refer to appendix 1.
- Enable internal and external remote access as required.

RWIN10:

- Upgrade the application software to version 6.20 MR2.
- Enable internal and external remote access as required.

ABL9:***Windows 8:***

- Upgrade the application software to version 1.5.0.
- Enable internal and external remote access as required.

Windows 10:

- Upgrade the application software to version 1.5.0.
- Enable internal and external remote access as required.

ABL90:***RXPE:***

- Remove the possibility of connecting remotely (if not already done by the customer).
- Remove access to the Task Manager (registry change), please refer to Appendix 1).
The registry change also prevents an FSE from accessing the OS, and the only way to gain access is to reinstall the OS.

RWEST:

- Upgrade the application software to version 3.5 MR11.

- Remove access to Task Manager (registry change), please refer to Appendix 1.
- Enable internal and external remote access as required.

RWIN10:

- Upgrade the application software to version 3.5 MR11.
- Enable internal and external remote access as required.

AQT90:**RXPE:**

- Remove the possibility of connecting remotely (if not already done by the customer).
- Remove access to the Task Manager (registry change), please refer to Appendix 1.
The registry change also prevents an FSE from accessing the OS, and the only way to gain access is to reinstall the OS.

RWES7:

- Upgrade application software to version 8.13 MR2.
- Remove possibility to remote connect.
- Remove access to Task Manager (registry change), please refer to appendix 1).

RWIN10:

- Upgrade the application software to version 8.14, which is expected to be released in February 2026.
- Enable internal and external remote access as required.

7. Consolidate the software upgrade for all affected analyzers in the “Field Action Effectiveness Data Sheet” (Excel) enclosed with this FAN.

Please carry out the following actions for new AQT90 customers:

These actions remain in effect until you begin delivering analyzers with software version 8.14.

1. Provide version “B” customer advisory letter and a recall response form to each customer at the time of the installation as follows,
 - Submit the customer advisory letter and a recall response form to the customers, or
 - Visit the customers to hand over the customer advisory letter and the recall response form, and explain the problem.
2. Collect and consolidate recall response forms in the “Field Action Effectiveness Data Sheet” (Excel) enclosed with this FAN. Please note that a response must be received from all affected customers.
3. Once software version 8.14 has been released, contact each of the new customers to schedule a visit to upgrade the software to version 8.14.
4. Visit the customers to upgrade the software.
5. Compose a complete list of new customers and analyzers and document that the version “B” of the customer advisory letter and recall response form has been provided, that the completed recall response form has been received, and that the software has been upgraded to version 8.14.

Completion Dates: The actions for existing customers must be completed by the dates stated:

- **Actions #1, #2, and #3** must **before December 17, 2025**, be completed and confirmed to RMED by submitting the following:
 - Relevant translated customer advisory letters and recall response forms
 - List of affected customers using the relevant “Field Action Effectiveness Data Sheets”
 - “**FAC1** - Customer advisory letter”
- **Action #4** must before **January 21, 2026**, be completed and confirmed to RMED by submitting the following:
 - Relevant “Field Action Effectiveness Data Sheets”
 - “**FAC2** – Customer response”
- **Actions #5, #6, and #7** must before **December 17, 2026**, be completed and confirmed to RMED by submitting the following:
 - Relevant completed “Field Action Effectiveness Data Sheets”
 - “**FAC3** – Permanent solution

Tools:**The following tools are available:**

- Customer advisory letters
 - ABL9 Customer advisory letter (for existing customers)
 - ABL90 Customer advisory letter (for existing customers)
 - ABL800 Customer advisory letter (for existing customers)
 - AQT90 Customer advisory letter A (for existing customers)
 - AQT90 Customer advisory letter B (for new customers)
- Recall response forms
 - Recall response form A (for existing customers)
 - Recall response form B (for new AQT90 customers)
- Field Action Effectiveness Data Sheet
 - ABL9 Field Action Effectiveness Data Sheet
 - ABL90 Field Action Effectiveness Data Sheet
 - ABL800 Field Action Effectiveness Data Sheet
 - AQT90 Field Action Effectiveness Data Sheet
- 936-070 ABL90 software version 3.5 MR11
- 936-059 ABL800 software version 6.20MR2
- 911-091 ABL9 software version 1.5.0

Inquiries:

Please refer to the departments below for inquiries related to this Field Action Note:

- For technical, commercial, and practical questions, please contact RMED Technical Product Support and Service:
 - CRM users: Escalate a support request in CRM
 - Non-CRM users: Send an e-mail to product.support@radiometer.dk
- For questions from your local national competent authorities, please contact RMED Vigilance:
 - Email: vigilance@radiometer.dk
- To confirm receipt and submit customer lists, translated letters, FACs, Customer Response Sheets, etc., please use:
 - Email: fan@radiometer.dk

Regulatory: For regulatory reasons, you must email a complete list of affected customers to RMED.

USA: Not reportable.

Canada: Not reportable.

EEA and UK: Not reportable.

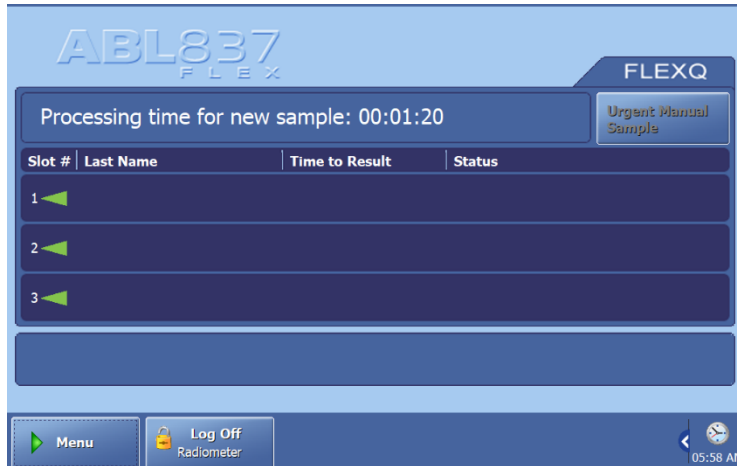
China, Japan, South Korea, Australia, New Zealand, South Africa, India, Hong Kong, and Malaysia:
The affected product has been distributed to these countries. The local Subsidiary will assess if reporting is required locally.

Prepared by: Mogens Thomasen
Senior Technical Product Manager
Technical Product Support and Service

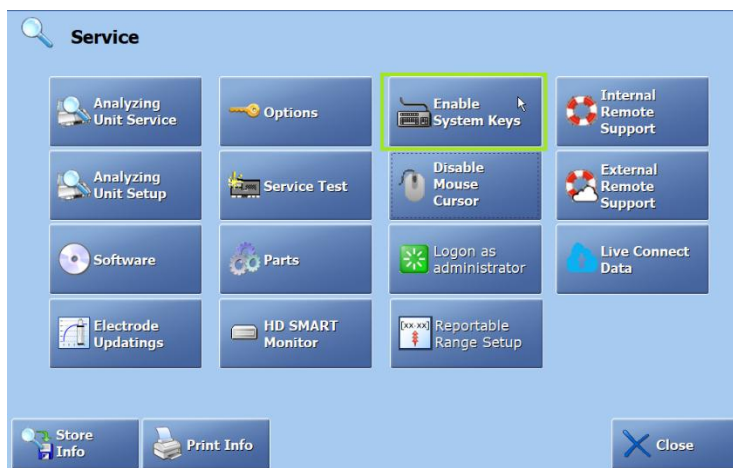
Appendix 1, Remove access to Task Manager (registry change)

ABL800:

1. Connect the physical keyboard or connect the device as an external remote if available.
2. Log in as the Radiometer FSE user in case of updating directly in the device.

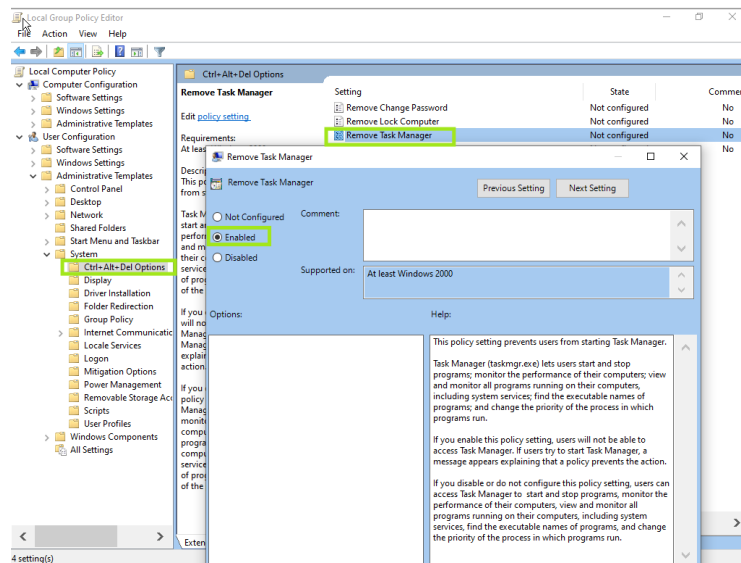


3. Enable System Keys in the service menu if logged in as a Radiometer FSE user.



4. Press **Ctrl+Alt+Delete**. (In case of external remote press the same combination using the option in the proxy gateway viewer)
5. Open the Task Manager.
6. Open and run in cmd: `gpedit.msc`.

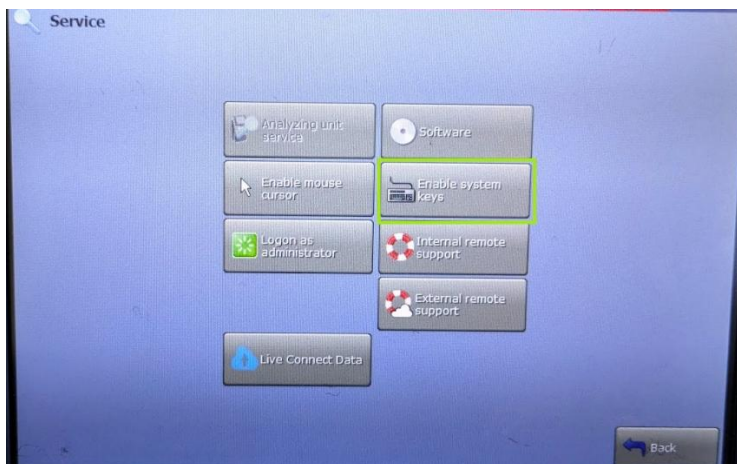
- Change policy User Configuration > Administrative Templates > System > Ctrl+Alt+Del Options enabling the "Remove Task Manager" setting.



- Reboot the analyzer and wait for the analyzer to start up.
- Press *Ctrl + Alt + Delete* and verify that the analyzer does not respond to the keystrokes.

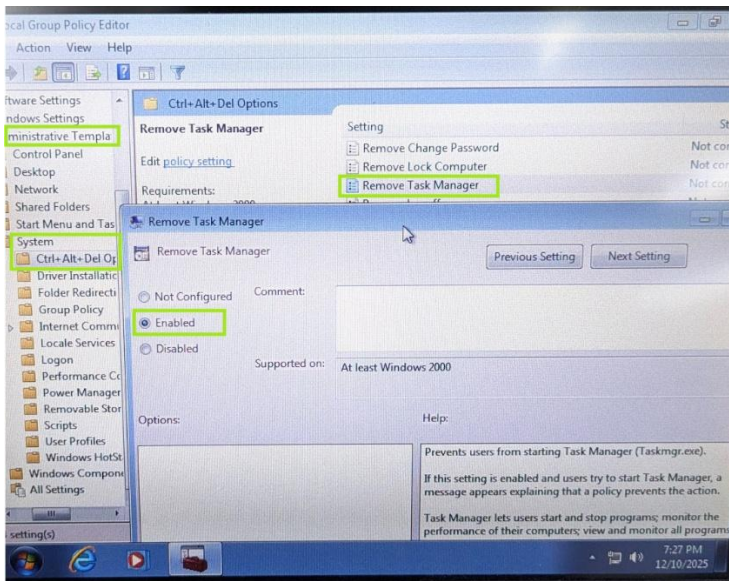
ABL90 (shown for RWES7 as an example):

- Connect the physical keyboard or connect device as external remote if available.
- Login as Radiometer FSE user in case updating directly in device.
- Enable System Keys in the service menu if login as Radiometer FSE user.



- Press *Ctrl+Alt+Delete*. (In case of external remote press same combination using option in proxy gateway viewer)
- Open the Task Manager.
- Disable write filter using command "fbwfmgr /disable"
- Reboot and wait for application to run.
- When application shows failing to load due to "write filter", exit and open task manager using *Ctrl+Alt+Delete*
- Now, run gpedit.msc.

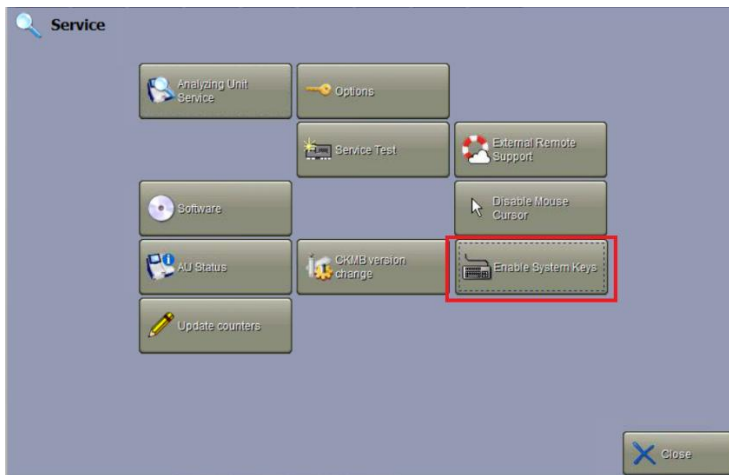
- Change policy User Configuration > Administrative Templates > System > Ctrl+Alt+Del Options and then enable the "Remove Task Manager" setting as shown below:



- Enable write filter using the command "fbwfmgr /enable".
- Reboot the analyzer and wait for application.
- Press *Ctrl + Alt + Delete* and verify that the analyzer does not respond to the keystrokes.
- Log off.

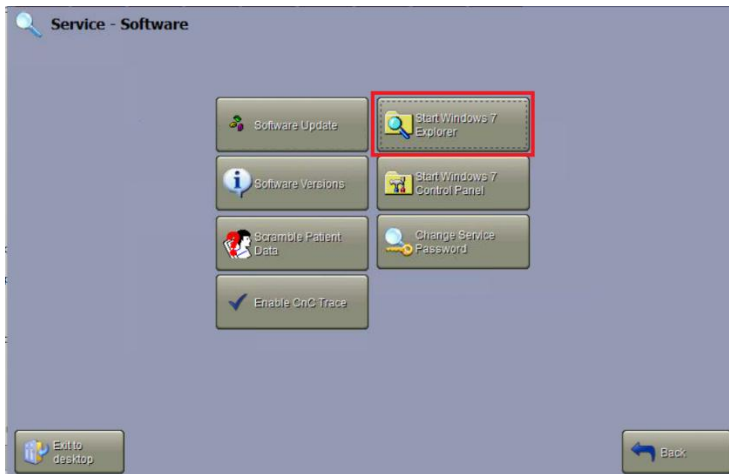
AQT90 (shown for RWES7 as an example):

- Login to Analyzer by using the service password.
- Enable System Keys in the Service Menu by following the path [Menu] -> [Utilities] -> [Service]

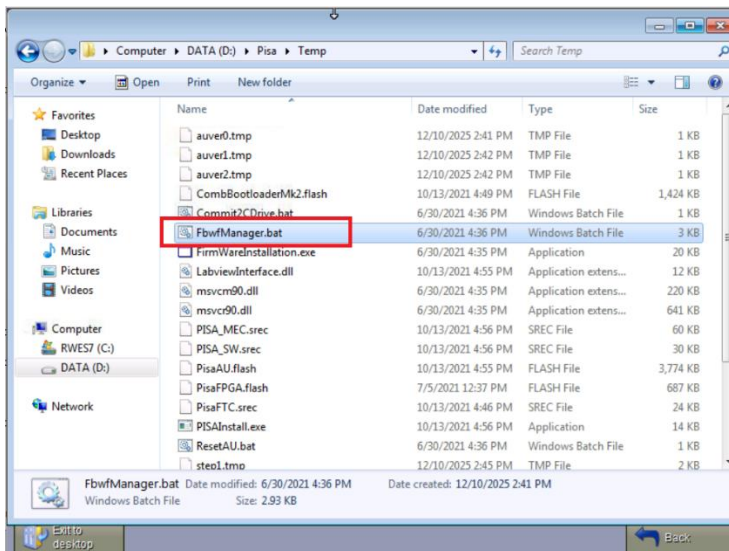


- Connect the alphanumeric keyboard to one of rear/backside USB ports.

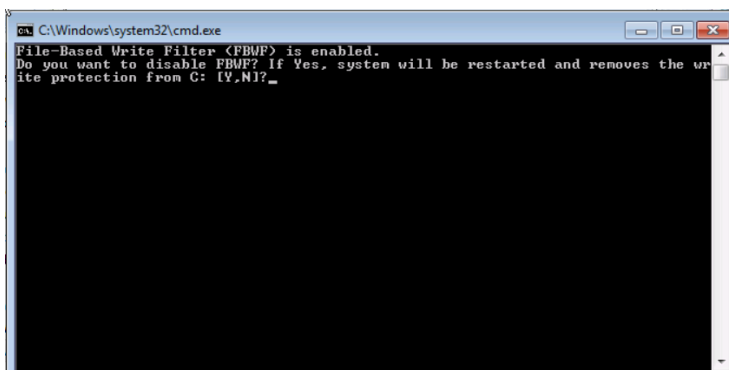
- Open the Explorer by following the path [Menu] -> [Utilities] -> [Service] -> [Software] -> [Start windows 7 Explorer]



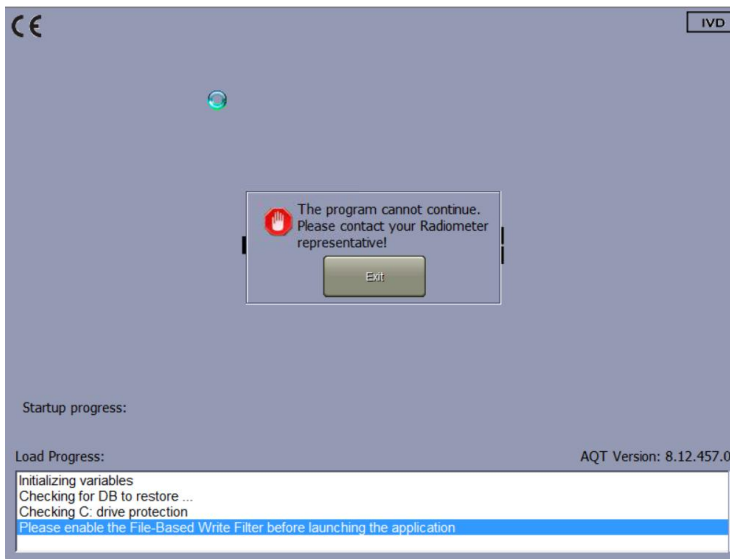
- Disable File-Based Write Filter: run **FbwfManager.bat** from the path D:\Pisa\Temp.



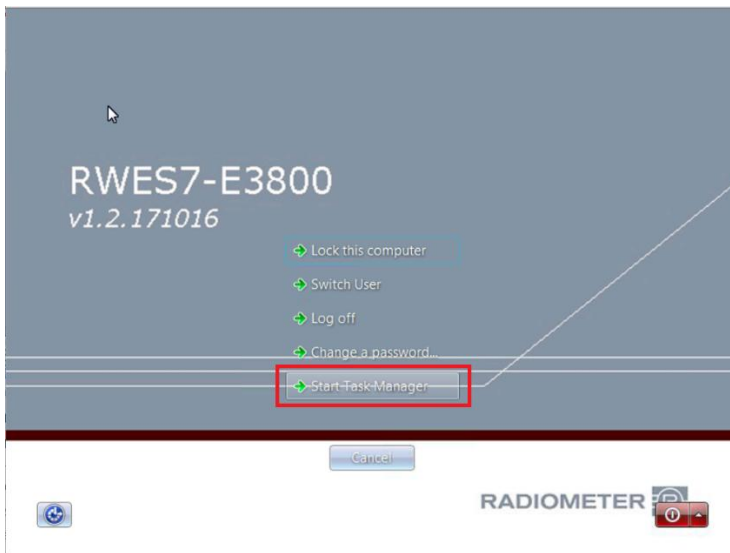
- Press Y to disable the write filter and restart the analyzer.



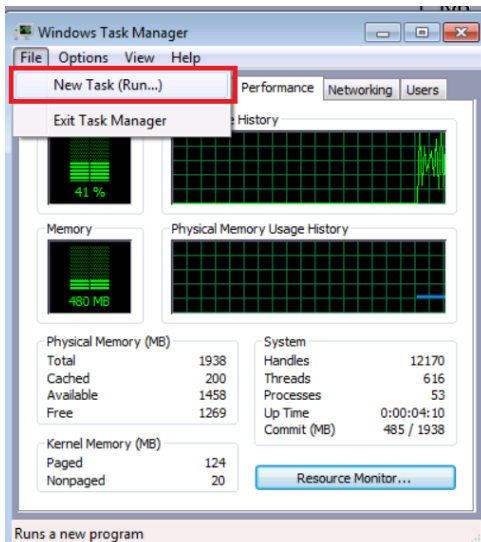
- 7. When the error below appears, to contact Radiometer representative, press *Ctrl + Alt + Delete*.

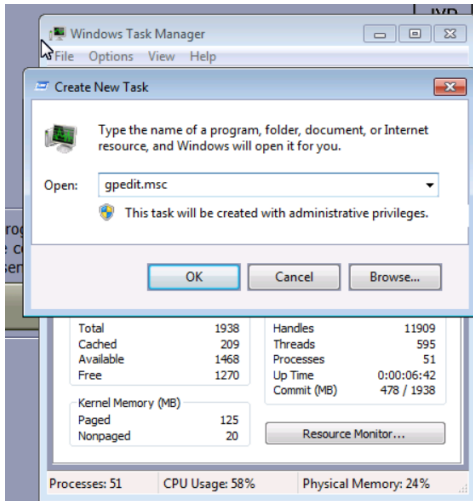


- 8. Open Task Manager.

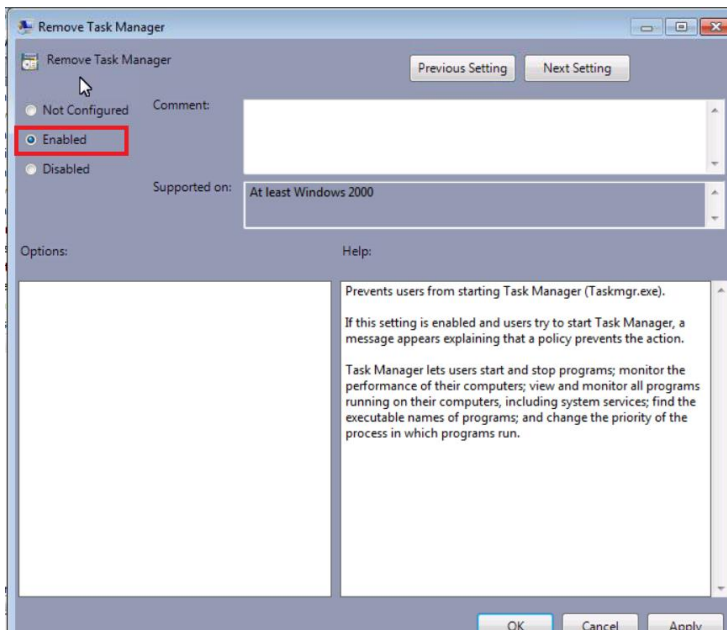
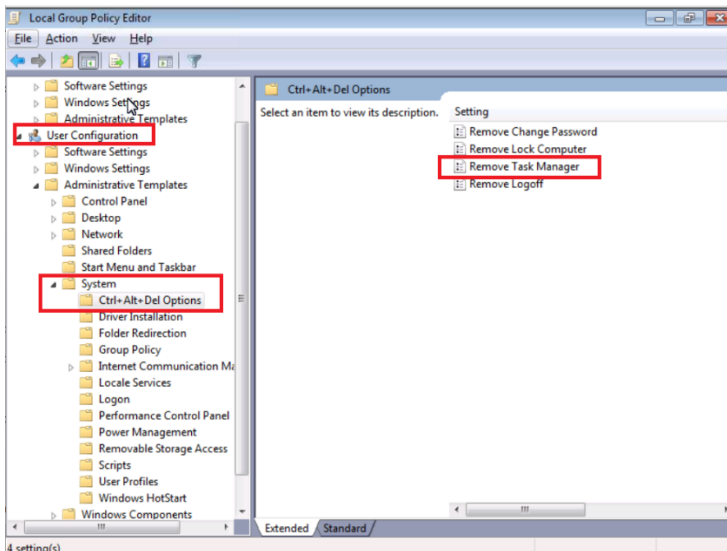


- 9. Open and run in cmd: `gpedit.msc`.

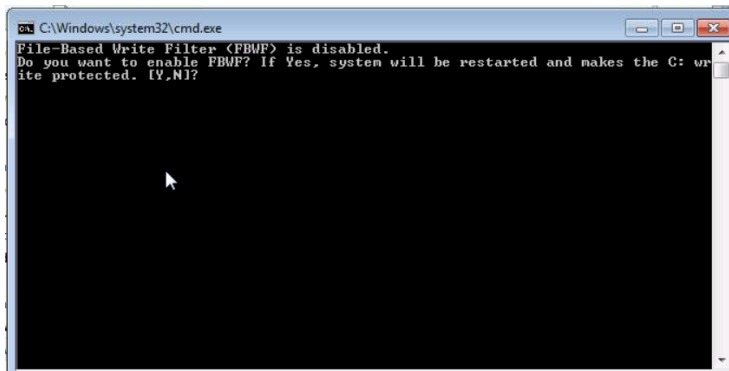




10. Change policy by following the instructions, select 'User Configuration', then select 'Administrative Templates', select 'System', and click on 'Ctrl + Alt + Delete Options' to enable the "Remove Task Manager" setting.



11. Open Explorer and Enable File-Based Write Filter: run **fbwfManager.bat** from D:\Pisa\Temp.



12. Press Y to enable write filter and restart the analyzer.
13. After comes out of startup mode, Disable System Keys in the service menu by following the path Menu -> Utilities -> Service
14. Logoff from Service.
15. Press **Ctrl + Alt + Delete** and verify that the analyzer does not respond to the keystrokes.